Technical Brief
Number 38

Automated-Entry Patient-Generated Health Data for Chronic Conditions: The Evidence on Health Outcomes

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Key Messages

- We conducted a thorough evidence review of automated-entry patient-generated health data (PGHD) devices and mobile apps for the prevention or treatment of 11 chronic conditions, specifically looking for evidence on their impact on health outcomes such as mortality, quality of life, and symptom improvement.
- We included 114 controlled studies that used 118 unique devices and 26 mobile apps.
- For three chronic conditions (coronary artery disease, heart failure, and asthma), we found a possible positive effect of PGHD technologies on health outcomes.
- For obesity, we classified the health outcome data as unclear, and we found consistent evidence of a lack of effect of PGHD interventions on the surrogate outcome of body mass index/weight.
- For hypertension, we classified the health outcome data as unclear, and we found evidence of a possible positive effect of PGHD interventions on the surrogate outcome of blood pressure.
- For cardiac arrhythmias, we classified the health outcome data as unclear but found consistent evidence of a beneficial effect of PGHD interventions on the surrogate outcome of time to arrhythmia detection.
- The evidence on both health outcomes and surrogate outcomes was unclear for the other five conditions (chronic obstructive pulmonary disease, diabetes prevention, sleep apnea, stroke, and Parkinson's disease).
- PGHD technologies are often provided as part of a multicomponent intervention, and future studies should attempt to determine the specific impact of PGHD, place a greater emphasis on the measurement of health outcomes, and study long-term effects.

This report is based on research conducted by the ECRI-Penn EPC under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2015-00005-I) with funding provided by the Centers for Disease Control and Prevention (CDC). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program website at www.effectivehealthcare.ahrq.gov. Search on the title of the report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new healthcare technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate before developing their reports and assessments.

This EPC evidence report is a Technical Brief. A Technical Brief is a rapid report, typically on an emerging medical technology, strategy, or intervention. It provides an overview of key issues related to the intervention—for example, current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. Although Technical Briefs generally focus on interventions for which limited published data exist and too few completed protocol-driven studies to support definitive conclusions, the decision to request a Technical Brief is not solely based on the availability of clinical studies. The Technical Brief's goals are to provide an early objective description of the state of the science, a potential framework for assessing the applications and implications of the intervention, a summary of ongoing research, and information on future research needs. In particular, through the Technical Brief, AHRQ hopes to gain insight on the appropriate conceptual framework and critical issues that will inform future research.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

If you have comments on this Technical Brief, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted a panel of Key Informants who represent subject experts and end-users of research. Key Informant input can inform key issues related to the technical brief's topic. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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Peer Reviewers

Before publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Automated-Entry Patient-Generated Health Data for Chronic Conditions: The Evidence on Health Outcomes

Structured Abstract

Background. Automated-entry consumer devices that collect and transmit patient-generated health data (PGHD) are being evaluated as potential tools to aid in the management of chronic diseases. The need exists to evaluate the evidence regarding consumer PGHD technologies, particularly for devices that have not gone through Food and Drug Administration evaluation.

Purpose. To summarize the research related to automated-entry consumer health technologies that provide PGHD for the prevention or management of 11 chronic diseases.

Methods. The project scope was determined through discussions with Key Informants. We searched MEDLINE and EMBASE (via EMBASE.com), In-Process MEDLINE and PubMed unique content (via PubMed.gov), and the Cochrane Database of Systematic Reviews for systematic reviews or controlled trials. We also searched ClinicalTrials.gov for ongoing studies. We assessed risk of bias and extracted data on health outcomes, surrogate outcomes, usability, sustainability, cost-effectiveness outcomes (quantifying the tradeoffs between health effects and cost), process outcomes, and other characteristics related to PGHD technologies. For isolated effects on health outcomes, we classified the results in one of four categories: (1) likely no effect, (2) unclear, (3) possible positive effect, or (4) likely positive effect. When we categorized the data as "unclear" based solely on health outcomes, we then examined and classified surrogate outcomes for that particular clinical condition.

Findings. We identified 114 unique studies that met inclusion criteria. The largest number of studies addressed patients with hypertension (51 studies) and obesity (43 studies). Eighty-four trials used a single PGHD device, 23 used 2 PGHD devices, and the other 7 used 3 or more PGHD devices. Pedometers, blood pressure (BP) monitors, and scales were commonly used in the same studies. Overall, we found a "possible positive effect" of PGHD interventions on health outcomes for coronary artery disease, heart failure, and asthma. For obesity, we rated the health outcomes as unclear, and the surrogate outcomes (body mass index/weight) as likely no effect. For hypertension, we rated the health outcomes as unclear, and the surrogate outcomes (systolic BP/diastolic BP) as possible positive effect. For cardiac arrhythmias or conduction abnormalities we rated the health outcomes as unclear and the surrogate outcome (time to arrhythmia detection) as likely positive effect. The findings were "unclear" regarding PGHD interventions for diabetes prevention, sleep apnea, stroke, Parkinson's disease, and chronic obstructive pulmonary disease. Most studies did not report harms related to PGHD interventions; the relatively few harms reported were minor and transient, with event rates usually comparable to harms in the control groups. Few studies reported cost-effectiveness analyses, and only for PGHD interventions for hypertension, coronary artery disease, and chronic obstructive pulmonary disease; the findings were variable across different chronic conditions and devices. Patient adherence to PGHD interventions was highly variable across studies, but patient acceptance/satisfaction and usability was generally fair to good. However, device engineers independently evaluated consumer wearable and handheld BP monitors and considered the user

experience to be poor, while their assessment of smartphone-based electrocardiogram monitors found the user experience to be good. Student volunteers involved in device usability testing of the Weight Watchers Online app found it well-designed and relatively easy to use.

Implications. Multiple randomized controlled trials (RCTs) have evaluated some PGHD technologies (e.g., pedometers, scales, BP monitors), particularly for obesity and hypertension, but health outcomes were generally underreported. We found evidence suggesting a possible positive effect of PGHD interventions on health outcomes for four chronic conditions. Lack of reporting of health outcomes and insufficient statistical power to assess these outcomes were the main reasons for "unclear" ratings. The majority of studies on PGHD technologies still focus on non-health-related outcomes. Future RCTs should focus on measurement of health outcomes. Furthermore,future RCTs should be designed to isolate the effect of the PGHD intervention from other components in a multicomponent intervention.

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Evidence Summary

Main Points

- We conducted a thorough evidence review of automated-entry patient-generated health data (PGHD) devices and mobile apps for the prevention or treatment of 11 chronic conditions, specifically looking for evidence on their impact on health outcomes such as mortality, quality of life, and symptom improvement.
- We included 114 controlled studies that used 118 unique devices and 26 mobile apps.
- For three chronic conditions (coronary artery disease, heart failure, and asthma), we found a possible positive effect of PGHD technologies on health outcomes.
- For obesity, we classified the health outcome data as unclear, and we found consistent evidence of a lack of effect of PGHD interventions on the surrogate outcome of body mass index (BMI)/weight.
- For hypertension, we classified the health outcome data as unclear, and we found evidence of a possible positive effect of PGHD interventions on the surrogate outcome of blood pressure.
- For cardiac arrhythmias, we classified the health outcome data as unclear but found consistent evidence of a beneficial effect of PGHD interventions on the surrogate outcome of time to arrhythmia detection.
- The evidence on health outcomes and surrogate outcomes was unclear for the other five conditions (chronic obstructive pulmonary disease, diabetes prevention, sleep apnea, stroke, and Parkinson's disease).
- PGHD technologies are often provided as part of a multicomponent intervention, and future studies should attempt to determine the specific impact of PGHD, place a greater emphasis on the measurement of health outcomes, and study long-term effects.

Background and Purpose

Automated-entry consumer devices that collect and transmit PGHD are currently being evaluated as potential tools to aid in the management of chronic diseases. The majority of consumer health technologies entering the U.S. market have not undergone FDA scrutiny. While these technologies provide much *information* to patients and providers, we focused on whether they improve *health outcomes* for patients with *chronic conditions* (e.g., hypertension, obesity, coronary artery disease). **In summary, we examined the evidence on health outcomes related to automated-entry consumer technologies that provide PGHD for the prevention or management of 11 chronic diseases**.

Methods

We employed methods consistent with those outlined in the AHRQ EPC Program Methods Guidance (https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview), and we describe these in the full report. Our searches covered publication dates up to May 12, 2020. We determined whether each study had constructed comparisons group(s) that isolated the effect of the PGHD technology. For isolated effects on health outcomes, we classified the results in one of four categories: (1) likely no effect, (2) unclear, (3) possible positive effect, or (4) likely positive effect. If the results consistently demonstrate the lack of an effect (via narrow confidence

intervals around a null effect), we coded it as "likely no effect." We examined key surrogate outcomes (e.g., blood pressure for hypertension, BMI for obesity) whenever the direct health outcome data were unclear. We also tabulated data on the frequency of device usage, ease of use, technical problems, and cost-effectiveness.

Results

Table A lists results of the evidence review for the 11 clinical conditions.

Table A. Evidence review results by clinical condition

Clinical Condition	Results Categorization for Isolated Health Outcomes	Comments
Obesity	Unclear for health outcomes Likely no effect on surrogate outcomes	3 of 43 included trials reported whether there were isolated effects on health outcomes (specifically, quality of life), and overall results were unclear. 14 trials reported whether there were isolated effects of device presence on surrogate outcomes (BMI or weight), and all 25 point estimates were less than the minimal important difference (5% body weight).
Diabetes Prevention	Unclear for health outcomes Unclear for surrogate outcomes	None of the three trials reported whether there were isolated effects on health outcomes. One trial reported a surrogate outcome (metabolic syndrome risk) and it found an advantage of PGHD, however it was at high risk of bias.
Sleep Apnea	Unclear for health outcomes Unclear for surrogate outcomes	None of the three trials reported whether there were isolated effects on health outcomes. One trial reported a surrogate outcome (number of days on which apnea events were witnessed) and it found no statistically significant difference and was at high risk of bias.
Hypertension	Unclear for health outcomes Possible positive effect on surrogate outcomes	A total of 51 studies were included. Of these, 18 examined the effect of PGHD devices in isolation. The remaining 33 examined the effects when PGHD devices were combined with other interventions. Six of the 18 isolated effect studies reported on health outcomes (including quality of life, mortality, and hospitalizations), and the overall results were unclear. Sixteen studies reported whether there were isolated effects of device presence on surrogate outcomes (SBP, DBP, and BP control), and results generally favored PGHD arms. Among BP monitor studies, 16/29 SBP point estimates and 10/29 DBP point estimates were greater than the mimimal important difference (2 mmHg for both SBP and DBP).
Coronary Artery Disease	Possible positive effect	Mortality was significantly lower in the PGHD arm in the only study that reported it. Rehospitalization was also lower but did not reach statistical significance.
Heart Failure	Possible positive effect	Different quality of life measures favored the PGHD intervention group in two studies that isolated the effect of PGHD.
Cardiac Arrhythmias or Conduction Abnormalities	Unclear for health outcomes Likely positive effect for surrogate outcomes	There were no statistically significant between-group differences in health outcomes that favored the PGHD intervention. One low risk study found a higher rate of emergency room visits in the AliveCor group, but a positive effect of PGHD for time to arrhythmia detection. Overall, the effect of PGHD on health outcomes is unclear.

Clinical Condition	Results Categorization for Isolated Health Outcomes	Comments
Stroke	Unclear for health outcomes Unclear for surrogate outcomes	The single trial did not report whether there were isolated effects on health outcomes.
Parkinson's Disease	No data	No studies met inclusion criteria.
COPD	Unclear for health outcomes Unclear for surrogate outcomes	3 of 10 RCTs reported isolated effects on health outcomes, but data were unclear. Data on surrogate outcomes (e.g., lung function) were also unclear.
Asthma	Possible positive effect	1 study met inclusion criteria (moderate risk of bias), and it found better symptom control in the PGHD group overall and in the pediatric population alone.

BP = blood pressure; COPD = chronic obstructive pulmonary disease; DPB = diastolic blood pressure; PGHD = patient-generated health data; RCT = randomized controlled trial; SBP = systolic blood pressure

Also, student volunteers involved in usability testing of the Weight Watchers Online app found it well-designed and relatively easy to use. Device engineers independently evaluated consumer wearable and handheld blood pressure monitors and considered the user experience to be poor, while their assessment of smartphone-based electrocardiogram monitors found the user experience to be good.

Strengths and Limitations

The above findings summarize studies that used an isolated-effect design (e.g., PGHD alone vs. no intervention, or PGHD+X vs. X alone). Many other studies used multicomponent interventions (of which PGHD was one component), making it impossible to determine the impact of PGHD. Furthermore, many included studies reported only surrogate outcomes, or only followed patients for a short amount of time (e.g., 3 months).

Implications and Conclusions

Automated-entry consumer PGHD technologies provide a wealth of information for patients and providers, and for three chronic conditions, evidence suggests a possible positive effect on health outcomes. Clinicians might consider recommending that patients with these conditions use a consumer technology for self-monitoring.

For many other conditions, however, the available evidence is unclear on the PGHD effect on health outcomes. More studies with an isolated-effect design, measuring health outcomes in the long term, may help reduce the uncertainty of the impact of PGHD technologies.

For hypertension, even though the evidence was unclear for health outcomes, we found a possible positive effect of PGHD technologies on the surrogate outcome of blood pressure. For cardiac arrhythmias, we found a likely positive effect of PGHD technologies on the surrogate outcome of time to arrhythmia detection. For obesity, we found that there is likely no effect of PGHD technologies on the surrogate outcome of BMI/weight.

Introduction

Background

Chronic diseases (including coronary artery disease [CAD], hypertension, diabetes mellitus, obesity, and stroke) increase morbidity, mortality, and cost to the health care system and society, thereby creating a substantial public health burden. According to the Centers for Disease Control and Prevention (CDC), 6 in 10 adults have 1 or more chronic conditions and 4 in 10 adults have 2 or more conditions (https://www.cdc.gov/chronicdisease/about/index.htm). Self-management strategies that educate and assist patients to manage and monitor their chronic disease have the potential to improve health outcomes, maintain or slow the worsening of progressive conditions, and reduce costs.

The Office of the National Coordinator for Health Information Technology defined patient-generated health data (PGHD) as "health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern."[1] The emergence of PGHD can be partially attributed to 2 dominant digitalization trends: the integration of mobile phones in daily lives and the increasing health-related use of internet-based media. These technologies, which include mobile apps and wearable monitors, have the potential to improve health outcomes of patients and can be important for preventing and managing disease. Health care providers have identified 3 main benefits of PGHD in the clinical setting: deeper insights into a patient's condition, more accurate patient information, and insight into a patient's health between clinic visits, enabling revision of care plans for improved health outcomes, while avoiding unnecessary clinic visits.[2]

For patients, generating one's own health information has the potential to provide an incentive for behavioral change and facilitate health literacy especially for chronic disease management.[3] Patients may also be more inclined to share PGHD if they knew their physician was using that information and it directly impacted their clinical care. Monitoring enabled by PGHD devices could enhance self-management and thereby lower the number of ambulatory clinic visits, emergency room visits, and hospitalizations associated with several chronic diseases. This would save time and resources for both patients and providers as well as lower overall costs. Additionally, patient's chronic diseases may remain better managed, thus leading to overall improved health outcomes among the population.

The field for PGHD has grown rapidly. A report by Research2Guidance in October 2016 found that there are more than 259,000 mobile health apps available for download from major app stores, including the Apple App Store and Google Play. A 2017 Gartner forecast estimated that the overall wearable market will expand from 310 million devices in 2017 to more than 500 million devices in 2021.[4] Common technologies used for capturing PGHD include sensor device or mobile functionality (e.g., GPS, camera, smartphone) and wearable devices (e.g., Fitbit).[5] It is important to determine which of the available technologies have been assessed to determine efficacy related to health outcomes for consumers with (or at risk for) chronic diseases. Additionally, some insurance companies have started offering free wearables as a part of emerging wellness programs and incentivizing their patients to share select PGHD. In the future, insurers will be more likely to reimburse patients for the use of these technologies once these tools are shown to improve outcomes and reduce consumption of resources. However, the availability and development of the technologies have, in many instances, outpaced the publication of trials designed to evaluate health outcomes, usability, interoperability, and benefits and harms of these technologies.

One meta-ethnographic review of patients' perceptions of mobile health apps found many patients worried about the scientific validity of the information provided by apps, unless the app was recommended by their physician. In terms of the information uploaded by the patient, the main concern was security, with patients worrying about "hackers" and "big brother." Patients also expressed concern over their access to apps, such as the connectivity and cost. Older patients with low digital literacy were most affected by user interface issues.[6]

Over the past few years, consumer health technologies entering the U.S. market has surged, with the majority being products not undergoing FDA scrutiny. Consumer health technologies marketed in the United States can be broadly divided into those FDA considers medical devices that are regulated (i.e., devices that claim to diagnose, prevent, or treat medical conditions) and those that FDA considers to be general wellness products (https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device; https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices). Manufacturers of FDA-regulated devices typically are required to demonstrate, through testing, that their devices meet any stated performance/clinical claims. In contrast, manufacturers of non-FDA-regulated devices cannot legally make these claims, although manufacturers will often allude to the performance of their devices through carefully worded marketing. Consumers and providers may find it challenging to distinguish between devices that are FDA regulated and those that are not.

There are also issues with regulating software-based medical devices. Via internet connectivity, these types of devices can be continually modified and updated. This feature brings the challenges of changing product safety and efficacy and cybersecurity and interoperability concerns. As the traditional approach to regulating medical devices does not work with these software-based devices, FDA is looking at alternate approaches. As part of this effort, FDA is piloting a Software Precertification Program, which aims to improve the efficiency of oversight by focusing on the software developer first to confirm commitment to quality before looking at the individual products (https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program).

Many studies evaluate multicomponent interventions, with PGHD technologies representing only one component, and they do not separately evaluate the PGHD component's effect. While many apps or other PGHD technologies are meant to be used in combination with other interventions for chronic disease, the studies still need to be designed to measure impact of the PGHD techhnology when added to the other components. Mobile apps that have similar functions have rarely been directly compared in clinical studies to help clinicians identify the most useful apps to recommend for their patients.[7]

Several issues may influence PGHD's effectiveness for improving patient outcomes. Concerns surround the accuracy of some of the new devices when measuring patient health data (e.g., Apple Watch). From the patient perspective, some patients may lack access to PGHD technologies (particularly in rural or underserved communities with limited internet access) or have a low comfort level with these new technologies and, as such, may use them in a suboptimal manner, limiting their effectiveness; they may even abandon use of the device. Alternatively, even if patients can use the technologies effectively, some may be unwilling to share the data with clinicians due to privacy and security concerns. On the other hand, clinicians may not have the infrastructure to store and process the information from PGHD technologies. If an infrastructure does exist, there is no guarantee that the data will be reviewed by the clinician since this can be time-consuming, and is not a billable activity.

Guiding Questions

1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?
2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?
3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?
4. What are the harms or adverse events associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?
5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

Methods

We followed established AHRQ processes for Technical Briefs, including interviewing Key Informants (KIs), soliciting additional unpublished materials to inform our review through a Federal Register notice, and using peer and public review. Because AHRQ Technical Briefs focus on emerging and rapidly changing technologies, strength-of-evidence assessments are not typically conducted, and we did not evaluate strength of evidence in this review. This draft report was sent to all KIs and selected peer reviewers who did not serve as KIs; it was also posted to the Effective Healthcare website for public comment.

Discussion With Key Informants

Seven KIs representing diverse perspectives, including FDA, clinical effectiveness, the challenges of telemedicine, policy analysis, and patient advocacy, provided input on this review (listed on p. vi). The intent of KI interviews was to provide context and guidance on areas most important to consider. KIs provided input on the review's scope, including the proposed populations, interventions, comparators, outcomes, timing/setting (PICOTS). We asked specific questions about use of consumer products, automated data entry, data transmission to health care staff, and confounding factors in interpreting the literature.

We presented to the KIs our list of eight chronic conditions of interest (obesity, hypertension, prevention of type 2 diabetes, coronary artery disease, heart failure, stroke, chronic obstructive pulmonary disease, asthma), and their input led to the addition of chronic conditions: cardiac arrhythmias or conduction abnormalities, Parkinson's disease, and sleep apnea. These additions were due to KIs believing that PGHD technologies could potentially provide important benefits for patients with these conditions.

KIs agreed with our proposal to focus on technologies available to consumers without a prescription that provide automated data capture, as well as our proposal to not require that data be automatically transmitted to health care staff. Devices eligible for our review employed automated data collection but could have automated or manual transmission of collected data to the provider. While data transmission is possible with many PGHD technologies (e.g., via a downloadable application), KIs agreed that patients may gain health benefits by being aware that their health data was being monitored in the first place. Some KIs felt that "telemedicine" and "telehealth" should be excluded from the scope; however, because these terms have no standard definitions and because many studies of key PGHD technologies, such as mobile apps and wearables, might use those terms, we decided not to exclude studies for using those terms. Instead, the requirement that the studies use a consumer-purchasable device would help focus the project.

Regarding outcomes, the KIs agreed on the importance of health outcomes (e.g., survival, symptoms, quality of life) but disagreed in the importance of non-health outcomes that define certain medical conditions, such as weight for obesity, blood pressure (BP) for hypertension, and hemoglobin A1c (HbA1c) for diabetes prevention. While these latter outcomes are not "health" outcomes, they do influence clinicians' decision making. The review team decided to include and tabulate these data, but to maintain an overall focus on the health outcomes. We reported any included outcome that was reported in any study that met inclusion criteria, regardless of whether it was collected automatically or manually.

Regarding possible confounding variables, KIs felt it was important to consider the degree of patient engagement, noting that patients vary greatly in the degree to which they actually use

PGHD devices during a study. Further, study participants may be more motivated to engage than participants outside studies, and this issue can inform a discussion of applicability. Other applicability concerns raised by KIs involved the possibility that study participants have unrepresentatively high familiarity and comfort with technology (e.g., ready internet access or already have a cell phone) and are more likely to be from urban (not rural) areas.

In summary, KI input helped the review team expand the list of clinical conditions, confirm the focus on consumer technologies without requiring data transmission, refine the approach for surrogate outcomes, and enrich the considerations for applicability.

PICOTS and Inclusion Criteria

Table 1 displays the inclusion criteria according to PICOTS. For outcomes, note that we made a key distinction between "health" and "surrogate" outcomes. Health outcomes are those that matter most to patients and clinicians: for example, mortality, quality of life, emergency room visits, hospital admissions, disease severity, disease progression, and quality of life. By contrast, surrogate measures are disease-specific clinical markers of a condition that are strongly associated with health outcomes, such as BMI for obesity and blood pressure for hypertension. While they often are used by clinicians to guide management, they are not, in and of themselves, the outcomes that matter most. As detailed in the Results Classification section below, we first looked for evidence on health outcomes, and if that was unclear, we then looked for evidence on surrogate outcomes. Regardless, we included both types of outcomes in our evidence tables, so that readers can access the data.

Table 1. Inclusion criteria

Category	Criteria
Populations	**INCLUDE:** Individuals who have (or may potentially develop) one or more of the following 11 chronic conditions: obesity, type 2 diabetes primary prevention only (hereafter referred to as diabetes prevention), hypertension, sleep apnea, coronary artery disease, heart failure, cardiac arrhythmias or cardiac conduction abnormalities, Parkinson disease, stroke, chronic obstructive pulmonary disease, or asthma. **EXCLUDE:** Individuals with other conditions, pregnant women, postpartum women.
Interventions	**INCLUDE:** Consumer health technology, defined as devices consumers use on their own to address health issues and improve quality of life. The purpose could be prevention or treatment (but see above that for diabetes, we only included studies of prevention). They are also referred to as direct-to-consumer medical devices, consumer health-based technologies/devices, over-the-counter devices, consumer-based medical devices, and consumer-grade medical devices. Consumer products do not require a health professional, and may be purchased directly by consumers without a prescription. The technology must collect and store patient data without necessitating manual input that can potentially be used by the patient or sent to a healthcare professional (data transmission is not required, but could be via the same technology or a different technology). We included both U.S.-marketed and non-U.S.-marketed technologies that meet these criteria. However, any technology subject to FDA approval must have received FDA approval to be included. To determine whether a device was a consumer product, we required that the device name or model number be provided. **EXCLUDE:** PGHD technologies that are not consumer technologies or that rely on manual input.
Comparators	**INCLUDE:** Comparators could include non-PGHD interventions, other PGHD interventions, or no intervention. **EXCLUDE**: Comparators that included the same PGHD intervention do not address the efficacy/safety of the PGHD intervention and were excluded.

Category	Criteria
Outcomes	**INCLUDE:** Health outcomes, surrogate outcomes, or economic outcomes: • *Health outcomes* are those widely recognized as direct measures of health, such as mortality, survival, ER visits, hospital admissions, disease severity, disease progression, disease exacerbations, and quality of life. • Surrogate outcomes (e.g., weight loss for obesity, HbA1c for diabetes prevention, blood pressure for hypertension) are not health outcomes, but were included for studies of that same condition, and were excluded for studies of other conditions for either treatment or prevention (e.g., weight loss for diabetes, blood pressure for obesity). • Outcomes that represent potential harms of PGHD interventions (e.g., underprescription or overprescription of medications due to inaccurate PGHD data, leading to unnecessary hospitalization or failure to hospitalize when appropriate). • Outcomes quantifying total costs as a function of the valuations on the effectiveness of multiple interventions (or intervention and active control/usual care) were extracted if the study also reported one of the two outcome categories above. We will note whether cost analyses were reported. Other outcomes were extracted only from studies that reported health outcomes or condition-defining outcomes as defined above. These other outcomes included process outcomes, such as physician-ordered changes in management (e.g., dose alteration, diagnostic testing), and outcomes on interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records. **EXCLUDE:** Surrogates such as prescription filling behavior, biomarkers that do not define the condition (e.g., blood pressure in patients with obesity), adherence, disease knowledge, beliefs, opinions, dietary behavior, activity level, and steps per day.
Timing/Setting	**INCLUDE:** No limitations on timing. Setting must be at home or otherwise outside of a hospital or healthcare center.
Study Designs	**INCLUDE:** Any study design with a separate comparison group of patients who received a different intervention strategy, or single-arm registry studies. Systematic reviews were only used for the purpose of screening their included studies to ensure none were missed by the database searches. **EXCLUDE:** Reviews, case reports, editorials, comments, letters, meeting abstracts, and studies with <10 patients/arm at followup.
Language	**INCLUDE:** English.

ER = emergency room; FDA = Food and Drug Administration; HbA1c = hemoglobin A1c; PGHD = patient-generated health data.

Search Strategies

We searched MEDLINE and EMBASE (via EMBASE.com), In-Process MEDLINE and PubMed unique content (via PubMed.gov), and the Cochrane Database of Systematic Reviews for systematic reviews or randomized controlled trials published from inception through August 27, 2019. We updated these searches on December 23, 2019 and again on May 12, 2020. We also searched ClinicalTrials.gov for active studies through June 19, 2020. We also searched the websites of the following organizations for systematic reviews, technology assessments, and guidelines: Agency for Healthcare Research and Quality (AHRQ), U.S. Food and Drug Administration (FDA), American Health Information Management Association (AHIMA), American Medical Informatics Association (AMIA), Healthcare Information and Management Systems Society (HIMSS).

Study Selection

Using DistillerSR (Evidence Partners, Ottawa, Ontario, Canada), three reviewers screened titles, and six screened abstracts and full articles. For titles, only one reviewer was used to assess general relevance to the topic. For abstract screening, two reviewers were necessary to exclude an article from further consideration, but only one was necessary to order the full text. At full

text, two reviewers assessed the study against the inclusion criteria and disagreements were resolved by a (senior-level) third reviewer. Full-text screening also involved determining which publications were associated with other included publications (e.g., subsequent publications of the same trial).

To confirm that the included PGHD devices were consumer products, we enlisted the assistance of device engineers. Three engineers examined the list of PGHD devices (manufacturer and model names) and determined whether any of the devices were not available for purchase directly by consumers. Any trials that had *only* included nonconsumer devices (e.g., devices requiring a prescription) were excluded.

Study-Level Data Extraction

For each included trial, one reviewer extracted general trial information (design, country, enrollment dates, statistical power methods, N at baseline, study duration), patient characteristics (key inclusion criteria, mean age, % female, baseline disease severity, and whether the population was rural), treatment details (including which specific PGHD device[s] were given to which treatment group[s]), risk-of-bias items (see next section), and outcome data (outcome category, specific outcome, results, and statistical tests). We extracted up to six categories of outcomes for each trial:

- Health outcomes (e.g., symptoms, quality of life [QOL], major health events such as strokes/heart attacks, exacerbations. mortality, survival, ER visits, hospital admissions, disease severity, disease progression)
- Surrogate outcomes (e.g., body mass index [(BMI]) for obesity, blood pressure (BP) for hypertension)
- Outcomes pertaining to Guiding Question 2 (interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) (only if the trial reported either health outcomes and/or surrogate outcomes)
- Cost-effectiveness (quantifying the tradeoff between health effects and cost) (only if the trial reported health outcomes)
- Process outcomes (e.g., medication changes, diagnostic tests ordered, other health-care-centered outcomes) (only if the trial reported health outcomes)
- Whether the article reported cost-only data

Risk of Bias

For each trial, one reviewer assessed the risk of bias using nine items:

1. Random sequence generation?
2. Allocation concealment?
3. Groups similar at baseline or were differences controlled for?
4. Isolated effect?
5. Were outcomes pre-specified and reported?
6. Were participants analyzed based on originally assigned groups across time points?
7. Was attrition low and adherence high?
8. Were outcome assessors and data analysts masked?
9. Were reliable measures of outcomes used consistently across all participants?

We categorized each item as Low, High, or Unclear as follows:

1. Low if allocation sequence was generated via computer, random numbers table, etc. High if allocation was not random or used pseudo-random approach (e.g., alternating assignment, year of birth, etc.). Unclear if studies were described as random with no further details.
2. Low if the study staff assigning treatments did not know what the next patient's assignment would be, using methods including sealed envelopes.
3. Low if there were no statistically significant differences or differences were small for important characteristics. Also Low, if important differences were controlled for in the analysis. Baseline characteristics considered included age, sex, and important condition-specific characteristics (e.g., body mass index for obesity).
4. Low if at least one comparison where the only difference between groups involved the PGHD device. High if in all comparisons, additional intervention(s) were received in one group but not the other.
5. Low if outcomes listed in protocol and results paper are similar. Also Low if protocol is not on hand, but primary and secondary outcomes are clearly stated. Unclear if no available protocol and primary and secondary outcomes not clearly stated.
6. High if crossover is present and patients analyzed by received treatment rather than assigned treatment. Otherwise Low.
7. Low if at least 80% for those enrolled have data at a key timepoint, and there is no substantial differential attrition. Otherwise High.
8. Low if there was a clear statement that either outcome assessors or data analysts were masked. Otherwise High.
9. Low if measures used have been tested and provide consistent information.

We draw the reader's attention to item 4, "Isolated effect?" With this item, we determined whether the treatments in the study permitted an estimate of a PGHD intervention's isolated effect. This would be true, for example, if the control group received educational materials only, and the intervention group received the same educational materials along with a single PGHD device and no other interventions. However, in the majority of trials, the intervention group received additional intervention(s) beyond the PGHD intervention, such as an additional PGHD device, or a PGHD device combined with physical activity goals (e.g., 10,000 steps a day) in obesity trials. In these "multicomponent" situations, no isolated estimate is possible, so we assigned High risk of bias to item. As per EPC guidance, the funding source of the study was not a component of the risk of bias rating.[8]

After completing the nine items, we categorized the trial as at Low, Moderate, or High risk of bias overall. We subjectively judged the overall risk of bias based on the items as well as the overall assignment process used in the AHRQ report titled "Mobile Applications for Self-Management of Diabetes."[9]

Results Classification

For isolated effects on health outcomes, we classified the results in one of four categories: (1) likely no effect, (2) unclear, (3) possible positive effect, or (4) likely positive effect. If the results consistently demonstrate the lack of an effect (via narrow confidence intervals around a null effect), we coded it as "likely no effect." If the results have inconsistency in direction of effect and/or study authors could not reach a conclusion, the findings were coded as "unclear" for that outcome. If one or more outcomes have minor inconsistency in findings, but at least one

study with moderate or low risk of bias showed a positive effect, the findings were coded as "possible positive effect." If the results had a consistent positive effect, we coded it as "likely positive effect."

When we categorized the data as "unclear" based solely on health outcomes, we then examined surrogate outcomes for that particular clinical condition. We then assigned one of the four categories to the surrogate outcome data.. To help interpret surrogate outcome data on BMI or weight for studies of obese patients, we used a minimal important difference of 5% of body weight, [10] which corresponds to 1.67 BMI units (5 kilograms) in a woman of typical baseline weight and of average height. To help interpret surrogate outcome data on SBP or DBP for studies of patients with hypertension, we used a minimal important difference of 2 mmHg.[11,12]

Evaluation of Economic Evaluations

Risk of bias of economic evaluations were assessed using a modified version of the Consensus Health Economic Criteria (CHEC) tool previously described in the AHRQ report titled "Telehealth for Acute and Chronic Care Consultations."[13] All 11 specific items appear in Table C-27, C-34, and C-60 of Appendix C. These criteria related specifically to concerns of internal validity and the potential introduction of bias. All studies, regardless of economic evaluation design, were categorized as "low risk of bias," "moderate risk of bias," or "high risk of bias" after reviewing individual components of the modified CHEC tool.

Device Similarity and Usability Testing

Many users of research would like to know the degree of similarity between a device tested in trials and the set of devices that are available for purchase. For example, suppose a trial uses a device that is dissimilar to all products currently in the field. This would mean that its results are less important, since it would be difficult to use that research to make decisions about device purchasing. For each PGHD device, device engineers assessed similarity to device(s) currently on the market by that manufacturer. They used the following scale:

1. This model is similar to one currently available from this manufacturer
2. This model is SOMEWHAT different than any that are currently available from this manufacturer
3. This model is VERY different than any that are currently available from this manufacturer
4. We could not reliably determine the similarity of this model to the ones currently available from this manufacturer.

Key Question 2 addresses the published data on the usability of PGHD devices, but none of the trials were primarily designed to address in-depth usability problems. Therefore, as a pilot investigation of the type of information usability testing can provide,[14] we conducted our own usability testing on one of the apps for obesity (specifically Weight Watchers Online).We chose this app due to its availability on both iphones and Android phones, its high visibility (975,000 reviews on iphone as of January 2020), and its high ratings (it was one of 17 apps rated best weight loss app of 2019).[15] This project did not have sufficient resources for us to conduct additional usability testing. The results of this usability testing appear in the obesity subsection of the Findings section.

Specifically, in February 2020, a usability assessment of the Weight Watchers (WW) app was conducted by five undergraduate students who are affiliated with the Interaction Design and Engineering for Advanced Systems (IDEAS) lab at Rowan University. These students

downloaded the WW app onto their mobile phones, all of which were Apple devices, and used $25 iTunes gift cards to pay for a single month membership, which cost $24. (Since the version of the WW app for Android devices available on Google Play did not allow users to use a Google Play gift card to pay the monthly membership fee, and the app appeared to require users to sign up for a counseling session to start, the IDEAS lab was unable to test the app's Android version.) The student testers used the app for 7–10 days before conducing a heuristic evaluation to identify both positive features and potential usability issues. WW Online was also the intervention investigated by an included obesity study.

Once all students had reviewed the app, a superset of all issues and positive features was created. Then the students they met as a group, facilitated by a human factors psychology professor. During the meeting all feedback was reviewed and, if necessary, explained, and students were asked to assign severity ratings to the issues and priority ratings. Issues were rated on a 0 to 3 scale with 0=not an issue, 1=minor, 2=moderate, 3=major issue. The suggestions for improvement were rated on a 3 point scale with 1=consider only if time/resources allow, 2=worth discussing , 3=strongly recommended. None of the issues or benefits had an average rating greater than 2. Finally, the professor worked with the students to create two prioritized lists, one listing suggestions for changes that could increase usability and the other listing ideas for future enhancements, new features.

In addition, device engineers provided analyses they had recently completed on two types of consumer PGHD devices that were deemed to be of high interest to users: handheld and wearable blood pressure (BP) devices (for hypertension management) and Smartphone-enabled ECG monitors (for cardiac arrhythmia detection). For both device types, HD engineers performed a range of physical tests, reviewed product literature/specifications, and asked users about their experience with the device. They rated the devices in the categories of performance, safety, workflow, interoperability, maintenance, patient experience, and user experience. The rating ranged from Poor to Excellent, and each category rating contributed to an overall rating for the device.

Data Presentation

We created six sets of evidence tables—one set per clinical condition. The first listed ongoing clinical trials identified in ClincalTrials.gov, the second listed general study information, the third listed patient characteristics, the fourth described the treatment groups, the fifth listed the individual risk-of-bias items for each trial included our overall judgment, and the sixth listed the included outcomes and statistical results. See the above section Study-Level Data Extraction for the specific information we extracted.

Peer Review and Public Commentary

We invited telehealth experts to provide external peer review of this technical brief; AHRQ and an associate editor also provided comments. The draft report will be posted on the AHRQ website for 3 weeks to elicit public comment. We will address all reviewer comments, revising the text as appropriate, and document everything in a disposition of comments report that will be made available 3 months after AHRQ posts the final technical brief to its website.

Findings

Results of Literature Searches

Our searches identified 8,667 potentially relevant articles, of which we excluded 5,755 at the title level (not relevant), 1,755 at the abstract level, 165 were secondary publications of other articles, and 435 were systematic reviews. We dual-screened the full text for the remaining 557. The review team included 126 of these, but upon further review of study devices by device engineers, 12 studies had used only non-consumer devices and were therefore excluded (see the list of full-text exclusions in Appendix Table B-1). The remaining 114 unique studies were described in 166 publications.

Overview of Evidence

Among the 11 chronic conditions, hypertension (51 studies) and obesity (43 studies) had the number of included studies most (Table 2). The most common categories were pedometers, accelerometers, and BP monitors.

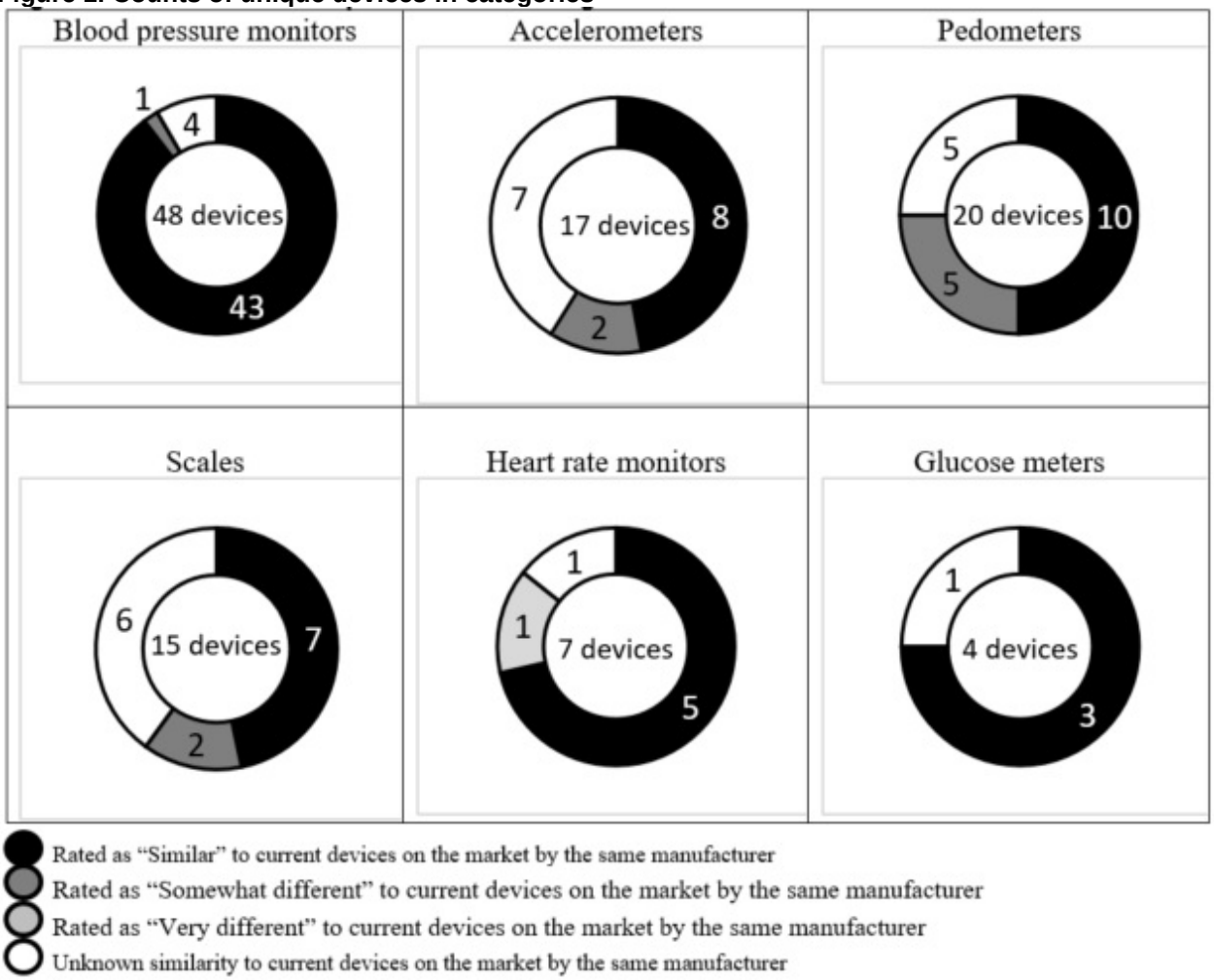
Table 2. Overview of evidence

Chronic Condition	# of Included Studies	Typical Categories
Obesity	43	17 pedometers, 14 accelerometers, 5 BP monitors, 8 scales, 2 glucose meters, 1 body composition monitor, 1 energy expenditure monitor, 1 pedal machine, 1 combined accelerometer/heart rate monitor/galvanic skin response monitor/cutaneous temperature monitor
Diabetes Prevention	3	2 pedometers, 1 accelerometer, 1 BP monitors, 1 glucose meter, 1 heart rate monitor
Sleep Apnea	3	2 pedometers, 1 BP monitor
Hypertension	51	41 BP monitors, 4 pedometers, 3 glucose meters, 3 scales, 2 heart rate monitors
Coronary Artery Disease	7	3 BP monitors, 3 heart rate monitors, 1 accelerometer
Heart Failure	6	7 BP monitors, 6 scales, 3 heart rate monitors, 1 pedometer, 1 pulse oximeter
Cardiac Arrhythmias or Conduction Abnormalities	4	1 ECG monitor
Stroke	1	1 BP monitor
Parkinson's Disease	0	NA
COPD	10	4 accelerometers, 3 pedometers, 1 BP monitor, 1 forehead thermometer, 1 heart rate monitor
Asthma	1	1 spirometers

BP = blood pressure; ECG = electrocardiogram; COPD = chronic obstructive pulmonary disease; N.A.= not applicable.
Note: The numbers in the table add to more than 114 because some studies were included for multiple chronic conditions.

Eighty-four of the 114 studies used a single PGHD device, 23 used 2 PGHD devices, and the other 7 used 3 or more PGHD devices. When the same study used two PGHD devices, it was most commonly either pedometer and scale or BP monitor and scale. Regarding device similarity, BP monitors were often similar to those currently available, whereas other devices were mostly rated either as similar or of unknown similarity. A graphic showing the six most common device categories appears in Figure 1 below. The devices are listed in Appendix Table C-1.

Figure 1. Counts of unique devices in categories



Note: All specific devices are listed in Appendix Table C-1, along with similarity ratings, clinical condition(s), and specific studies in which the devices were used. Single devices not listed in the graphic above include an ECG monitor (rated as similar), an energy expenditure and physical activity monitor (unknown similarity), forehead thermometer (rated as similar), pedal machine (rated as similar), pulse oximeter (unknown similarity), and a spirometer (rated as similar), a bite counter (rated as similar), a body composition monitor (rated as somewhat different), and a combined accelerometer, heart rate monitor, galvanic skin response monitor, and cutaneous temperature monitor (rated as similar).

Current costs of PGHD devices are best obtained searching the internet, or by visiting specific manufacturer's websites. Manufacturers whose device(s) were used in at least three studies include Omron (see www.omronhealthcare.com for blood pressure monitors and pedometers), A&D (see https://medical.andonline.com/home for blood pressure monitors and scales), Yamax (see https://www.yamaxx.com/digi/ for pedometers), Fitbit (see www.fitbit.com for accelerometers), Tanita (see www.tanita.com for scales), Microlife (see www.microlife.com for blood pressure monitors), and AliveCor (see www.alivecor.com for ECG monitors).

Twenty-four of the 114 studies used one or more mobile apps (listed in Appendix Table C-2). Fifteen of the apps were used in trials of obesity. Eight trials used an app but did not provide its name. As of June 2020, we determined that 9 of the 18 named apps were available on iPhones, and 7 were available on Android™ phones.

In the sections below, for each of the 11 clinical conditions, we address the five Guiding Questions. Appendix C contains all evidence tables.

Obesity

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Obesity

The 43 obesity trials used 50 different PGHD devices: 17 pedometers, 13 accelerometers, 8 scales, 5 BP monitors, 2 glucose meters, 1 pedal machine, 1 bite counter, 1 energy expenditure and physical activity monitor, 1 body composition monitor, and 1 combined accelerometer/heart rate monitor/galvanic skin response monitor/cutaneous temperature monitor. All these devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1. The similarity judgments (how similar each device is to those currently on the market by this manufacturer) were:

- Pedometers: 8 similar, 5 somewhat different, 0 very different, 4 unknown
- Accelerometers: 5 similar, 1 somewhat different, 0 very different, 7 unknown
- Scales: 3 similar, 1 somewhat different, 0 very different, 4 unknown
- BP monitors: 3 similar, 0 somewhat different, 0 very different, 2 unknown
- Glucose meters: 1 similar, 0 somewhat different, 0 very different, 1 unknown
- Pedal machine: 1 similar, 0 somewhat different, 0 very different, 0 unknown
- Bite counter: 1 similar, 0 somewhat different, 0 very different, 0 unknown
- Energy expenditure and physical activity monitor: Unknown
- Body composition monitor: Somewhat different
- Combined accelerometer, heart rate monitor, galvanic skin response monitor, and cutaneous temperature monitor: Similar

Studies in Progress: Obesity

We identified 11 records in ClinicalTrials.gov on preventing or treating obesity that, once published, may potentially meet our inclusion criteria. As of June 19, 2020, 1 was not yet recruiting patients, 5 were recruiting, 1 was enrolling by invitation, 3 were active but not recruiting, and 1 was unknown. More details about these records (including hyperlinks) appear in Appendix Table C-3.

Study Designs: Obesity

All 43 included obesity studies were randomized trials. Twenty-seven trials were conducted in the United States, and other prominent countries included South Korea (5 trials), Australia

(2 trials), and the United Kingdom (2 trials). The median number of patients at baseline was 96 (interquartile range [IQR] 44 to 177). Patient enrollment dates (reported by 29 trials) ranged from September 2001 to October 2017, the median study enrollment period was 1 year (IQR 6 months to 24 months), and the median month of patient enrollment was March 2012. The next sections describe additional aspects of these trials, which are tabled in detail in Appendix Table C-4, C-5, and C-6.

Inclusion/Exclusion Criteria: Obesity

Studies generally included obese or overweight adults who did not have other major medical conditions and were willing and able to start a new exercise regimen. Seven trials enrolled only older adults (e.g., age ≥60), and another seven trials enrolled only children, adolescents, or young adults. Seventeen trials enrolled only patients with a specific comorbidity (e.g., 3 trials of overweight patients with sleep apnea). Twenty-one trials required comfort with technology, such as already owning a smartphone and/or the willingness and ability to receive ongoing text messages as part of a weight-loss intervention.

Additional Patient Characteristics: Obesity

All 43 studies reported mean age, and the median was 47 years old (IQR 41 to 55) All 43 studies reported the percentage of patients who were female, and the median was 71% (IQR 50% to 83%) Forty-one of 43 studies reported the BMI at baseline, and the median was 32 (IQR 29 to 34.6). In a woman of average height, a BMI of 32 corresponds to 84 kilograms (185 pounds). Only three of 43 studies enrolled patients in rural settings (northern Finland,[16] lower Mississippi delta,[17] and Piedmont county in North Carolina).[18] Twenty of 43 studies required some degree of technological expertise. Specifically, 13 required patients to have internet access, 12 required them to own mobile phones, 5 required to own computers, 3 required the ability to send/receive text messages, and 2 required basic computer skills.

Statistical Power Analyses: Obesity

Twenty-five of the 43 trials conducted *a priori* power analyses. Eight had based effect-size estimates on prior work and had also accounted for anticipated attrition. Another 10 accounted for anticipated attrition, but did not state the bases for anticipated effect sizes. Another five stated the bases for anticipated effect sizes but did not account for anticipated attrition. The other two mentioned neither prior work nor attrition. Of the 25 power analyses, 12 were based on BMI/weight, 6 were based on physical activity level such as steps/day or sedentary time, 1 was based on blood pressure, 1 was based on self-monitoring frequency, and 5 did not report the outcome on which the power analysis was based.

Followup Length: Obesity

The median followup length in the 43 obesity trials was 26 weeks (6 months), with an IQR from 3 to 12 months.

Adherence Measurement: Obesity

Device adherence was typically measured by the number of days during followup that patients used the consumer device or app or provided data to study staff.

Comparators: Obesity

The 43 obesity trials were notable for the complexity of their comparisons. Twenty-seven of 43 trials had 2 treatment groups, 14 had 3 groups, 1 had 4 groups, and 1 had 5 groups. Four trials had a waitlist control group (i.e., not seen by study staff during the trial), and 30 trials had a control group seen by study staff during the trial but not receiving the PGHD device. In five trials, the control group did use at least one PGHD device (e.g., just a scale), and their outcomes were compared to an intervention group that received multiple PGHD devices (e.g., both a scale and an accelerometer). In 11 trials, 2 groups received the same device(s), but one group's treatment was enhanced in some way (e.g., Facebook group to share performance). In five trials, a control group received a PGHD device in a different device category (e.g., a scale instead of an accelerometer), or the control group received a different PGHD device in the same category (e.g., a Fitbit Aria scale vs. a Tanita digital scale).

Outcomes Reported: Obesity

Only 16 of the 43 obesity trials reported a health outcome, which was invariably either QOL or adverse effects (AEs). Almost all (41 of 43) reported a surrogate outcome (BMI or weight), and most (30 of 43) reported data informing device usage or ease of use or technical problems (which are the subject of Guiding Question 2, which appears next). None reported process outcomes, cost-only data, or cost-effectiveness data.

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Below, we discuss the pertinent obesity data for this Guiding Question separately for accelerometers/pedometers, scales, and other devices. All these data appear in the top section of Appendix Table C-8. After these sections, we discuss our usability testing of the WW App.

Studies varied greatly in the degree of device interoperability employed during the study. Twenty-five of 43 studies used automatic data transfer from the PGHD device, another 4 required patients to upload the data that had been automatically collected by the device, and the other 14 either only employed manual data entry or did not mention device interoperability. Seventeen of the 25 studies using automatic data transfer had also used manual data entry for other types of data in the same study (typically dietary intake, but sometimes manual entry from additional PGHD devices). The end target for the data transfer was a smartphone in 20 studies, with 7 of these also accepting data to a website and another 3 accepting data to a study database or electronic health records. Another 15 studies collected data only on a website. Study personnel received the data automatically in 28 of 43 studies (either from a shared app or website), three studies required data download directly from PGHD devices, three studies provided data to study personnel only through patient sharing (e.g., text messages from patients), one study intentionally did not make data available to study personnel during the study, and the other 8 studies did not mention how or whether data were transferred to study personnel.

Accelerometers/Pedometers: Obesity

Patient usage of these devices was highly variable across the trials, ranging from 37% to 95% of trial days (median 64%). Among those who consistently used their devices, they wore it for most of their waking hours (range 9 to 14 hours a day). Satisfaction and ease of use were rated highly by patients in almost all the studies reporting such data. For example, in the study by Cadmus-Bertram et al. (2015),[19,20] all 26 patients in the intervention group "liked" the accelerometer, and 76% would recommend it to a friend (56% preferred a clip-on, 29% preferred wrist-worn, and the other 24% had no preference). One exception to the general positive reaction was in the study by Smith et al., (2019)[21] in which only two-thirds of patients reported a "positive impact of the device," whereas the other 33% "negatively viewed the device." Regarding technical problems, six studies reported some issues involving "equipment malfunction" (not further described by the authors), lost or broken device, difficulty downloading or logging in or saving step counts, and incompatibility with certain smartphones.

Scales: Obesity

Use of body weight scales was also highly variable (18% to 79% of study days). One study[22] reported ease of use of body weight scales and had found that 66% of patients (19/29) rated the scale as "helpful." Two studies reported technical problems, with one reporting issues with Internet connectivity preventing scale initialization, and the other did not report what the technical problems with the scale were.

Other Devices: Obesity

The study by Yoo et al. (2009)[23] reported that patients sent their BP readings (using the Omron T5M BP monitor) an average of 1.72 times/day (86% adherence). Green et al. (2014)[24] provided patients with a BP monitor (Omron 711DLX), and they found it "extremely helpful" to monitor their BP at home and share readings with their provider.

The Bite counter, used by Turner-McGrievy et al. (2017)[25,26] as a device that is now available for either iPhone or Android as an app, detects hand movement when eating in order to count bites. The study found that patients used it an average of 1.9 meals/day and 3.6 days/week. Oh et al. (2015)[27,28] reported ease-of-use data on their "SmartCare" service, which included the body composition monitor by Biospace (InBody IH-U070B). Patients rated the convenience of using this device at a mean of 3.5 out of 5 possible points.

Mameli et al. (2018)[29] gave patients the Empatica E3 wristband from Italy, which is not only an accelerometer, but also a heart rate monitor, galvanic skin response monitor (sweat gland activity), and cutaneous temperature monitor. Patients used the wristband only 37% of days.

Jakicic et al. (2016)[30] reported usage data for a combined energy expenditure and physical activity monitor called the FIT Core by Body Media. Patients wore the device a median of 31% of days (170 days in the 18-month period), for a median of 4 hours/day.

Yoo et al. (2009)[23] provided patients the Anycheck glucose meter by Insung, and they sent blood glucose recordings an average of 1.84 times per day (adherence rate 92%). Carr et al. (2013)[31] provided workers access to a pedal machine (MagneTrainer by 3D Innovations) at their workplace. They used it an average of 38% of possible days, for about 30 minutes per day. Workers rated the pedal machine biofeedback as extremely helpful (median of 5 on scale from 1 to 5).

Usability Testing of the Weight Watchers Online App: Obesity

Regarding the WW Online app, all usability comments and recommendations from the five students at Rowan University appear in Appendix Table C-9. Note that this app was also tested in the included study by Thomas et al. (2017),[32] which enrolled patients from May 2013 to March 2014, and the app was likely altered in the intervening 6-year period.

Overall, the students found the WW app to be well-designed and relatively easy to use. Some of the features that were highlighted as particularly beneficial include 24/7 chat to get immediate answers; the recipes feature; the ability to enter foods through different methods, including voice-recognition, bar code scanning, and manual entry supported by searching an extensive database (e.g., by brand names or restaurant names); and the activities and training videos that help users integrate exercise into their daily schedules. They also found the initial landing/home page and the success checklist to be well-organized and easy to navigate and the information in the FAQs section to be helpful.

Suggestions for improving usability include:

- Adding a + sign to the food recording screen rather than just showing a search option
- Using arrows (conventional for mobile apps) rather than buttons (unconventional) to navigate between weeks
- Adding a button or link to allow users to skip the tutorial that is shown on the Success Checklist page rather than requiring users to view the whole video before interacting further with the app
- Automatically launching a tutorial or presenting instructions or a guide upon first opening the app
- Organizing the FAQs into topic areas.

Suggestions for feature enhancements/upgrades include adding personalization to the recipes feature for users with specialized diets (e.g., low salt, vegan, gluten free), allowing users to access their total nutritional intake per day and providing tips connected to specific aspects of their diets (watch sodium, need vitamin C), and providing pointers to new articles or reminders of how healthy foods can help improve aspects of users' health. After using the app for at least a week, students were also unclear about a few things (e.g., why is goal weight accessed through the settings section rather than entered during initial setup? and what would happen if they indicated they wanted "a little extra support" at a particular time of day?).

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

Below, we first provide an overall summary of the most relevant data: studies that investigated whether there is an isolated effect of PGHD technologies on health outcomes. Because these data did not lead to a clear statement, we then discuss surrogate outcomes (i.e., BMI or weight) reported by isolated-effect studies, to determine whether we could use the surrogate data to make a statement about health outcomes. We then discuss studies investigating the multicomponent effects of PGHD technologies on either health outcomes or surrogate outcomes. All risk-of-bias assessments are in Appendix Table C-7, and the results are in Appendix Table C-8.

Isolated Effects on Health Outcomes: Obesity

For preventing or treating obesity, three trials have examined whether PGHD technologies have isolated effects on health outcomes. In all three trials, the specific health outcome was QOL, which was measured using the SF-12 in two trials, and the SF-36 in one trial. We next discuss each trial in detail.

Fukuoka et al. (2019)[33-38] (Low risk of bias) compared three groups: control group (Omron active style Pro HJA-350IT, which showed daily steps/intensity), regular (same accelerometer, plus 3-month access to the "mPED" app, which provided daily messages and physical activity diary, and "plus" (same as regular group except that they had 9-month app access). Researchers measured QOL at both 3 months and 9 months. Physical QOL for the two groups with app access was better than that for the control group at 3 months (means not reported, but p=0.04), but was not better than that for the control group at 9 months. For mental QOL, authors found no difference between groups at either time point.

Smith et al. (2019)[21] (Moderate risk of bias) compared two groups: Exercise (16-week home-based program, with weekly calls to the study physiologist) and Exercise plus fitness tracker (same program and either the Fitbit Flex or the Fitbit One, which provided feedback on steps, stairs, and calories expended). At 16 weeks, authors found no statistical significant differences in either mental or physical QOL between the 2 groups.

Richardson et al. (2016)[39] (High risk of bias) compared three groups: time-based walking goals (no PGHD device, but they set walking goals), simple pedometer (Yamax Digiwalker SW 200 and instructed to wear it daily, and step counts were reviewed over the phone with study staff, and step count goals modified accordingly), and "enhanced" pedometer (SportBrain iStep X), with the same step count review and goal modification, and on a website they received motivational messages, viewed graphs of their step counts over time, and engaged with an online community. For the SF-12 physical scores, the study found no difference in QOL between groups from baseline to 26 weeks. However, for the SF-12 mental scores, the two pedometer groups had larger improvements in mental QOL. Baseline scores were about 37-38 in all 3 groups (using a scale range 0-100 where higher scores are better; these baselines are considerably lower than published population averages of 70-80).[40] Scores had improved to about 40 in the pedometer groups, but had decreased to 36 in the no-device group. This is approximately a 4% difference in mental QOL. We rated the study at high risk of bias due to several factors, including unclear randomization and allocation concealment, relatively high attrition, and unmasked outcome assessors.

In summary, we categorized this evidence as "unclear".One low risk of bias study found a positive effect at 3 months that vanished by 9 months, and the single moderate-quality study found no statistically significant effects. The one study that did report a persistent positive effect (about a 4% difference in mental QOL, but no effect on physical QOL) we rated at high risk of bias.

Isolated Effects on Surrogate Outcomes: Obesity

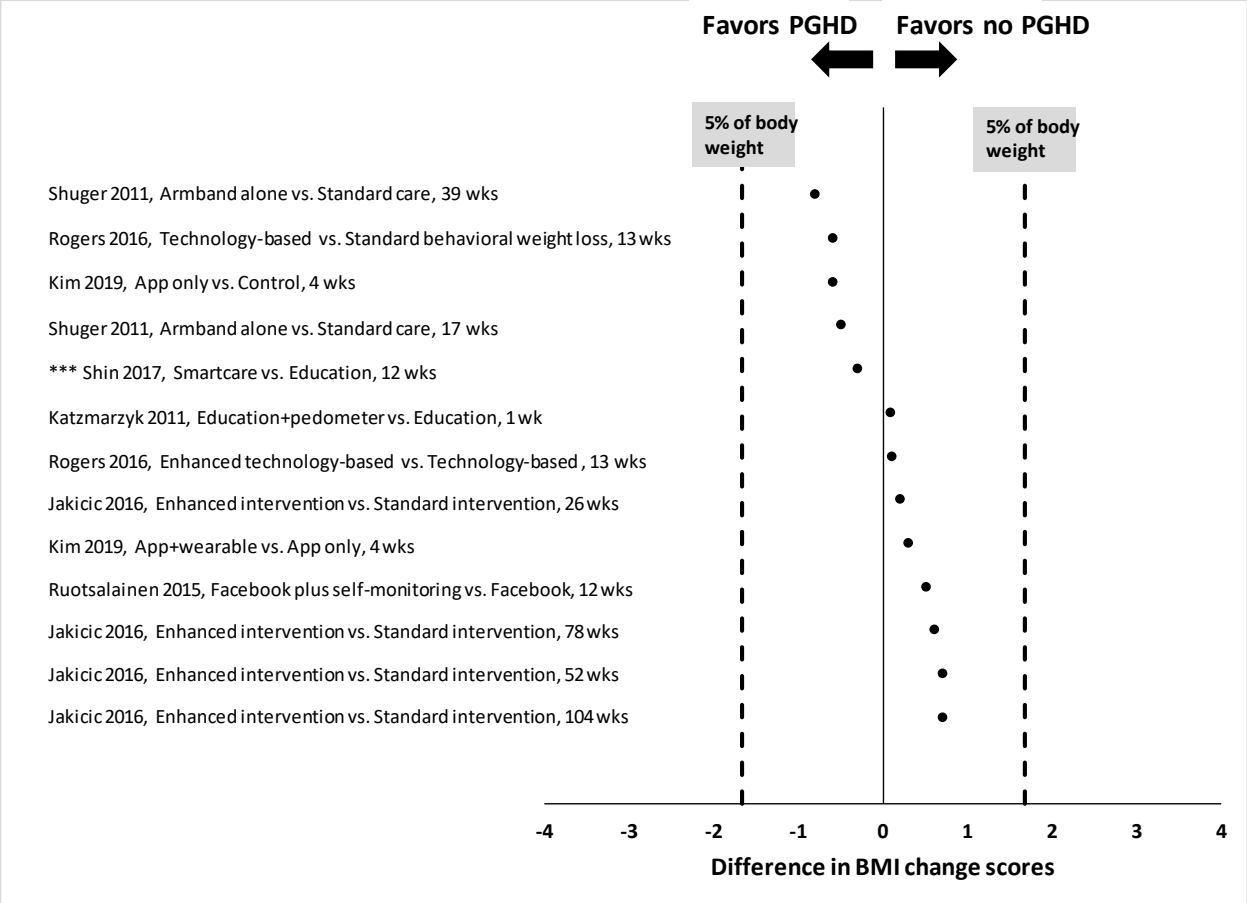
Due to the lack of clarity about health outcomes, we turned to surrogate outcomes. Sixteen obesity trials reported isolated effects on BMI or weight. We prioritized the BMI data because it controls for height, and only extracted weight data authors did not report BMI. To help interpret BMI reductions, note that for a person of average height (5'7" or 1.72 meters), a BMI reduction of 1 unit corresponds to 3 kilograms, which is 6.6 pounds. Due the complexity of treatment

groups and comparisons (the 16 trials had 44 treatment groups), we separately discuss the results for 3 types of comparisons:

- Device presence: PGHD device vs. no PGHD device, or adding another PGHD device
- Across-category. One PGHD device vs. a PGHD device in a different category (e.g., accelerometer vs. scale)
- Within-category. One PGHD device vs. a different PGHD device in the same category (e.g., 1 pedometer vs. another)

Fourteen of the 16 trials reported the effect of device presence, and the point estimates for their surrogate outcome data appear in Figure 2 (BMI) and Figure 3 (weight). Each point is a study result reflecting the between-group difference in change scores. One[21] of the 14 studies appears in neither graph because authors only reported that the between-group difference was not statistically significant (no numerical data reported).

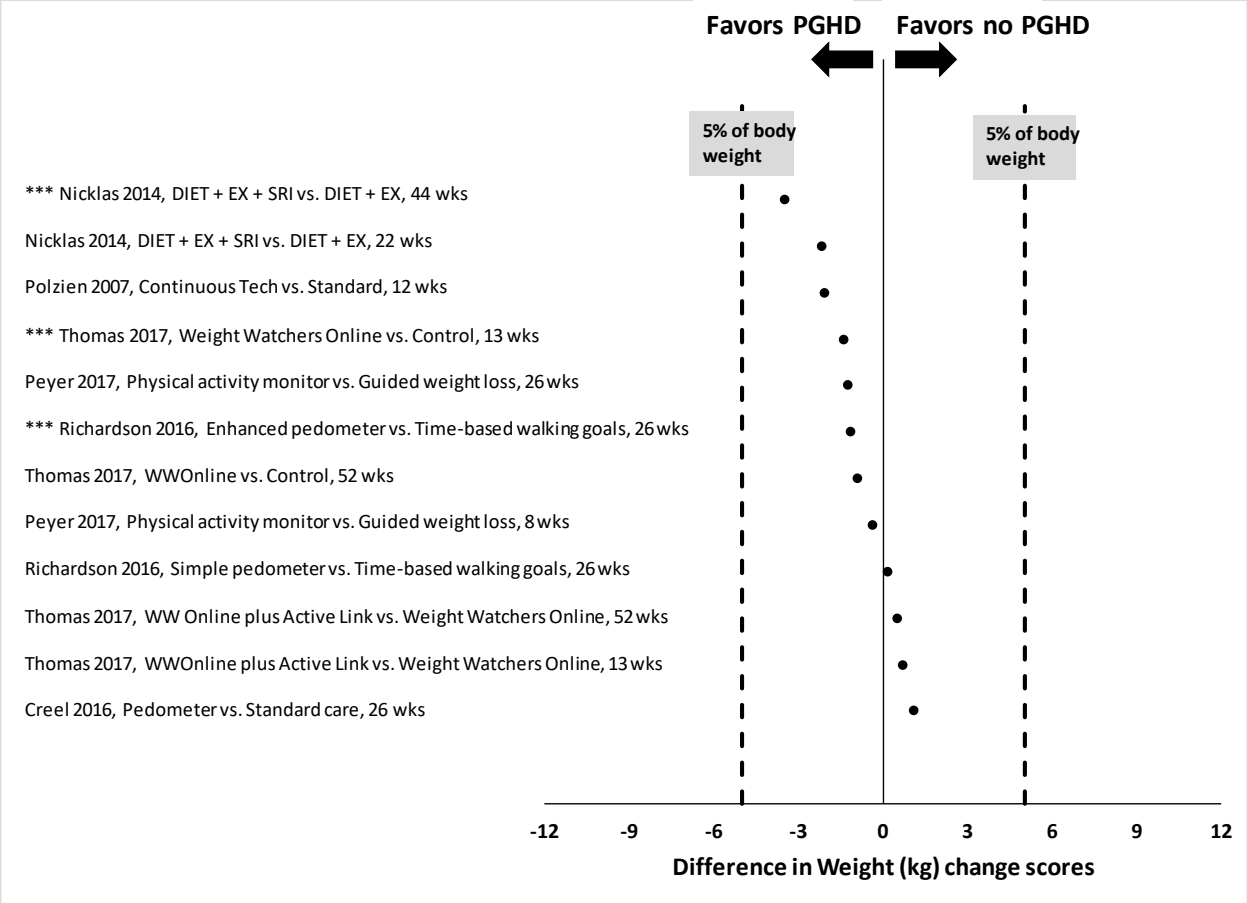
Figure 2. BMI differences in studies of isolated effects of device presence/absence



***statistically significant between-group difference

Note: Each filled circle is a point estimate of the difference in BMI change scores. Points to the left of the middle line suggest that the PGHD technology resulted in greater weight loss than without the PGHD technology, whereas points to the right of the middle line suggest the reverse. The two dashed lines represent the minimal important difference of 5% body weight (differences less than this are considered not clinically important).[10] For BMI, assuming patients were of average height, this is about 1.67 BMI units (or 5 kilograms), based on the overall average baseline weights.

Figure 3. Weight differences in studies of isolated effects of device presence/absence



***statistically significant between-group difference

Note: Each filled circle is a point estimate of the difference in weight change scores. Points to the left of the middle line suggest that the PGHD technology resulted in greater weight loss than without the PGHD technology, whereas points to the right of the middle line suggest the reverse. The two dashed lines represent the minimal important difference of 5% body weight (differences less than this are considered not clinically important).[10] For BMI, assuming patients were of average height, this is about 1.67 BMI units (or 5 kilograms), based on the overall average baseline weights.

Only 4 of the 14 trials found any statistically significant differences:

- Shin et al. (2017)[41,42] (low risk of bias) had given two of three groups an accelerometer (Suwon Fitlife), and one of them had greater BMI reduction at 12 weeks than the nondevice group (1 BMI unit lost vs. 0.2 BMI units lost), but the other device group did not (0.5 BMI units lost).
- Richardson et al. (2016)[39] (high risk of bias) found larger weight reductions in their enhanced pedometer group (SportBrain iStep X) then in their time-based walking goals group. They had lost an average of about 2 kg over 6 months, whereas the nondevice group had only lost 0.7 kg. Their simple pedometer group was not statistically significantly different in weight loss compared with the nondevice group.

- In Thomas et al. (2017)[32] (low risk of bias), one of the two app groups (WW app alone) had statistically significantly greater weight reduction at 13 weeks (mean reduction of 2.7 kg, representing a 2.9% reduction from baseline) than the nondevice group (mean reduction of 1.3 kg, representing a 1.5% reduction from baseline), but there was no difference at 1 year. The other app group (WW app plus ActiveLink) had no different weight reduction from the nondevice group at either time point.
- Nicklas et al. (2014)[43] (moderate risk of bias) found that their accelerometer group (Suzuken Lifecorder Plus) had great weight reduction at 44 weeks (average 8.5 kg lost) than their nondevice group (average 5 kg lost).

Based on the above, there is likely no effect of PGHD technologies on on the surrogate outcomes of BMI/weight when used to prevent or treat obesity. This is based on the observation that all 25 point estimates in the above figures indicate less than a 5% body weight difference between groups. All four statistically significant results had point estimates less than 5% body weight. Regarding studies' *a priori* power analyses, 5 of the 14 studies reported the outcome on which power analyses were based. This was weight/BMI for 4 studies, [30,32,39,44] and steps per day in one study.[45] Therefore, taken together with the small point estimates, low power was likely not the reason for the general lack of statistical significance.All of the above data (isolated effects of device presence on either helth outcomes or surrogate outcomes) are summarized in Table 3 and Table 4 below.

Table 3. Obesity: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Quality of life		A, C	B		
Health outcomes not reported by 12 isolated-effect studies					

Statement about health outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect.

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect
* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data.

Table 4. Obesity: categorization of isolated effects on surrogate outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
BMI		A	A, B, B, B, B, B, B, C		
Weight		A, B, C	B, C		
Surrogate outcomes not reported by 1 isolated-effect study					

Statement about surrogate outcomes: Likely no effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect.

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect
* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

BMI = body mass index; PGHD = patient generated health data.

There were 6 *across-category* comparisons among the 16 trials; 2 were statistically significant:

- Turner-McGrievy et al. (2017)[25,26] (moderate risk of bias) found that those who used the Calorie Counter app had greater BMI reduction at 26 weeks (average 6.8 BMI units) than those who received the Bite Counter (average reduction 3 BMI units).
- Ross et al. (2016)[46] (moderate risk of bias) had given both an accelerometer (Fitbit Zip) and a smart scale (Fitbit Aria) to two of their three treatment groups, with one of these two groups also receiving reminder phone calls from study staff. They compared both groups to a third group that received only a pedometer (specific device not reported). The study found greater weight reduction among the Tech+Phone group at 26 weeks (average 6.4 kg lost) than the pedometer group (average 1.3 kg lost). However, the Tech-only group's reduction (average 4 kg lost) was not statistically different than that for the pedometer group.

Finally, there was one *within-category* comparison among the 17 trials. Richardson et al. (2016)[39] (high risk of bias) found that an enhanced pedometer group (SportBrain iStep X) had lost more weight (1.9 kg at 26 weeks) than the simple pedometer group (Yamax Digiwalker SW 200, 0.6 kg at 26 weeks).

Multicomponent Effects on Health Outcomes: Obesity

Ten obesity trials reported multicomponent effects on health outcomes ("multicomponent" means that patients received other intervention[s] in addition to PGHD device[s], making it difficult to attribute improvements to the devices themselves). Therefore, we do not discuss each study in detail, but rather describe general aspects of the studies and results and refer the reader to Appendix Table C-8.

Six[24,47-51] of the 10 studies were at high risk of bias, and the other four[52-57] were at moderate risk of bias. Typical issues involved nonisolated effects, unclear randomization and allocation concealment, and unblinded outcome assessors. The reported health outcome was QOL in all 10 trials, and they used 11 different QOL instruments.

Eight of the 10 trials reported that QOL between groups was statistically nonsignificant at followup, regardless of the specific instrument used. By contrast, Haggerty et al. (2017)[49] (high risk of bias) found that SF-12 scores were better in their telemedicine group (the group received a Withings WiFi scale and recorded diet and physical activity on a website) than in a group receiving feedback text messages along with a different scale (Eat Smart Precision Digital Scale). Interestingly, however, a third group that received no PGHD device ("enhanced usual care") had better mean QOL than the telemedicine group, though authors did not report whether the difference was statistically significant. The other study reporting a statistically significant effect was Vorrink et al. (2016)[50,58] (high risk of bias). The study's two groups were usual care (no intervention) and intervention (which included an accelerometer embedded in a smartphone, physical activity goals, and physiotherapist monitoring via a website for step viewing and goal adjustment). Authors used the chronic respiratory questionnaire to measure QOL. For the dyspnea subscale, authors found no statistically significant difference between groups at followup. For the fatigue subscale, outcome data showed a statistically significant between-group difference, and authors stated "this was probably caused by great variability in the data rather than the intervention." This comment reveals a misunderstanding of statistical testing, which accounts for data variability along with effect sizes.

Multicomponent Effects on Surrogate Outcomes: Obesity

Due to this evidence's highly indirect nature, we do not discuss it; instead, we refer the reader to the tabulated data in Appendix Table C-8.

Of the 11 obesity-related records in clinicaltrials.gov, only 3 made PGHD-related comparisons and stated that they were collecting data on a health outcome (quality of life).

Guiding Question 4. What are the harms or adverse events associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

Only 6 of the 43 obesity trials reported data on adverse events (AEs) (see the Health Outcomes section of Appendix Table C-8). The reported types of events were:

- Overall number# of events
- Number of emergency room or urgent care visits
- Number# of significant medical/mental problems that restricted walking at least 7 consecutive days
- AEs requiring hospitalization
- Serious AEs
- Serious event alerts (device alert triggered when the patient had an overnight hospitalization or surgery)
- Depression alerts (device alert triggered when the patient had a score of 13 or greater on the CES-D questionnaire)
- Nonserious event alerts (study did not report how this alert was triggered)
- Rapid weight loss event alerts (device alert triggered when the patient experienced 6% or greater weight loss during a 4-week period)
- Resting BP alerts (device alert triggered when resting systolic blood pressure [SBP] ≥140 or resting diastolic blood pressure [DBP] ≥90)

Only two of the six trials reported whether the between-groups comparison was statistically significant. Arbillaga-Etxarri et al. (2018)[52] reported a statistically nonsignificant difference (p=0.363) in the rate of any AEs between their usual care group that received no PGHD device (73%) and their Urban Training group (77%) that had received six-components, which had included a pedometer (OnStep 50 Geonaute). The other study was Fukuoka et al., (2019)[33-38] which compared a control group given an accelerometer (Omron active style Pro HJA-350IT) to an intervention group that also received an app, and authors reported three different types of AEs:

- For any AEs, there were nonsignificant findings for both the first 3 months of the study (p=0.23) and the next 6 months (p=0.46). However, the bases for the study power calcuations were not harms, but rather efficacy.
- For AEs requiring hospitalization, authors reported no statistical between-group comparison, but 5 events occurred among 69 control group participants and 2 events among 140 intervention group participants.

- For AEs of significant medical/mental problems that restricted walking at least 7 consecutive days, at 3 months authors found a statistically significantly higher rate among the intervention group (20%) than among the control group (9%) (p=0.05). However, for the subsequent 6 months, the between-group difference was not statistically significant (intervention 34%, control 27%, p=0.71).

Overall, few obesity trials reported AEs (6/43 or 14%), they only occasionally made statistical comparisons (2 of 6 trials), and there were inconsistent results from those 2 trials (all tests statistically nonsignificant, except for 1 test favoring a control group at 1 of 2 time points).

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

None of the 43 included obesity trials reported cost-effectiveness data or cost-only data.

Diabetes Prevention

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Diabetes Prevention

The three diabetes prevention trials used six different PGHD devices. The similarity judgments (how similar each device is to those currently on the market by this manufacturer) were:

- Two pedometers: Gruve pedometer (judged as Similar) and the Omron HJ-150 (judged as somewhat different)
- One accelerometer: Jawbone SenseWear armband: Unknown similarity
- One BP monitor: A&D UA-767 Plus BT: Similar
- One glucose meter: Lifescan OneTouch Ultra2: Similar
- One heart rate monitor: Suunto Memory Belt: Very different

All these devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1.

Studies in Progress: Diabetes Prevention

We identified two records in ClinicalTrials.gov on diabetes prevention that, once published, may potentially meet our inclusion criteria. As of June 19, 2020, one was not yet recruiting patients, and one was active but not recruiting. More details about these records (including hyperlinks) appear in Appendix Table C-10.

Study Designs: Diabetes Prevention

Two[57,59] of the three trials were randomized, and the other[60] was nonrandomized. In the nonrandomized study, authors stated that "all participants attending appointments during week 1 were randomized to the intervention group, those attending appointments during week 2 were randomized to the control group, and so on." Therefore, assignment to groups was alternating, not random.

One randomized controlled trial (RCT)[59] was from the United States (89 patients enrolled, 26-week followup, median patient enrollment month January 2011), another RCT[57] was from the United Kingdom (177 patients enrolled, 1-year followup, median patient enrollment month June 2011), and the nonrandomized trial[60] was from Canada (149 patients enrolled, 1-year followup, median patient enrollment month June 2010). The next sections describe additional aspects of these trials, which are tabled in detail in Appendix Table C-11, C-12, and C-13.

Inclusion/Exclusion Criteria: Diabetes Prevention

The U.S. RCT included obese adults in central Iowa (95% Caucasian), the U.K. RCT included young obese adults at risk of type 2 diabetes, and the Canadian study included rural adults who had at least two risk factors of metabolic syndrome.

Additional Patient Characteristics: Diabetes Prevention

All three studies reported mean age (32.8 in Biddle et al. (2015),[57] 39 in Peyer et al. (2017),[59] and 57 in Petrella et al. (2014)).[60] All three studies reported the percentage of patients who were female (68.5% in Biddle et al. (2015),[57] 60% in Peyer et al. (2017),[59] and 74% in Petrella et al. (2014)).[60] Mean baseline fasting plasma glucose was 4.8 mmol/L in Biddle et al. (2015),[57] 5.2 mmol/L in Petrella et al. (2014)[60] and 94 mg/dL in Peyer et al. (2017).[59] Mean baseline HbA1c was 5.48 in Biddle et al. (2015)[57] and 5.8 in Petrella et al. (2014)[60] (HbA1c was not reported by Peyer et al. (2017).[59] Only one of the three studies (Petrella et al. 2014)[60] enrolled patients in rural settings (which were small rural communities in Ontario, Canada). None of the three studies required that patients have technological expertise.

Statistical Power Analyses: Diabetes Prevention

The U.S. RCT did not mention power analysis. The U.K. RCT's power analysis was based on sedentary time, had used prior data, and had anticipated attrition. The Canadian study's power analysis was based on blood pressure, did not refer to prior data, but did plan for attrition.

Followup Length: Diabetes Prevention

One RCT[59] followed patients for 6 months, and the other two studies followed patients for 1 year.

Adherence Measurement: Diabetes Prevention

Only the Canadian study reported device adherence, which was measured as the percentage of measurements that patients completed, separately for BP measurements, fasting plasma glucose (FPG) measurements, pedometer measurements, and body weight measurements.

Comparators: Diabetes Prevention

The U.S. trial enrolled three groups: Guided weight loss (no device, but had weekly meetings with a health coach), physical activity monitor (SenseWear armband), and combined (received both of the other groups' interventions). The U.K. trial enrolled two groups: control (educational leaflet) and intervention (Gruve accelerometer). The Canadian study enrolled two groups: active control (tailored exercise program) and intervention (same exercise program plus a smartphone (Blackberry Curve 8300 or 8530), app (Healthanywhere), BP monitor (A&D UA-767PBT), glucose meter (Lifescan One Touch Ultra2), and heart rate monitor (Suunto Memory Belt).

Outcomes Reported: Diabetes Prevention

The U.K. trial (QOL) and the Canadian study (adverse effects) reported health outcomes. All three trials reported surrogate outcomes: fasting glucose and HbA1c by both the U.K. trial and the Canadian trial; 2-hour glucose test by the U.K. trial; and metabolic syndrome score by the U.S. trial. Only the Canadian study (discussed next) reported outcomes pertaining to Guiding Question 2. None reported process outcomes, cost-only data, or cost-effectiveness data.

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Regarding interoperability, Petrella et al. (2014)[60] employed automatic entry of data from the PGHD device(s) to a smartphone, then manual entry of that data to an app on the smartphone, and the app transferred data automatically to study personnel. Peyer et al. (2017)[59] had SenseWear armband data transferred automatically from device to a website (and additional data were manually entered), but authors did not report whether study personnel received that data. Biddle et al. (2015)[57] did not mention device interoperability.

The U.S. trial and the U.K. trial did not report additional data for this Guiding Question. The Canadian study reported the percentage of measurements that patients provided at various time points (see data in Appendix Table C-15):

- For BP measurements, the overall percentage was 83%, which had decreased from 91% in weeks 1–12 to 78% in weeks 25–52.
- For fasting plasma glucose measurements, the overall percentage was 82%, which had decreased from 90% in weeks 1–12 to 77% in weeks 25–52.
- For pedometer measurements, the overall percentage was 71%, which had decreased from 84% in weeks 1–12 to 63 in weeks 25–52.
- For body weight measurements, the overall percentage was 42%, which had decreased from 64% in weeks 1–12 to 28% in weeks 25–52.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

The risk-of-bias assessments are in Appendix Table C-14, and the results are in Appendix Table C-15.

Isolated Effects on Health Outcomes: Diabetes Prevention

None of the three diabetes prevention studies reported whether there were isolated effects on health outcomes. As a result, we rated this evidence as unclear.

Isolated Effects on Surrogate Outcomes: Diabetes Prevention

The U.S. study by Peyer et al. (2017)[59] (high risk of bias) found that the metabolic syndrome score (the sum of the z scores for 5 metabolic syndrome risk factors;0 represents average risk, and high positive values represent higher metabolic syndrome risk) had improved more greatly in the group receiving both guided weight loss treatment and a SenseWear armband (average 2-point improvement from a baseline of +0.7) than in the group that received only guided weight loss treatment (average 0.8-point improvement from a baseline of -0.4). The armband-only group (average 1.1-point improvement from a baseline of -0.2) was not statistically different from the other two groups. The other two studies had multicomponent effects.

Overall, there is an unclear effect of PGHD technologies on health and surrogate outcomes when used to prevent diabetes (Table 5 and Table 6). Only one of three trials used an isolated-effect design, and even though the trial did find lower risk of metabolic syndrome among those using an armband, the trial was at high risk of bias.

Table 5. Diabetes prevention: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Health outcomes not reported by 1 isolated-effect study					

Statement about health outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect
* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data.

Table 6. Diabetes prevention: categorization of isolated effects on surrogate outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Metabolic syndrome score	C				
Surrogate outcomes not reported in zero isolated-effect studies					

Statement about surrogate outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect
* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data.

Multicomponent Effects on Health Outcomes

The U.K. study by Biddle et al. (2015)[57] (moderate risk of bias) reported that QOL (as measured by the EuroQol 5D) was not statistically different between their groups (see Appendix Table C-15).

Multicomponent Effects on Surrogate Outcomes

Due to this evidence's highly indirect nature, we do not discuss it; instead, we refer the reader to the tabulated data in Appendix Table C-15.

Of the four diabetes-prevention-related records in clinicaltrials.gov, none made PGHD-related comparisons and stated that they were collecting data on a health outcomes.

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

The U.S. trial and U.K. trial did not report these data. The Canadian study reported four AEs among three control group patients and none in the intervention group. The intervention group, also reported device-initial alarms for high SBP (no alarms during the 1-year followup), high DBP (7 alarms), and high glucose (12 alarms, but 11 were from a single patient). See more details in Appendix Table C-15.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

None of the three diabetes prevention trials reported cost-effectiveness data or cost-only data.

Sleep Apnea

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Sleep Apnea

The three sleep apnea trials used three different PGHD devices. The similarity judgments (how similar each device is to those currently on the market by this manufacturer) were:

- Two pedometers: Misfit Shine (judged as somewhat different) and the Samsung Charm (judged as similar)
- One BP monitor: Omron 705CP (judged as similar)

All three devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1.

Studies in Progress: Sleep Apnea

We identified three records in ClinicalTrials.gov on sleep apnea that, once published, may potentially meet our inclusion criteria. As of June 19, 2020, two were recruiting, and one was active but not recruiting. More details about these records (including hyperlinks) appear in Appendix Table C-16.

Study Designs: Sleep Apnea

All three included sleep apnea trials were randomized. Kim et al. (2019)[61] was conducted in South Korea (43 patients enrolled, 4-week followup, median patient enrollment month July 2017), Mendelson et al. (2014)[47] was conducted in France (107 patients enrolled, 17-week followup, median patient enrollment month October 2010), and Cho et al. (2018)[62] was conducted in South Korea (47 patients enrolled, 4-week followup, median patient enrollment month September 2016).

The next sections describe additional aspects of these trials, which are tabled in detail in Appendix Table C-17, C-18, and C-19.

Inclusion/Exclusion Criteria: Sleep Apnea

Kim et al. (2019)[61] included obese/overweight adults with sleep apnea who could use a mobile app and a wearable device. Mendelson et al. (2014)[47] included adults with sleep apnea and BMI <40 kg/m^2 with a high cardiovascular risk score (cardiovascular risk SCORE >5%) or history of cardiovascular disease. Cho et al. (2018)[62] included obese/overweight adults with habitual snoring or witnessed sleep apnea but not using a continuous positive airway pressure or similar device.

Additional Patient Characteristics: Sleep Apnea

All three studies reported mean age (43 in Cho et al. (2018),[62] 42 in Kim et al. (2019),[61] and 63 in Mendelson et al. (2014).[47] All three studies reported the percentage of patients who were female (11% in Cho et al. (2018),[62] 15% in Kim et al. (2019),[61] and 17% in Mendelson et al. (2014).[47] The baseline mean apnea/hypopnea index was 22 in Cho et al. (2018)[62] and 39 in Mendelson et al. (2014).[47] Kim et al. (2019)[61] did not report this index, but did report that at baseline, patients averaged of 3.9 days/week with witnessed sleep apnea. None of the three studies enrolled rural populations. Only one of the three studies required that patients have some technological expertise (Kim et al. (2019)[61] required that patients could use a mobile app).

Statistical Power Analyses: Sleep Apnea

Only Mendelson et al. (2014)[47] mentioned power analyses; these were based on blood pressure, had used prior data and had also accounted for possible attrition

Followup Length: Sleep Apnea

The two trials from South Korea each had a 4-week followup, whereas Mendelson et al. (2014)[47] had a 17-week followup.

Adherence Measurement: Sleep Apnea

Only Kim et al. (2019)[61] reported device adherence, which was measured by the percentage of days on which patient data were collected regarding physical activity, sleep parameters, and weight.

Comparators: Sleep Apnea

Kim et al. (2019)[61] compared three groups: no device, App only (MyHealthKeeper) which used the phone's accelerometer, and App+pedometer (Samsung Charm). Mendelson et al. (2014)[47] had two groups: Standard (SenseWear Pro2 armband) and Telemedicine (BP monitor Omron 705CP plus SenseWear Pro2 armband). Cho et al. (2018)[62] had two groups: Control (no device) and App+pedometer (Misfit Shine).

Outcomes Reported: Sleep Apnea

Only Mendelson et al. (2014)[47] reported health outcomes (QOL as measured by the "MCS" and "PCS," which the authors did not define). All three trials reported a surrogate outcome (number of days/week apnea was witnessed, or the Epworth sleepiness scale, or the apnea-hypopnea index, lowest oxygen saturation, or the oxygen desaturation index). Only Kim et al. (2019)[61] reported data for Guiding Question 2.

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Regarding interoperability, for all three studies, some data were transferred from PGHD device(s) to a smartphone or a study database, other data were entered manually, and at least some data were sent automatically to study personnel. In addition, Mendelson et al. (2014)[47] required some uploading of data by patients and downloading of data by study personnel.

Only Kim et al. (2019)[61] reported additional data pertinent to this Guiding Question. The two intervention groups (app only, or app+pedometer) each had data collection rates of 50% (of study days) for physical activity, 32% for sleep data, and 32%–33% for weight data. Patient satisfaction was measured as whether patients responded to daily clinician feedback on the app, with a maximum of 7 if the patient responded "satisfied" to each daily clinician comment over the 7 days. No response was scored as "not satisfied." These scores ranged from 3.1 to 4.2 over the 4 weeks for the app-only group and 3.7 to 4.7 for the app+wearable group. No statistical comparison was made, but the latter group had higher means for each of the 4 weeks, suggesting the pedometer increased app engagement.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

The risk-of-bias assessments are in Appendix Table C-20, and the results are in Appendix Table C-21.

Isolated Effects on Health Outcomes: Sleep Apnea

None of the three sleep apnea trials reported whether there were isolated effects on health outcomes. As a result, we rated this evidence as unclear.

Isolated Effects on Surrogate Outcomes: Sleep Apnea

Kim et al. (2019)[61] (high risk of bias) reported statistically nonsignificant differences between their three groups at 4 weeks with respect to the number of days/week when apnea was witnessed.

Overall, there is an unclear effect of PGHD technologies on health and surrogate outcomes when used to treat sleep apnea (Table 7 and Table 8). Only one of three trials used an isolated-effect design, it found no statistically significant difference between group in the number of days/week when apnea was witnessed, and it was at high risk of bias.

Table 7. Sleep apnea: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Health outcomes not reported by 1 isolated-effect study					

Statement about health outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect
* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data

Table 8. Sleep apnea: categorization of isolated effects on surrogate outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Number of days/week when apnea was witnessed			C		
Surrogate outcomes not reported by zero isolated-effect studies					

Statement about surrogate outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect
* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data

Multicomponent Effects on Health Outcomes: Sleep Apnea

Mendelson et al. (2014)[47] reported statistically nonsignificant differences between their standard group and their telemedicine group in QOL at 17 weeks.

Multicomponent Effects on Surrogate Outcomes: Sleep Apnea

Due to this evidence's highly indirect nature, we do not discuss it; instead, we here refer the reader to the tabulated data in Appendix Table C-21.

Of the six sleep-apnea-related records in clinicaltrials.gov, two made PGHD-related comparisons and stated that they were collecting data on a health outcomes (sleep apnea symptoms).

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

None of the three sleep apnea trials reported data harms or AEs.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

None of the three sleep apnea trials reported cost-effectiveness data or cost-only data.

Hypertension

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Hypertension

The 51 hypertension trials used 53 different PGHD devices: 41 BP monitors, 4 pedometers, 3 glucose meters, 3 scales, and 2 heart rate monitors. Of the 41 BP monitors, 34 were arm devices, two were wrist devices, and the other five we could not determine if they were wrist or arm devices. All these devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1. An additional unspecified Omron BP digital monitor was

included in the comparison group for one study. The similarity judgments (how similar each device is to those currently on the market by this manufacturer) were:

- BP monitors: 38 similar, 1 somewhat different, 0 very different, 2 unknown
- Pedometers: 3 similar, 1 somewhat different, 0 very different, 0 unknown
- Glucose meters: 2 similar, 0 somewhat different, 0 very different, 1 unknown
- Scales: 1 similar, 0 somewhat different, 0 very different, 2 unknown
- Heart rate monitors: 1 similar, 0 somewhat different, 1 very different, 0 unknown

Studies in Progress: Hypertension

We identified 9 records in ClinicalTrials.gov on preventing or treating hypertension that, once published, may potentially meet our inclusion criteria. As of June 19, 2020, four were active but not recruiting, three were recruiting, one was not yet recruiting, and one was suspendended due to COVID-19. More details about these records (including hyperlinks) appear in Appendix Table C-22.

Study Designs: Hypertension

Forty-nine of the 51 hypertension studies were randomized trials, and two were nonrandomized comparative studies. Twenty-three studies were conducted in the United States, and other notable countries included the United Kingdom (6 studies), Canada (3 studies), Denmark (2 studies), Finland (2 studies), and South Korea (2 studies). The median number of patients per study at baseline was 223 (IQR 101 to 416). Patient enrollment dates were reported in 29 studies and ranged from May 1999 to June 2017. The next sections describe additional aspects of these trials, which are tabled in detail in Appendix Table C-23, C-24, and C-25.

Inclusion/Exclusion Criteria: Hypertension

Studies generally included adult patients with a diagnosis of primary hypertension or uncontrolled BP with antihypertensive medication. Patients with comorbidities, such as diabetes or chronic kidney disease, were often included. Common exclusion criteria included diagnosis of secondary hypertension, severe cognitive impairment, and pregnancy. Multiple studies also considered the comfort with technology as inclusion or exclusion criteria, such as requiring patients to own a smartphone or excluding patients who were unable to use the telehealth device.

Additional Patient Characteristics: Hypertension

The mean baseline age of patients included in the 51 hypertension studies ranged from 45 to 73 years. The percentage of female patients ranged from 5% to 88%, with one study not reporting gender. The most common measures of disease severity were baseline SBP and DBP. Mean SBP was reported in 45 studies and ranged from 125 to 161 mmHg; mean DBP was reported in 42 studies and ranged from 71 to 97 mmHg. Other disease severity measures reported included BP control, arterial BP, and duration of hypertension. Five studies did not report any disease severity measure. Four studies reported being conducted in a rural setting, 23 in urban settings, and the remaining 24 did not report whether the setting was rural or urban.

Statistical Power Analyses: Hypertension

Forty of the 51 studies reported information about power analyses. Of these, 20 accounted for anticipated attrition and 5 reported using data from previous work to estimate the potential effect size. One study explicitly stated the analysis was retrospective, and two studies stated that no

power analyses were performed. No studies were powered to detect differences in health outcomes. Twenty-nine were powered to detect differences in surrogate outcomes, including SBP, DBP, and BP control. Five were powered to detect other types of outcomes, including adherence and weight. Six did not clearly report the outcome they were powered for.

Followup Length: Hypertension

The median length of followup in the 51 hypertension studies was 6 months, with an IQR from 4 to 12 months.

Adherence Measurement: Hypertension

Device adherence was typically measured by the number of BP readings automatically transmitted to the study data collection center out of the total BP readings that were expected to be sent in compliance with the study protocol.

Comparators: Hypertension

Forty-four of 51 studies had 2 treatment groups, 4 studies had 3 groups, and 3 studies had 4 groups. Forty-two studies included a usual care control group. Five of the studies used a PGHD device in the control group. The remaining four studies used active comparators without a PGHD device, such as diet alone, counseling alone, or exercise program alone.

Outcomes Reported: Hypertension

Only 21 of the 51 hypertension studies reported on health outcomes, including mortality (3), hospitalizations or emergency room visits (2), QOL (13), and AEs (13). All 51 studies reported a surrogate outcome, including SBP, DBP, or BP control. Twenty-eight reported on device usage, ease of use, or technical problems. Of studies including health outcomes, 12 reported on process outcomes (e.g., number of primary care consultations or antihypertensive medication changes) and 3 reported on economic outcomes. Seven reported on costs.

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Below, we discuss the characteristics of PGHD devices for hypertension. More details are provided in Appendix Table C-25. We also discuss the findings by device engineers on wearable and handheld BP monitors.

Of the 51 studies, 20 reported using the devices to automatically transmit patient data. Data was commonly transmitted via smartphone or wirelessly-connected mobile phone with the end target being a study database or website. In one case, data could be transmitted to the electronic health record. Six studies reported manual entry with electronic transmission of PGHD data, such as by inputing results in a web form or text message to be transmitted to a study database or website. Twenty-six studies reported no automatic transmission of data, such as inputting data on a web form or writing down results in logs and mailing them. The remaining five studies did not report any information on interoperability.

Other device characteristics were reported in 28 studies, of which 26 focused on BP monitors. Adherence to use of BP monitors ranged from 38% to 89% of patients. Some studies reported that adherence declined over time. For example, Bosworth et al. (2009)[63] reported that during the first 2 months, 91% of those using the PGHD device were adherent, while 64% were adherent during the last 2 months. Studies also measured BP monitor use in various ways, including total number of transmissions over the study and average number of transmission per week. Studies measuring ease of use or satisfaction of BP devices found that patients tended to view them favorably. For example, Magid et al. (2013)[64] reported that 68% of patients using the monitor found it very or extremely easy to use, and Rifkin et al. (2013)[65] reported that 96% of patients reported they would continue to use the BP device. Two of the studies reported problems with the devices. Bosworth et al. (2011)[66-68] found that 35 alerts were triggered by the monitoring system due to device problems, which represented 5% of the total alerts that occurred during the study. Lakshminarayan et al. (2018)[69] found that some patients experienced issues with the BP device and smartphone provided to transmit BP data, including an inability to hold charge and difficulty using the phone app to see BP data.

Two studies reported use of glucometers. Earle et al. (2010)[70,71] found that 4,099 readings were taken over the course of the study, with an average transmission rate of 1.8 readings per person per month. Yoo et al. (2009)[23] found that patients transmitted blood glucose recordings an average of 1.84 times per day (adherence rate 92.2%).

Two studies examined use of weight scales. Bennett et al. (2018)[18,72,73] reported that 36% of patients weighed themselves at least 5 days a week on average. Yoo et al. (2009)[23]found that patients transmitted body weight measurements 0.87 times per day (adherence rate 87.4%).

One study evaluated a pedometer app and a heart rate monitor app. Chandler et al. (2020)[74] reported that over 12 months, monthly mean adherence ranged between 68.2% and 61.5% for the Runkeeper pedometer app and between 78.0% and 69.8% for the Tension Tamer heart rate monitor app.

Technical Report on Wearable and Handheld BP Devices

Device engineers performed independent evaluations of one handheld and two wearable BP devices. These evaluations included device performance, safety, workflow, interoperability, cybersecurity, maintenance, user experience, and cost of ownership.[75] The evaluations were carried out as follows:

- Performance: The accuracy of each device was tested against a hospital-grade, cuff-type Welch Allyn 6000 series vital signs monitor. SBP and DBP values were considered accurate if they conformed to the Association for the Advancement of Medical Instrumentation SP10 criteria, which require a mean difference no greater than 5 mmHg with a standard deviation of ≤8 mmHg. Manufacturer's recommendations for maintaining accuracy with its device were also assessed.
- Safety: Device design and features that facilitate interpretation of BP readings were examined, including notification or alarms related to abnormal blood pressures measured, risk of pressure injury from band, and risk of burn injury from device light source.
- Workflow: Evaluated based on the ease of using a system to provide a physician with trended blood pressure data.
- Interoperability: The ability of the device to work with the smartphone app and whether the app interferes with common uses for the phone, including communication, was evaluated.

- Cybersecurity: Cybersecurity experts looked at the devices and associated smartphone apps to determine if there were any special cybersecurity concerns.
- Maintenance, the performance of the device's rechargeable battery was evaluated, including battery operating time, recharging frequency, and time to full charge.
- User experience: Evaluated based on the ease of the use of the device and how the design would encourage regular use.
- Cost: Estimated from the initial purchase price, available accessories, annual operational costs (such as replacement parts), and the minimum estimated life of the device.

The BodiMetrics Performance Monitor is a mobile handheld device that consumers can use to measure their SBP without applying a cuff.[76] This consumer-marketed device has not undergone FDA review for its BP-measuring technology, and it does not have the same accuracy as BP monitors regulated by FDA. Device engineers rated device performance as poor mainly because it does not measure DBP (a major disadvantage), and assessing BP as a cardiovascular risk factor requires measurement of SBP and DBP. Also, SBP measurements were less accurate than required for clinical applications and did not meet guidelines recommended by the American Medical Association or by the U.S. Centers for Disease Control and Prevention for selecting a device for home monitoring. Workflow was rated as excellent due to retention of BP trend information, data storage when device is not linked with the smartphone app, and forwarding data to the physician or caregiver (all considered major advantages). Device engineers rated interoperability and cybersecurity as good. Maintenance was rated as excellent due to the major advantages of relatively infrequent intervals between battery charging (every 3 to 5 weeks) and relatively short battery recharging time (1 hour). Despite the device being intuitive to use, user experience was rated as poor due to the major disadvantage of lack of adequate user support (calls and e-mails not returned). Safety was rated good, with the minor advantage that the smartphone app plots graphs that allow users to see whether they have elevated SBP. Cost of ownership was estimated as $300 over a 3-year period, with the price of the device itself accounting for the entire cost. Overall, device engineers rated the device as poor due to its inability to measure DBP and inadequate technical support.

The Everlast TR10 Heart Rate Activity Tracker is one of two wrist-wearable BP devices that device engineers evaluated.[77] Consumers can use the device to measure their SBP and DBP without applying a cuff. This consumer-marketed device has not undergone FDA review for its BP- measuring technology, and it does not have the same accuracy as BP monitors regulated by FDA. Device engineers rated device performance as fair. Minor disadvantages of the TR10 include a lack of a recommended interval for calibration, no recommendation on frequency of calibration in the user manual, and both SBP and DBP measurements were less accurate than required for clinical applications. Workflow was rated as poor due to major disadvantages that include inability to store data when the wearable device is offline and disconnected from the smartphone app and inability to forward BP data to a physician or caregiver digitally. A minor advantage was that the smartphone app allows users to set a generic alarm to remind them when to measure their BP. Device engineers rated interoperability and cybersecurity as good. Maintenance was rated as excellent due to the major advantages of relatively infrequent intervals between battery charging (once per week) and relatively short battery recharging time (1 to 2 hours). Despite the major advantage of being comfortable to wear, user experience was rated as poor due to the major disadvantage of lack of adequate user support (lack of device information on the manufacturer website, calls and emails not returned) and a weak wristband securement system (e.g., if the wristband catches on something it can easily fall off). Safety was rated good,

with the minor advantage that the smartphone app provides notification that allows users to see whether they have high BP. Cost of ownership was estimated as $70 over a 3-year period, with the price of the device itself accounting for the entire cost. Overall, device engineers rated the device as poor due to the inability to store BP measurements in the absence of Internet connectivity between the smartphone app and the TR10 and the lack of user support.

The Heartisans Blood Pressure Watch is the second wrist-wearable device that device engineers evaluated.[78] Consumers can use it to measure their SBP and DBP without applying a cuff. This consumer-marketed device has not undergone FDA review for its BP-measuring technology, and it shows significantly less accuracy than BP monitors regulated by FDA. Device engineers rated device performance as unacceptable because during testing they found that, for both SBP and DBP, the mean absolute difference between measurements taken with the device and a conventional, hospital-grade cuff-type BP monitor exceeded 10 mmHg. This could lead to missed instances of elevated BP or false readings of elevated BP. Workflow was rated as excellent because the smartphone app for the Heartisans Watch retains multiple weeks of daily measurements that are both time- and date-stamped, allowing the user to review measurements. Also, data can be stored even when the device is not connected to the smartphone app, and data can be forwarded to a clinician or caregiver as a PDF attachment in an e-mail. Device engineers rated interoperability and cybersecurity as good. Maintenance was rated as fair despite a short battery charging time (1.5 hours) due to the major disadvantage of short battery life (only 8 or 9 hours during testing). Despite the major advantage of being a water-resistant device (can be completely submerged for 30 minutes), user experience was rated as poor due to the major disadvantage of lack of user support (no response to e-mails and no phone number listed on the product website). Safety was rated good, with the minor advantage that the smartphone app provides notification that allows users to see whether they have high BP. Cost of ownership was estimated as $149 over a 3-year period, with the price of the device itself accounting for the entire cost. Overall, device engineers rated the device as unacceptable due to its very low accuracy compared to that of FDA-approved hospital-grade, cuff-type BP monitors. They recommend against using the device to track BP.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

Below, we discuss the efficacy results in four categories: (1) isolated effects on health outcomes, (2) isolated effects on surrogate outcomes, (3) multicomponent effects on health outcomes, and (4) multicomponent effects on surrogate outcomes. Risk-of-bias assessments are in Appendix Table C-26, and the results are in Appendix Table C-28.

Isolated Effects on Health Outcomes: Hypertension

Six studies evaluated the isolated effects of a PGHD intervention on health outcomes. The PGHD devices that these studies examined were the following BP monitors: iHealth BP7 Wireless Wrist Monitor, Omron 637, Omron 773AC, Omron HEM-705 CP, Omron HEM-712C, and Omron M10-IT.

Bosworth et al. (2009)[63] (moderate risk of bias) compared the Omron 773AC or 637 (depending on patient arm circumference) to usual care in terms of hospitalizations. A third

group received behavioral management alone, and a fourth received a combination of PGHD and behavioral management. The proportion of hospitalized patients did not differ across groups (range 19.5% to 22.6%, p=0.91).

Broege et al. (2001)[79] (high risk of bias) evaluated the impact of using Omron HEM-702 compared to a clinic-only group on Short Form (SF)-36 QOL. After 3 months, overall QOL scores decreased in both groups but were not significantly different between groups (PGHD: -6; clinic: -4).

Green et al. (2008)[80,81] (low risk of bias) evaluated the use of Omron HEM-705 CP compared to usual care for SF-12 QOL. A third group received a combination of PGHD and pharmacist care. At 12-month followup, there were no significant differences between PGHD alone and usual care groups for the SF-12 general health (PGHD: 66.6, SD: 20.9; usual care: 67.1, SD: 20.4; between group difference: -0.1, 95% confidence interval [CI]: -4.0 to 3.7), physical health (PGHD: 77.7, SD: 30.3; usual care: 78.1, SD: 27.7; between group difference: -0.4, 95% CI: -5.6 to 4.7), or emotional health (PGHD: 72.1, SD: 16.8; usual care: 71.5, SD: 17.7; between-group difference: 0.5, 95% CI: -2.7 to 3.8) subscales.

Hebert et al. (2012)[82] (low risk of bias) evaluated use of the Omron HEM-712C BP monitor compared to usual care and reported on mortality. A third group received a combination of PGHD and nurse management. Over 18 months, 8 deaths occurred in the study. There was no significant difference across the groups (p=0.453).

McManus et al. (2018)[83-86] (low risk bias) compared the impact of using the Omron M10-IT BP monitor to usual care on the EuroQol 5-dimension (EQ-5D)-5L score. A third group received a combination of the PGHD device and telemonitoring. At 12 months, there was no significant difference between the PGHD alone and usual care groups (mean difference [MD]: -0.01; 95% CI: -0.04 to 0.02; p-value: 0.4862).

Zha et al. (2019)[87] (moderate risk of bias) compared the iHealth BP7 Wireless Wrist Monitor to usual care for the SF-36 QOL score. At 6 months, there was a significant difference between the groups for the mental health subscale, favoring usual care (PGHD: 54.49, SD: 20.11; usual care: 80.73, SD: 18.73; p-value: 0.003); however, it should be noted that at baseline, the usual care group also had significantly higher scores than the PGHD group. There were no significant differences between the groups for the physical function (PGHD: 57.21, SD: 23.97; usual care: 56.82, SD: 35.81; p-value: 0.51), role function (PGHD: 60.00, SD: 20.11; usual care: 67.54, SD: 29.3; p-value: 0.53), bodily pain (PGHD: 43.69, SD: 25.31; usual care: 55.46, SD: 33.84; p-value: 0.84), general health (PGHD: 42.38, SD: 21.22; usual care: 57.71, SD: 20.49; p-value: 0.08), vitality (PGHD: 45.71, SD: 17.43; usual care: 50.46, SD: 15.95; p-value: 0.08), social function (PGHD: 50.29, SD: 31.78; usual care: 60.50, SD: 36.71; p-value: 0.31), and role emotional (PGHD: 48.62, SD: 25.64; usual care: 67.99, SD: 27.35; p-value: 0.07) subscales, as well as for the physical (PGHD: 42.63, SD: 11.21; usual care: 44.25, SD: 11.17; p-value: 0.72) and mental (PGHD: 43.11, SD: 10.23; usual care: 49.65, SD: 11.87; p-value: 0.18) component summary scores.

Overall, based on the health outcomes alone, PGHD interventions have unclear effects on health outcomes. Only a small number of the studies reported on health outcomes, and those that did were generally reported being powered based on surrogate outcomes. See Table 9 for a summary of the study findings.

Isolated Effects on Surrogate Outcomes: Hypertension

Eighteen studies[63,69,79-100] examined the isolated effects of PGHD interventions on surrogate outcomes. All evaluated the effect of device presence except for two studies,[69,95] each of which compared a BP monitor which automatically transmited data to one that did not. Of the device presence studies, 15 evaluated BP monitors alone, while one[92] evaluated a combination of PGHD interventions (BP monitor, pedometer, and scale) and did not isolate the effects of the individual interventions.

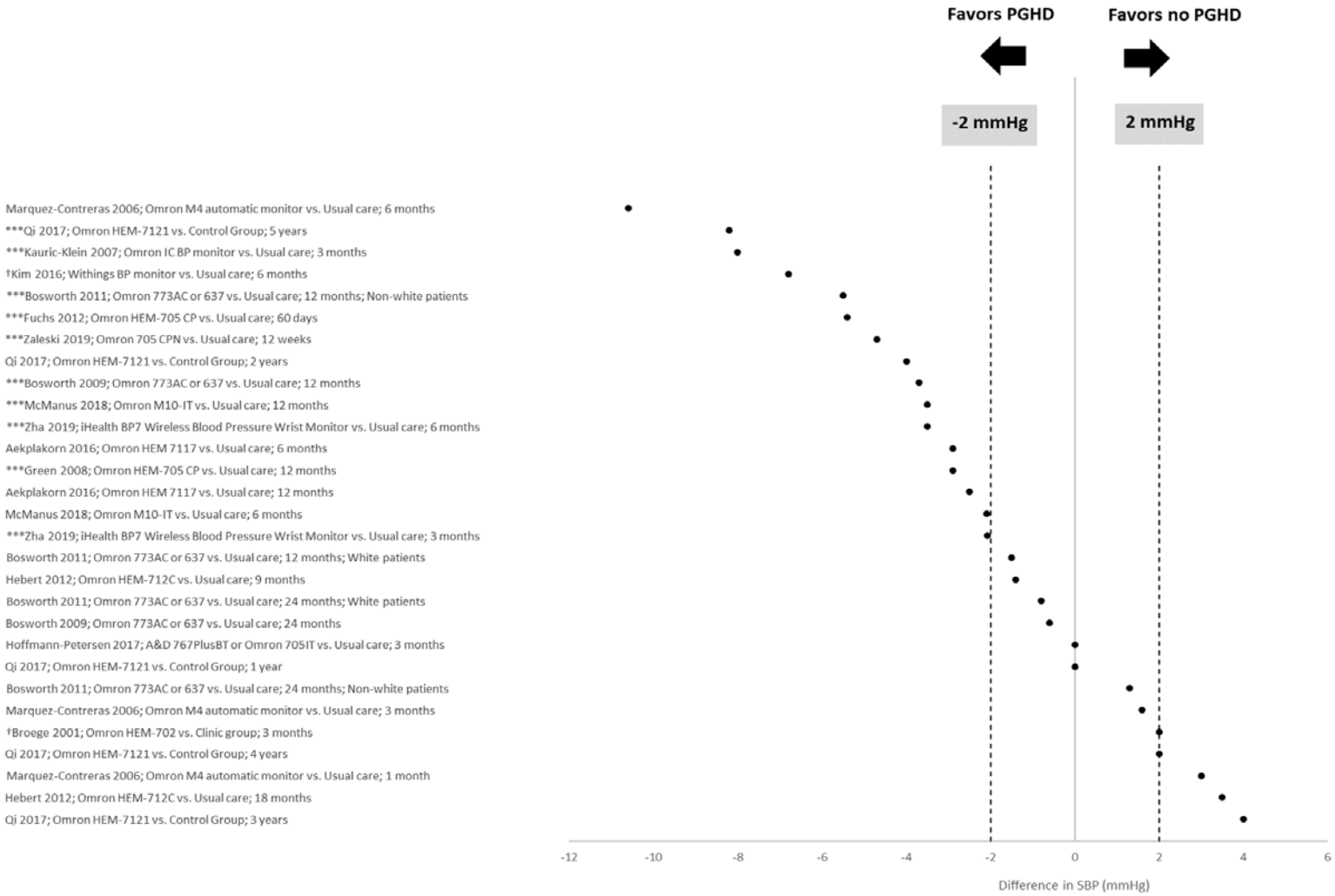
All 18 studies reported on the effects of PGHD interventions on SBP. Six[80,81,83-86,89-91,93,96,99] found that those receiving a PGHD device had significantly improved SBP compared to those in the control group, though in some cases, results for only specific subgroups or time points were significant. For example, Bosworth et al. (2011)[89-91] found significant improvement only for nonwhite patients at 12 months; differences were not significant for white patients at any timepoint or at 24 months for any subgroup. Based on a mimimal important difference of 2 mmHg,[11,12] 16/29 point estimates from the 15 BP monitor presence studies suggest BP monitors may have meaningful effects on SBP reduction (see Figure 4). One study[95] found that a BP monitor which automatically transmitted data significantly improved SBP compared to one that did not, while a second study[69] found no significant differences between the two types of BP monitors.

All but one of the studies[69] reported on PGHD's impact on DBP. The overall findings for DBP were similar to those for SBP. Five[83-86,89,93,98,99] studies found that PGHD interventions significantly reduced DBP compared to control, but like for SBP, in some cases significance was seen only for particular subgroups or time points in a study. Based on a mimimal important difference of 2 mmHg,[11,12] 10/29 point estimates from 15 device presence studies suggest PGHD interventions may have meaningful effects on DBP reduction (see Figure 5). One study[95] found no significant differences in DBP in comparing a BP monitor which automatically transmitted data to one that did not.

Ten studies[63,80-82,88,92-94,97-99,101] examined BP control. Most studies defined BP control as <140/90 mmHg, but one[92] used SBP <140 mmHg without the DBP component and one[94] used <135/85 mmHg. Three[63,82,94] included a separate definition of <130/80 mmHg for diabetes patients. Two of the studies[93,99] reported significant improvements in BP control among those using the PGHD intervention. The remaining studies generally found nonsignificant improvements in BP control.

Overall, taking into account the data on surrogate outcomes, PGHD interventions have a possible positive effect on health outcomes. See Table 10 for a summary of findings on surrogate outcomes from the device-presence studies reporting isolated effects.

Figure 4. SBP differences in studies of isolated effects of BP monitor presence/absence



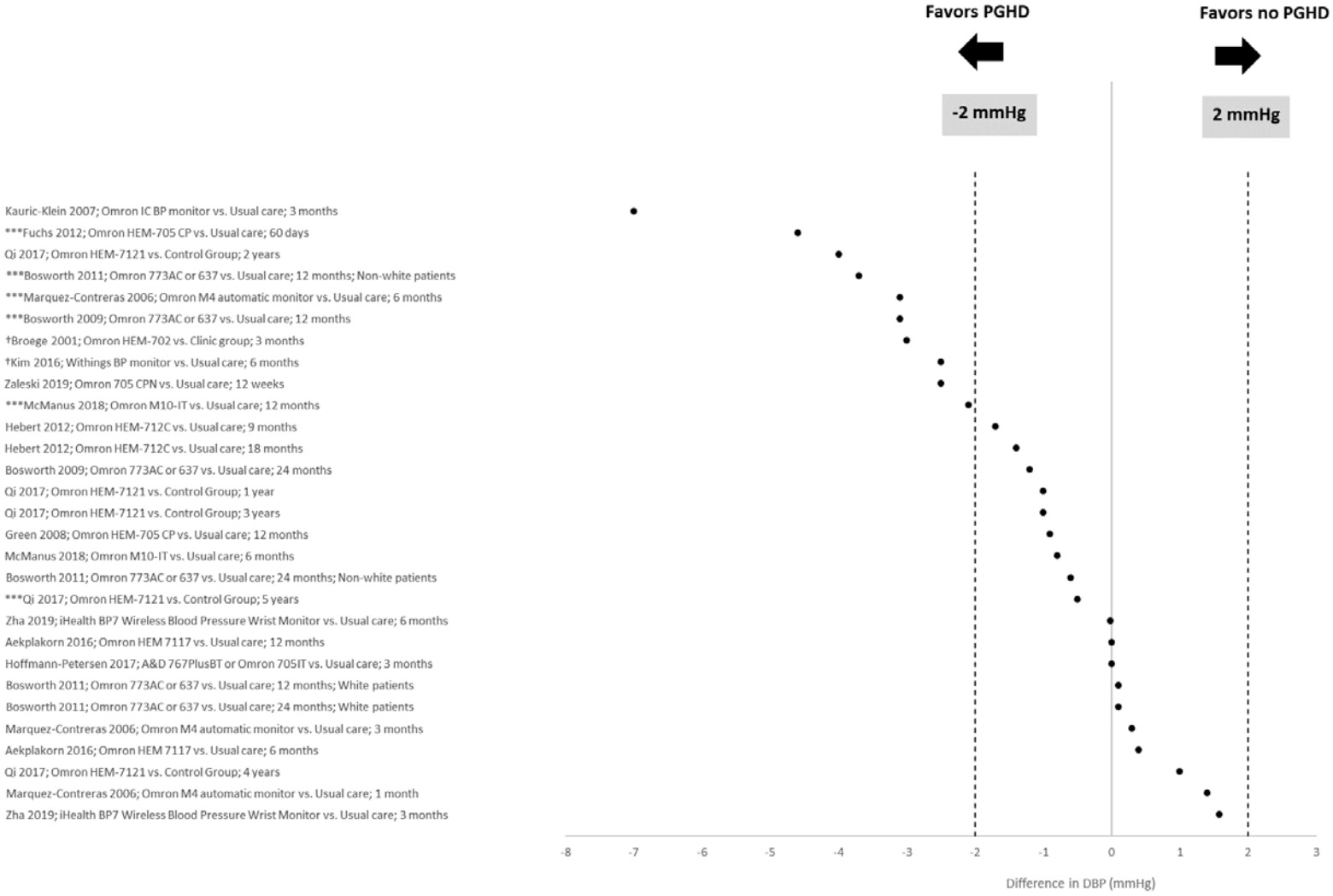
Change from baseline prioritized over followup values if both reported; followup values used otherwise.

***statistically significant between-group difference

† statistical significance not reported

BP = blood pressure; PGHD = patient generated health device; SBP = systolic blood pressure.

Figure 5. DBP differences in studies of isolated effects of BP monitor presence/absence



Change from baseline prioritized over followup values if both reported; followup values used otherwise

***statistically significant between-group difference

† statistical significance not reported

BP = blood pressure; DBP = diastolic blood pressure; PGHD = patient generated health device

Table 9. Hypertension: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant†	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Quality of life			A, A, B, C		
Mortality			A		
Hospitalizations			B		
Health outcomes not reported in 11 isolated-effect studies					

Statement about health outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks), multiple patient subgroups (without providing results for overall study population), or multiple outcomes within a category (e.g., multiple quality of life scales), and data showed statistical significance for some but not all time points/subgroups/outcomes.

† Two studies did not report if differences in surrogate outcomes were statistically significant; they have conservatively been grouped with the non-significant studies

PGHD = patient generated health data

Table 10. Hypertension: categorization of isolated effects on surrogate outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant †	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
SBP	A, B	A, A, A, B, B	A, A, A, B, B, B, C, C, C		
DBP		A, A, A, B, B, B	A, A, A, A, B, B, B, C, C, C		
BP control	B	A	A, A, A, A, B, B, B, C		
Surrogate outcomes not reported in zero isolated-effect studies					

Statement about surrogate outcomes: Possible positive effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks), multiple patient subgroups (without providing results for overall study population), or multiple outcomes within a category (e.g., multiple quality of life scales), and data showed statistical significance for some but not all time points/subgroups/outcomes.

† Two studies did not report if differences in surrogate outcomes were statistically significant; they have conservatively been grouped with the non-significant studies

BP = blood pressure; DBP = diastolic blood pressure; PGHD = patient generated health data; SBP = systolic blood pressure.

Multicomponent Effects on Health Outcomes: Hypertension

Sixteen studies[47,60,63,64,80-86,102-124] examined the multicomponent effect of PGHD on health outcomes.

Eleven studies[47,80,81,83-86,102-122,124] reported the effect of PGHD multicomponent with other interventions on QOL measures. One study[102] found that multicomponent PGHD significantly improved QOL compared to usual care on the EQ-5D-3L scale, while another study[83-86] reported that multicomponent PGHD significantly decreased QOL on the EQ-5D-5L scale. The remaining studies generally found modest nonsignificant differences between multicomponent PGHD and usual care, though the direction of the effects generally favored PGHD.

Three studies[82,113-115,123] evaluated multicomponent PGHD's impact on mortality. Mortality was low, and there were no significant differences between the multicomponent PGHD and control groups.

Three studies[63,64,113-115] examined multicomponent PGHD's effect on hospitalizations. None of these studies reported significant differences compared to control groups.

Two studies[64,113-115] examined multicomponent PGHD's effects on emergency room visits. Neither reported significant differences compared to control groups.

Multicomponent Effects on Surrogate Outcomes: Hypertension

Thirty-eight studies[18,23,24,47,60,63-68,70-74,80-86,88-91,102-140] evaluated multicomponent PGHD for surrogate outcomes, including SBP, DBP, and BP control. See Appendix Table C-28 for further details.

One of the nine ongoing studies including hypertension patients that may potentially meet our inclusion criteria identified on ClinicalTrials.gov reported that they were planning to examine health outcomes (quality of life).

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

Only 12 of the 51 hypertension studies[18,60,63,66-68,72,73,83-86,100,103-121,123] reported data on AEs (see the Health Outcomes section of Appendix Table C-28). The reported types of events were:

- Overall number of events
- Individual serious AEs (including deaths, strokes, and myocardial infarction)
- Individual AEs (including pain, fatigue, and stiffness)
- Alerts for high or low BP (device alert triggered when SBP >220 or <60 or DBP >110 or <40)

Two of the 12 studies[83-86,116-120] reported statistically significant differences between PGHD and control groups in terms of AEs. McManus et al. (2010)[116-120] found that swelling of legs was significantly higher for those in the PGHD group (combination of Omron 705IT BP monitor and medication management) than for those in the usual care group, although for other AEs reported, including stiff joints, pain, and fatigue, there were no significant differences between the groups. McManus et al. (2018)[83-86] found that occurrence of dry mouth was significantly higher in the PGHD group (Omron M10-IT) than in the usual care group, although for the other reported AEs, including pain, stiff joints, and sleep difficulties, there were no significant differences. In the

remaining studies, AEs were not significantly or substantially different between the PGHD and control groups.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

Four of the 51 hypertension studies[83-86,106-120] reported PGHD's impact on economic outcomes. Risk-of-bias evaluations are in Appendix Table C-27, and the results are in Appendix Table C-28.

Margolis et al. (2013)[106-112] examined PGHD's cost-effectiveness (A&D Medical 767PC BP monitor plus pharmacist management) compared to usual care. They estimated that use of the PGHD intervention would increase cost by $139 (95% CI: $46 to $347) per mmHg of reduced SBP, by $265 (95% CI: $83 to $743) per mmHg of reduced DBP, and by $7,337 (95% CI: $2278 to $26 329) per person achieving BP control (defined as <140/90 mmHg).

McKinstry et al. (2013)[113-115] evaluated PGHD (Stabil-O-graph mobile BP monitor) compared to usual care and found that the costs per patient were higher and mean ambulatory SBP per patient was lower in the PGHD group, with an incremental cost-effectiveness ratio (ICER) of £25.60 per mmHg ambulatory SBP reduction (95% CI: £16.05 to £46.69).

McManus et al. (2010)[116-120] evaluated PGHD (combination Omron 705IT BP plus medication management) compared to usual care. For men, using PGHD modeled over a lifetime (defined by the study as 35 years) results in a 0.24 increase in quality-adjusted life-years (QALYs) (PGHD 9.16 gained; usual care 8.92 gained), with an ICER of £1624. For women, using PGHD modeled over a lifetime (35 years) results in a 0.12 increase in QALYs (PGHD: 10.57 gained; usual care: 10.46 gained), with an ICER of £4923/QALY.

McManus et al. (2018)[83-86] evaluated PGHD (Omron M10-IT BP monitor) compared to usual care and estimated that use of the PGHD device would result in 11.0447 QALYs compared to 11.0040 with usual care. The ICER was £3035/QALY.

Coronary Artery Disease

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Coronary Artery Disease

The seven included coronary artery disease (CAD) trials used 10 different PGHD devices: three heart rate monitors, four BP monitors, two accelerometers, and one weight scale. The similarity judgment (how similar each device is to those currently on the market by this manufacturer) was "similar" for all 10 devices. All these devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1.

Studies in Progress: Coronary Artery Disease

We identified 5 records in ClinicalTrials.gov that potentially involved PGHD interventions to prevent or treat CAD. As of June 19, 2020, two were not yet recruiting patients, two were recruiting, and one was active but not recruiting. More details about these records (including hyperlinks) appear in Appendix Table C-29.

Study Designs: Coronary Artery Disease

All seven included CAD studies were randomized trials. Two trials were conducted in Belgium, one in Canada, one in France, one in Spain, and two in The Netherlands. Patient enrollment dates (reported by 5 trials) ranged from December 2007 to December 2018, and the mean study enrollment period was 104 weeks. The mean number of patients per study at baseline was 108 (range 78 to 203). The next sections describe additional aspects of these trials, which are tabled in detail in Appendix Table C-30, C-31, and C-32.

Inclusion/Exclusion Criteria: Coronary Artery Disease

Six studies included patients with documented CAD/acute coronary syndrome either with or without prior CAD events (myocardial infarction or revascularization procedures). One trial included patients with cardiovascular risk factors or history of CAD. Four trials required patients to have Internet access with or without a computer.

Additional Patient Characteristics: Coronary Artery Disease

The seven included CAD studies enrolled patients with a mean age between 59.7 and 63 years; between 11% and 22% of enrolled patients were female. Disease severity was measured inconsistently across studies. Three studies reported the percentage of patients who received prior coronary artery bypass grafting (CABG), which ranged from 24.4% to 62.2%. Three studies reported that the percentage of patients with prior percutaneous coronary intervention (PCI) ranged from 37.8% to 74%. One study was conducted in a rural setting, one study in an urban setting, and the remaining four studies did not report whether the setting was rural or urban.

Statistical Power Analyses: Coronary Artery Disease

Four studies conducted *a priori* power analyses (a fifth study may have conducted power analysis *a priori*, but this was unclear). Three studies based effect-size estimates on prior work and accounted for anticipated attrition. Two studies stated the anticipated effect size but only one provided the basis for this effect size. Two studies based power calculations on blood pressure, one study based power analyses on physical activity energy expenditure, and one study based power analyses on cardiovascular risk profile improvement. The other two studies provided no information on power analysis.

Followup Length: Coronary Artery Disease

The mean followup length in the seven CAD trials was 44.4 weeks (range 17 to 68 weeks).

Adherence Measurement: Coronary Artery Disease

One study measured device adherence and one other study measured only adherence to training sessions.

Comparators: Coronary Artery Disease

Four studies had control groups consisting of usual/standard care. Two studies had control groups that received center-based cardiac rehabilitation (CR). One study had a control group that used a modified motion sensor and did not receive physician feedback. The remaining study had a control group that received home CPAP.

Outcomes Reported: Coronary Artery Disease

Regarding health outcomes, four studies reported QOL, two studies reported mortality, and rehospitalization, hospitalization for heart failure, emergency room visits, and exercise capacity (function) were reported in one study each. One study reported economic outcomes (QALYs and societal costs). In addition, three studies reported acceptability.

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Below, we discuss the pertinent CAD data for this Guiding Question separately for heart rate monitors, BP monitors, and accelerometers. The risk-of-bias assessments are in Appendix Table C-33, and the results are in Appendix Table C-35.

Interoperability varied among the studies. Only one study reported automatic data transfer from several PGHD devices through a Smartphone app which also automatically integrated the data in the patient's electronic medical record. Five studies required patients to manually upload data (that had been automatically recorded by PGHD devices) to a website or platform where they could be viewed by medical personnel. One study did not report whether data were automatically or manually transmitted from PGHD interventions for assessment by medical personnel.

Heart Rate Monitors: Coronary Artery Disease

Four trials included heart rate monitors as part of the intervention. One trial (Treskes et al.[141]) reported that 89% of patients in the intervention group were satisfied with the ECG device. Another trial (Kraal et al.[142]) reported on acceptability and fidelity (adherence) to the overall home training program (which involved heart rate monitoring). Patients in the home-based group were more satisfied with their cardiac rehabilitation program than patients in the center-based group (home-based: 8.7/10, center-based: 8.1/10, p=0.02).

BP Monitors: Coronary Artery Disease

Three trials included BP monitors as part of the intervention. Treskes et al.[141] reported a patient satisfaction rate of 88% for the BP monitor. Another trial (Blasco et al.[143]) reported on acceptability of the wireless application protocol (WAP) used to transmit data from BP monitors and other devices through their mobile phones. Almost all patients (98%) completed more than 50% of WAP sessions, and more than 83% completed more than 75% of them. Only 0.5 messages per patient were missed due to the mobile phone being turned off.

Accelerometers/Pedometers: Coronary Artery Disease

Treskes et al.[141]reported a patient satisfaction rate of 4% for the step counter used in that study. One other study[144] used an accelerometer but did not report any data related to Guiding Question 2.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

Below, we discuss the efficacy results in four categories: (1) isolated effects on health outcomes, (2) isolated effects on surrogate outcomes, (3) multicomponent effects on health outcomes, and (4) multicomponent effects on surrogate outcomes. For specific outcome data, see Appendix Table C-35.

Health Outcomes: Coronary Artery Disease

Of the four studies that reported QOL outcomes, none found a statistically significant difference between the PGHD arm and the control arm (scores were almost identical in each group).[47,142,143,145] The findings were similar in studies with isolated effects and studies with multicomponent effects.

The two studies that reported mortality had somewhat conflicting findings. One study found a significant reduction in mortality in the PGHD arm compared to usual care (0 vs. 5 deaths, p=0.029).[143]Because three PGHD devices were used in the PGHD arm and none in the control arm, the effects of the individual devices could not be isolated. The other study reported no difference in number of deaths between groups (2 vs. 2 deaths, p=0.62).

One study each[141,144,146] reported hospitalization, hospitalization for heart failure or emergency room visit outcomes, and none found a statistically significant between-group difference in these outcomes. Event rates were on average two-fold higher in the control arms, but the studies lacked adequate statistical power to detect a difference because the overall event rates were low. Two of these studies[141,144] isolated the PGHD intervention's effect.

One study[146] reported a significant increase from baseline in total time on exercise stress test (seconds) in the PGHD arm compared to the control arm. However, the PGHD intervention's effect was not isolated because the PGHD group also received scheduled chat sessions and education sessions with medical personnel that the usual care group did not receive.

Overall, the evidence suggests a possible positive effect of PGHD devices on health outcomes for patients with CAD. See Table 11 summarizing the findings of studies that isolated effects of PGHD devices.

Surrogate Outcomes: Coronary Artery Disease

None of the studies reported surrogate outcomes.

Out of 5 ongoing trials of PGHD in patients with CAD identified in ClinicalTrials.gov, all planned to measure a health outcome or outcomes related to CAD.

Table 11. Coronary artery disease: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Quality of life			B, B, C		
Mortality	B		B		
Hospitalization			B, B		
Health outcomes not reported in zero isolated-effect studies					

Statement about health outcomes: Possible positive effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data.

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

None of the included studies identified or reported any AEs related to the PGHD technologies.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

One study by Kraal et al.[142] reported QALYs and societal costs associated with a home-based cardiac rehabilitation (CR) training program that used heart rate monitoring with data transmission for patient and physician review (see risk-of-bias evaluation in Appendix Table C-34). The QALYs calculated for the center-based group (0.78 +/- 0.08) were similar to the QALYs for the home-based CR group (0.77 +/- 0.13, p=0.73). From a societal perspective (i.e., the sum of healthcare and non-health-care costs), costs per patient were lower for patients in the home-based group, although the difference did not reach statistical significance (p=0.09).

Heart Failure

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Heart Failure

The 6 heart failure (HF) trials used 15 different PGHD devices: 6 BP monitors, 5 scales, 3 heart rate monitors, and 1 pulse oximeter. All these devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1. The similarity judgments (how similar each device is to those currently on the market by this manufacturer) were:

- BP monitors: 5 similar, 0 somewhat different, 0 very different, 1 unknown
- Scales: 3 similar, 1 somewhat different, 0 very different, 1 unknown
- Heart rate monitors: 2 similar, 0 somewhat different, 0 very different, 1 unknown
- Pulse oximeter: 0 similar, 0 somewhat different, 0 very different, 1 unknown

Studies in Progress: Heart Failure

We identified two records in ClinicalTrials.gov that potentially involved PGHD interventions to management of heart failure. As of June 19, 2020, one was not yet recruiting patients and one was recruiting. More details about these records (including hyperlinks) appear in Appendix Table C-36.

Study Designs: Heart Failure

All six included heart failure studies were randomized trials. Two trials were conducted in the United States and one each in Canada, Austria, Denmark, and Germany. Patient enrollment dates (reported by 5 trials) ranged from October 2003 to May 2017, and the mean study enrollment period was 123 weeks. The mean number of patients per study at baseline was 613 (range 100 to 1571). The next sections describe additional aspects of these trials, which are tabled in detail in Appendix Table C-37, C-38, and C-39.

Inclusion/exclusion Criteria: Heart Failure

All studies enrolled patients with heart failure, but each had slightly different criteria. One study included patients with heart failure rated as New York Heart Association (NYHA) class 2, 3 or 4. Another study included patients with heart failure rated as NYHA Class 2 or 3 and had a left ventricular ejection fraction of 45% or lower (or if more than 45%, were being treated with oral diuretics). Another study required current hospital admission or recent discharge (within prior 2 weeks) with a primary diagnosis of heart failure, considered high risk for readmission (history of hospital readmissions for cardiac-related reasons or ejection fraction $\leq$20%). Two studies enrolled patients with decompensated heart failure (defined as heart failure with the initiation of or an increase in diuretic treatment). The remaining study included ambulatory patients given a diagnosis of heart failure with a left ventricular ejection fraction less than 40%.

Additional Patient Characteristics: Heart Failure

The six included heart failure studies enrolled patients with a mean age between 63.7 and 74 years; between 19.1% and 46.9% of enrolled patients were female. Five studies reported a mean left ventricular ejection fraction (LVEF) ranging from 25% to 42.9%. The majority of patients in the four studies that reported New York Heart Association (NYHA) Class were in NYHA Class II and III. Four studies appeared to be conducted in an urban setting and the remaining two studies did not report whether the setting was rural or urban.

Statistical Power Analyses: Heart Failure

Four studies conducted *a priori* power analyses. All four studies described the basis for their effect-size estimates, but only one cited a prior study as a basis for the estimate. Only one study mentioned accounting for anticipated attrition. Of the four power analyses, one was based on the composite outcome all-cause death or unplanned cardiovascular hospital admissions, one was based on the composite outcome of cardiovascular mortality or rehospitalization for worsening heart failure, one was based on hospital readmission, and one was based on the Self-Care for Heart Failure index. The other two studies provided no information on power analysis.

Followup Length: Heart Failure

The mean followup length in the 6 trials was 34.7 weeks (range 26 to 52 weeks).

Adherence Measurement: Heart Failure

Two studies measured patient adherence based on daily transmission of data to the monitoring center.

Comparators: Heart Failure

Five studies had control groups consisting of usual/standard care. The remaining study specified pharmacologic treatment (a component of usual care) as the comparator.

Outcomes Reported: Heart Failure

All studies reported health outcomes. The most commonly reported health outcomes were QOL (4 studies), hospitalization or readmission (3 studies), mortality (3 studies), and emergency room visits (2 studies). Four studies reported outcomes related to Guiding Question 2 (3 studies reported adherence, and 1 reported acceptability). One study reported a process outcome (physician adjustment of medication).

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Below, we discuss the pertinent HF data for this Guiding Question separately for heart rate monitors, BP monitors, and accelerometers. All these data appear in Appendix Table C-40.

Interoperability varied among the studies. Four studies reported automatic data transfer from a PGHD device via mobile phones to a clinical center or platform where they could be assessed by medical personnel. The remaining study required patients to manually upload data (that had been automatically recorded by PGHD devices) to the internet for assessment by medical personnel.

Heart Rate Monitors: Heart Failure

All trials included heart rate monitors as part of the intervention. Three trials[147-149] reported data on adherence, but this was not specific to heart rate monitors. The studies measured adherence to data transmission to the monitoring centers; these data included information from other devices (BP monitors, scales) in addition to heart rate monitors. Studies reported adherence differently, with one study reporting overall 95% adherence, another study reporting that 97% of patients were 70% adherent with daily data transmission, and another study reporting a range of adherence rates for patients within the study. One study[150] reported acceptability; of 20/42 patients (48%) who filled out a questionnaire, 100% reported that the equipment was simple and easy to use and the program made them feel more in control of their health. The equipment included multiple devices, not just a heart rate monitor.

BP Monitors: Heart Failure

All trials included BP monitors as part of the intervention. See information under heart rate monitors above, as all trials included both devices and did not measure adherence or acceptability separately for each device.

Scales: Heart Failure

All studies included scales. See information under heart rate monitors above, as all trials included both devices and did not measure adherence or acceptability separately for each device.

Pulse Oximeters: Heart Failure

One trial[150] included a pulse oximeter as part of the intervention. Although this study reported data on acceptability (see under heart rate monitors above), it included all devices in the measurement of acceptability.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

Below, we discuss the efficacy results in four categories: (1) isolated effects on health outcomes, (2) isolated effects on surrogate outcomes, (3) multicomponent effects on health outcomes, and (4) multicomponent effects on surrogate outcomes. Risk-of-bias assessments are in Appendix Table C-40, and the results are in Appendix Table C-41.

Health Outcomes: Heart Failure

There was some inconsistency in findings regarding QOL among HF studies. Two studies isolated the effect of the combined PGHD interventions but could not isolate the effect of the individual PGHD devices used as part of the intervention. These studies used different QOL instruments: one used the SF-36 mental (MCS) and physical component scores (PCS) and a disease-specific instrument.[151] This study found no statistically significant between-group difference in the SF-36 PCS or the disease-specific instrument score, but did find a difference in the SF-36 mental component score favoring the PGHD intervention. The other study used the disease-specific Minnesota Living with Heart Failure Questionnaire (MLHFQ) and found a statistically significant between-group difference favoring the PGHD intervention.[149]

Two studies that combined PGHD and other interventions used the MLHFQ and reported mixed findings, with one study[152] reporting a significant between-group difference favoring the PGHD intervention while the other study found no significant between-group difference.[147]

Of three studies that reported mortality,[147,149,152] one[147] reported a statistically significant between-group difference in mortality (favoring lower mortality in the PGHD arm). This study combined multiple PGHD devices with another intervention, so the PGHD intervention's effect could not be isolated.

Three studies that reported hospitalizations or hospital readmissions did not find a statistically significant between-group difference and did not show consistency in the direction of effect.[149,150,152]These studies all used combinations of PGHD devices and did not isolate the effect of individual devices.

Two studies reported emergency room visits and neither found a statistically significant between-group difference.[149,150]

Overall, the evidence suggests a possible positive effect of combined PGHD devices in patients with heart failure, but because all studies combined multiple PGHD devices together, the possible effect of any individual PGHD device remains unclear. See Table 12 summarizing the findings of studies that isolated effects for PGHD interventions.

Surrogate Outcomes: Heart Failure

No studies reported surrogate outcomes that met inclusion criteria.

Both ongoing trials identified in ClinicalTrials.gov addressing PGHD for heart failure planned to measure a health outcome or outcomes.

Table 12. Heart failure: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Quality of life	B	C			
Mortality			B		
Hospitalizations			B, C		
Emergency room visits			B, C		
Health outcomes not reported in zero isolated-effect studies					

Statement about health outcomes: Possible positive effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data.

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

None of the included studies identified or reported any AEs related to the PGHD technologies.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

None of the included studies performed an economic evaluation.

Cardiac Arrhythmias

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Cardiac Arrhythmias

The four included cardiac arrhythmia trials all used the same electrocardiogram (ECG) monitor: the AliveCor Kardia. We rated the model as similar to other model(s) currently available from the manufacturer. This device (along with devices included in trials of other clinical conditions) appears in Appendix Table C-1.

Studies in Progress: Cardiac Arrhythmias

We identified five records in ClinicalTrials.gov that potentially involved PGHD interventions to prevent or treat cardiac arrhythmias. As of June 19, 2020, one was not yet recruiting patients, three were recruiting, and one was active but not recruiting. More details about these records (including hyperlinks) appear in Appendix Table C-42.

Study Designs: Cardiac Arrhythmias

All four included studies were randomized trials. Two trials were conducted in the United States and two in the United Kingdom. Patient enrollment dates (reported by 2 trials) ranged from November 2013 to January 2018, and the mean study enrollment period was 78 weeks. The mean number of patients per study at baseline was 386 (range 58 to 1004). The next sections

describe additional aspects of these trials, which are tabled in detail in Appendix Table C-43, C-44, and C-45.

Inclusion/Exclusion Criteria: Cardiac Arrhythmias

One study included patients documented with at least one atrial fibrillation (AF) risk factor, another study included patients with paroxysmal AF, a third study included patients presenting with an episode of palpitations or pre-syncope with no obvious cause, and the remaining study included individuals >65 years of age with a CHADS-VASc score ≥2 not in receipt of oral anticoagulation therapy without a known diagnosis of AF currently, a known contraindication to anticoagulation, or permanent cardiac pacing implantation. Three studies required patients have the ability to use the AliveCor heart monitor and have a smartphone or Internet access.

Additional Patient Characteristics: Cardiac Arrhythmias

The four included cardiac arrhythmia trials enrolled patients with a mean age between 39.6 and 72.6 years; between 22.7% and 56.6% of enrolled patients were female. Each trial reported different measures of disease severity, making it difficult to compare across trials (see Table C-44 in Appendices for details). Three studies appeared to be conducted in an urban setting and the remaining study did not report whether the setting was rural or urban.

Statistical Power Analyses: Cardiac Arrhythmias

Three studies conducted *a priori* power analyses. One study had based effect-size estimates on prior work, and two studies had accounted for anticipated attrition. One study stated the anticipated effect size but did not provide the basis for this effect size. Of the three power analyses, one was based on symptomatic rhythm detection, one was based on time to AF detection, and one was based on time to detection of recurrent AF or atrial flutter. One study provided no information on power analysis.

Follow-up Length: Cardiac Arrhythmias

The mean followup length up in the 4 trials was 42 weeks (range 12 to 80 weeks).

Adherence Measurement: Cardiac Arrhythmias

One study measured device adherence by the number of times patients recorded a daily ECG. No other studies measured adherence.

Comparators: Cardiac Arrhythmias

Three studies had control groups consisting of usual/standard care. The remaining study had a control group of patients who received continuous anticoagulation.

Outcomes Reported: Cardiac Arrhythmias

All studies reported health outcomes, with mortality the most commonly reported outcome (3 studies), followed by stroke, major/clinically significant bleeding, and emergency room visits (2 studies each). Other health outcomes included quality of life, hospitalization, deep vein thrombosis/pulmonary embolism, and major adverse cardiac events (1 study each). Three studies reported outcomes related to Guiding Question 2 (adherence/fidelity to protocol in 2 studies, acceptability in 1 study). Two studies reported a process outcome (medication initiation or medication change).

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Below, we discuss the pertinent data for this Guiding Question separately for the AliveCor ECG monitor. The data appear in Appendix Table C-47.

Regarding interoperability, all four studies required patients who experienced an arrhythmia event to transmit data from their ECG monitor (all studies used the AliveCor ECG monitor which automatically captured ECG traces) to a secure center or site for review by medical personnel. An independent evaluation described below rated the interoperability of AliveCor devices as good because the Kardia app generates PDF reports, which can be imported into a patient's electronic medical record.

Heart Rate Monitors: Cardiac Arrhythmias

All trials included the AliveCor ECG monitors as part of the intervention. Two trials[153,154] reported adherence/fidelity to protocol. Goldenthal et al.[153] reported that 41 patients (36%) recorded greater than 180 times, on average once per day, and 77 (67%) used the device in the last month of their study period. Ninety-three (81%) averaged transmission at least once per week, and 86 (75%) used the device in the second half of the study. Stavrakis et al.[154] reported that 4/29 patients (14%) in the intermittent anticoagulation arm crossed over to the continuous anticoagulation arm due to failure to submit rhythm strips. The 29 patients in the intermittent arm had a median of 3 failed submissions of rhythm strips (IQR 0 to 5). Reed et al.[155] was the only study that reported acceptability; 80/92 (87.0%) patients considered the AliveCor monitor easy to use.

Technical Report on Smartphone-Enabled ECG Monitors

Device engineers independently evaluated three Smartphone-enabled ECG monitors. These evaluations included device performance, safety, workflow, patient experience, interoperability, maintenance, user experience, and cost of ownership.[156] The evaluations were carried out as follows:

- Performance: testing focused on the ability of the system to record an ECG in the uncontrolled environment of a patient's home, as well as key features that enable the system to be used as intended.
- Safety: evaluated whether there are safety concerns introduced by the device.
- Workflow: testing focused on how easily an untrained user can operate the system, as well as on features that help the user communicate with a clinician.
- Patient experience: evaluated capabilities and features that impact the user, such as battery life and trending information in the smartphone application.
- Interoperability: considered privacy and security issues related to patient data.
- Maintenance: examined the cleaning instructions for the device.
- User experience: volunteers were asked to use the device and fill out a usability survey.
- Cost: considered the cost of the handheld device. The smartphone applications are available for free.

The AliveCor KardiaMobile[157] and KardiaBand[158] Smartphone-enabled ECG monitors (KardiaBand is a watchband for the Apple Watch) both use the Kardia app, which can be used on a smartphone or Apple Watch. Device engineers performed a range of physical tests, reviewed product literature/specifications, and asked users about their experience with the device. They rated device performance as excellent because the detection algorithm works within the Kardia app even when the smartphone is not connected to the Internet or (for KardiaBand) when the paired iPhone is out of range (considered a major advantage). It also has a guest mode that allows users to share the device with others while keeping the primary user's own data separate from other users' data. It also includes orientation correction in case a user holds the device in the wrong orientation. Workflow was rated as good, as the Kardia app has a voice notes feature that allows users to record a message while recording their ECG; messages are automatically transcribed. Interoperability was rated as good because the Kardia app generates PDF reports, which can be imported into a patient's electronic health record (EHR), allowing clinicians to track the patient's condition within their EHR system. Device engineers rated maintenance as good, with no significant issues identified. They rated the user experience as good based on human factors testing; volunteers generally liked the Kardia system and found it easy to use despite having no previous experience with it. Device engineers further noted that the long battery life (1 year for KardiaMobile and 2 years for KardiaBand) is a major advantage in providing a good patient experience. A major disadvantage was that neither device provides a battery-replacement warning, so users may be confused if and when the device stops working. Safety was rated as good, as no serious safety concerns were identified. The estimated cost of ownership for a 2-year period was $310 for KardiaMobile and $400 for KardiaBand. The overall rating for both of the AliveCor devices across all categories was good.

Device engineers also evaluated another smartphone-enabled ECG monitor (Cardiac Designs ECG Check).[159] Similar to the AliveCor devices, the ECG Check was rated as good in the categories of interoperability, maintenance, patient/user experience, and safety. However, it was rated as inferior to the AliveCor devices in the categories of performance and workflow. Performance was rated as fair due to the major disadvantage of inability to record ECGs without a network connection. Workflow was rated as fair because user-entered symptoms are not included in the report that users can e-mail to their clinicians. The device's overall rating was fair because of these disadvantages. Cost of ownership was estimated at $140 over a 2-year period.

Although their original analysis was performed in 2018, device engineers looked at current models and did not note significant changes that would affect the overall device rating.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

Below, we discuss the efficacy results in four categories: (1) isolated effects on health outcomes, (2) isolated effects on surrogate outcomes, (3) multicomponent effects on health outcomes, and (4) multicomponent effects on surrogate outcomes. The risk-of-bias assessments are in Appendix Table C-46, and the data are in Appendix Table C-47.

Health Outcomes: Cardiac Arrhythmias

Three studies[154,155,160] that reported mortality and isolated the effect of the AliveCor monitor found no statistically significant between-group difference in mortality rates. However, these studies lacked adequate statistical power to detect a small difference due to the low number of deaths.

One study that reported stroke alone[154] and another study that reported combined stroke/transient ischemic attack[160] did not find a statistically significant between-group difference in these outcomes. Both studies isolated the effect of the AliveCor monitor. However, these studies lacked adequate statistical power to detect a small difference due to the low number of events.

Two studies[154,160] found no significant between-group difference in major bleeding. Both isolated the effect of the AliveCor monitor but lacked adequate statistical power due to the low number of events.

One study[155] that isolated the effect of AliveCor reported a statistically significant higher rate of emergency room visits for palpitation or pre-syncope in the AliveCor group. The authors hypothesized that some patients may have needed more reassurance than remote ECG transmission provided. Another study[153] that did not isolate the effect of AliveCor from other interventions (text messaging) did not find a significant between-group difference in emergency room visits, although the number of visits was higher in the usual care group.

No outcomes reported by a single study (quality of life, hospitalization, deep vein thrombosis/pulmonary embolism, or major adverse cardiac events) reported a statistically significant between-group difference, but for most outcomes the studies lacked adequate statistical power to detect a difference due to the low event rates.

Surrogate Outcomes: Cardiac Arrhythmias

The only potential surrogate outcome reported in studies of isolated effects was time to arrhythmia detection. The single study[155] that reported this outcome found a statistically significant between-group difference favoring the AliveCor arm for reducing the time to arrhythmia detection. One other study[160] of isolated effects did not specifically report differences in time to arrhythmia detection but showed Kaplan-Meier curves of arrhythmia detection over time that indicated a significant between-group difference favoring AliveCor. This data suggests a likely positive effect on the surrogate outcome.

Although no statistically significant between-group differences in health outcomes favored the PGHD intervention, the studies lacked sufficient statistical power to detect differences in those outcomes. However, one low risk study found a higher rate of emergency room visits in the AliveCor group, and the reason for this remains uncertain. Therefore, the effect of AliveCor on health outcomes in patients with cardiac arrhythmias is unclear.

See Table 13 and Table 14 summarizing PGHD effects on outcomes in studies of isolated effects. For health outcomes, we deemed the evidence unclear on whether health outcomes are improved by PGHD interventions, but the AliveCor device appear to have a likely positive effect on a surrogate outcome.

Out of five ongoing trials of PGHD for cardiac arrhythmias, four planned to measure a health outcome or outcomes.

Table 13. Cardiac arrhythmias: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Mortality			A, B, C		
Stroke/transient ischemic attack			B, C		
Major bleeding			B, C		
Emergency room visits for palpitation or pre-syncope					A
Major adverse cardiac events			A		
Deep vein thrombosis/ pulmonary embolism			B		
Health outcomes not reported in zero isolated-effect studies					

Statement about health outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect
PGHD = Patient generated health data.

Table 14. Cardiac arrhythmias: categorization of isolated effects on surrogate outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Time to arrhythmia detection	A, B				
Surrogate outcomes not reported in one isolated-effect study					

Statement about surrogate outcomes: Likely positive effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

PGHD = Patient generated health data.

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

None of the included studies identified or reported any AEs related to the PGHD technologies, although one study reported a higher rate of emergency room visits for palpitation or pre-syncope in the AliveCor group.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

None of the included studies performed economic evaluations.

Stroke

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Stroke

We included one trial on stroke. It used a BP monitor (Omron M6), and we judged it as similar to those currently on the market by this manufacturer.

Studies in Progress: Stroke

We identified two records in ClinicalTrials.gov on stroke that, once published, may potentially meet our inclusion criteria. As of June 19, 2020, both were recruiting. More details about these records (including hyperlinks) appear in Appendix Table C-48.

Study Designs: Stroke

Kerry et al. (2013)[103-105] was a randomized trial in the United Kingdom that enrolled 381 patients and followed them for 1 year, and had a median enrollment month of June 2008. The next sections describe additional aspects of this trial, which are tabled in detail in Appendix Table C-49, C-50, and C-51.

Inclusion/Exclusion Criteria: Stroke

Kerry et al. (2013)[103-105] included patients with hypertension with a history of stroke or transient ischemic attack.

Additional Patient Characteristics: Stroke

The mean age was 72, and 42% of patients were female. Regarding disease severity, 8% had a Rankin score of 0, 27% had a score of 1, 27% had a score of 2, and 18% had a score of 3 or more. Patients were not rural, and researchers did not require technological expertise.

Statistical Power Analyses: Stroke

Kerry et al. (2013)[103-105] performed a power analysis (based on blood pressure) that accounted for possible attrition, but did not mention use of prior data to inform the power analysis.

Followup Length: Stroke

One year.

Adherence Measurement: Stroke

Kerry et al. (2013)[103-105] reported the percentage of patients who required the assistance of a care provider to take their BP, the percentage who recorded a full set of BP readings in the preceding 4 weeks, the percentage who said they still used the BP monitor 1.5 years after the cessation of nursing support, and the percentage who said they used the BP monitor at least once a month.

Comparators: Stroke

Kerry et al. (2013)[103-105] compared a group receiving only usual care to another group that received a BP monitor (Omron M6) as well as monthly calls from the nurse to check technique and review BP readings.

Outcomes Reported: Stroke

Kerry et al. (2013)[103-105] reported health outcomes (QOL as measured by the EuroQol 5D), AEs (falls, recurrent stroke), device usage, and a process outcome (number of primary care consultations).

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Kerry et al. (2013)[103-105] mentioned nothing about device interoperability. They did report that 30% of intervention patients (51/168) required the assistance of a care provider to take their BP, 48% (80/168) recorded a full set of BP readings in the previous 4 weeks, 80 of 84 (95%) intervention patients answering questions at 18 months (after cessation of nurse support) said

they still used the monitor, and 57 said they used it at least once a month. The data appear in Appendix Table C-53.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

The risk-of-bias assessments are in Appendix Table C-52, and the results are in Appendix Table C-53.

Isolated Effects on Health Outcomes: Stroke

The trial did not report whether there were isolated effects on health outcomes. As a result, we rated this evidence as unclear.

Isolated Effects on Surrogate Outcomes: Stroke

The trial did not use an isolated-effect design.

Table 15. Stroke: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Health outcomes not reported in zero isolated-effect studies					

Statement about health outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data.

Table 16. Stroke: categorization of isolated effects on surrogate outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Surrogate outcomes not reported in zero isolated-effect studies					

Statement about surrogate outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data.

Multicomponent Effects on Health Outcomes: Stroke

Kerry et al. (2013)[103-105] reported data on the 1-year rates of falls as well as recurrent stroke. The rate of falls was 17% in the usual care group and 19% in the BP monitoring group (difference not statistically significant). The rate of recurrent stroke was 8% in the usual care group and 6% in the BP monitoring group (difference not statistically significant). They also reported QOL as measured by the EuroQol 5D, and the groups did not have statistically significant differences at 1year.

Multicomponent Effects on Surrogate Outcomes: Stroke

Due to this evidence's highly indirect nature, we do not discuss it; instead, we here refer the reader to the tabulated data in Appendix Table C-53.

Process Outcomes: Stroke

Kerry et al. (2013)[103-105] reported that over the 1-year period, the usual care group had an average of 5.4 primary care consultations compared to 5.2 in the BP monitoring group (difference not statistically significant).

Of the four stroke-related records in clinicaltrials.gov, one made a PGHD-related comparison and stated that they were collecting data on a health outcomes (quality of life).

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

The trial reported data on both falls and recurrent stroke, which we summarized in Guiding Question 3 above.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

The stroke trial did not report either economic outcomes or cost-only data.

Parkinson's Disease

No included studies addressed Parkinson's disease. We identified four records in ClinicalTrials.gov that potentially involved PGHD interventions to prevent or treat Parkinson's disease. As of June 19, 2020, one was enrolling by invitation, two were recruiting, and one was not yet recruiting. More details about these records (including hyperlinks) appear in Appendix Table C-54.

Chronic Obstructive Pulmonary Disease

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Chronic Obstructive Pulmonary Disease

The ten chronic obstructive pulmonary disease (COPD) trials used ten different PGHD devices: four accelerometers, three pedometers, one BP monitor, one forehead thermometer, and one heart rate monitor. All these devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1. The similarity judgments (how similar each device is to those currently on the market by this manufacturer) were:

- Accelerometers: 2 similar, 1 somewhat different, 0 very different, 1 unknown
- Pedometers: 1 similar, 0 somewhat different, 0 very different, 2 unknown
- BP monitors: 1 similar, 0 somewhat different, 0 very different, 0 unknown
- Forehead thermometer: 1 similar
- Heart rate monitor: 1 similar

Studies in Progress: Chronic Obstructive Pulmonary Disease

We identified two records in ClinicalTrials.gov to prevent or treat COPD that, once published, may potentially meet our inclusion criteria. As of June 19, 2020, both were recruiting patients. More details about these records (including hyperlinks) appear in Appendix Table C-55.

Study Designs: Chronic Obstructive Pulmonary Disease

All ten studies of PGHD devices for COPD were RCTs. The RCTs were conducted in The Netherlands (3), Spain (2), Belgium (1), Brazil (1), Germany (1), Japan (1), and the United Kingdom (1). Patient enrollment dates were not reported in three RCTs and ranged from September 2010-December 2010 to June 2015-July 2016 in the remaining seven RCTs. There were between 27 and 407 patients at the baseline visit per study. The next sections describe additional aspects of these trials, which are tabled in detail in Appendix Table C-56, C-57, and C-58.

Inclusion/Exclusion Criteria: Chronic Obstructive Pulmonary Disease

Patients with a diagnosis of COPD were enrolled in all ten RCTs. Eight out of ten RCTs excluded patients with significant comorbidities, including significant cardiovascular comorbidities, mobility problems, and sarcoidosis. Four RCTs enrolled only patients 40 years of

age or older, and a fifth RCT enrolled only patients 35 years of age or older. A sixth RCT enrolled retirees but did not specify a minimum age requirement for study entry. Two RCTs recruited patients who were either current smokers or had a history of smoking. None of the studies had criteria for family income, although one study did report that 73% of the patients in both treatment arms were of low socioeconomic status. One study specified that patients had to have internet access, one study required a home telephone line, and three studies excluded patients who were unable to understand or operate the device of interest. Additional details appear in Appendix Table C-57.

Additional Patient Characteristics: Chronic Obstructive Pulmonary Disease

The ten included COPD studies enrolled patients with a mean age between 62.5 and 74.6 years. Between 5% and 50.3% of enrolled patients were female. The mean FEV1 % pred ranged from 38 (SD: 10) to 59 (SD: 20). One study indicated it was conducted in an urban setting while the other nine studies did not report whether the setting was urban or rural.

Statistical Power Analyses: Chronic Obstructive Pulmonary Disease

Four RCTs did not perform sample size calculations. The remaining six RCTs were calculated to detect a clinically meaningful difference in steps per day (2), exacerbation-free weeks (1), moderate-intensity physical activity (1), meters on a 6MWT (1), and a measure not clearly specified (1).

Followup Length: Chronic Obstructive Pulmonary Disease

The followup length was 1 to 12 months.

Adherence Measurement: Chronic Obstructive Pulmonary Disease

Three RCTs did not report PGHD device adherence.

Pedometer

Arbillaga-Etxarri et al. (2018)[52] measured device adherence in two ways. Physiotherapists administering both interventions noted patients' spontaneous reports of unwillingness to follow the instructions at the baseline visit, as well as spontaneous reports of nonadherence (i.e., not having followed the instructions) at the 12-month visit. At the 12-month followup visit, patients also answered a questionnaire about satisfaction with the study components and any potential AEs experienced during or after walks in the previous 12 months.

Demeyer et al. (2017)[161] measured Fitbug adherence by chart review.

Accelerometer

Vorrink et al. (2016)[50,58] measured adherence to the intervention as the percentage of days the intervention was used, and as percentage of days the physical activity goal was obtained.

Kawagoshi et al. (2015)[162] reported that adherence was measured when the patient comes for a consultation every 2 to 4 weeks. The accelerometer stores data for up to 36 days, which investigators retrieved at patient visits.

Tabak et al. (2014)[163] measured adherence in the intervention group by number of visits to the web portal and the time the activity sensor was worn. Only those days were included where at least 50% of the day was measured. Adherence was calculated by dividing the number of days

the activity sensor was worn by the minimal number of days that was prescribed (i.e., ≥four days/week).

Blood Pressure

Jodar-Sanchez et al. (2013)[164,165] measured adherence automatically. After taking these measurements, patients' data were sent via a hub (Tele-Modem, Aerotel Medical Systems) connected to the patient's home telephone line. Once measurements had been recorded by each connected instrument, the user pressed a button to activate data transmission.

Forehead Thermometer

Boer et al. (2019)[166] measured adherence based on the web-based interface, although this measure is not specific to the forehead thermometer of interest.

Comparators: Chronic Obstructive Pulmonary Disease

The comparator in seven of ten RCTs was usual care, which included education on COPD. Pulmonary rehabilitation (PR) was the comparator in two RCTs. In one study, PR entailed a multidisciplinary home-based program, including breathing training, exercise training, and an intensive educational program. In the other RCT, PR was an outpatient program lasting 8 weeks, with two supervised sessions per week. In the final RCT, physiotherapy in the form of weekly group training sessions at the local physiotherapy practice was the comparator.

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Below, we discuss the pertinent COPD data for this Guiding Question (see Appendix Table C-61).

Three RCTs did not report PGHD device adherence.

Reporting of interoperability was varied across studies. Automatic data transmission was not a feature of the Arbillaga-Etxarri et al. (2018),[52] Kawagoshi et al. (2015),[162] Mendes de Oliveira et al. (2010),[167] or Nolan et al. (2017),[168] studies.

In the Boer et al. (2019)[166] study patients received a mobile phone, a pulse oximeter (CMS50D, Contec Medical Systems,), a spirometer (PiKo-1 monitor, nSpire), and a forehead thermometer (FTN, Medisana AG), which is the PGHD of interest. Patients answered questions concerning symptoms using the touch screen on the mobile phone complemented by measurements with the pulse oximeter, spirometer, and forehead thermometer. Data were sent to a secured Web-based interface and were monitored by the research team.

Patients in the Demeyer et al. (2017)[161] study received the Fitbug Air, a step counter that provides direct feedback on a 2 × 3 cm display, a smartphone with Fitbug application and a project-tailored coaching application. The application provided automated coaching by displaying an activity goal and feedback on a daily basis. Telephone contacts were triggered in the case of non-compliance with wearing the step counter, failure to transmit data or failure to progress. No description of how the data was transmitted was provided.

In the study by Jehn et al. (2013),[169] patient data were transmitted via a mobile network directly to the study center.

In the study by Jodar-Sanchez et al. (2013),[164,165] data were sent via a hub (Tele-Modem, Aerotel Medical Systems) connected to the patient's home telephone line. Once measurements had been recorded by each connected instrument, the user pressed a button to activate data transmission.

In Tabak et al. (2014),[163] patients used an activity coach for ambulant activity registration and feedback and a web portal with a symptom diary for self-treatment of exacerbations and an overview of their activity levels. The activity coach consisted of the three-dimensional-accelerometer (MTx-W sensor, Xsens Technologies, Enschede, the Netherlands), and a smartphone (HTC P3600/3700). The sensor had a wireless connection with the smartphone by Bluetooth. Every day, participants were asked to fill in the diary on the web portal.

Vorrink et al. (2016)[50,58] examined a smartphone application and a website for the physiotherapists. The application showed physical activity in real time, measured by the accelerometer embedded in the smartphone (HTC Desire A8181; HTC, Taoyuan, Taiwan). The physiotherapists could monitor their patients via the (secure) website.

Pedometer

Arbillaga-Etxarri et al. (2018)[52] reported that of the 132 Urban Training patients participating in the followup visit, 90% used the pedometer and satisfaction with the pedometer was high or very high (9.0±1.8).

Demeyer et al. (2017)[161] reported patients wore the Fitbug step counter for a median (Q1-Q3) of 91% (84-98%) of the days they were included in the coaching program, representing 6.3 (5.8-6.8) days/week.

Accelerometer

Vorrink et al. (2016)[50,58] reported the intervention was used on 89±18.5% of the study days. The personal physical activity goal was obtained on 34±16% of these days.

Kawagoshi et al. (2015)[162] reported that patients wore their pedometers for 293 (SD: 49) days of a year (80.4%, SD: 13.3%).

Tabak et al. (2014)[163] reported that the activity coach was worn more than prescribed over the course of the one month study: for 17.5±2.2 days on average, which is 109% of prescribed use. Only two patients used the system for fewer than the prescribed 16 days (13 and 14 days). In other words, 86% of the patients complied with the activity coach. The average duration per day was almost 10 hours (588±101 minutes).

Blood Pressure

Jodar-Sanchez et al. (2013)[164,165] reported that patients in the telehealth group took daily BP measurements on 75% of days (average 90 days; SD: 0.22).

Forehead Thermometer

Boer et al. (2019)[166] report that 38 of the 43 patients (88%) in the PGHD group used the app 727 times in total during followup. No usage data were available for five patients. The range in frequency of usage per participant was 1 to 250 times with a median of 7 (IQR: 3 to 14). Results of the evaluation questionnaire showed that more patients reported to have used their mHealth

tool often (scores 6 and 7 on the 7-point rating scale) compared with patients in the control group who used their paper action plan (44.4% vs. 17.2%, respectively).

Boer et al. (2019)[166] also had participants evaluate the supportive function of either the mHealth tool (as a whole unit) or the paper action plan by using a paper survey, including closed-ended questions regarding the use, difficulty in use, and intended future use of the mHealth tool or the paper action plan. Additionally, three questions were asked related to clarity, suitability, and followup of the advice given by the mHealth tool or the paper action plan. All questions included answers on a 7-point rating scale, from strongly disagree (score 1) to strongly agree (score 7). The survey also included one question about frequency of usage at times of symptom worsening, with answers on a 7-point rating scale varying from 1=never to 7=always. In addition, participants of the intervention group were asked to complete the System Usability Scale (SUS). The SUS contains 10 questions on system usability, which are calculated into 1 total score between 0 and 100. SUS scores less than 68 are considered as low, greater than or equal to 68 and less than or equal to 80.3 as good, and greater than 80.3 as excellent. A total of 58 (67%) participants returned an evaluation form, of which 28 were in the intervention group. The mHealth tool was rated as a more useful support tool than the paper action plan (p=0.02). No differences were found between the mHealth tool and the paper action plan in the self-reported frequency of use; in difficulty and future use of the tool; or in clarity, suitability, and followup of the advice. Twenty-six participants in the PGHD group completed all 10 SUS questions, with a mean score of 78.5 (SD: 14.4).

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

The risk-of-bias assessments are in Appendix Table C-59, and the results are in Appendix Table C-61. Below, we discuss the efficacy results in four categories: (1) isolated effects on health outcomes, (2) isolated effects on surrogate outcomes, (3) multicomponent effects on health outcomes, and (4) multicomponent effects on surrogate outcomes

Isolated Effects on Health Outcomes: Chronic Obstructive Pulmonary Disease

Kawagoshi et al. (2015),[162] Nolan et al. (2017),[168] and Vorrink et al. (2016)[50,58] were the only RCTs that were designed in a way that allowed the effects of the PGHD of interest to be isolated. Both Kawagoshi and Nolan assessed PR plus pedometer use (Kenz Lifecorder EX, Nagoya, Japan and Yamax Digi-walker CW700; Yamax, Bridgnorth, United Kingdom, respectively) versus PR alone. Vorrink assessed usual care plus accelerometer (HTC Desire accelerometer) versus usual care alone.

Kawagoshi et al. (2015)[162] reported that one patient in each treatment arm died and one patient in each treatment arm required hospitalization due to a COPD exacerbation. No tests of statistical significance were performed. Kawagoshi enrolled retired, ambulatory patients with stable COPD ranging from mild to very severe stage. The authors did not provide specific data on the characteristics of those patients who died or required hospitalization.

Kawagoshi et al. (2015)[162] also reported Chronic Respiratory Questionnaire (CRQ) total scores. Both groups improved over time but study authors did not perform a between group test

of statistical significance. The results were: PGHD baseline: 98 (SD: 20), 1-year followup: 108 (SD: 19) and UC: 99 (SD: 19) and 1-year followup: 110 (SD: 19). The authors reported on the subscales dyspnea (only PGHD group improved over time) and fatigue (neither group improved significantly over time). Again, no between group test of statistical significance was performed.

Nolan et al. (2017)[168] also reported on deaths and hospitalizations. Two patients in each study arm died during the study. No test of statistical significance was performed. Nolan found a nonsignificant difference in rates of hospitalization between the PGHD and usual care groups. There were 56 total hospital admissions (PGHD: 23; usual care: 33; p=0.50). Thirty of these admissions were for COPD (PGHD: 14; usual care [UC]: 16; p=0.29). Nolan enrolled patients with COPD who were ≥35 years, had a Medical Research Council dyspnea score ≥2, and no significant cardiovascular comorbidities. The authors did not provide specific data on the characteristics of those patients who died or required hospitalization during the study.

Nolan et al. (2017)[168] also reported on CRQ dyspnea scores (5 to 35, higher scores better health status). The authors found nonstatistically significant differences between the two study arms: change from baseline to immediately following PR, PGHD: 3.7 (95% CI: 2.1 to 5.2) versus usual care: 5.6 (95% CI: 4.2 to 7.0), p=0.07 and change from baseline to 6 months following PR: PGHD: 1.8 (95% CI: -0.1 to 3.6) versus usual care: 3.7 (95% CI: 2.1 to 5.3), p=0.10.

For CRQ total scores (range 20 to 140, with higher scores representing better health), change from baseline to immediately following PR, PGHD: 11.0 (95% CI: 3.0 to 20.0) versus usual care: 20.0 (95% CI: 8.0 to 27.0), p=0.008 and change from baseline to 6 months following PR: PGHD: 3.0 (95% CI: -8.0 to 16.0) versus usual care: 10.0 (95% CI: -2.0 to 19.0), p=0.07. Nolan et al. (2017)[168] note that "unexpectedly, short-term improvements in CRQ scores following PR were significantly greater in the control group than in the intervention group for the total score (p=0.01)". The authors also adjusted for baseline CRQ values, and the group effect for differences in the total scores remained significant. Between-group differences in CRQ did not persist at 6 months.

Vorrink et al. (2016)[50,58] also reported CRQ results for dyspnea and fatigue (scores range from 1 to 7 for each subscale). Only fatigue showed a significant group by time interaction, however one group was not consistently favored over the other.

For dyspnea, the results were as follows: PGHD baseline: 4.84 (SD: 0.15), change at 3 months: 0.17 (95% CI: -0.45 to 0.38), change at 6 months: 0.11 (95% CI: -0.14 to 0.35), change at 12 months: -0.17 (95% CI: -0.44 to 0.09) and UC baseline: 4.79 (SD: 0.15), change at 3 months: 0.01 (95% CI: -0.21 to 0.23), change at 6 months: -0.13 (95% CI: -0.33 to 0.08), and change at 12 months: -0.08 (95% CI: -0.30 to 0.14), showing no differences between the groups (p=0.859). The group by time interaction was also nonsignificant (p=0.179).

For fatigue, the results were: PGHD baseline: 4.35 (SD: 0.1), change at 3 months: 0.05 (95% CI: -0.15 to 0.26), change at 6 months: -0.19 (95% CI: -0.39 to 0.01), change at 12 months: -0.14 (95% CI: -0.35 to 0.07) and UC baseline: 4.20 (SD: 0.13), change at 3 months: -0.06 (95% CI: -0.28 to 0.17), change at 6 months: 0.13 (95% CI: -0.12 to 0.37), change at 12 months: -0.12 (95% CI: -0.37 to 0.13).

Vorrink enrolled patients with stable COPD who were ≥40 years, GOLD stage 2 or 3, who had recently completed a PR program of 3 months duration, lived independently, and who did not have a comorbidity that would greatly influence their ability to engage in physical activity. Vorrink did not report any subgroup data for patient characteristics of interest.

Isolated Effects on Surrogate Outcomes: Chronic Obstructive Pulmonary Disease

Vorrink et al. (2016)[50,58] reported on lung function but did not find a statistically significant between-group difference for this outcome. FEV1/FVC showed no between group difference (p=0.34) or group by time interaction (p=0.908), meaning that the decline over time was not significantly different between the groups. FEV1 was significantly higher in the intervention group at the end of followup (PGHD group decreased at an average of 56 mL over the 1-year followup period and 98 mL in the UC group [p=0.05]). However, the group by time interaction was non-significant (p=0.508), meaning that there was no effect of the intervention on FEV1.

Kawagoshi et al. (2015)[162] reported 6-minute walk test (6MWT) and found both groups significantly improved on this outcome. The results were as follows: PGHD baseline: 369 (SD: 119), 1-year followup: 445 (SD: 138) and UC baseline: 404 (SD: 148) and 1-year followup: 467 (SD: 151). No between groups comparison was performed.

Nolan et al. (2017)[168] reported results from the Incremental Shuttle Walk Test (m). The authors did not find a significant between group difference for either the end of treatment time point or the 6-month followup visit. The results were as follows: change from baseline to end of treatment (PGHD: 60 [95% CI: 20 to 90] and UC: 50 [95% CI: 10 to 90], p=0.83) and change from baseline to 6-month followup (PGHD: 30 [95% CI: 0 to 70] and UC: 10 [95% CI: -30 to 70], p=0.25).

Vorrink et al. (2016)[50,58] also reported 6MWT results and did not find a statistically significant difference for this outcome either. There was no significant decrease in 6 minute walk distance over time (p=0.53), and no differences between the groups (p=0.485). The group by time interaction was also nonsignificant (p=0.585). The results were as follows: PGHD baseline: 456 (SD: 14), change at 3 months: 4.1 (95% CI: -2.8 to 11.1), change at 6 months: 4.8 (95% CI: -3.9 to 13.5), change at 12 months: 0.8 (95% CI: -8.8 to 10.3) and UC baseline: 461 (SD: 8), change at 3 months: 1.9 (95% CI: -4.1 to 7.9), change at 6 months: 3.3 (95% CI: -2.9 to 9.6), and 4 (-2.4 to 10.3).

See Table 17 for a summary of isolated effects on health outcomes outcomes, and Table 18 for a summary of isolated effects on surrogate outcomes.

Of the two records related to COPD identified in clinicaltrials.gov, both made PGHD comparisons and also stated that they would measure health outcomes (https://ClinicalTrials.gov/show/NCT03857061mentioned health-related quality of life and MRC dyspnea scale and https://ClinicalTrials.gov/show/NCT03238339 mentioned hospitalizations and acute exacerbations).

Table 17. COPD: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Death			A, C		
Hospitalization			A, C		
Quality of life			B, C	A	
Health outcomes not reported in zero isolated-effect studies					

Statement about health outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.
COPD = chronic obstructive pulmonary disease; PGHD = patient generated health data

Table 18. COPD: categorization of isolated effects on surrogate outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
FEV1 and FEV1/FVC			B		
6-minute walk distance/Incremental shuttle walk test			A, B, C		
Surrogate outcomes not reported in zero isolated-effect studies					

Statement about surrogate outcomes: Unclear effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

COPD = chronic obstructive pulmonary disease; FEV1 = forced expiratory volume in one second; FEV1/FVC = forced expiratory volume in one second/forced vital capacity; PGHD = patient generated health data

Multicomponent Effects on Health Outcomes: Chronic Obstructive Pulmonary Disease

Six RCTs assessed PGHD devices used in multicomponent telehealth interventions. On the whole, the interventions assessed did not improve health outcomes but may lead to more AEs. The one exception was the study by Jehn et al., (2013)[169] which examined the AiperMotion 300 accelerometer combined with other at-home nonconsumer devices. See below for more details.

Arbillaga-Etxarri et al. (2018)[52] reported that the Urban training group (including the pedometer Onstep-50, Geonaute) experienced more lower-extremity muscle pain than the control group. For all other outcomes, including other AEs, exacerbations (severe leading to hospital or ER admission) and QoL assessed by COPD assessment test (CAT) and Clinical COPD Questionnaire (CCQ) they did not find significant between-group differences.

Boer et al. (2019)[166] assessed a forehead thermometer (FTN, Medisana AG) combined with other nonconsumer devices and reported COPD hospitalizations, exacerbation-free weeks, and QOL assessed by Nijmegen Clinical Screening Instrument. Boer did not find any statistically significant between-group differences for any of these outcomes.

Demeyer et al. (2017)[161] studied the Fitbug Air combined with other interventions and reported on exacerbations, AEs, and QOL assessed by CAT and CCQ. Although Demeyer et al. found no between-group differences in exacerbations; they found that patients in the Fitbug Air arm had more musculoskeletal AEs than control group patients. For QOL, patients in the Fitbug Air arm had better scores on the functional state domain of the CCQ than control.

Jehn et al. (2013)[169] examined the Aipermotion 300 accelerometer plus other at-home nonconsumer devices and reported exacerbations, hospital admissions due to exacerbations, and hospital length of stay for a COPD exacerbation. For all these outcomes, the PGHD group was favored. QOL measured by CAT scores was also reported. No test of significance was performed for differences in CAT scores between the groups at followup.

Jodar-Sanchez et al. (2013)[164,165] assessed BP with the UA-767 BT, A&D Company as part of a multicomponent intervention. The authors reported death (1 from each group), COPD-related emergency room visits (favors PGHD), COPD-related hospitalizations and length of stay (no between group differences found) and QOL measured with the St George Respiratory Questionnaire (SGRQ)15 (no between-group differences found), EuroQol-5D (no between-group differences found), and a nonstandardized instrument (favors PGHD).

Tabak et al. (2014)[163] reported only QOL as measured by the CCQ (no between-group difference found) and the Medical Research Council Dyspnea Scale (no between-group difference found).

Multicomponent Effects on Surrogate Outcomes: Chronic Obstructive Pulmonary Disease

Four RCTs of multicomponent effects reported a surrogate outcome. Arbillaga-Etxarri et al. (2018)[52] did not find a significant between group difference in 6MWT. Demeyer et al. (2017)[161] found the change in 6MWT was significantly different (13.4, 95% CI: (3.40 to 23.5) m, $p<0.01$), favoring the PGHD. Jehn et al. (2013)[169] reported that the PGHD group showed a significant improvement in 6MWT distance between baseline and 9-month followup (Mean Difference in 6MWT: +87.0 (SD: 65.7) meters, $p=0.006$) versus UC group, which showed no significant change (MD: +23.9 (SD: 70.3) meters, $p=0.23$). There was no between group difference found. Mendes de Oliveira et al. (2010)[167] found a clinically significant improvement in the distance

walked between the pre-post data for patients in the at home PR plus PGHD group (73.2±50.2 meters, $p<0.05$) while the control group demonstrated no change at the end of the study compared to baseline ($p>0.05$). The between group comparison favored at home PR plus PGHD.

Jehn et al. (2013)[169] also examined the Aipermotion 300 accelerometer plus other at-home nonconsumer devices and reported FEV1%. At 9-month followup, the PGHD group increased by 2.5% (SD: 5.2%) while UC decreased by 0.07% (SD: 9.2%). Both groups remained unchanged from baseline to 9-month followup, and the authors did not find statistically significant between group differences.

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

Only one of ten RCTs of COPD PGHD reported device-specific harms. Nolan et al. (2017)[168] gathered data on AEs throughout the study (no further explanation provided). These authors report that one participant experienced an allergic reaction to the nickel baseplate of the accelerometer during baseline assessments and as a result was not randomly assigned.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

A different version of the Kenz Lifecorder is currently unavailable from Amazon (https://www.amazon.in/Kenz-Lifecorder%C2%AE-Activity-Monitor-Pedometer/dp/B07RKDHVZC), so price information is not listed at this time. Yamax Digi-walker CW700; Yamax, Bridgnorth, United Kingdom, is available for $32.00 US. See https://www.yamax.co.uk/yamax-pedometers/cw700-cw701-digi-walker/ for more details. The HTC Desire accelerometer embedded in a smartphone A8181, HTC, Taoyuan, Taiwan, is available for $85.00 US at https://www.amazon.com/HTC-Smartphone-Touchscreen-Bluetooth-International-Warranty/dp/B0035ER8OY.

One study on COPD provided data from a cost-utility analysis. Jodar-Sanchez et al. (2013)[164,165] reported costs in Euros at 2014 prices. Our risk-of-bias evaluation is in Appendix Table C-60. The analysis included: (1) accident and emergency department visits, specialized care consultations and hospital admissions evaluated according to public prices, (2) time employed by the clinical call center was estimated according to the alert type generated in the triage application: 25 min for clinical alerts, 15 min for alerts generated by nonadherence to the system, nonreceipt of data and technical reinforcement, and 10 min for alerts generated for other reasons. The clinical call center's cost per hour was calculated in line with the salary rates of the Andalusian Health Service. (3) The time employed by the case manager was estimated depending on the exacerbation's level of seriousness: 20 min for mild to moderate exacerbations, 25 min for severe exacerbations, and 30 min for very severe exacerbations. The case manager's cost per hour was also calculated in line with the salary rates of the Andalusian Health Service. (4) The time employed by technical staff was estimated as 60 min for equipment installation and 30 min for technical incidents. This cost includes travel to the patient's house, which was calculated by the company supplying the service. (5) The software and equipment cost was

provided by the service-supplying company and was calculated using the equivalent annual cost, a method which accounts for both depreciation and the opportunity cost of the capital. The lifetime of the equipment and software was set at 5 years and the discount rate at 3%. To calculate the software's cost, authors allowed for a maximum 0 patients telemonitored with this infrastructure/ software and used this information to estimate the cost associated for each patient.

EuroQol-5D was used to estimate a utility score. The telehealth program's effectiveness was estimated as a QALYs gain. For each patient, QALYs were calculated by using the area under the curve analysis, with linear interpolation of utility scores between baseline and 4 months of followup. Deceased patients were assigned a EuroQol-5D utility score of zero at 4 months. For each patient, the QALY (not taking into account the differences in the basal utility scores) and QALY gain (taking into account the differences in the basal utility scores) corresponding to the 4 months of monitoring was calculated. Results of cost-utility analysis were expressed in terms of the ICER, calculated as the difference in the average costs between the PGHD group and the control group divided by the difference in the average QALY gain between PGHD group and control group. Discounting of costs and QALYs was not necessary because the time horizon of the study, 4 months, did not extend beyond 12 months. To analyze uncertainty and verify the ICER's robustness, the authors conducted an analysis using a nonparametric bootstrap with 5000 replications.

Average healthcare cost was €2064 for the PGHD group and €1103 for the UC group (a difference of €961; 95% CI: -809 to 2731). The average total cost was €2300 for the PGHD group and €1103 for the UC group (difference of €1197; 95% CI: -579 to 2973). The utility score's average increase was 0.036 for the PGHD group and 0.003 for the UC group (difference of 0.032 score; 95% CI: -0.12 to 0.19). The UC group obtained a higher average QALY than the PGHD group, determined by the differences in the basal utility scores.

Cost-utility analysis based on 5000 bootstrap replications: The average total cost per patient was €2300 for the PGHD group and €1103 for the UC group, resulting in an incremental cost of €1197 (-498.97 to 2892.80). Corresponding figures for patients without and with comorbidities are as follows: PGHD: 855.13 vs. UC: 1353.85, ICER: -498.72 (-2451.38 to 1453.94) and PGHD: 2781.73 vs. UC: 948.91, ICER: 1832.83 (-223.00 to 3888.66). The average QALY gain for all patients combined was 0.0059 for the PGHD group and 0.0006 for the UC group, resulting in an incremental QALY gain of 0.0053 (-0.0193 to 0.0300). For patients without comorbidity, the figures are PGHD: 0.0288 vs. UC: 0.0082, ICER: 0.0206 (-0.0259 to 0.0671) and for patients with comorbidity PGHD:-0.0017 vs. UC: -0.0041, ICER: 0.0024 (-0.0251 to 0.0300).

Authors obtained an ICER of 223,726 €/QALY. The acceptability curve showed that for a willingness to pay of 30 000 €/QALY, the telehealth program's probability of being cost-effective was 15%.

Asthma

Guiding Question 1. Which specific consumer automated-entry PGHD applications/technologies/devices have been studied for measurement of health outcomes? What studies are in progress of consumer PGHD devices?

a. What study designs have been used?
b. What were the inclusion/exclusion criteria?
c. What statistical analysis and data were used to determine study size and power?
d. How long were patients followed?
e. How was adherence measured?
f. What was the comparator?
g. Which outcomes were measured?

Devices: Asthma

The one identified asthma trial used a single PGHD device: a spirometer (Medical International Research, SmartOne). We rated it as "similar" to other devices on the market by this manufacturer. All devices (along with devices included in trials of other clinical conditions) appear in Appendix Table C-1.

Studies in Progress: Asthma

We identified three records in ClinicalTrials.gov to prevent or treat asthma that, once published, may potentially meet our inclusion criteria. As of June 19, 2020, all three were recruiting patients. More details about these records (including hyperlinks) appear in Appendix Table C-62.

Study Designs: Asthma

The single study of a PGHD device for asthma used a randomized crossover design. It was conducted in Sweden. Patients were enrolled from May 2016 to September 2018. There were 77 patients at the baseline visit. The next sections describe additional aspects of this trial, which are tabled in detail in Appendix Table C-63, C-64, and C-65.

Inclusion/Exclusion Criteria: Asthma

The study subjects were children aged ≥6 years and adults with a doctor's diagnosis of asthma and Asthma Control Test/(ACT)/Childhood Asthma Control Test (C-ACT) scores <20 points. A mean score ≤19 points indicated uncontrolled asthma in both tests. Exclusion criteria were presence of any comorbidity with significant impact on symptom control, participation in drug trials, and patient/caregiver difficulties in reading Swedish. There was no criteria for family income or internet access.

Additional Patient Characteristics: Asthma

The single included asthma study enrolled patients with a mean age of 22 years (SD: 14.5 years), a mean ACT/C-ACT score of 15.6 (SD: 3.1), and a mean FEV1 % pred of 86.4 (SD: 14.2). Sixty percent of patients were female. The study was conducted in Stockholm, Sweden, in

the primary healthcare sector and specialized pediatric healthcare, at Liljeholmen Health Care Centre, Sophiahemmet Health Care Centre and Astrid Lindgren Children's Hospital. The authors did not indicate if this area is rural.

Statistical Power Analyses: Asthma

The sample size was estimated assuming that AsthmaTuner would improve the average ACT/C-ACT score by 2 points compared with conventional treatment (mean SD: 3.3). Assuming a dropout rate up to 10%, power calculations estimated that enrollment of 43 adults and 43 children would be clinically relevant and feasible to attain 80% power at a 5% significance level. The authors did not indicate that this estimate was based on prior research.

Followup Length: Asthma

The followup length was 2 months.

Adherence Measurement: Asthma

Device adherence to AsthmaTuner was captured by the cloud-based system's backend data storage feature.

Comparators: Asthma

The comparator in Ljungberg et al. (2019)[170] was usual care with an individualized printed treatment plan. Specifically, usual care was defined as nondigital self-management using individual printed treatment plans, which contained treatment adjustments of prescribed medications according to symptoms of controlled, partly controlled, or uncontrolled asthma, along with instructions according to national guidelines.

Guiding Question 2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, sustainability, feasibility, fidelity, or integration into electronic health records) of these specific consumer automated-entry PGHD technologies?

Below, we discuss the pertinent asthma data for this Guiding Question (see results in Appendix Table C-67.

The study by Ljungberg et al. (2019)[170] assessed the SmartOne Spirometer as part of the AsthmaTuner (MediTuner, Stockholm, Sweden), a certified (CE-marked) cloud computing-based system with a healthcare interface and a downloadable patient app (Android or iOS). The intended use of AsthmaTuner was to automate asthma self-management by letting patients register symptoms and measure FEV1 with the SmartOne, which is a Bluetooth spirometer. The patient then received immediate feedback on the status of symptom control and a treatment recommendation. The back-end data storage of the cloud-based system provided information about participant adherence with AsthmaTuner use.

MIR SmartOne, Part of the AsthmaTuner system

Approximately 81% (62/77) of patients used AsthmaTuner (including the SmartOne spirometer, the PGHD of interest) on average once weekly or more. This figure included 73% (27/37) of adult patients with asthma and 87.5% (35/40) of pediatric patients with asthma

assigned to the intervention. This was the only data provided in Ljungberg et al. (2019)[170] that addressed Guiding Question 2.

Guiding Question 3. What is the influence of specific consumer automated-entry PGHD technologies on health outcomes? Does this vary across different patient populations, different settings, or other modifiers of effectiveness?

The risk-of-bias assessments are in Appendix Table C-66, and the results are in Appendix Table C-67.

Isolated Effects on Health Outcomes: Asthma

Asthma symptom control was assessed at baseline and at the end visit of each treatment period with the ACT questionnaire in patients aged ≥12 years and C-ACT in children aged 6-11 years. The PGHD group experienced better symptom control than patients receiving UC. However, when the patients were divided into subgroups by age, only pediatric patients using the PGHD had better symptom control than patients receiving UC.

The mean ACT/C-ACT score was 19.45 (95% CI: 18.70 to 20.21) for the PGHD group vs. 18.75 (17.97 to 19.53) for UC, difference: 0.70 (95% CI: 0.06 to 1.34, p=0.03). These figures were: PGHD: 19.14 (18.08 to 20.19) vs. UC: 18.78 (95% CI: 17.63 to 19.94), difference: 0.33 (95% CI: -0.68 to 1.35, p=0.51) for adult patients and PGHD: 19.75 (95% CI: 18.65 to 20.85) vs. UC: 18.73 (17.61 to 19.84), difference: 0.97 (95% CI: 0.13 to 1.81, p=0.02) for pediatric patients.

A summary of the health outcomes appears in Table 19 below.

Of the three records related to asthma identified in clinicaltrials.gov, all three made PGHD comparisons and also stated that they would measure health outcomes (https://ClinicalTrials.gov/show/NCT04365556 mentioned Asthma Severity Score and ACT, https://ClinicalTrials.gov/show/NCT03503812 mentioned ACT and symptoms in the past 4 weeks, and https://ClinicalTrials.gov/show/NCT04132778 mentioned symptom control and exacerbations).

Table 19. Asthma: categorization of isolated effects on health outcomes due to device presence/absence

Specific Outcome	All Results Were p<0.05 in Favor of PGHD	Mixed Results,* but Most p<0.05 Results Favored PGHD	No Results Were Statistically Significant	Mixed Results,* but Most p<0.05 Results Against PGHD	All Results p<0.05 Against PGHD
Symptom Control		B			

Statement about health outcomes: Possible positive effect

Note: This table only displays studies that used an *isolated-effect design* to compare the *presence vs. absence* of a PGHD device. p<0.05 refers to whether the effect was statistically different from a null effect

A: Low risk of bias study of an isolated effect; B: Moderate risk of bias study of an isolated effect; C: High risk of bias study of an isolated effect

* "Mixed results" means that a study investigated either multiple time points (e.g., both 13 weeks and 26 weeks) or multiple comparisons (e.g., PGHD device A vs. no device, and PGHD device B vs. no device), and data showed statistical significance for some but not all time points/comparisons.

PGHD = patient generated health data

Guiding Question 4. What are the harms or AEs associated with these specific consumer automated-entry PGHD technologies? Which patients in which settings are most at risk of harms?

Ljungberg et al. (2019)[170] reported that three patients (one each) terminated the study due to severe snake bite, pertussis, and another respiratory diagnosis. The study provided no other details.

Guiding Question 5. For the technologies demonstrating associations with outcomes of interest, what full economic evaluations provide information on the relative value for consumers?

Ljungberg et al. (2019)[170] did not report economic outcomes or cost-only data. The PGHD device is available through Amazon at a cost of $109.00 US. See https://www.amazon.com/MIR-Smart-Personal-Pocket-Spirometer/dp/B07LGZ64KB for more details.

Summary and Implications

Much research has investigated the use of automated-entry consumer devices to collect patient data to prevent or treat chronic conditions. Many of these devices, such as pedometers and BP monitors, have been on the market for many years, and therefore are in relatively mature phases of their product cycles. Others are relatively new (e.g., ECG monitors, body composition monitors), and there are far fewer manufacturers for certain device categories. Overall, PGHD devices are clearly providing a wealth of data to both patients and their providers.

But has this information actually improved health? Overall, we found mixed evidence; our primary results are summarized in Table 20 below and graphically in

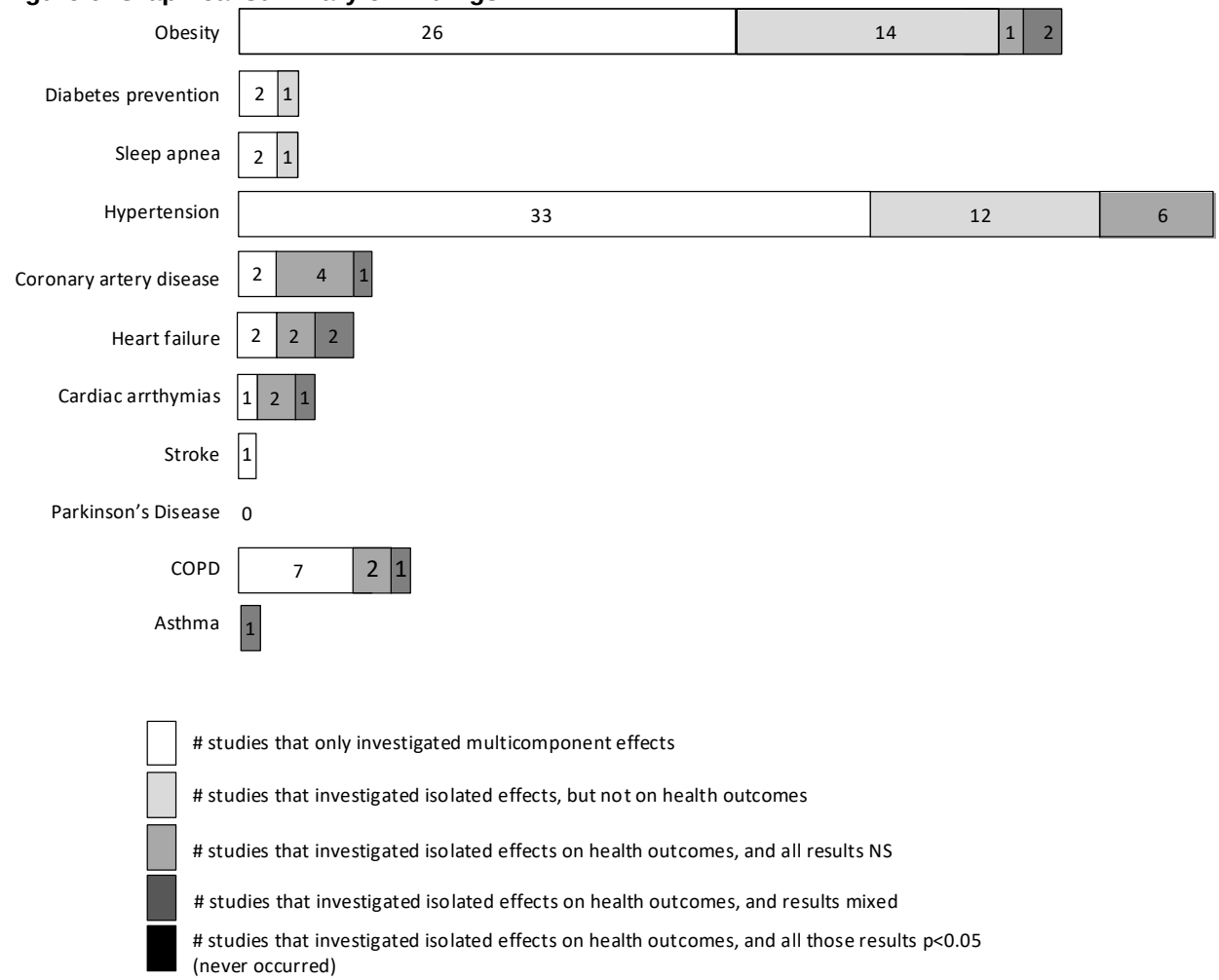
Figure 6 below. We found "possible positive effects" on health outcomes for three conditions: CAD (BP monitors, heart rate monitors), heart failure (BP monitors, scales), and asthma (spirometer). For obesity, we classified the health outcome data as unclear, and we found consistent evidence of a lack of effect of PGHD interventions on the surrogate outcome of BMI/weight. For hypertension, we classified the health outcome data as unclear, and we found consistent evidence of a beneficial possible positive effect of PGHD interventions on the surrogate outcome of blood pressure. For cardiac arrhythmias, we classified the health outcome data as unclear, but found consistent evidence of a beneficial effect of PGHD interventions on the surrogate outcome of time to arrhythmia detection. The evidence was unclear for the other five conditions (for both health outcomes and surrogate outcomes)

Table 20. Primary findings

Clinical Condition	Results Categorization for Isolated Outcomes	Comments
Obesity	Unclear for health outcomes Likely no effect on surrogate outcomes	3 of 43 included trials reported whether there were isolated effects on health outcomes (specifically, quality of life): • 1 (low risk of bias) found a benefit of PGHD on physical quality of life at 3 months but not at 9 months, and no effect at either time point for mental quality of life. • 1 (moderate risk of bias) found statistically nonsignificant differences. • 1 (high risk of bias) found a statistically nonsignificant effect on physical quality of life, but found a small benefit (4%) of PGHD on mental quality of life at 6 months. 14 trials reported whether there were isolated effects of device presence on surrogate outcomes (BMI or weight), and all 25 point estimates were less than the minimal important difference (5% body weight).
Diabetes Prevention	Unclear for health outcomes Unclear for surrogate outcomes	None of the three trials reported whether there were isolated effects on health outcomes. One trial reported a surrogate outcome (metabolic syndrome risk) and it found an advantage of PGHD, however it was at high risk of bias.
Sleep Apnea	Unclear for health outcomes Unclear for surrogate outcomes	None of the three trials reported whether there were isolated effects on health outcomes. One trial reported a surrogate outcome (number of days on which apnea events were witnessed) and it found no statistically significant difference and was at high risk of bias.

Clinical Condition	Results Categorization for Isolated Outcomes	Comments
Hypertension	Unclear for health outcomes Possible positive effect on surrogate outcomes	Six of the 51 included studies reported whether there were isolated effects on health outcomes (including quality of life, mortality, and hospitalizations) • Four studies (one high risk of bias, one moderate, and two low) found overall no significant effects on quality of life, although one study found a significant effect favoring usual care for one subscale. • One study (moderate risk of bias) found no significant effects on hospitalizations. • One study (low risk of bias) found no significant effects on mortality. Sixteen studies reported whether there were isolated effects of device presence on surrogate outcomes (SBP, DBP, and BP control). • Six of the 16 studies reporting on SBP found statistically significant findings favoring PGHD. Sixteen of 29 point estimates were greater than the minimal important difference of 2 mmHg. • Five of 16 studies reporting on DBP found statistically significant findings favoring PGHD. Ten of 29 point estimate were greater than the minimal important difference of 2 mmHg. • Two of 10 studies reporting on BP control found statistically significant findings favoring PGHD.
Coronary Artery Disease	Possible positive effect	Mortality was significantly lower in the PGHD arm in one of the two studies that reported it. Re-hospitalization was also lower but did not reach statistical significance.
Heart Failure	Possible positive effect	Different quality of life measures favored the PGHD intervention group in two studies that isolated the effect of PGHD (although since multiple PGHD devices were used in each study the effect of any individual PGHD device could not be isolated).
Cardiac Arrhythmias or Conduction Abnormalities	Unclear for health outcomes Likely positive effect for surrogate outcomes	There were no statistically significant between-group differences in health outcomes that favored the PGHD intervention. However, one low risk study found a higher rate of emergency room visits in the AliveCor group, and the reason for this remains uncertain. Therefore, despite the significant positive effect of PGHD observed for time to arrhythmia detection in this same study, the effect of PGHD on health outcomes in patients with cardiac arrhythmias is unclear.
Stroke	Unclear for health outcomes Unclear for surrogate outcomes	The single trial did not use an isolated-effect design.
Parkinson's Disease	No data	No studies met inclusion criteria.
COPD	Unclear for health outcomes Unclear for surrogate outcomes	3 of 10 RCTs reported isolated effects on health outcomes and surrogate outcomes. None of the 3 RCTs conducted power calculations based on health outcomes. 1 RCT each assessed Kens Lifecorder EX pedometer (High risk of bias, hospitalization, death and quality of life), Yamax Digi-walker CW700 pedometer (Low risk of bias, quality of life, hospitalization, death); and the HTC Desire accelerometer (Moderate risk of bias, quality of life).
Asthma	Possible positive effect	1 study met inclusion criteria (moderate risk of bias), and it found better symptom control in the PGHD group overall and in the pediatric population alone.

Figure 6. Graphical summary of findings



We have some concerns about the applicability of the patients and interventions in the included trials. Most of the patients enrolled in the included studies had typical characteristics of specific chronic conditions. However, females were underrepresented in studies of CAD and sleep apnea (<20% of enrolled patients in all studies for these conditions) and in some studies of COPD. Furthermore, only nine studies out of the 114 studies summarized in this report included rural populations for whom home-based PGHD interventions might be advantageous, since in-person visits with healthcare providers may be more of a burden for these populations (e.g., lack of nearby health care offices/clinics may mean longer travel time). Also, many studies required that participants have access to smartphones or the internet and have enough technical knowledge to operate remote monitoring technologies. Therefore, individuals without such access or knowledge are not well-represented in the literature. PGHD adherence generally was highly variable and continuous usage adherence is concerningly low for patients included in controlled clinical trials. This may limit generalizability to other populations using PGHD devices outside of clinical trials where adherence may be expected to be even lower.

Regarding the applicability of the interventions in the included studies, we note four issues:

- Some tested devices are available only in certain countries (e.g., body composition monitor InBody IU-U070B by Biospace in South Korea, or the Creta scale by Soehnle in Germany). Sixty-two of the 114 studies (54%) were conducted outside the United States, and their devices' U.S. availability may be unclear.
- Some devices tested in these trials are no longer available, or their versions have been substantially updated since the trials completed. Across all clinical conditions, there were 118 unique devices, and device engineers rated 80 as similar to current devices, 11 as somewhat different, 1 as very different, and 26 as unknown.
- Some components of PGHD interventions are highly specialized or multicomponent with non-device related interventions and may not be feasible at other institutions. An example is the Arbillaga-Etxarri et al. (2018) study,[52] where in addition to receiving a pedometer, patients spoke with a "respiratory physiotherapist" who was "adequately trained in behavioral strategies" and conducted "motivational interviews" that were "centered on empathy, reflective listening and affirmation, and addressed patients' resistance (personal difficulties, barriers and limitations) to eliciting behavioral change."
- Some technologies may require additional supportive technologies not available at all institutions. A key example is whether health care settings have the technology to receive electronically transmitted data and possibly include automatically into the electronic medical record. Websites and apps are often used to receive data, but it is unclear whether routine health care settings could easily access those data to improve patient management.

There has been a growing number of studies focused on recent PGHD technologies involving Apple products that were not reviewed in this report because they did not meet inclusion criteria. In particular, the Apple Heart study[171] was a recent large observational study enrolling over 400,000 participants that tested a smartwatch (Apple Watch) app's ability to identify atrial fibrillation during typical use. Because this was a single-arm study that did not include a control group of patients who received either usual care or another intervention, it did not meet inclusion criteria for our review. This study also focused on arrhythmia detection and did not report any health outcomes relevant to our review, except for AEs.

A recent evidence map for PCORI on mobile health technologies for self-management of several chronic diseases revealed some similarities and differences with the findings of this Technical Brief. The maps can be found at https://www.pcori.org/evidence-maps/results-strength-evidence-mHealth-systematic-reviews-2. We conducted a systematic literature search and identified 99 relevant systematic reviews published between 2010 and 2017. Some of the mobile health technologies (e.g., text messaging) included in that report did not meet the definition of consumer PGHD used in the Technical Brief. The only chronic diseases that overlapped with the ones examined in the current Technical Brief are cardiovascular disorders (encompassing CAD, chronic arrhythmias and heart failure), obesity, and respiratory disorders (encompassing asthma and COPD). The majority of systematic reviews in the PCORI report had unclear findings regarding health outcomes, which is consistent with the overall findings of the Technical Brief. However, for cardiovascular disorders the PCORI evidence map found no systematic reviews that reported a possible positive effect of mobile apps or wearable monitors, whereas the PGHD Technical Brief found a possible positive effect for health outcomes in studies of CAD and heart failure. Conversely, for obesity the PCORI evidence map found three systematic reviews that reported a possible positive effect and two that reported a positive effect

on health outcomes (3 other systematic reviews were unclear and one showed no effect). The evidence base on obesity in this Technical Brief suggested there was likely no effect of PGHD interventions on the surrogate outcome of BMI/weight. The reason for this discrepancy may be that the PCORI report did not determine whether weight loss in the systematic reviews was clinically significant, while our Technical Brief did make this distinction. For respiratory disorders the majority of systematic reviews in the PCORI report were unclear, but two reviews found a possible positive effect and one review found a positive effect on clinical outcomes. Our Technical Brief found unclear evidence for the effect of PGHD interventions on COPD but a possible positive effect on asthma. We note that many of the systematic reviews in the PCORI report covered multicomponent interventions that did not isolate the effect of mobile apps or devices, and some devices included in that report would not have met the definition of consumer PGHD technologies used in the Technical Brief. These are likely reasons for some of the differences in findings between the two reports.

Next Steps

For each clinical condition, we discuss the types of future research that are mostly likely to benefit patients with these conditions. A major limitation of the current literature is that most RCTs only evaluated the short-term efficacy of PGHD for management of chronic conditions. Since these conditions require long-term management, and many health outcomes require longer followup for detection of benefits or harms, trials with longer-term followup are needed to determine the efficacy of PGHD interventions for chronic conditions. Similarly, the current evidence base is limited in understanding time to health outcome event of various PGHD interventions and whether effects are durable over longer followup time periods. Harms of PGHD interventions were generally not assessed in the included studies we included, possibly due to an unwarranted assumption of harmlessness. Some potential harms (e.g., distress from seeing no improvement, hospitalization due to inaccurate device measurements, or unmet patient expectations) may be difficult to measure or to attribute to the intervention..

A key ingredient in the contribution of PGHD devices is adherence: some patients may not use the device in the manner instructed, or as often as instructed, which may compromise any apparent efficacy. We found high variability in the measured levels of adherence across clinical topics and even within studies of a given clinical topic. Future research might address questions such as what are the primary barriers to good adherence (e.g., poor usability), and how much device adherence is necessary to improve health (e.g., perhaps intermittent use could still be beneficial).

For patients who are obese, there is a critical need to measure health outcomes, rather than merely BMI or weight. Few of the obesity studies even chose to measure health outcomes.

Regarding diabetes prevention, only one of the included studies used a glucose meter, and this may be a promising target for future research. Use of a glucose meter could educate patients about the correspondence between eating/exercise behavior and their short-term glucose level, which may prevent later rises in HbA1c and progression to diabetes.

None of the three included sleep apnea studies used a sleep-specific consumer device. This makes sense given that CPAP devices require a prescription, and CPAP is the leading therapy for sleep apnea. However some newer devices, such as the Apple Watch, could help accelerate the diagnosis of sleep apnea in select patients by providing information to signal that a patient has a high probability of having the condition. This would be helpful since the current method of checking for sleep apnea is based on a patient's habitus, and it is not routinely screened for.

Although current evidence on hypertension suggests PGHD may improve surrogate outcomes, most promisingly SBP, there is still some inconsistencies in the findings. Furthermore, few existing studies address important health outcomes, such as mortality and cardiovascular events, directly. Longer-term RCTs that isolate PGHD's effects are needed to clarify impacts on both surrogate and health outcomes.

For patients with CAD, future RCTs evaluating PGHD interventions should attempt to enroll more female patients because they are underrepresented in currently available RCTs (<20% of enrolled patients). More studies of CAD should evaluate health outcomes, including overall mortality, cardiovascular mortality, hospitalizations, and emergency room visits.

For patients with cardiac arrhythmias, more RCTs are needed to evaluate the effect of home-based smartphone-connected ECG monitors on health outcomes, including prevention of stroke, hospitalization, or death. Although not reported in the evidence base, the potential harms related to false positives (e.g., patients unnecessarily visiting emergency rooms) should be investigated in future studies. In particular, the increasing popularity of the Apple Watch and its app for

cardiac arrhythmia detection means that RCTs are needed to evaluate this technology's impact on the health outcomes noted above.

For patients with heart failure, current RCTs have generally combined different PGHD interventions (BP monitors, ECG monitors, and weighing scales) without attempting to isolate any individual device's effect on health outcomes. Future RCTs should attempt to isolate the effect of individual PGHD devices to determine which devices are most useful to help patients to manage heart failure. These studies should examine upstream outcomes such as hospitalization, medication adherence and change in care.

For patients with stroke, we included only one trial that used BP measurements and showed no isolated effects on health outcomes. A future important PGHD study to evaluate stroke would involve home-based post-stroke rehabilitation using rehabilitation technologies. Regular rehabilitation is essential in stroke recovery and to improve long-term impact on patients' QOL, especially in terms of mobility. Other stroke studies should focus on secondary prevention, since the recurrence rate is significant in this patient population.

Patients with Parkinson's disease might benefit from PGHD devices that measure mobility. We found four relevant records in ClincialTrials.gov on this condition, and one planned to use a device (ParkinPal) that "utilizes a smartwatch to periodically record motion data," and the data are "processed in a connected smartphone and translated into symptom scores for dyskinesia, slowness, and tremor." The symptom scores can be used by providers to adjust medications and signal if the disease is getting worse or better.

Future researchers of COPD need to understand the importance of isolating the effect of individual monitoring strategies, so their unique contributions can be understood. Patients with severe comorbidities, including mobility limitations and cardiovascular issues, were generally excluded from the COPD evidence base. Future research should test some of these monitoring strategies on patients with COPD and comorbidities to determine whether they are more or less effective in higher risk COPD populations.

Regarding patients with asthma, future research should focus on patients with adult asthma with comorbidities and patients with asthma living in other settings and countries and determine why up to 20% of patients did not adhere to device use.

An important target of future research for all of these chronic conditions should be testing the efficacy of PGHD interventions in rural populations. As noted earlier, we identified only 9/114 studies that enrolled rural populations, and this is problematic because rural populations have higher rates of many chronic conditions covered in this Technical Brief. Future research is needed to determine the potential benefits of PGHD interventions in this underserved and underrepresented demographic.

In general, enrolling demographically diverse populations (ensuring representation for patients of different genders, races and age groups) should be a goal in future studies of PGHD interventions for patients with chronic conditions. Registry data could enhance the evidence on PGHD interventions for a more representative population. Our searches did identify a few registry studies, but they were not included in our evidence since they were not of consumer devices or they did not capture data automatically.

Future high quality studies isolating the affect of PGHD devices on surrogate or health outcomes may bolster the evidence on comparative efficacy and clinical utility of PGHD devices for various conditions and populations. While the scope of this report was quite broad, there exist other applications of PGHD technologies that may influence the decision to use PGHD by

patients and their healthcare professionals that were out of scope for the assessments and statements made in this report.

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Appendix A. Search Strategies

EMBASE/MEDLINE (via EMBASE.com)

Concepts	Set Number	Concept	Search Statement
mHealth Concepts	#1	mHealth	"mHealth" OR "m-Health" OR "mobile health" OR "ehealth" OR "e-health" OR "e health" OR telemonitor* OR telehealth* OR tele-monitor* OR tele-health* OR telemedicin* OR tele-medicin*
	#2	Smartphones	'Mobile phone'/de OR 'mobile application'/de OR Smartphone* OR 'cell phone' OR cellphone* OR 'iPhone' OR ((mobile OR wireless OR Bluetooth OR cellular OR android) NEAR/2 (health* OR device OR phone OR internet OR application* OR app OR apps))
	#3	Social Media	'social media'/de OR 'social media' OR twitter OR tweet OR Facebook OR Instagram* OR snapchat*
	#4	Portable computing devices	laptop OR (tablet NEAR/3 computer*) OR iPad OR chromebook OR "personal digital assistant"
	#5	Apps	App:ti OR apps:ti OR 'web based' OR 'web-based' OR 'internet-based' OR 'internet based' OR 'information technology-based' OR 'app-based' OR 'application based' OR 'web 2.0'
	#6	Combine sets	#1 OR #2 OR #3 OR #4 OR #5
Automated Patient-Generated Health Concepts	#7	Biosensors/ wearables/web-based/internet/ automated entry	'wireless communication'/de OR Biosens* OR ((remote OR passive OR wearable OR digital OR electronic OR transdermal) NEAR/3 (device* OR monitor* OR sensor* OR sensing*)) OR fitbit* OR hexoskin* OR (biometric* AND (shirt* OR vest OR vests OR wristband* OR garment*)) OR ((fitness OR activity) NEAR/3 (monitor* OR track*)) OR acceleromet* OR smartwatch OR 'Apple watch' OR sensewear* OR 'iwatch' OR 'I watch' OR garmin*:ti,ab,de OR GPS OR 'step counter' OR 'step count' OR wireless* OR Bluetooth* OR automat* OR semiautomat* OR semi-automat* OR 'real time' OR 'real-time' OR "heart rate" OR "blood pressure" OR electrocardiogram* OR ECG OR inhalation OR "EIMD" OR 'electronic inhalation monitor '
	#8	Patient generated data/remote monitoring	(patient NEXT/2 generat*) OR pghd OR ((self* OR home) NEAR/3 monitor*)) OR consumer OR 'over the counter'
	#9	Combine sets	#7 OR #8
	#10	Combine sets	#6 AND #9
	#11	Specific search for consumer self-monitoring devices	(((fitness OR activity) NEAR/3 (monitor* OR track*)):ti) OR fitbit*:ti OR acceleromet*:ti OR smartwatch:ti OR 'apple watch':ti OR sensewear*:ti OR 'iwatch':ti OR 'i watch':ti OR garmin*:ti,ab,de OR gps:ti OR 'step counter':ti OR 'step count':ti OR wireless*:ti OR bluetooth*:ti OR actigraph*:ti OR ((((remote OR passive OR wearable OR digital OR electronic OR transdermal) NEAR/3 (device* OR monitor* OR biosensor* OR sensor* OR sensing*)):ti) OR fitbit*:ti OR hexoskin*:ti OR (biometric*:ti AND (shirt*:ti OR vest:ti OR vests:ti OR wristband*:ti OR garment*:ti))) AND ((patient NEXT/2 generat*) OR pghd OR ((self* OR home) NEAR/3 monitor*) OR consumer OR 'over the counter')
	#12	Remove items focused on implantable devices	#11 NOT implant*:ti
	#13	Combine sets	#10 OR #12

Concepts	Set Number	Concept	Search Statement
	#14	Remove unwanted publication types	#13 NOT (abstract:nc OR annual:nc OR book/de OR 'case report'/de OR 'case study'/de OR conference:nc OR 'conference abstract':it OR 'conference paper'/de OR 'conference paper':it OR 'conference proceeding':pt OR 'conference review':it OR congress:nc OR editorial/de OR editorial:it OR erratum/de OR letter:it OR note/de OR note:it OR meeting:nc OR sessions:nc OR 'short survey'/de OR symposium:nc)
	#15	Limit to English & human	#14 AND [humans]/lim AND [English]/lim
Selected Chronic Conditions	#16	COPD	'chronic obstructive lung disease'/exp OR ((chronic NEXT/1 obstruct* NEXT/2 (lung* OR pulmonary*)):ti) OR copd*:ti
	#17	Asthma	asthma/exp OR 'allergic asthma'/exp OR 'asthmatic state'/exp OR 'extrinsic asthma'/exp OR 'intrinsic asthma'/exp OR 'mild intermittent asthma'/exp OR 'mild persistent asthma'/exp OR 'nocturnal asthma'/exp OR 'occupational asthma'/exp OR 'severe persistent asthma'/exp OR asthma*:ti
	#18	Hypertension	hypertension/exp OR 'elevated blood pressure'/exp OR hyperten*:ti OR ((high OR elevat*) AND “blood pressure”):ti
	#19	Obesity	'obesity'/exp OR 'body weight loss'/exp OR 'bariatric surgery'/exp OR 'bariatrics'/exp OR obese:ti OR obesity:ti OR bariatric*:ti OR ((weight NEAR/3 (loss OR lose OR reduc*)):ti)
	#20	Coronary Artery Disease	'coronary artery disease'/exp OR (coronar*:ti AND arter*:ti AND (disease*:ti OR syndrome*:ti OR atheroscleros*:ti OR anomal*:ti OR occlus*:ti OR thrombos*:ti OR calcif*:ti))
	#21	Heart Failure	'heart failure'/exp OR (((heart OR cardio* OR cardiac OR cardiogen*) NEAR/2 (failure OR shock OR death OR infarc* OR arrest*)):ti)
	#22	Stroke	'cerebrovascular accident'/exp OR 'brain ischemia'/exp OR stroke*:ti OR (((cerebrovasc* OR brain OR cerebral) NEXT/1 (accident* OR attack* OR infarct* OR insult* OR ischem* OR ischaem* OR clot* OR thromb* OR embol*)):ti)
	#23	Diabetes Prevention	'diabetes mellitus'/exp/dm_pc OR ('diabetes mellitus'/exp AND ('primary prevention'/exp/mj OR 'secondary prevention'/exp/mj OR 'tertiary prevention'/exp/mj OR 'prevention'/mj)) OR (diabet* AND prevent*):ti
	#24	Cardiac Arrhythmias or Conduction Abnormalities	'heart arrhythmia'/exp OR ((cardiac OR cardio* OR heart*) NEAR/3 (rhythm* OR arrhythm* OR conduction OR channelopath* OR palpitation* OR proarrhythm*)):ti OR (bradycardia OR channelopath*):ti OR ((heart OR artrial OR ventricul* OR ventricle*) NEXT/2 fib*):ti OR (parasystol* OR tachycardia OR “carotid sinus syndrome”):ti OR ((brugada OR “long QT” OR “long-QT” OR “short QT” OR “short-QT”) NEXT/2 syndrome*):ti OR parasystol*:ti
	#25	Sleep apnea	‘sleep disordered breathing’/exp OR (Sleep* NEAR/4 (apnea* or apnoea* OR breathing* OR hypoventilat*)):ti OR (OSA OR OSAS OR OSAHS):ti
	#26	Parkinson disease	'Parkinson disease'/exp OR Parkinson*:ti
	#27	Combine conditions	#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26
	#28	Combine sets – conditions and mHealth	#15 AND #27
	#29	Limit to Systematic Reviews/Meta-analyses	#28 AND ('research synthesis' OR pooled OR 'systematic review'/de OR 'meta analysis'/de OR (('evidence base' OR 'evidence based' OR methodol* OR systematic OR quantitative* OR studies OR search*) AND ('review'/de OR review/it))

Concepts	Set Number	Concept	Search Statement
	#30	Limit to Randomized Controlled trials	#28 AND ('randomized controlled trial'/exp OR 'randomization'/de OR 'double blind procedure'/de OR 'single blind procedure'/de OR 'placebo'/de OR 'crossover procedure'/de OR placebo* OR random*:de,ti OR crossover* OR 'cross over' OR ((singl* OR doubl* OR tripl* OR trebl*) AND (blind* OR mask* OR sham*)) OR 'latin square' OR isrtcn* OR actrn* OR (nct* NOT nct))
	#31	Combine sets	#29 OR #30

PubMed In-Process Citations

Concepts	Set Number	Concept	SearchStatement
mHealth Concepts	#1	mHealth	"mHealth" OR "m-Health" OR "mobile health" OR "ehealth" OR "e-health" OR "e health" OR telemonitor* OR telehealth* OR tele-monitor* OR tele-health* OR telemedicin* OR tele-medicin*
	#2	Smartphones	Smartphone* OR "cell phone" OR cellphone* OR "iPhone" OR (android* AND phone*) OR "mobile phone" OR "wireless phone" OR "cellular phone" OR "IPhone" OR Android OR "mobile device" OR "wireless device" OR "mobile application" OR "mobile app" OR "mobile apps"
	#3	Social media	"social media" OR twitter OR tweet OR Facebook OR Instagram* OR snapchat*
	#4	Portable computing devices	laptop OR (tablet[tiab] AND computer[tiab]) OR iPad OR chromebook OR "personal digital assistant"
	#5	Apps	app[ti] OR apps[ti] OR “web based” OR "web-based" OR "internet-based" OR Bluetooth* OR "web 2.0" OR "application based" OR "app-based" OR wireless
	#6	Combine	#1 OR #2 OR #3 OR #4 OR #5
Automated Patient-Generated Health Concepts	#7	Biosensors/ wearables/ automated data entry	Biosens* OR ((remote OR passive OR wearable OR digital OR electronic OR transdermal) AND (device* OR monitor* OR sensor* OR sensing*)) OR fitbit* OR hexoskin* OR (biometric* AND (shirt* OR vest OR vests OR garment* OR wristband*)) OR ((fitness OR activity) AND (monitor* OR track*)) OR accelerometer* OR "smartwatch" OR "Apple watch" OR sensewear* OR "iwatch" OR "I watch" OR garmin*[tiab] OR GPS OR “step counter” OR “step count” OR wireless* OR Bluetooth* OR automat* OR semiautomat* OR semi-automat* OR "heart rate" OR "blood pressure" OR electrocardiogram* OR ECG OR inhalation OR "EIMD" OR electronic inhalation monitor*
	#8	Patient generated data/remote monitoring	"patient generated" OR pghd OR ((self OR home) AND monitor*) OR consumer OR "over the counter"
	#9	Combine sets	#7 OR #8
	#10	Combine sets	#6 AND #9
	#11	Specific search for consumer self-monitoring devices	((fitness[ti] OR activity[ti]) AND (monitor*[ti] OR track*[ti])) OR accelerometer*[ti] OR smartwatch[ti] OR "Apple watch" [ti] OR sensewear*[ti] OR "iwatch" [ti] OR "I watch" [ti] OR garmin*[ti] OR GPS[ti] OR "step counter" [ti] OR "step count" [ti] OR wireless*[ti] OR Bluetooth*[ti] OR actigraph*[ti] OR fitbit*[ti] OR (((remote[ti] OR passive[ti] OR wearable[ti] OR digital[ti] OR electronic[ti] OR transdermal[ti]) AND (device*[ti] OR monitor*[ti] OR biosensor*[ti] OR sensor*[ti] OR sensing*[ti])) OR hexoskin*[ti] OR (biometric*[ti] AND (shirt*[ti] OR vest[ti] OR vests[ti] OR wristband*[ti] OR garment*[ti]))) AND ("patient generated" OR pghd OR ((self OR home) AND monitor*) OR consumer OR "over the counter")

Concepts	Set Number	Concept	SearchStatement
	#12	Remove items focused on implantable devices	#11 NOT implant*[ti]
	#13	Combine Sets	#10 OR #12
	#14	Remove unwanted publication types	#13 NOT (case reports[pt] OR comment[pt] OR editorial[pt] OR letter[pt] OR news[pt] OR Textbooks[pt] OR "Book Reviews"[pt] OR "Book Illustrations"[pt] OR book OR books OR textbook* OR meeting* OR conference* OR symposia OR symposium*)
	#15	Limit to Systematic Reviews/Meta-analyses	#14 AND (meta-analysis OR meta-analysis[pt] OR "Systematic Review"[pt] OR (systematic*[tiab] AND review*[tiab]))
	#16	Limit to Randomized Controlled Trials	#14 AND (“randomized controlled” OR “double-blind” OR “double-blinded” OR “single-blind” OR “single blinded” OR "single-dummy" OR "double-dummy" OR random*[ti] OR ISRCTN* OR ACTRN*)
	#17	Combine sets	#15 OR #16
	#18	Limit to in-process citations	#17 AND ("inprocess"[sb] OR publisher[sb] OR pubmednotmedline[sb])
Selected Chronic Conditions	#19	COPD	chronic obstructive lung disease* OR chronic obstructive pulmonary disease* OR copd
	#20	Asthma	asthma*
	#21	Hypertension	Hyperten* OR ((high OR elevated) AND “blood pressure”)
	#22	Obesity	Obese* OR obesity OR bariatric OR “weight loss” OR “weight reduction”
	#23	Coronary Artery Disease	Coronary artery diseas* OR coronary arterial diseas* OR atherosclero*
	#24	Heart Failure	(heart OR cardio* OR cardiac OR cardiogen*) AND (failure OR shock OR death OR infarc* OR arrest*)
	#25	Stroke	(cerebrovasc* OR brain OR cerebral) AND (accident* OR attack* OR infarct* OR insult* OR ischem* OR ischaem* OR clot* OR thromb* OR embol*)
	#26	Diabetes Prevention	(diabet* AND prevent*[ti]) OR prediabet* OR “metabolic syndrome”
	#27	Cardiac arrhythmias	((cardiac OR cardio* OR heart*) AND (rhythm* OR arrhythm* OR conduction OR channelopath* OR palpitation* OR proarrhythm*)) OR bradycardia OR channelopath* OR ((heart OR artrial OR ventricul* OR ventricle*) AND fibrillat*) “a-fib” OR “a fib” OR parasystol* OR tachycardia OR “carotid sinus syndrome” OR ((brugada OR “long QT” OR “long-QT” OR “short QT” OR “short-QT”) AND syndrome*)
	#28	Sleep apnea	(Sleep* AND (apnea* or apnoea* OR breathing* OR hypoventilat*)) OR OSA OR OSAS OR OSAHS
	#29	Parkinson Disease	Parkinson*[tiab]
	#30	Combine conditions	#19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29
	#31	Combine sets	#18 AND #30

Cochrane Database of Systematic Reviews (Note: this search was not limited to selected chronic conditions)

Concepts	Set Number	Concept	Search Statement
mHealth Concepts	#1	mHealth	"mHealth" OR "m-Health" OR "mobile health" OR "ehealth" OR "e-health" OR "e health" OR telemonitor* OR telehealth* OR tele-monitor* OR tele-health* OR telemedicin* OR tele-medicin*
	#2	Smartphones	Smartphone* OR "cell phone" OR cellphone* OR "iPhone" OR (android* AND phone*) OR "mobile phone" OR "wireless phone" OR "cellular phone" OR "IPhone" OR Android OR "mobile device" OR "wireless device" OR "mobile application" OR "mobile app" OR "mobile apps"
	#3	Social media	"social media" OR twitter OR tweet OR Facebook OR Instagram* OR snapchat*
	#4	Portable computing devices	laptop OR (tablet NEAR computer) OR iPad OR chromebook OR "personal digital assistant"
	#5	Apps	app OR apps OR “web based” OR "web-based" OR "internet-based" OR Bluetooth* OR "web 2.0" OR "application based" OR "app-based" OR wireless
	#6	Combine	#1 OR #2 OR #3 OR #4 OR #5
Automated Patient-Generated Health Concepts	#7	Biosensors/ wearables/ automated data entry	Biosens* OR ((remote OR passive OR wearable OR digital OR electronic OR transdermal) AND (device* OR monitor* OR sensor* OR sensing*)) OR fitbit* OR hexoskin* OR (biometric* AND (shirt* OR vest OR vests OR garment* OR wristband*)) OR ((fitness OR activity) AND (monitor* OR track*)) OR accelerometer* OR "smartwatch" OR "Apple watch" OR sensewear* OR "iwatch" OR "I watch" OR garmin* OR GPS OR “step counter” OR “step count” OR wireless* OR Bluetooth* OR automat* OR semiautomat* OR semi-automat* OR "heart rate" OR "blood pressure" OR electrocardiogram* OR ECG OR inhalation OR "EIMD" OR electronic inhalation monitor*
	#8	Patient generated data/remote monitoring	"patient generated" OR “patient-generated” OR pghd OR ((self OR home) AND monitor*) OR consumer OR "over the counter"
	#9	Combine sets	#7 OR #8
	#10	Combine sets	#6 AND #9
	#11	Specific search for consumer self-monitoring devices	((fitness OR activity) AND (monitor* OR track*)) OR accelerometer* OR smartwatch OR "Apple watch" OR sensewear* OR "iwatch" OR "I watch" OR garmin* OR GPS OR "step counter" OR "step count" OR wireless* OR Bluetooth* OR actigraph* OR fitbit* OR (((remote OR passive OR wearable OR digital OR electronic OR transdermal) AND (device* OR monitor* OR biosensor* OR sensor* OR sensing*)) OR hexoskin* OR (biometric* AND (shirt* OR vest OR vests OR wristband* OR garment*))) AND ("patient generated" OR pghd OR ((self OR home) AND monitor*) OR consumer OR "over the counter")
	#12	Remove items focused on implantable devices	#11 NOT implant*
	#13	Combine Sets	#10 OR #13

Appendix B. Excluded Publications

Table B-1. Excluded publications (references located in reference list of main report)

Article	Reason for Exclusion
Abraham 2015[172]	Not a comparison of interest
Adams 2017[173]	Not a comparison of interest
Adams 2018[174]	Not a comparison of interest
Akers 2012[175]	Not a comparison of interest
Aktas 2018[176]	Not an clinical condition of interest
Alencar 2019[177]	All groups received the same PGHD device(s)
Allen 2013[178]	Not automated data entry
Andersen 2012[179]	Not a comparison of interest
Andersen 2013[180]	Not a comparison of interest
Antoniades 2012[181]	Not a consumer device
Antonicelli 2008[182]	Not a consumer device
Antonicelli 2016[183]	Not automated data entry
Anttalainen 2016[184]	Other study design
Artinian 2007[185]	Not a consumer device
Ashe 2015[186]	N<10 in an arm at follow-up
Baillot 2016[187]	Not a comparison of interest
Balk-Møller 2017[188]	Not automated data entry
Baltaxe 2020[189]	Not a clinical condition of interest
Barlow 2020[190]	Single-arm study and not a registry
Barnason 2009[191]	Not a consumer device
Barnason 2019[192]	Not a comparison of interest
BaronFaust 2013[193]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Becofsky 2017[194]	Not a comparison of interest
Beleigoli 2018[195]	Not automated data entry
Benezet-Mazuecos 2018[196]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Bennett 2013[197]	Not a comparison of interest
Bentley 2014[198]	Not a consumer device
Bentley 2016[199]	N<10 in an arm at follow-up
Bernabe-Ortiz 2020[200]	Not a comparison of interest
Bernocchi 2018[201]	Not a consumer device
Blackford 2016[202]	Not a comparison of interest
Blanchard 1993[203]	Not a comparison of interest
Blum 2014[204]	Not a consumer device
Bohm 2016[205]	Not a consumer device
Boriani 2017[206]	Not a consumer device
Bosworth 2018[207]	Not automated data entry
Bowles 2009[208]	Not a consumer device
Bowles 2011[209]	Not a consumer device
Boyne 2012[210]	Not a consumer device
Brath 2013[211]	Not a clinical condition of interest
Brindal 2012[212]	Not a comparison of interest
Brindal 2016[213]	Not automated data entry
Bringsvor 2018[214]	Not a comparison of interest
Brown 2020[215]	Narrative review
Burke 2011[216]	Not a comparison of interest

Article	Reason for Exclusion
Burke 2012[217]	Not automated data entry
Burkhart 2007[218]	Not a comparison of interest
Byrd-Williams 2010[219]	Single-arm study and not a registry
Cadmus-Bertram 2016[220]	All groups received the same PGHD device(s)
Cairns 2018[221]	Pregnancy-related
Capomolla 2004[222]	Not a consumer device
Carmeli 2011[223]	Inpatient or laboratory
Carpinella 2017[224]	Not a consumer device
Carrasco 2008[225]	All groups received the same PGHD device(s)
Carter 2013[226]	Not automated data entry
Castelnuovo 2011[227]	Not a consumer device
Celis-Morales 2016[228]	Other study design
Chambliss 2011[229]	Not a consumer product
Chan 2007[230]	Not a consumer product
Chandra 2012[231]	Not a comparison of interest
Chao 2017[232]	Pregnancy-related
Chatterjee 2017[233]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Chau 2012[234]	Not a consumer device
Chaudhry 2010[235]	Not automated data entry
Chen 2013[236]	Not a comparison of interest
Cheung 2019[237]	Pregnancy-related
Chmiel 2014[238]	Not a comparison of interest
Choi 2016[239]	Not a consumer device
Chokshi 2018[240]	Not a comparison of interest
Cingi 2015[241]	Not automated data entry
Cleland 2005[242]	Not a consumer device
Com?n-Colet 2016[243]	Not a consumer device
Coultas 2018[244]	Not a comparison of interest
Cox 2019[245]	Not a comparison of interest
Cramer 2019[246]	Not a comparison of interest
Cruz-Correia 2007[247]	Unable to obtain
Cruz-Correia 2007[248]	No outcomes of interest
Cubo 2017[249]	Not a consumer device
Cuffee 2019[250]	Not a consumer device
Dalal 2019[251]	Not a comparison of interest
Dang 2017[252]	Not automated data entry
Daniali 2017[253]	Inpatient or laboratory
Danks 2016[254]	Inpatient or laboratory
Dansky 2008[255]	Not a consumer device
Dansky 2009[256]	Not automated data entry
Dar 2009[257]	Not a consumer device
Davis 2016[258]	Not a comparison of interest
de Almeida 2014[259]	Not a comparison of interest
De Jongste 2009[260]	Not a consumer device
De Lusignan 2001[261]	N<10 in an arm at follow-up
de Roon 2017[262]	Not a comparison of interest
De San Miguel 2013[263]	Not a consumer device
Deitz 2014[264]	Not a comparison of interest
DeJesus 2009[265]	N<10 in an arm at follow-up

Article	Reason for Exclusion
Demment 2014[266]	Pregnancy-related
Dendale 2012[267]	Not a consumer device
Deschildre 2012[268]	Not a consumer device
Desteghe 2018[269]	Other study design
Dinesen 2012[270]	Not a consumer device
Dörr 2019[271]	Single-arm study and not a registry
Dorsch 2015[272]	Inpatient or laboratory
Drummond 1994[273]	Not automated data entry
Du Moulin 2009[274]	N<10 in an arm at follow-up
Dunbar 2015[275]	Not a comparison of interest
Duncan 2018[276]	Not automated data entry
Dzewaltowski 2010[277]	Not a comparison of interest
Ellis 2019[278]	All groups received the same PGHD device(s)
Etiwy 2019[279]	Inpatient or laboratory
Farmer 2017[280]	Not a consumer device
Feigin 2015[281]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Fields 2016[282]	Not a consumer device
Finkelstein 2006[283]	Did not report data specificaly for a clinical condition of interest
Finkelstein 2015[284]	All groups received the same PGHD device(s)
Fjeldsoe 2016[285]	Not a comparison of interest
Fonseca 2006[286]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Forman 2019[287]	Not a comparison of interest
Foster 2017[288]	Other study design
Fox 2012[289]	Not a consumer device
Frederix 2015[290]	Not a consumer product
Frias 2017[291]	Inpatient or laboratory
Fu 2015[292]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Fukuoka 2015[293]	Not a comparison of interest
Gallagher 2017[294]	Not a comparison of interest
Garcia-Ortiz 2018[295]	Not a consumer device
Garde 2016[296]	No outcomes of interest
Gellis 2012[297]	Not a consumer device
Georges 2015[298]	Not a comparison of interest
Gerin 2007[299]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Ginis 2016[300]	Not a consumer device
Giordano 2009[301]	Not a consumer device
Godino 2016[302]	Not a comparison of interest
Goldberg 2003[303]	Not a consumer device
Goldfield 2006[304]	All groups received the same PGHD device(s)
Goldfield 2008[305]	Not a comparison of interest
Graham Thomas 2015[306]	No outcomes of interest
Greene 2013[307]	Not a consumer product
Grey 2019[308]	Specific device not named
Griauzde 2019[309]	No outcomes of interest
Gropler 2018[310]	Single-arm study and not a registry
Guendelman 2004[311]	Not automated data entry
Guiraud 2012[312]	No outcomes of interest
Gustafson 2012[313]	Not a comparison of interest
Hägglund 2015[314]	Not a consumer device

Article	Reason for Exclusion
Haines 2018[315]	Not a comparison of interest
Hale 2016[316]	Not a consumer device
Hales 2016[317]	Not a comparison of interest
Hanley 2015[318]	Not a consumer device
Hansel 2017[319]	Not a consumer device
Harris 2017[320]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Harvey-Berino 2004[321]	Not a comparison of interest
Hashimoto 2011[322]	Not a consumer device
Healey 2015[323]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Heldman 2017[324]	N<10 in an arm at follow-up
Hernandez 2014[325]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Hernandez-Quiles 2020[326]	Narrative review
Hernández-Reyes 2020[327]	Not automated data entry
Hernández-Reyes 2020[328]	Not a comparison of interest
Hickman 2015[329]	Not a comparison of interest
Hindricks 2014[330]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Hirshberg 2018[331]	Not a consumer device
Hong 2014[332]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Hu 2009[333]	Not a consumer device
Huang 2018[334]	Not a comparison of interest
Hung 2014[335]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Hurling 2007[336]	All groups received the same PGHD device(s)
Hwang 2017[337]	Not a consumer device
Hwang 2018[338]	Not a consumer device
Idris 2015[339]	Not a consumer device
Ifejika 2020[340]	Not a comparison of interest
Inglis 2008[341]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Izawa 2012[342]	Inpatient or laboratory
J?dice 2015[343]	N<10 in an arm at follow-up
Jakicic 1998[344]	Not a comparison of interest
Jakobsen 2015[345]	Not a consumer device
Jan 2007[346]	All groups received the same PGHD device(s)
Janssen-Boyne 2014[347]	Not automated data entry
Järvelä-Reijonen 2018[348]	Not a comparison of interest
Johnson 2019[349]	Not a comparison of interest
Johnston 2013[350]	Not automated data entry
Joseph 2013[351]	Not a comparison of interest
Kalter-Leibovici 2017[352]	Not a consumer device
Kamps 2001[353]	Not a comparison of interest
Kanaya 2012[354]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Karhula 2015[355]	Not a consumer device
Kashem 2008[356]	Not a consumer device
Kaufman 2018[357]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Kempf 2018[358]	All groups received the same PGHD device(s)
Kempf 2019[359]	Specific device not named
Kenealy 2015[360]	Not automated data entry
Kenealy 2015[360]	Not automated data entry
Kennedy 2013[361]	Not a clinical condition of interest
Kenyon 2018[362]	Not a comparison of interest

Article	Reason for Exclusion
Kerr 2017[363]	Not a consumer device
Kessler 2018[364]	Not automated data entry
Khusial 2020[365]	Not a consumer device
Kim 2012[366]	Not a consumer device
Kim 2017[367]	Not a comparison of interest
Kim 2020[368]	Not a comparison of interest
Kliemann 2019[369]	Not automated data entry
Koehler 2011[370]	Not a consumer device
Koff 2009[371]	Not a consumer device
Kong 2014[372]	Not a comparison of interest
Konstam 2011[373]	Not a consumer device
Kosse 2019[374]	Not automated data entry
Kotooka 2018[375]	Not a consumer product
Kotzian 2019[376]	Not a consumer device
Kraai 2015[377]	Not a consumer product
Krishnamurthi 2019[378]	Not a comparison of interest
Kronish 2016[379]	Not a comparison of interest
Krumholz 2011[380]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Kulzer 2016[381]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Kurek 2017[382]	Not a consumer device
Kurscheid 2019[383]	Not in English
Kurtzman 2018[384]	All groups received the same PGHD device(s)
Kwon 2018[385]	Not a consumer device
Labovitz 2017[386]	Not a consumer device
Laing 2014[387]	Not automated data entry
Lang 2016[388]	Not a comparison of interest
Lawrie 2018[389]	N<10 in an arm at follow-up
Lee 2012[390]	Not a comparison of interest
Lee 2017[391]	Not a consumer device
Lewis 2010[392]	Not a consumer device
Lewis 2010[393]	Not a consumer device
Li 2019[394]	Not a consumer device
Lin 2014[395]	Not a comparison of interest
Lin 2015[396]	No outcomes of interest
Linde 2015[397]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Lipsmeier 2018[398]	Single-arm study and not a registry
Liu 2011[399]	Not a consumer device
Lopez-Villegas 2018[400]	Not a consumer device
Lu 2019[401]	Not a comparison of interest
Lubans 2012[402]	Not a comparison of interest
Luley 2011[403]	Specific device not named
Lunde 2020[404]	Not a comparison of interest
Luque 2019[405]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Luscher 2016[406]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Ma 2019[407]	Not a comparison of interest
Mabo 2012[408]	Not a consumer device
Maddison 2015[409]	Not a consumer device
Madigan 2013[410]	Not a consumer device
Madigan 2014[411]	Not automated data entry

Article	Reason for Exclusion
Madsen 2008[412]	All groups received the same PGHD device(s)
Madsen 2011[413]	All groups received the same PGHD device(s)
Mair 2002[414]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Maltais 2008[415]	Not a comparison of interest
Mangieri 2019[416]	Not automated data entry
Mani 2016[417]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Mansfield 2015[418]	Inpatient or laboratory
Marquez Contreras 2018[419]	Not a comparison of interest
Martin 2015[420]	Not a consumer device
Martin 2015[421]	No outcomes of interest
Martínez 2018[422]	Not a consumer device
Martin-Lesende 2013[423]	Not an clinical condition of interest
McCabe 2016[424]	Not a comparison of interest
McClure 2008[425]	Not automated data entry
McDoniel 2010[426]	Not a consumer device
McDowell 2015[427]	Not a consumer device
McGillicuddy 2013[428]	N<10 in an arm at follow-up
Melchart 2017[429]	Inpatient or laboratory
Memon 2018[430]	Not a comparison of interest
Merchant 2016[431]	Not a consumer device
Merchant 2018[432]	Not automated data entry
Meurer 2019[433]	All groups received the same PGHD device(s)
Miller 2003[434]	Other study design
Mohamad 2019[435]	Not a consumer device
Moir 2016[436]	Not a comparison of interest
Monroe 2019[437]	Not a comparison of interest
Moon 2019[438]	No outcomes of interest
Moore 2014[439]	All groups received the same PGHD device(s)
Morawski 2018[440]	Not a comparison of interest
Mummah 2016[441]	N<10 in an arm at follow-up
Mummah 2017[442]	Not automated data entry
Murphy 2020[443]	Single-arm study and not a registry
Muxfeldt 2015[444]	Single-arm study and not a registry
Myers 2020[445]	Not a comparison of interest
Nanditha 2020[446]	Not a comparison of interest
Negarandeh 2019[447]	Not a comparison of interest
Nemanic 2019[448]	Not a consumer device
Nguyen 2008[449]	Not automated data entry
Nguyen 2009[450]	Not a comparison of interest
Niiranen 2010[451]	Not a comparison of interest
Niiranen 2015[452]	Not a comparison of interest
No author 2004[453]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
No author 2016[454]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Nouryan 2019[455]	Not a consumer device
Nyholm 2004[456]	Not automated data entry
Nystrom 2017[457]	Not a comparison of interest
Odeneg 2019[458]	Not a consumer device
Ohta 2015[459]	Not a comparison of interest
Olivari 2018[460]	Not a consumer device

Article	Reason for Exclusion
Olson 2016[461]	Not a comparison of interest
O'Neil 2014[462]	Not a comparison of interest
Or 2016[463]	Not a consumer device
Or 2020[464]	Not a consumer device
Orme 2018[465]	N<10 in an arm at follow-up
Ostojic 2005[466]	N<10 in an arm at follow-up
Padman 2017[467]	Not a comparison of interest
Paez 2014[468]	Pregnancy-related
Pan 2018[469]	Not a consumer device
Parati 2009[470]	All groups received the same PGHD device(s)
Paré 2013[471]	Not a consumer device
Park 2020[472]	Not a consumer device
Partridge 2015[473]	Not automated data entry
Patel 2019[474]	Not automated data entry
Paul 2016[475]	N<10 in an arm at follow-up
Pealing 2019[476]	Pregnancy-related
Pearson 2004[477]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Pedone 2013[478]	Not a consumer device
Pedone 2015[479]	Not a consumer device
Pekmezaris 2012[480]	Not automated data entry
Pekmezaris 2018[481]	Not a consumer device
Pépin 2019[482]	Not a consumer device
Persell 2020[483]	Not a consumer device
Phan 2018[484]	No outcomes of interest
Piette 2015[485]	Not a comparison of interest
Pinna 2007[486]	No outcomes of interest
Pinnock 2013[487]	Not a consumer device
Piotrowicz 2015[488]	Not a consumer device
Piotrowicz 2015[489]	Not a consumer device
Piron 2008[490]	N<10 in an arm at follow-up
Prochaska 2017[491]	Not a comparison of interest
Quinn 2018[492]	No outcomes of interest
Rajakariar 2018[493]	Single-arm study and not a registry
Ram 2003[494]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Rand 2014[495]	Not a comparison of interest
Rasu 2010[496]	Not a comparison of interest
Real 2019[497]	Not automated data entry
Redman 2017[498]	Pregnancy-related
Richardson 2003[499]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Richardson 2010[500]	Not a comparison of interest
Rikkers-Mutsaerts 2012[501]	Not a consumer device
Ringbæk 2015[502]	Not a consumer device
Rixon 2017[503]	Not a consumer device
Robinson 2019[504]	Not a comparison of interest
Rogers 2002[505]	Not automated data entry
Rousset 2017[506]	Single-arm study and not a registry
Ruifrok 2014[507]	Pregnancy-related
Ryan 2009[508]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Ryan 2012[509]	All groups received the same PGHD device(s)

Article	Reason for Exclusion
Saletu 2018[510]	Inpatient or laboratory
Santo 2018[511]	Not automated data entry
Sardu 2016[512]	Not a consumer device
Schatz 2009[513]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Schermer 2002[514]	Not a consumer device
Schroder 2010[515]	Not a comparison of interest
Schuna 2014[516]	Not a comparison of interest
Schwamm 2019[517]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Schwarz 2008[518]	Not a consumer device
Seto 2012[519]	Not a consumer device
Shany 2017[520]	Not a consumer device
Shrestha 2013[521]	N<10 in an arm at follow-up
Shukla 2005[522]	Not a comparison of interest
Skobel 2017[523]	Not a consumer device
Smolis-Bk 2015[524]	Not a consumer device
Sniehotta 2019[525]	Not a consumer device
Soran 2010[526]	Not a consumer device
Soriano 2018[527]	Not a consumer device
Sorknaes 2013[528]	Not a consumer device
Soureti 2011[529]	Not a comparison of interest
Southard 2006[530]	Not a comparison of interest
Spark 2015[531]	Not automated data entry
Spring 2013[532]	Not automated data entry
St George 2018[533]	Not a comparison of interest
Stahlman 2006[534]	Not a consumer device
Staiano 2017[535]	No outcomes of interest
Steinberg 2013[536]	Not a consumer product
Steinhubl 2018[537]	Not a consumer device
Stephens 2017[538]	Not automated data entry
Stepnowsky 2007[539]	Not a consumer device
Stergiou 2014[540]	All groups received the same PGHD device(s)
Stukus 2018[541]	Not automated data entry
Svetkey 2008[542]	Not automated data entry
Tabak 2014[543]	Not a consumer product
Takata 2002[544]	Not a consumer device
Talvik 2018[545]	Not a consumer device
Tarakji 2015[546]	Single-arm study and not a registry (exclude)
Tarraga Marcos 2017[547]	Not automated data entry
Thomas 2015[548]	Not automated data entry
Thomas 2017[549]	Not a consumer device
Thomas 2019[550]	Not automated data entry
Thompson 2014[551]	All groups received the same PGHD device(s)
Thorndike 2012[552]	Not automated data entry
Tiessen 2012[553]	No outcomes of interest
Tomita 2009[554]	Not a consumer device
Tousman 2011[555]	Not a comparison of interest
Turner 1998[556]	Not a consumer product
Turner-McGrievy 2011[557]	Not a comparison of interest
Turner-McGrievy 2014[558]	Not automated data entry

Article	Reason for Exclusion
Tzourio 2017[559]	All groups received the same PGHD device(s)
Udsen 2017[560]	Not a consumer device
Uijen 2012[561]	Not a comparison of interest
Van 2009[562]	Not automated data entry
van 2015[563]	Not an clinical condition of interest
van Beurden 2019[564]	Not automated data entry
Van Den Berg 2016[565]	Inpatient or laboratory
Varas 2018[566]	Not a comparison of interest
Venter 2012[567]	Not a consumer device
Verberk 2007[568]	All groups received the same PGHD device(s)
Versteeg 2019[569]	Not a consumer device
Vianello 2016[570]	Not a consumer device
Villani 2014[571]	Not a consumer device
Vitacca 2009[572]	Not a comparison of interest
Vloothuis 2018[573]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Voorend-Van Bergen 2015[574]	Not a consumer device
Vuorinen 2014[575]	Not a consumer device
Wade 2011[576]	Not a consumer device
Wagenaar 2019[577]	Not a consumer device
Wakefield 2011[578]	Not a consumer device
Waldmann 2008[579]	Not a consumer device
Walker 2018[580]	Not a consumer device
Wallén 2014[581]	Single-arm study and not a registry
Walters 2013[582]	Not a comparison of interest
Wan 2018[583]	Not a comparison of interest
Wang 2014[584]	No outcomes of interest
Wang 2015[585]	Not a comparison of interest
Wang 2016[586]	Not a comparison of interest
Watanabe 2020[587]	Not a consumer device
Watson 2012[588]	All groups received the same PGHD device(s)
Watson 2012[589]	Not a comparison of interest
Wei 2019[590]	Not a consumer device
Weinstein 2019[591]	Not a comparison of interest
Wensley 2004[592]	All groups received the same PGHD device(s)
West 2020[593]	Not a consumer device
Whitten 2007[594]	Not automated data entry
Widmer 2017[595]	Not a comparison of interest
Willems 2007[596]	Not a consumer device
Willems 2008[597]	Not a consumer device
Wilson 2019[598]	Not a comparison of interest
Winett 2011[599]	Not a comparison of interest
Wing 1986[600]	Not automated data entry
Wolf 2015[601]	Not a consumer device
Wolf 2016[602]	Not a consumer device
Womble 2004[603]	Not a comparison of interest
Wong 2018[604]	Not automated data entry
Woodend 2008[605]	Not a consumer device
Wu 2017[606]	Not a comparison of interest
Wylie-Rosett 2001[607]	Not a comparison of interest

Article	Reason for Exclusion
Yang 2017[608]	Not a consumer device
Yun 2020[609]	Not a clinical condition of interest
Zairina 2016[610]	Pregnancy-related
Zambrana 2019[611]	Single-arm study and not a registry
Zhang 2013[612]	Narrative review/Protocol/Commentary/Guideline/Editorial/Letter
Zhang 2020[613]	Not automated data entry

Appendix C. Evidence Tables

Table C-1. PGHD devices in included trials

Device Category	Product	Similarity Judgment*	Clinical Condition(s) in Included Studies	Included Studies That Used This Device
Accelerometer	Aipermon GmbH & Co. KG, AiperMotion 300 PfH	1	COPD	Jehn et al. (2013)[169]
Accelerometer	Body Media, SenseWear armband	4	Obesity	Polzien et al. (2007)[614]
Accelerometer	Fitbit, Flex	1	Obesity	Smith et al. (2019)[21] Chen et al. (2017)[56,615]
Accelerometer	Fitbit, One	1	Obesity	Smith et al. (2019)[21] Cadmus-Bertram et al. (2015)[19,20]
Accelerometer	Fitbit, Zip	1	Obesity	West et al. (2016)[22] Ross et al. (2016)[46]
Accelerometer	FitLife, Fitmeter	4	Obesity	Shin et al. (2017)[41,42]
Accelerometer	HTC, Desire A8181	4	Obesity, COPD	Vorrink et al. (2016)[50,58]
Accelerometer	Jawbone, BodyMedia FIT	4	Obesity	Rogers et al. (2016)[616]
Accelerometer	Jawbone, SenseWear armband	4	Obesity	Shuger et al. (2011)[44] Peyer et al. (2017)[59]
Accelerometer	Kempele, Polar Electro Kempele Oy	4	Obesity	Ruotsalainen et al. (2015)[16]
Accelerometer	Kens, Lifecorder EX	1	COPD	Kawagoshi et al. (2015)[162]
Accelerometer	Omron, Active Style Pro HJA-350IT	1	Obesity	Fukuoka et al. (2019)[33-38]
Accelerometer	Phillips, ActiveLink PA	4	Obesity	Thomas et al. (2017)[32]
Accelerometer	Polar, FA 20	1	Coronary artery disease	Frederix et al. (2015)[144]
Accelerometer	Shimmersensing, Shimmer	2	Obesity	Spring et al. (2017)[617,618]
Accelerometer	Suzuken, Lifecorder Plus	1	Obesity	Nicklas et al. (2014)[43]
Accelerometer	Xsens Technologies , MTX-w sensor	2	COPD	Tabak et al. (2014)[163]
Bite counter	Apple or Google, Bit counter app for apple watch or android watch	1	Obesity	Turner-McGrievy et al. (2017)[25,26]
Body composition monitor	Biospace, InBody IH-U070B	2	Obesity	Oh et al. (2015)[27,28]
BP monitor	A&D, Lifesource UA-767 (Arm)	1	Hypertension	Logan et al. (2012)[132]
BP monitor	A&D, UA-702 (Arm)	1	Hypertension	Mehos et al. (2000)[122]
BP monitor	A&D, UA-767 BT (Arm)	1	COPD	Jodar-Sanchez et al. (2013)[164,165] Koehler et al. (2018)[147,619] Earle et al. (2010)[70,71]
BP monitor	A&D, UA-767 PC (Arm)	1	Hypertension	Margolis et al. (2013)[106-112] Bosworth et al. (2011)[66-68]
BP monitor	A&D, UA-767 Plus (Arm)	1	Hypertension	Sarfo et al. (2018)[138,139]
BP monitor	A&D, UA-767 Plus BT (Arm)	1	Hypertension	Hoffmann-Petersen et al. (2017)[94] Bernocchi et al. (2014)[125] Petrella et al. (2014)[60] Kim et al. (2015)[130] Seto et al. (2012)[149] Rifkin et al. (2013)[65]
BP monitor	A&D, UA-767 Plus BT BP (Arm)	1	Hypertension	Sarfo et al. (2018)[138,139]
BP monitor	Bosch & Sohn, BosoMedicus (Arm)	1	Heart failure	Scherr et al. (2009)[148]

Device Category	Product	Similarity Judgment*	Clinical Condition(s) in Included Studies	Included Studies That Used This Device
BP monitor	Card Guard, CG800BP (Arm)	4	Obesity	Goulis et al. (2004)[51]
BP monitor	Ideal Life, BP-Manager (Arm)	4	Heart failure	Ong et al. (2016)[152]
BP monitor	IEM, Stabil-o-Graph (Arm)	1	Hypertension	Neumann et al. (2011)[134,135]
BP monitor	IEM, Stabil-o-Graph Mobile (Arm)	1	Hypertension	McKinstry et al. (2013)[113-115]
BP monitor	iHealth Lab, iHealth BP7 (Wrist)	1	Hypertension	Zha et al. (2019)[87]
BP monitor	Lifesource, UA-767 (Arm)	1	Hypertension	Magid et al. (2011)[133]
BP monitor	Lifesource, UA779 (Arm)	1	Heart failure, coronary artery disease	Lear et al. (2015)[146]
BP monitor	Microlife, 3AC1-AP (Arm)	1	Hypertension	Bove et al. (2013)[92]
BP monitor	Microlife, BP 3AC1-1 PC (Arm)	1	Hypertension	Ogedegbe et al. (2014)[123]
BP monitor	Microlife, BP3AC1 (Arm)	1	Hypertension	Klarskov et al. (2018)[131]
BP monitor	Microlife, Watch BP home (Arm)	1	Hypertension	McManus et al. (2014)[121]
BP monitor	Nonin Medical, UA-767 plus BT-C (Arm)	1	Heart failure	Cichosz et al. (2019)[151,620]
BP monitor	Omron Colin, JPN1 (Arm)	1	Hypertension	Kao et al. (2019)[102]
BP monitor	Omron Marshall, 85 (Arm)	1	Hypertension	Zarnke et al. (1997)[124]
BP monitor	Omron, 705 IT (Arm)	1	Hypertension	Hoffmann-Petersen et al. (2017)[94] McManus et al. (2010)[116-120]
BP monitor	Omron, 705CP (Arm)	1	Obesity, sleep apnea, hypertension, coronary artery disease	Mendelson et al. (2014)[47]
BP monitor	Omron, 711-DLX (Arm)	1	Obesity, hypertension	Green et al. (2014)[24]
BP monitor	Omron, HEM 637 (Wrist)	1	Hypertension	Bosworth et al. (2011)[89] Bosworth et al. (2009)[63]
BP monitor	Omron, HEM 705 CPN (Arm)	1	Hypertension	Zaleski et al. (2019)[100]
BP monitor	Omron, HEM 705-CP (Arm)	1	Hypertension	Fuchs et al. (2012)[93] Green et al. (2008)[80,81]
BP monitor	Omron, HEM 7117 (Arm)	1	Hypertension	Aekplakorn et al. (2016)[88]
BP monitor	Omron, HEM 715-C (unclear if arm or wrist)	1	Hypertension	Hebert et al. (2012)[82]
BP monitor	Omron, HEM 773AC (Arm)	1	Hypertension	Bosworth et al. (2011)[89] Bosworth et al. (2009)[63]
BP monitor	Omron, HEM-702 (unclear if arm or wrist)	1	Hypertension	Broege et al. (2001)[79]
BP monitor	Omron, HEM-70801C (Arm)	1	Hypertension	Kaihara et al. (2014)[95]
BP monitor	Omron, HEM-7121 (Arm)	1	Hypertension	Qi et al. (2017)[99]
BP monitor	Omron, HEM-712C (Arm)	1	Obesity, hypertension	Dorough et al. (2014)[126]
BP monitor	Omron, HEM-722-C (Arm)	1	Hypertension	Niiranen et al. (2014)[136]
BP monitor	Omron, HEM-7251G (Arm)	1	Hypertension	Kaihara et al. (2014)[95]
BP monitor	Omron, HEM-737 (Arm)	1	Hypertension	He et al. (2017)[128]
BP monitor	Omron, HEM-790IT (Arm)	1	Hypertension	Stewart et al. (2014)[140] Magid et al. (2013)[64]
BP monitor	Omron, IC (unclear if arm or wrist)	1	Hypertension	Kauric-Klein et al. (2007)[96]
BP monitor	Omron, M10-IT (Arm)	1	Hypertension	McManus et al. (2018)[83-86]

Device Category	Product	Similarity Judgment*	Clinical Condition(s) in Included Studies	Included Studies That Used This Device
BP monitor	Omron, M4 (Arm)	1	Hypertension	Marquez-Contreras et al. (2006)[98] Halme et al. (2005)[127]
BP monitor	Omron, M4-I (Arm)	1	Coronary artery disease	Blasco et al. (2012)[143]
BP monitor	Omron, M6 (Arm)	1	Hypertension, stroke	Kerry et al. (2013)[103-105]
BP monitor	Omron, T5M (Arm)	4	Obesity, hypertension, asthma	Yoo et al. (2009)[23]
BP monitor	Samsung, SHB-200w (P/N 323101456) (unclear if arm or wrist)	4	Hypertension	Hosseininasab et al. (2014)[129]
BP monitor	Welch Allyn, 52500 (unclear if arm or wrist)	1	Hypertension	Rogers et al. (2001)[137]
BP monitor	Withings, Withings Blood Pressure Monitor (Arm)	2	Hypertension, Coronary artery disease	Lakshminarayan et al. (2018)[69] Kim et al. (2016)[97,101] Treskes et al. (2020)[141]
Combined accelerometer, heart rate monitor, galvanic skin response monitor, and cutaneous temperature monitor	Empatica (Italy), WB wristband E3	1	Obesity	Mameli et al. (2018)[29]
ECG monitor	AliveCor, Kardia	1	Cardiac arrthymias, Coronary artery disease	Halcox et al. (2017)[160] Stavrakis et al. (2017)[154] Reed et al. (2019)[155] Goldenthal et al. (2019)[153,621] Treskes et al. (2020)[141]
Energy expenditure and physical activity monitor	Body Media, FIT Core	4	Obesity	Jakicic et al. (2016)[30]
Forehead thermometer	Medisana AG, FTN	1	COPD	Boer et al. (2019)[166]
Glucose meter	Abbott Diabetes Care Inc, Freestyle Optium Glucose Meter	1	Obesity	Jospe et al. (2017)[622]
Glucose meter	Insung Information, Anycheck	4	Obesity, hypertension	Yoo et al. (2009)[23]
Glucose meter	Lifescan, Lifescan OneTouch Ultra2	1	Hypertension, diabetes prevention	Petrella et al. (2014)[60]
Glucose meter	Lifescan, OneTouch Ultra	1	Hypertension	Earle et al. (2010)[70,71]
Heart rate monitor	Bosch & Sohn, BosoMedicus	4	Heart failure	Scherr et al. (2009)[148]
Heart rate monitor	Garmin, Forerunner 210	1	Coronary artery disease	Avila et al. (2020)[145,623]
Heart rate monitor	Garmin, FR70	1	Heart failure, coronary artery disease	Kraal et al. (2017)[142,624]
Heart rate monitor	Polar Electro Oy, FT7	1	Hypertension	Zaleski et al. (2019)[100]
Heart rate monitor	Polar, s610i	1	Heart failure, coronary artery disease	Lear et al. (2015)[146]
Heart rate monitor	Polar, s810	1	COPD	Mendes de Oliveira et al. (2010)[167]

Device Category	Product	Similarity Judgment*	Clinical Condition(s) in Included Studies	Included Studies That Used This Device
Heart rate monitor	Suunto, Suunto Memory Belt	3	Hypertension, diabetes prevention	Petrella et al. (2014)[60]
Pedal machine	3D Innovations, MagneTrainer	1	Obesity	Carr et al. (2013)[31]
Pedometer	A&D Engineering, Wellness Connected Wireless Activity Monitor XL-20	4	Obesity	Martin et al. (2015)[625]
Pedometer	Accusplit, 120XL	1	Obesity, hypertension	Dorough et al. (2014)[126]
Pedometer	Fitbit, Charge	1	Obesity	Ferrante et al. (2018)[48]
Pedometer	Fitbug, Air	4	COPD	Demeyer et al. (2017)[161]
Pedometer	Geonaute, Onstep 50 Geonaute	4	Obesity, COPD	Arbillaga-Etxarri et al. (2018)[52]
Pedometer	Gruve, Gruve	1	Obesity, diabetes prevention	Biddle et al. (2015)[57]
Pedometer	Misfit, Shine	2	Obesity, sleep apnea	Cho et al. (2018)[62]
Pedometer	New Lifestyles, NL-800	1	Obesity	Nanchahal et al. (2009)[626,627]
Pedometer	Omron, HJ-105	2	Obesity	Chen et al. (2017)[56,615]
Pedometer	Omron, HJ-113	2	Obesity	Creel et al. (2016)[45]
Pedometer	Omron, HJ-150	2	Obesity	Carr et al. (2013)[31] Petrella et al. (2014)[60]
Pedometer	Withings, PulseOx	1	Coronary artery disease	Treskes et al. (2020)[141]
Pedometer	Samsung, Charm	1	Obesity, sleep apnea	Kim et al. (2019)[61]
Pedometer	SportBrain, i Step X	4	Obesity	Richardson et al. (2016)[39]
Pedometer	Suzuken, Kenz Lifecorder GS	2	Obesity	Nakata et al. (2019)[628]
Pedometer	Yamax, Digi Walker CW 600	1	Obesity	Shapiro et al. (2012)[629]
Pedometer	Yamax, Digi Walker CW 700	1	COPD	Nolan et al. (2017)[168]
Pedometer	Yamax, Digi Walker SW 200	1	Obesity	Katzmarzyk et al. (2011)[17] Nanchahal et al. (2009)[626,627] VanWormer et al. (2009)[630,631] Bove et al. (2013)[92] Richardson et al. (2016)[39]
Pedometer	Yamax, SW 650/651	1	Obesity, hypertension	Bennett et al. (2018)[18,72,73]
Pedometer	Zencro, TW64S	4	Obesity	Edney et al. (2020)[53-55]
Pulse oximeter	Smiths medical, BCI	4	Heart failure	Kulshreshtha et al. (2010)[150]
Scale	A&D Engineering, Wellness Connected Wireless Precision Scale UC-324THX	4	Obesity	Martin et al. (2015)[625]
Scale	A&D, Precision Health Scale UC 321PBT-C	1	Heart failure	Cichosz et al. (2019)[151,620]
Scale	A&D, UC-321PBT	1	Heart failure	Seto et al. (2012)[149]
Scale	Cardiocom, Thin-Link	4	Obesity	VanWormer et al. (2009)[630,631]
Scale	Eat Smart, Precision Digital Scale	1	Obesity	Haggerty et al. (2017)[49]
Scale	Fitbit, Aria	2	Obesity	Ross et al. (2016)[46] West et al. (2016)[22]
Scale	Ideal Life, Body Manager	1	Heart failure	Ong et al. (2016)[152]
Scale	Lifesource, Digital weight scale	4	Heart failure	Kulshreshtha et al. (2010)[150]
Scale	Soehnle, Creta	2	Heart failure	Scherr et al. (2009)[148]
Scale	Tanita, BC-569	1	Obesity	Nakata et al. (2019)[628]
Scale	Tanita, Digital weight scale	4	Obesity, hypertension	Dorough et al. (2014)[126]
Scale	Tanita, HD308	1	Obesity, hypertension	Yoo et al. (2009)[23]

Device Category	Product	Similarity Judgment*	Clinical Condition(s) in Included Studies	Included Studies That Used This Device
Scale	Taylor, Digital LCD scale	4	Hypertension	Bove et al. (2013)[92]
Scale	Withings, WiFi Scale	4	Obesity	Haggerty et al. (2017)[49]
Scale	Withings, Smart Body Scale Analyzer	1	Coronary artery disease	Treskes et al. (2020)[141]
Spirometer	Medical International Research, SmartOne	1	Asthma	Ljungberg et al. (2019)[170]

*The similarity judgment involved an assessment of the similarity of this device to the devices currently on the market from this manufacturer: 1: very similar, 2: somewhat different, 3: very different, 4: similarity could not be determined.
For BP monitors, type of monitor (arm or wrist) is reported in parentheses in Product column.
BP = blood pressure; COPD = chronic obstructive pulmonary disease; LCD = liquid crystal display

Table C-2. Mobile apps in included trials

App name	Clinical Condition(s) in Included Studies	Iphone availability	Android Availability	Included Trials That Used This App
Active Team	Obesity	yes	no	Edney et al. (2020)[53-55]
Bite counter	Obesity	yes	yes	Turner-McGrievy et al. (2017)[25,26]
Calorie Counter (by FatSecret)	Obesity	yes	yes	Turner-McGrievy et al. (2017)[25,26]
ENGAGED	Obesity	no	no	Spring et al. (2017)[617,618]
Fitbit	Obesity	yes	yes	Chen et al. (2017)[56,615] Ross et al. (2016)[46]
iStart Smart for Teens	Obesity	no	no	Chen et al. (2017)[56,615]
MeTeDa srl	Obesity	no	no	Mameli et al. (2018)[29]
mPED	Obesity	no	no	Fukuoka et al. (2019)[33-38]
MyFitnessPal	Obesity	yes	yes	Jospe et al. (2017)[622]
MyHealthKeeper	Obesity, Sleep apnea	yes	no	Kim et al. (2019)[61]
Weight Watchers Online	Obesity	yes	yes	Thomas et al. (2017)[32]
Unnamed app	Obesity, sleep apnea, hypertension, coronary artery disease	?	?	Mendelson et al. (2014)[47]
Unnamed app	Obesity	?	?	Shin et al. (2017)[41,42]
Unnamed app	Obesity, COPD	?	?	Vorrink et al. (2016)[50,58]
Unnamed app	Obesity, Sleep apnea	?	?	Cho et al. (2018)[62]
Healthanywhere	Hypertension, diabetes prevention	no	no	Petrella et al. (2014)[60]
HealthyCircles	Hypertension	no	no	Kim et al. (2016)[97,101]
iHealth MyVitals	Hypertension	yes	yes	Zha et al. (2019)[87]
Runkeeper	Hypertension	yes	yes	Chandler et al. (2020)[74]
Tension Tamer	Hypertension	no	no	Chandler et al. (2020)[74]
Unnamed app	Hypertension	?	?	Sarfo et al. (2018)[138,139]
Fitbug	COPD	no	no	Demeyer et al. (2017)[161]
Wireless Application Protocol session	Coronary artery disease	no	no	Blasco et al. (2012)[143]
Unnamed app	Heart failure	?	?	Cichosz et al. (2019)[151,620]
Unnamed app	COPD	?	?	Boer et al. (2019)[166]
Unnamed app	Asthma	?	?	Ljungberg et al. (2019)[170]

Table C-3. Obesity and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Activity Coaching in Patients Post Lung Transplantation https://ClinicalTrials.gov/show/NCT04122768	Recruiting	Lung Transplantation	Behavioral: Multi-component Physical Activity Tele-coaching Intervention Behavioral: Light Coaching Intervention	Leuven, Belgium
BOOSTH: Serious Gaming in Combination With Physical Activity Promotion https://ClinicalTrials.gov/show/NCT03435575	Active, not recruiting	Physical Activity, Serious Game, Childhood Obesity, Overweight and Obesity	Device: Boosth	Maastricht University Medical Center, Maastricht, Limburg, Netherlands
Creating an Optimized Technology-Based Weight Loss Program for Cardiac Rehabilitation Patients https://ClinicalTrials.gov/show/NCT03845283	Recruiting	Cardiovascular Diseases, Obesity	Behavioral: Online Behavioral Weight Loss Program Behavioral: Physical Activity Intervention Behavioral: Bite Counter Behavioral: Virtual Reality Behavioral: Virtual Meetings	The Weight Control and Diabetes Research Center, Providence, Rhode Island, United States
Dynamo: A Tailored Lifestyle Promotion Intervention Among Pediatric Patients With Cardiometabolic Risk Factors https://ClinicalTrials.gov/show/NCT01736748	Recruiting	Obese	Behavioral: Sensor-based PA Intervention Behavioral: Traditional PA Counseling	CHU Sainte-Justine, Montreal, Quebec, Canada
Effectiveness to Weight Loss in Sedentary and Overweight People Using a Smartphone Application. https://ClinicalTrials.gov/show/NCT03175614	Recruiting	Healthy	Other: Intervention Group Other: Control: Lifestyle counseling	Primary Care Research Unit - The Alamedilla Center for Health, Salamanca, Spain
Improving Physical Activity Through a mHealth Intervention in Cardio-metabolic Risk Patients https://ClinicalTrials.gov/show/NCT02551640	Active, not recruiting	Diabetes Mellitus, Type 2, Prediabetic State, Hypertension, Prehypertension, Obesity	Other: FeatForward App (on study smartphone)	Mass General: Charlestown Healthcare Center, Charlestown, Massachusetts, United States Mass General Revere HealthCare Center, Revere, Massachusetts, United States
Increasing Physical Activity Among Sedentary Older Adults:What, Where, When, and With Whom https://ClinicalTrials.gov/show/NCT03124537	Unknown	Sedentary Lifestyle, Self Efficacy, Control Locus, Aging	Behavioral: App Experimental Condition Behavioral: App Condition Control	Brandeis University, Waltham, Massachusetts, United States

Title	Status	Conditions	Interventions	Locations
Increasing Steps Per Day in Rural Veterans https://ClinicalTrials.gov/show/NCT03930238	Enrolling by invitation	Obesity, Overweight	Behavioral: VA MapTrek Behavioral: Fitbit Only	VA Health Care System, Iowa City, Iowa, United States
Lifestyle Intervention Program for Former Elite Athletes https://ClinicalTrials.gov/show/NCT03031951	Active, not recruiting	Obesity	Behavioral: Lifestyle Intervention Group	Faculdade de Motricidade Humana, Oeiras, Cruz-Quebrada, Portugal
Overweight and Obesity in Preschoolers https://ClinicalTrials.gov/show/NCT03800823	Recruiting	Obesity, Overweight	Behavioral: Parent Group Behavioral: mHealth Component Behavioral: Standard Care	University of Medicine and Pharmacy "Victor Babes", Timi Yoara, Romania University of the Balearic Islands & CIBEROBN, Palma De Mallorca, Spain Karolinska Instituet, Huddinge, Sweden
Physical Activity With Tailored E-health Support for Individuals With Intellectual Disability https://ClinicalTrials.gov/show/NCT04079439	Not yet recruiting	Intellectual Disability	Behavioral: Physical Activity with tailored e-health support	

Table C-4. Obesity and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Arbillaga-Etxarri et al. (2018)[52]	RCT	Spain	Oct 2013 to Jan 2016	To detect a difference of 775 steps/day (primary outcome) between groups (based on previous research about the effects of behavioral interventions in the elderly), with a two-sided α=0.05 and a power of 80%, assuming a standard deviation of 3000 steps·day-1 and a correlation between baseline and final steps ≥0.7 (based on authors' data in COPD patients), a sample size of 142 patients per group was necessary. To account for a 30% dropout rate during follow-up, authors planned to recruit 202 participants per group (404 in total).	407	52
Bennett et al. (2018)[18,72,73]	RCT	USA	Jun 2013 to Sep 2015	Using data from previous work, mean weight was estimated at 81 kg with a standard deviation of 8 kg. Twelve months post-intervention, the authors hypothesized that there would be no change in the usual care group and a 2.6-kg reduction in the treatment group and that there will be an autocorrelation between baseline and follow-up weight values of 0.55. From these values, using a two-tailed test of differences at the alpha=0.05 level, it was estimated 80% power to detect a difference of 2.36 kg with 140 complete cases per group. 20% inflation to accommodate projected attrition.	351	52

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Biddle et al. (2015)[57]	RCT	UK	Mar 2011 to Oct 2011	Assuming a minimum clinically important difference of 10% (based on prior work) and a standard deviation of 12.1 hours/week [27], authors required 72 individuals to complete the study per arm assuming an alpha of 0.05 and 80% power. Target recruitment was set at 90 individuals per arm to allow for an estimated dropout rate of 20%.	177	52
Cadmus-Bertram et al. (2015)[19,20]	RCT	USA	Apr 2013 to Oct 2014	NR	51	16
Carr et al. (2013)[31]	RCT	USA	Jun 2011 to Jun 2012	A sample size of 40 (recruiting 49 assuming a 20% attrition) was necessary to detect, with 80% power, at α=0.05, a 30 min/day difference in daily sedentary time (30 min/day was based on a previous study).	40	12
Chen et al. (2017)[56,615]	RCT	USA	NR	No a priori power analysis, but authors stated that with 23 participants in the intervention group and 17 participants in the intervention group, authors had an 80% chance of detecting a larger effect size (0.90) between the two groups as significant at the 5% level (two tailed).	40	26
Cho et al. (2018)[62]	RCT	South Korea	Jul 2016 to Nov 2016	NR	47	4
Creel et al. (2016)[45]	RCT	USA	Mar 2010 to Jul 2014	Assuming a 25% drop out rate, randomizing 50 participants per group (38 analyzable per group) would provide 80% power to detect a 1,850-step difference among groups.	150	26
Dorough et al. (2014)[126]	RCT	USA	NR	NR	23	10
Edney et al. (2020)[53-55]	RCT	Australia	2016 to 2017	Sample size calculations were based on the primary outcome of objective moderate vigorous physical activity at 3 months. Sample size calculations (a=0.05, b=0.20) indicated a sample of 440 as sufficient to detect a small effect size (Cohen's f2=0.13, d=0.25, based on prior work) for between - group differences on the primary outcome.	444	39
Ferrante et al. (2018)[48]	RCT	USA	Jan 2016 to Oct 2017	NR	35	26

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Fukuoka et al. (2019)[33-38]	RCT	USA	May 2011 to Apr 2014	The planned overall sample size of 192 participants, randomized in equal proportions to the control, regular, and plus groups, was provided 90% power in 2-sided tests with a type I error rate of 5% to detect a difference between the regular and plus groups of 1100 steps per day in the average change from 3 to 9 months, after accounting for 12% loss to follow-up by 3 months and an additional loss of 13% during the 6-month maintenance period. Sample size calculations accounted for the intra-class correlations of the repeated outcomes as well as loss to follow-up.	210	39
Goulis et al. (2004)[51]	RCT	Greece	Sep 2001 to Dec 2002	Power calculation indicated that a minimum sample size of n=100 was required, assuming 0.10 level of significance and 80 percent statistical power.	154	26
Green et al. (2014)[24]	RCT	USA	2010 to 2011	The planned sample size of 100 randomized subjects provided 80% power to detect an effect size of 0.6 SD for the continuous outcomes, assuming 90% follow-up at the 6-month visit.	101	26
Haggerty et al. (2017)[49]	RCT	USA	NR	NR	41	26
Jakicic et al. (2016)[30]	RCT	USA	Oct 2010 to Oct 2012	Authors specified 2.3-kg or more mean weight loss for the enhanced intervention. Compared with the standard intervention, so that the mean weight loss in the enhanced intervention group was expected to be 5.7 kg at the end of month 24. This would allow participants in the enhanced intervention group to maintain a clinically meaningful weight loss of at least 5%. Using a standard deviation of 6.8 kg for both groups, a 2-sided t test at 5% level of significance had 90% power to detect a mean difference of 2.3 kg (effect size, 0.33) between the enhanced intervention and standard intervention groups if 24-month data were available for at least 191 patients in each group. Based on an expected attrition rate of 20%, the recruitment goal was 238 participants per group.	470	104
Jospe et al. (2017)[622]	RCT	Australia	NR	The study was designed to have 90% power to detect differences in weight of 4 kg (assuming standard deviation [SD] of 15 kg and a correlation between repeat measures of r=0.90), using a two-sided test at the 0.05 level (42/group), with n=250 in total after allowing for 15% loss to follow-up.	209	52
Katzmarzyk et al. (2011)[17]	RCT	USA	Jan 2010 to Feb 2010	NR	43	1
Kim et al. (2019)[61]	RCT	South Korea	Jul 2017 to Aug 2017	NR	43	4

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Mameli et al. (2018)[29]	RCT	Italy	Apr 2015 to Jul 2015	Sample size was calculated on the basis of the main outcome (weight change). When authors designed the RCT, a systematic review had estimated a weight loss of 1.5 kg as the mean effect that could be obtained with computer-based interventions in adults. In the absence of data for children, authors took this as a plausible and clinically relevant estimate for the effect of the present intervention in children. With a common standard deviation of the difference of 1.6 kg, 20 subjects per group give a power of 80% to detect a mean difference of -1.5 kg at an alpha level of 0.05.	43	13
Martin et al. (2015)[625]	RCT	USA	NR	NR	40	12
Mendelson et al. (2014)[47]	RCT	France	Jul 2009 to Jan 2012	Based on the decrease in arterial BP after CPAP treatment reported in a prior meta-analysis (-2.46±0.94 mmHg), authors supposed that BP would decrease by an additional 15% (i.e., -2.83 mmHg) when patients benefited from telemedicine. Authors expected a difference of 0.37 and a standard error of 0.94. Inclusion rate was set at 100 patients per group, based on statistical significance set at 0.05, and power at 80%. To account for a 10% dropout rate in the telemedicine arm, authors set inclusion at 110 patients per group. One blinded interim analysis of home self-measured BP was planned halfway through the inclusion process to look for premature evidence of benefits in the telemedicine versus standard care group, or of harm in any group. The results of this analysis showed that even if the set inclusion rate was met, no benefits would be found on the primary outcome measure (home self-measured BP); thus recruitment was interrupted at 107 patients.	107	17
Nakata et al. (2019)[628]	RCT	Japan	Aug 2014 to Nov 2014	Assuming a difference of 2.5 (4.0) kg in the 27-month weight change between groups, an alpha level of 5%, and a power of 80%, the required sample size for the final analysis was 84 in total. Assuming an eligibility rate of 90%, an achievement rate of 90% for 5% loss of baseline weight, and a drop-out rate of 20% in phase 2, the required sample size assessed for eligibility was determined to be 130.	95	116
Nanchahal et al. (2009)[626,627]	RCT	UK	Jul 2009 to Jan 2010	For the sample size calculation, authors wished to detect a mean weight difference of 6.9 kg at 12 months between the two groups with two-sided statistical significance of 1%, power at 90% and the correlation coefficient between baseline and follow-up values conservatively set at 0.7. Authors thus calculated a total sample size of 228 (114 per group). Assuming a loss to follow-up at 12 months of 40%, it was estimated that 380 participants would be required.	381	52

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Nicklas et al. (2014)[43]	RCT	USA	NR	NR	41	44
Oh et al. (2015)[27,28]	RCT	South Korea	Mar 2011 to Apr 2013	Each group initially consisted of 167 subjects chosen using a 5% significance level, 90% power, and estimating the mean difference in weight change between the 2 groups to be 1.81 kg (SD: 4.81 and 5.36 kg). Considering a 25% drop out rate, the final sample size consisted of 223 subjects for each group (n=446 subjects).	421	24
Peyer et al. (2017)[59]	RCT	USA	Fall 2010 to Spring 2011	NR	89	26
Polzien et al. (2007)[614]	RCT	USA	NR	NR	57	12
Richardson et al. (2016)[39]	RCT	USA	Jul 2005 to Nov 2007	The sample size was calculated so it would provide 80% power to detect a 1.4-kg difference in weight loss between pairs of active intervention conditions (e.g., time-based vs. simple pedometer) in the planned comparisons with alpha set at 0.05 for a two-tailed test. It is important to note that 1.4 kg represents the difference in weight change between the groups—not the absolute weight change. Based on prior observations, the SD of weight change over a 6-month period was estimated as 3 kg. Power analysis was conducted using Cohen's methods (11) and calculated with PASS2000 software that indicated the need for 82 subjects per group after accounting for attrition. In anticipation of up to 20% attrition, authors planned to recruit 103 patients per arm or a total of 300 participants (50 patients per site).	255	26
Rogers et al. (2016)[616]	RCT	USA	NR	NR	25	26
Ross et al. (2016)[46]	RCT	USA	NR	Using data from a previous technology-based weight management study, a power analysis was conducted using SAS, with an alpha of 0.05 and a power of 0.80. This analysis suggested a sample size of 84 would be needed to reach an actual power of 0.809 for testing the overall model for the primary aim.	72	26
Ruotsalainen et al. (2015)[16]	RCT	Finland	Spring 2012 to Summer 2012	No a priori power analyses conducted.	46	12

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Shapiro et al. (2012)[629]	RCT	USA	Jan 2011 to Dec 2011	A priori power analyses indicated that 128 participants would provide a power=0.84 to detect a group difference of d=0.5 at 6 months (i.e., with two repeated measures) and power=0.85 to detect the same effect at 12 months with alpha=0.05. Sample size was increased to 170 to allow for 25% attrition.	170	52
Shin et al. (2017)[41,42]	RCT	South Korea	Mar 2015 to Nov 2015	NR	98	12
Shuger et al. (2011)[44]	RCT	USA	Feb 2008 to Feb 2009	Given the target enrollment of 50 participants per treatment condition, the study design had 80% power to detect an effect size of 0.62 (assuming a=0.025) for weight loss and waist circumference reduction. Under 40% attrition the study design had 80% power to detect an effect size of 0.81 (assuming alpha=0.025) for weight loss and waist circumference reduction. If the standard deviation is approximately 7.0 for the baseline follow-up differences for two outcome measures of interest, authors had 80% power to detect a 0.434 kilogram difference in weight-loss and a 0.567 cm difference in waist size reduction.	197	39
Smith et al. (2019)[21]	RCT	USA	NR	NR	48	16
Spring et al. (2017)[617,618]	RCT	USA	Jul 2011 to Feb 2012	Power analyses were based on data from our previous Mobile Trial, where standard deviations (SD) of 3.8 and 4.9 kg were seen at months 3 and 6, respectively, with a correlation of 0.86 between the two time points. With 80% power and n=30 at the final end point in both the STND and TECH groups, a difference of 3 kg between these two groups was expected to be able to be detected. The power calculations were based on the second Helmert contrast, TECH versus STND, because this contrast contained the fewest number of subjects (30 in each group), and it was expected that this contrast would have the smallest effect sizes. The first Helmert contrast, STND and TECH versus SELF, had a larger sample size (60 vs. 30), and larger effect sizes were expected in this contrast due to the limited intensity of the SELF intervention. Therefore, by powering the study based on the second contrast, it was expected that there would be more than adequate power for the first contrast.	96	52
Thomas et al. (2017)[32]	RCT	USA	May 2013 to Mar 2014	This trial was designed to detect significant between-group differences in weight loss of at least 2.5 kg with 0.80 power at 3 and 12 months with n=270 and ≤30% attrition at 12 months, assuming a SD of no more than about 5 kg in weight loss at 3 and 12 months.	271	52

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Turner-McGrievy et al. (2017)[25,26]	RCT	USA	2015 to 2016	A similar previous 6-month trial was used to conduct sample size calculations (alpha 0.05 and power 80%) based on expected differences between groups in self-monitoring frequency. In that study, participants who self-monitored for a mean of 6 d/wk (n=10) lost a mean of 11.6% of body weight, compared to those who self-monitored a mean of 3 d/wk (n=12) who lost 2.8 +/- 4.1% body weight, corresponding to an effect size of 1.5 and seven participants needed per group. However, it was anticipated that the differences in self-monitoring frequency may be lower. Therefore, authors also compared weight loss between those who self-monitored for 2 d/wk or less (which was the study mean for self-monitoring frequency; -0.4% +/- 3.6% weight loss) and those who self-monitored more than 2 d/wk (-5.8 +/- 5.8%), which corresponded to an effect size of 0.53 and 45 participants per group. Allowing for 20% attrition at 6 months gave a minimum of 17 participants for a large effect size and 108 for a moderate effect size.	81	26
VanWormer et al. (2009)[630,631]	RCT	USA	NR	The sample size was based on 80% statistical power to detect a standardized between-groups difference of 0.4 at 6 months (assuming 20% attrition).	100	52
Vorrink et al. (2016)[50,58]	RCT	Netherlands	NR	Power calculations were based on the raw data of a previous study with similar subjects and protocol. With effect sizes based on this previous study by Effing et al., analysis with the random intercept, random slope linear mixed 'linear up' model calculations were made in software program PASS 11 for 60, 70, and 80 subjects per group. The power for the time-group interaction for these group sizes was ~72%, ~76%, and ~84% respectively (two-sided test, level of statistical significance: p=0.05). 70-80 subjects per group was deemed sufficient to achieve a satisfactory power.	157	52
West et al. (2016)[22]	RCT	USA	NR	NR	58	9
Yoo et al. (2009)[23]	RCT	South Korea	NR	NR	111	13

NR = not reported; RCT = randomized controlled trial

Table C-5. Obesity and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity (BMI or weight in kg)	Rural Population
Arbillaga-Etxarri et al. (2018)[52]	Overweight/obese older adults with COPD.	69	15	BMI 28	No
Bennett et al. (2018)[18,72,73]	Obese adults in primary care who owned a cellphone and willingness to send/receive 3-9 text messages per week.	51	68	BMI 36	Yes largely rural. Piedmont Health patients are predominantly racial/ethnic minority (70%); impoverished (96% are <200% of the federal poverty level); and either uninsured (45%) or hold public insurance (32% Medicaid/ State Children's Health Insurance Program).
Biddle et al. (2015)[57]	Young obese adults at risk of type 2 diabetes.	32.8	68.5	BMI 34.6	No
Cadmus-Bertram et al. (2015)[19,20]	Inactive postmenopausal overweight/obese women who were regular internet users, owned a computer/tablet, and could exercise safely.	60	100	BMI 29	No
Carr et al. (2013)[31]	Obese/overweight sedentary adult workers.	45	90	BMI 32	No
Chen et al. (2017)[56,615]	Obese adolescents (90% Chinese American) who owned a mobile phone and had access to a computer with internet access.	15	45	BMI 28	No
Cho et al. (2018)[62]	Obese/overweight adults with habitual snoring or witnessed sleep apnea but not using CPAP or similar device.	43	11	BMI 28	No
Creel et al. (2016)[45]	Obese adults enrolled soon after bariatric surgery and could walk without a walker or cane.	43	84	BMI 48 (before bariatric surgery)	No
Dorough et al. (2014)[126]	Obese/overweight adults with prehypertension without major chronic diseases.	54	70	BMI 32	No
Edney et al. (2020)[53-55]	Adult facebook users who owned a smartphone and were not exercising at least 150 minutes/week.	41	74	BMI 30	No
Ferrante et al. (2018)[48]	Older obese/overweight African-American breast cancer survivors with home internet access via computer or smartphone.	62	100	BMI 37	No
Fukuoka et al. (2019)[33-38]	Sedentary adult women with the intent to be physically active, and access to a home telephone or mobile phone.	52	100	BMI 30	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity (BMI or weight in kg)	Rural Population
Goulis et al. (2004)[51]	Obese/overweight adults who could operate regular phones and "electronic microdevices".	44	88	BMI 38	No
Green et al. (2014)[24]	Obese/overweight adults in primary care with hypertension and 10%-25% Framingham risk of cardiovascular disease.	57	42	BMI 34	No
Haggerty et al. (2017)[49]	Older obese women who survived endometrial cancer with access to either wireless internet or a smartphone.	62	100	BMI 39	No
Jakicic et al. (2016)[30]	Young overweight or obese adults with texting-equipped cell phones and internet access.	30.9	71	BMI 31.2	No
Jospe et al. (2017)[622]	Overweight/obese adults with regular internet access.	44	62	BMI 33	No
Katzmarzyk et al. (2011)[17]	Obese/overweight adults in a rural/semi-rural area.	51	84	BMI 31	Yes (lower Mississippi delta). A mix of rural and semi-rural populations, ethnically diverse (38% African American), and 26% of the population living in poverty.
Kim et al. (2019)[61]	Obese/overweight adults with sleep apnea who could use a mobile app and a wearable device.	42	15	BMI 29	No
Mameli et al. (2018)[29]	Obese Caucasian children.	13	37	BMI 29	No
Martin et al. (2015)[625]	Obese/overweight adults able to engage in moderate physical activity.	44	83	BMI 30	No
Mendelson et al. (2014)[47]	Adults with sleep apnea and BMI <40 with a high cardiovascular risk score or history of cardiovascular disease.	63	17	BMI 17	No
Nakata et al. (2019)[628]	Obese/overweight adults with at least one component of metabolic syndrome with personal computers and internet access.	56	62	BMI 28	No
Nanchahal et al. (2009)[626,627]	Obese/overweight adults in the general population.	49	72	BMI 33	No
Nicklas et al. (2014)[43]	Older sedentary obese adults.	70	76	BMI 33	No
Oh et al. (2015)[27,28]	Obese/overweight adults with metabolic syndrome.	49	50	BMI 29	No
Peyer et al. (2017)[59]	Obese adults in central Iowa (95% Caucasian).	39	60	BMI 37	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity (BMI or weight in kg)	Rural Population
Polzien et al. (2007)[614]	Sedentary obese/overweight adults with a computer and Internet access and deomnstrated adequate computer skills.	41	98	BMI 33	No
Richardson et al. (2016)[39]	Overweight/obese adult male veterans with at least one comorbidity (diabetes, coronary artery disease, high cholesterol, hypertension, or obesity) who could comfortably walk one block, and be insufficiently active at baseline.	56	0	BMI 36	No
Rogers et al. (2016)[616]	Sedentary adults with morbid obesity with a compatible smartphone and access to the internet with a computer.	40	80	BMI 40	No
Ross et al. (2016)[46]	Obese/overweight adults with access to a computer and W-Fi at home.	51	85	Weight 89kg	No
Ruotsalainen et al. (2015)[16]	Overweight/obese adolescents with no other health issues.	15	70	BMI 28	Yes, northern Finland, a rural area, according to the authors
Shapiro et al. (2012)[629]	Overweight/obese adults with regular internet access and owned a cellphone with text messaging and ability to perform moderate physical activity.	42	65	BMI 32	No
Shin et al. (2017)[41,42]	Overweight/obese young male university students who were smartphone users.	28	0	BMI 30	No
Shuger et al. (2011)[44]	Sedentary obese/overweight adults with access to the internet.	47	82	BMI 33	No
Smith et al. (2019)[21]	Older obese adults who had undergone total knee arthroplasty in the last 10-18 months with medical clearance to participate in exercise.	64	56	BMI 37	No
Spring et al. (2017)[617,618]	Obese adults willing to self-monitor (on smartphone or paper) and wear an accelerometer daily for 6 months.	39	84	BMI 35	No
Thomas et al. (2017)[32]	Overweight/obese adults with access to an Internet enabled computer and basic computer skills.	55	77	BMI 34	No
Turner-McGrievy et al. (2017)[25,26]	Obese/overweight adults interested in losing weight who owned either an iphone or an Android phone.	48	83	BMI 33	No
VanWormer et al. (2009)[630,631]	Obese employees of HealthPartners willing to perform daily self-weighing.	46	91	BMI 38	No
Vorrink et al. (2016)[50,58]	Overweight/obese older adults with COPD without another comorbidity that influences physical activity.	63	50	BMI 27	No
West et al. (2016)[22]	Young college students in a health class on Facebook with internet access and/or mobile phone.	22	81	BMI 24	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity (BMI or weight in kg)	Rural Population
Yoo et al. (2009)[23]	Obese/overweight adults with type 2 diabetes and hypertension for at least a year.	58	41	BMI 26	No

NR = not reported

Table C-6. Obesity and PGHD: treatment details

Study	Treatment 1	Other Treatment Groups
Arbillaga-Etxarri et al. (2018)[52]	Usual care: Usual standardized pharmacological and/or non-pharmacological treatment for COPD, including pulmonary rehabilitation, at the discretion of their physician and without any intervention by the research team.	Urban Training: 6 components: 1) At baseline, a respiratory physiotherapist adequately trained in behavioral strategies used motivational interviewing techniques, integrated with a stage-matched approach, for a maximum of 1 h. The interview was centered on empathy, reflective listening and affirmation, and addressed patients' resistance (personal difficulties, barriers and limitations) to eliciting behavioral change. Information on the remaining components of the intervention was provided during this interview. During the follow-up period, the physiotherapist administered up to four phone calls lasting 5–10 min to maintain motivation, depending on patients' self-efficacy and stage of change. 2) Participants received a dossier containing various maps of Urban Training walking trails, previously validated, according to their mobility options and preferences. Concisely, trails of different intensities (low, moderate or high, combining urban elements of varying intensity (stairs, ramps and types of surfacing)) were available in several walkable public spaces (boulevards, beaches and parks) of the five municipalities. The physiotherapist provided a complete explanation of trails, characteristics and instructed patients to train following the FITT (frequency, intensity, time and type) principle. Each patient was advised to start with a trail of intensity appropriate to his/her baseline dyspnea and 6-min walking distance (6MWD), and instructed how to increase progressively the volume (number of walks per day on the same trail) and/or the intensity of the trails during the following 12 months according to their symptoms and motivation. In all cases, the instructions were to walk at least one trail per day ≥5 days per week, at a pace reaching a dyspnea Borg scale score of 4–6) Patients were provided with both a pedometer (OnStep 50 Geonaute) and a personalized calendar to monitor their physical activity and maintain motivation. 4) Patients received the same ELF information brochure as the usual-care group and the link to the project website (www.entrenament-urba.cat/). They were requested to provide a personal cell phone number where they would receive phone text messages every 2 weeks with educational or motivational messages. 5) Once per month during the follow-up period, patients could join a walking group for walking a trail accompanied by an experienced physical activity trainer. 6) Patients were given a phone number to contact the physiotherapists for any questions during follow-up. Of note, the Urban Training intervention was proposed as a supplement to the physical activities of daily life and in no case as a substitute activity.

Study	Treatment 1	Other Treatment Groups
Bennett et al. (2018)[18,72,73]	Usual care: Received care from their primary care providers, self-help materials, list of community resources for healthy eating, physical activity, weight management, received quarterly with health tips newsletter.	Intervention: Based on social cognitive theory, with 6 components: 1 tailored behavioral goals using a pedometer (Yamax SW 650-651 Digi Walker), 2 self-monitoring of goals via phone and text messages, 3 daily self weighing using a cellular-connected scale (specific device NR but the manufacturer was BodyTrace) 4 skills training materials 5 18 weight loss counseling phone calls and 6 brief primary care provided weight loss counseling at medical visits.
Biddle et al. (2015)[57]	Control: Received an information leaflet for education.	Intervention: Attended a 3 hour educational workshop, given a Gruve accelerometer (Gruve Technologies) to monitor physical activity and sedentary behavior, and received a follow-up call 6 weeks after the workshop.
Cadmus-Bertram et al. (2015)[19,20]	Pedometer: Received a "basic" pedometer (device NR) and printed materials with tips for increasing steps. Asked to perform 150 minutes a week of moderate to vigorous physical activity, and 10,000 steps/day.	Web-based tracking group: Received an accelerometer (Fitbit One) and could view their own data and temporal patterns. Instructed how to use the software. Received a follow-up call at 4 weeks to evaluate progress and refine goals. Asked to perform 150 minutes a week of moderate to vigorous physical activity, and 10,000 steps/day.
Carr et al. (2013)[31]	Waitlist: Asked to maintain their current behaviors for 12 weeks.	Intervention: Encouraged to reduce sedentary time. 3 primary components: access at their worksite to an internet-connected portable pedal machine (Magne Trainer, 3D Innovations), 2) access to a motivational website (Walker Tracker) to receive tips and reminders and 3) a pedometer to use with the website (Omron HJ-150). Asked to keep the pedal machine connected to their work computer during working hours. Software provides real time feedback on pedal time, distance, speed, and caloric expenditure. No other interaction occurred between research staff and patients.
Chen et al. (2017)[56,615]	Control: Given a pedometer (Omron HJ-105) and a food and activity diary and asked to use them both for 3 months. Provided access to an online program with 8 modules related to general adolescent health, diet nutrition among other topics. Each module was less than 10 minutes.	Mobile phone: Provided access to an online program with 8 modules related to general adolescent health, diet nutrition among other topics. Each module was less than 10 minutes. Received an accelerometer (Fitbit Flex) and downloaded an app and a link to iStart Smart for Teens program on their mobile phone. They received in-person demonstrations on how to access the Fitbit data and the program/website. They could check real time statistics on their activity levels and also track dietary intake via the fitbit mobile app. They were encouraged to wear it every day and use the app every day. Weekly text messages served as reminders. They were encouraged to share their fitbit data with their primary care providers, but this sharing did not occur automatically.

Study	Treatment 1	Other Treatment Groups	
Cho et al. (2018)[62]	Control: Educated to modify their lifestyle to lose weight during the following 4 weeks. At two weeks into the study, patients met with physicians and the physicians could use self-reported lifestyle and diet reports to set goals.	App: Educated to modify their lifestyle to lose weight during the following 4 weeks using a smartphone app. The app had two modules: diet and physical activity. In the diet module, the participant recorded daily dietary intake. The app showed food intake allowances remaining for the day. The physical activity module gathered physical activity (daily steps) from a wrist-worn activity tracker (Misfit Shine). At two weeks into the study, app users' data was shown to the physician for discussion. Physician counseling set individualized goals for diet and physical activity.	
Creel et al. (2016)[45]	Standard care: Bariatric surgery only.	Pedometer: Bariatric surgery plus pedometer (HJ-113 by Omron) (provided before surgery and after) and a one-page sheet on using the pedometer to increase physical activity. Asked to record whether they wore the device each day, and their daily steps. Their records were collected but no continuous feedback was provided to patients.	Pedometer plus Counseling: Bariatric surgery plus pedometer (HJ-113 by Omron) (provided before surgery and after) and tailored counseling and goals from a medical professional.
Dorough et al. (2014)[126]	DASH 2 wellness only: Received eating plan guide, recommended low sodium diet, counseling from registered dietician, walking and weight program, digital weight scale (Tanita Digital Weight Scale), pedometer (Accusplit 120 XL).	DASH 2 wellness plus: Received all the interventions of the DASH 2 wellness group, and in addition received an Omron Automatic BP monitor (HEM-712C). They were instructed about how to use the BP monitor, how to complete weekly tracking forms online, and weekly electronic visits over 10 weeks from their assigned project director, who supported the patient in lifestyle changes, information on the eating plan, and in an exercise walking program.	
Edney et al. (2020)[53-55]	Waitlist: No intervention.	Self-monitoring: Received a wrist-worn pedometer (Zencro TW 64S) and measured daily steps, and had a daily goal as seen in an app called Active Team. Weekly email summarizing their daily step counts (which had been manually entered by them) and a reminder to log their daily steps onto an app. The Self-monitoring group had no access to the gamified feature or social features of the app.	Socially enhanced Self-monitoring: Also received the pedometer (Zencro TW 64S) and access to the app included all of its tracking features, social Facebook features, and game features. Daily reminders and encouragement. Link to facebook to their friends who were also using the app, game featured competition for the most steps/day and weekly step count on a leaderboard, and to compete in mini challenges.
Ferrante et al. (2018)[48]	Waitlist: No intervention.	Intervention: Received access to a website SparkPeople.com which has several weight loss educational materials, and also received one 30 minute educational session about the SparkPeople website if requested, and were instructed to self-monitor their diet at least weekly and their physical activity using the device (they received an accelerometer (either Fitbit Charge or Fitbit Alta) and study staff downloaded data from the Fitbase research platform weekly to collect data on physical activity and fitbit adherence). They also received weekly text messages for the first 3 months to log onto SparkPeople.	

Study	Treatment 1	Other Treatment Groups	
Fukuoka et al. (2019)[33-38]	Control: Asked to use an accelerometer (Omron active style Pro HJA-350IT) but did not receive any physical activity intervention or any app. They could view both daily steps and intensity (measured as METs).	Regular: Brief face to face physical activity intervention including short and long term goals, education about duration and intensity of brisk walking, identifying barriers to increasing physical activity, identifying social support, relapse prevention, education about healthy diet and weight maintenance, and physical activity safety. The plan was revisited and/or revised at the 1.5 and 3 months visits. They also received an accelerometer (Omron active style Pro HJA-350IT) and mPED app. The app provided a daily message or video clip, and a daily diary of physical activity. The message and clips contained reinforcements of the content of the brief in person educational session. If no activity was entered into the diary on the app, a reminder text message was sent to record daily steps and type/intensity of exercise. The regular group only had access to the app for the first 3 months of the study.	Plus: Same as the regular group, except that the Plus group used the app for 9 months instead of the 3 months for the regular group.
Goulis et al. (2004)[51]	Control: Outpatient obesity treatment program based on diet and physical activity guidelines.	Intervention: Same obesity treatment program, and in addition they received a BP monitor (Card Guard CG800BP) and an electronic scale (by Rowenta, specific device NR). Three times a week for 6 months they transmitted their BP and weight and answer two lifestyle questions, via a regular telephone. These transmitted data were not given to physicians or study staff and were not used for any clinical decisions. Monthly meetings with both the attending physician and the dietician.	
Green et al. (2014)[24]	Usual care: Told that their BP was high and encouraged to follow-up with their physician. Also received a copy of their lab results including their 10-year CVD risk.	Web dietician: Received the same information as the usual care group, and in addition received a scale (device NR), a pedometer, (device NR), and a home BP monitor (Omron 711-DLX) and trained to use those 3 devices. They met with a dietician and asked to complete a questionnaire about dietary habits, physical activity, prior attempts to lose weight, tobacco/alcohol use, and a standard 3-day food diary. Received education about the DASH diet from the dietician, and created a five-component action plan. They communicated via the web throughout the study.	
Haggerty et al. (2017)[49]	Enhanced usual care: Given handouts on each of 14 topics (1-3 pages each) on healthy eating, exercise, behavioral eating strategies. No goals provided.	Texting: Received a conventional scale (Eat Smart Precision Digital Scale). Received 3-5 texts a day and provided their weight once weekly via text message. Texts provided feedback, support, prompting, quiz items, and behavioral strategies. Encouraged to meet the same goals as those in the telemedicine group and had access to a website www.MyFitnessPal.com and encouraged to record their food and activity levels on paper or on the website.	Telemedicine: Phone counseling sessions with a psychology doctoral student or medical student (15-20 minutes each) weekly for 16 weeks and then biweekly for weeks 18-24. Received a Withings WiFi scale which transmitted weight through a smartphone to a website. Received a behavioral weight loss manual. Recorded their dietary and physical activity using www.myfitnesspal.com. Numerical goals for calories and physical activity.

Study	Treatment 1	Other Treatment Groups	
Jakicic et al. (2016)[30]	Standard intervention: Weekly group sessions for education about weight loss for the first 6 months, then monthly for months 7 to 24. During this latter phase, 10-minute phone contact once per month with study staff, and weekly text messages. Reported their daily food intake on a study website. Non-supervised moderate to vigorous physical activity was monitored by subjects weekly in a diary that was returned to study staff weekly during the first 6 months, and staff provided feedback on these diaries. For months 7-24, patients reported daily physical activity on the study website.	Enhanced intervention: Weekly group sessions for education about weight loss for the first 6 months, then monthly for months 7 to 24. During this latter phase, 10-minute phone contact once per month with study staff, and weekly text messages. Patients were given an accelerometer (FIT Core by BodyMedia) and could view their activity levels daily. Patients were not required to enter their good or activity data into the study website, but web-based software from the manufacturer made their activity data viewable, and they could enter their food intake into the website.	
Jospe et al. (2017)[622]	No support: Chose one of 3 diet options (Mediterranean, Paleo, intermittent fasting) and chose one of 2 exercise options (30 minutes moderate intensity 5 days/week, or vigorous	Brief support: Chose diet and exercise options (same options as control group). Monthly weigh-in and 5-10 minute conversation with research staff to assess progress and brainstorm solutions.	Daily weighing: Chose diet and exercise options (same options as control group). Asked to weigh themselves daily (scale NR) and text their weight to study staff or enter into an online database. Monthly emails for encouragement.

Study	Treatment 1	Other Treatment Groups	
	exercise for 5-15 minutes 3 times per week). No other intervention.	Diet Monitoring App: Chose diet and exercise options (same options as control group). Asked to track their diet using the MyFitnessPal app or website. Nutrient goals chosen, and asked to track dietary intake every day for the first month, and 1 week every month for the next 11 months.	Biochemical hunger training: Chose diet and exercise options (same options as control group). Every time they wanted to eat for the first 2 weeks, they were asked to test their capillary blood glucose by portable glucometer (Freestyle Optium Glucose Meter, Abbott Diabetes Care). If the reading was less than their individualized maximum, they could eat, and if not they were asked to retest in one hour. Blood glucose monitoring was optional for the rest of the trial. Asked to complete a hunger booklet (every meal for the first month, and 1 week/month for the rest of the year) in which they reported perceived intensity of hunger before and after every eating occasion, and recorded whether their hunger was stomach hunger or mouth hunger or heart hunger and record brief details of food consumed. During the first month, they visited the clinic twice to ensure understanding of the hunger monitoring process.
Katzmarzyk et al. (2011)[17]	Education: Received a brochure detailing the importance of physical activity for maintaining health, physical activity guidelines, and strategies for increasing physical activity.	Education+pedometer: Received the same brochure, and also received a pedometer (Yamax Digi Walker SW 200) and instructions on its use, and recorded their daily steps on a log sheet.	
Kim et al. (2019)[61]	Control: Conventional care for lifestyle modification, verbal advice from clinician to lose weight.	App only: Used an app called MyHealthKeeper, which collected automatic data on step counts (using the person's mobile phone, internal accelerometers of their phones NR) and patients' manually entered data on weight, food intake, sleep hours, and subjective daily stress. Clinicians viewed the data and gave weekly feedback.	App+wearable: Used the app, and also received a wearable activity monitor (Samsung Charm). Study did not report whether the wearable device provided any additional data that was not already being captured by the mobile phones of the App only group.

Study	Treatment 1	Other Treatment Groups
Mameli et al. (2018)[29]	Control: Encouraged to practice moderate to vigorous physical activity an hour a day, minimize screen time to <2 hours/day, and follow the Mediterranean diet.	Experimental: Same prescriptions for activity and diet and screen time, but also given a wristband accelerometer (E3, Empatica, Italy) and an app to go with it. The wristband measures not only activity but also heart rate, galvanic skin response, and cutaneous temperature. They were asked to wear it all day at least 5 days a week. Data were uploaded automatically at bedtime to the manufacturer website, and data made available to study staff. The associated app (MeTeDa srl, Italy) allows real time recording of food consumption. The study dietician checked that this was entered regularly. Study staff used all the data to develop personalized lifestyle programs. Weekly feedback via text message, addressing diet compliance, sedentary time, physical activity level, and gave goals. Each patient received 12 text messages.
Martin et al. (2015)[625]	Health education control: Received health information via text messages or emails to their smartphone (stress management, healthy eating, exercise, sleep hygiene. The number of text messages was made similar between the two groups by matching participants.	SmartLoss: Prescribed a diet consistent with the American Heart Association guideline, guidance on gradually increasing physical activity. Patients were shown a graph of their weight loss if they adhered to the calories prescriptions. They were also instructed to weigh themselves daily on a provided scale (Wellness Connected Wireless Precision Scale UC-324THX, A&D Engineering); this scale automatically and wirelessly transmitted the data to their counselor. They were loaned a Blackberry smartphone to see their weight data over time. They were also loaned a pedometer (Wellness Connected Wireless Activity Monitor XL-20, A&D Engineering); this device also wirelessly transmitted data to their counselor. They were instructed to wear the pedometer at all times, and counselors sent feedback to the participant via the smartphone at least once a week.
Mendelson et al. (2014)[47]	Standard: Fitted with a nasal mask and given an auto-titrating machine. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was transferred from their machines (adherence, mask leak, residual respiratory events). After 4 months of treatment, data were downloaded from the machine, and patients saw their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.	Telemedicine: Patients assigned to telemedicine were oriented to CPAP, fitted with a nasal mask, and given an auto-titrating machine. Patients received a smartphone with an application designed to transmit clinical information. The patients transmitted self-measured morning and evening BP (3-day measurements using the Omron 705CP), CPAP adherence, and subjective sleepiness weekly through a questionnaire-based application. Quality of life questionnaires were transmitted monthly. Patients received daily pictograms with diet and physical-activity related messages on their smartphones. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was reviewed. After 4 months of treatment, patients consulted their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.

Study	Treatment 1	Other Treatment Groups
Nakata et al. (2019)[628]	Control: Standard weight loss program including changes in diet and exercise, textbooks, notebooks, group based support sessions during weeks 1 2 3 4 6 8 10 and 12. Next 2 years had no intervention.	Web support: Received the standard weight loss intervention that was given to control patients, and also they were given a scale (Tanita BC-569) and an activity monitor (Kenz Lifecorder) and received weight-based weight loss maintenance over the 2 years after the standard intervention. Instructed to measure weight daily and wear the activity monitor during waking hours. Their uploaded (at least once a month) their weight and activity data and could view graphs of their weights and step counts. Personal goals set individually based on consultation with study staff. Feedback messages involved weight and activity and some concerns about diet.
Nanchahal et al. (2009)[626,627]	Usual care: Received the NICE quick reference guidelines on obesity from the primary care providers, and asked control patients to contact their physicians to received usual weight management care. They were also given the British Heart Foundation pamphlet "So you want to lose weight...for good".	Intervention: 14 sessions with an advisor (each was 30 minutes) detailing weight loss strategies of behavioral change, healthier eating, exercise, goal setting. A weight management software package (www.perfect-diet-trakcer.com) to record and monitor progress and keep session notes. They were also given handouts for each of the 14 sessions, including a tailored motivational booklet to encourage more physical activity and a book of walks in the local area. Patients received one of two pedometers: Yamax digiwalker DW701 if BMI <35, or a New Lifestyles NL-800 for BMI 35+. Study did not report whether steps/day were recorded or used to inform educational sessions.
Nicklas et al. (2014)[43]	DIET + EX: Prescribed low calorie diet and supervised exercise, and 2 meals/day were provided. Asked to eat only what was provided or approved from the breakfast menu, and keep a daily consumption log. Body weight measured weekly. Supervised treadmill walking 4 days/week under the direction of an exercise physiologist.	DIET + EX + SRI: In addition to all of the interventions administered to the first group, this group received an accelerometer (Lifecorder Plus by Suzuken) and asked to wear it daily for the 10 months of the study (5 months intervention and 5 months follow-up). Accelerometer data was viewable by patients and also by study stuff as a basis for feedback.
Oh et al. (2015)[27,28]	Control: Received a scale (NR specific device) and a pedometer (NR specific device), body weight journal, asked to record daily weigh and waist size at least 3x/week, asked to record daily walking.	Intervention: Received a mobile phone, body composition monitor (InBody IH-U070B by Biospace and a pedometer (specific device NR). Asked to measure weight and body composition 3x/week and the mobile phone transmitted their data to the central server. Pedometer data were entered manually into the mobile phone, and transmitted to the central server. Study staff could access these data and influenced health consultations.

Study	Treatment 1	Other Treatment Groups	
Peyer et al. (2017)[59]	Guided weight loss: Weekly meetings with a health coach lasting one hour each. Provided a booklet on diet and weight loss strategies and encouraged to make self-directed changes in lifestyle.	Physical activity monitor: Received a SenseWear armband (Jawbone, San Francisco) and instructions on use of its connected online system. Encouraged to use it daily and view real-time estimates of caloric expenditure, minutes of moderate and vigorous physical activity, and steps per day. Also encouraged to enter dietary intake into the online system and view reports. Weekly contact with coaches addressed technical issues with the online system, not on substantive weight loss advice.	Combined: Received both of the other two groups' interventions.
Polzien et al. (2007)[614]	Standard: 7 in-person individualized weight loss counseling sessions, held 1/week for the first month, twice during month 2, and once during month 3. Content involved eating and exercise behaviors for weight loss. Paper diaries to self-monitor eating and exercise.	Intermittent Tech: Received all of the components given to the Standard group, and in addition received a wearable body monitor (SenseWear, BodyMedia) for measuring energy expenditure, internet monitoring of energy intake, and feedback on energy balance. They were encouraged to wear the armband, upload its energy expenditure data, and log energy intake manually on the internet. Study staff reviewed these data before the in-person visits. The intermitted group only used the armband during weeks 1 5 and 9 of the 12 weeks, and they used paper diaries for the other weeks.	Continuous Tech: Same as the intermittent group except that they used the armband for all 12 weeks of the intervention period.
Richardson et al. (2016)[39]	Time-based walking goals: Received 5 sessions of one-on-one face-to-face nutritional counseling delivered by a dietician, and encouraged to walk at a comfortable pace. Encouraged to set time-based walking goals. Each one on one sessions involved discussion of the amount of walking done in the previous time period, and new walking goals set. Encouraged to increase their time goal by 10-15 minutes after each session.	Simple pedometer: Received 5 sessions of one-on-one face-to-face nutritional counseling delivered by a dietician, and encouraged to walk at a comfortable pace. Received a pedometer (Yamax Digiwalker SW 200). Instructed to wear the pedometer all day every day through the 6 month intervention, and manually log step counts in a paper diary. These diaries were reviewed during the phone sessions and goals were modified. Encouraged to increase daily walking target by 10% to 25% after each session.	Enhanced pedometer: Received 5 sessions of one-on-one face-to-face nutritional counseling delivered by a dietician, and encouraged to walk at a comfortable pace. Received a pedometer (SportBrain iStep X) which can store minute by minute step counts for about two weeks. Could upload steps data to their home computer and then to sportbrain.com. On the website they could view graphs of their progress and motivational messages and feedback. These online motivational messages were not provided to either of the other two groups. Encouragement to engage in an online community to read and post messages about their walking program. Dietician reviewed these data in preparation for each one-on-one sessions, and new walking goals were set. Encouraged to increase daily walking target by 10% to 25% after each session.

Study	Treatment 1	Other Treatment Groups	
Rogers et al. (2016)[616]	Standard behavioral weight loss: Weekly group meetings 30-45 minutes each, addressing barriers associated with physical activity and dietary intake. Weight measured at each weekly meeting. Self-monitoring encouraged via a paper diary and study staff provided feedback on it weekly.	Technology-based system: Received the same paper material as the standard group, but had no meetings. Provided with the BodyMedia FIT System (Jawbone), which includes a wearable device on the upper arm to monitor physical activity and energy expenditure. Data could be viewed on a portable digital display. They used their computers to upload activity monitor data to the web. At study start, there was a single meeting to instruct patients on the technology and review goals (dietary, physical activity). Phone call once a month in which patients discussed their data with study staff.	Enhanced technology-based system: Same technology, but it was transferred to the person's mobile phone on an app, to "increase the capacity for temporal proximity of self-monitoring and feedback on key weight loss behaviors".
Ross et al. (2016)[46]	Standard treatment (ST): Given a calorie reference book, pedometer (NR device), body weight scale if they did not have one at home, booklets to track 24 weeks' worth of caloric intake, physical activity, and weight each day. No other contact with study staff.	Technology (TECH): Given an accelerometer (FitBit Zip), a smart scale (Fitbit Aria), and asked to track caloric intake using at the fitbit app or website. The scale synched automatically with the weights and displayed graphics to the patient (continuous feedback). Patients asked to track their caloric intake and other data daily.	Technology + Phone: Received the same interventions as the TECH group, and also received phone calls from study staff (14 calls total). Call content involved the data on intake and calories and weight.
Ruotsalainen et al. (2015)[16]	Control: Counseling from the school nurse regarding health problems, "if they so required it".	Facebook: Received lifestyle counseling for obesity via Facebook for promoting physical activity and reducing sedentary time. There were 2 facebook groups: one for the adolescents and one for their parents. A physio-therapist was the tutor within the group, and a dietician visited the facebook group once a week. Content involved informational support (6 themes), social support, behavioral management skills, menu, and tailored exercise program. Public and private discussions with adolescents and parents were held weekly.	Facebook plus self-monitoring: Same as the facebook group, and in addition, adolescents received an accelerometer (Polar Electro, Kempele Oy) on their wrist. Instructed on how to use the device to monitor their daily physical activity, including intensity of activity, and showing individual steps/day and total energy expenditure in calories. The study did not report whether the physiotherapist or dietician had access to the patients' activity or eating data during the course of the study.

Study	Treatment 1	Other Treatment Groups	
Shapiro et al. (2012)[629]	Control: Received monthly e-newsletters with diet and physical activity advice (non-tailored), and had access to a website with health tips, recipes, food and physical activity logs, a personal weight chart, and USDA recommendations for a balanced diet.	Intervention: Received the same monthly e-newsletters, and were given a pedometer (Yamax Digi Walker CW 600), patients texted their step counts to study staff, every day, and their weight weekly, and received feedback text and multimedia cell messages 4 times a day for a year. Those who did not already have a scale were given a digital scale (model number not reported).	
Shin et al. (2017)[41,42]	Education: One to one education on diet and exercise from a trained nurse for 5 minutes.	Smartcare: Received an accelerometer (FitLife, Suwon). Associated smartphone app to monitor physical activity. No financial incentives.	Smartcare plus financial incentives: Same as the smartcare group except they could earn money for achieving daily physical activity goals.
Shuger et al. (2011)[44]	Standard care: Received a self-directed weight loss manual.	Group based behavioral weight loss education: Received a self-directed weight loss manual, participated in 14 group weight loss sessions from a facilitator, plus weekly weigh-in (all 14 were in the first 4 months. During the next 5 months, there were 6 one-on-one telephone counseling sessions for continued support	Armband alone: Received a self-directed weight loss manual, plus the SenseWear armband, and access to a personalized web account. The SenseWear watch provided real time feedback on energy expenditure, minutes spent in physical activity, and steps per day. Data were uploaded by patients from the armband to a website. Patients also recorded daily energy intake and body weight on the web account. They were asked to wear the armband 16 hours a day every day.
		Combined intervention: Received all interventions given to both the Group based behavioral weight loss education group and the Armband alone group.	
Smith et al. (2019)[21]	Exercise: 16 week home based exercise program, including tailored resistance and aerobic training, tailored to each individual. Weekly phone call with the study's exercise physiologist. To monitor compliance, assess progress, and modify the exercise prescription as needed.	Exercise plus fitness tracker: Same exercise program as the other group, and also received a fitness tracker (either the Fitbit Flex on the wrist, or the Fitbit One which is clipped to a necklace or waist or other clothing). This estimates and provides feedback on steps taken, stairs climbed, and estimates caloric expenditure.	

Study	Treatment 1	Other Treatment Groups	
Spring et al. (2017)[617,618]	Self: Attended one 60-minute educational sessions and their weight loss target and a calorie counting book and 6 months of paper self-monitoring diaries. Also received a set of DVDs called group Lifestyle Balance which presented 12 mock group treatment sessions. No additional in person sessions or coaching calls.	Standard: Attended weekly 90 minute group sessions led by a psychologist or exercise physiologist and focused on nutrition, physical activity, and behavior change strategies, which was followed by 30 minute group walking, and received a calorie counting book and paper diary. Received 10-15 minute calls from a trained coach to review self-monitoring and goal achievement. Competition between the four 8-person Standard groups for financial incentives for weight loss.	Tech: Attended weekly 90 minute group sessions led by a psychologist or exercise physiologist and focused on nutrition, physical activity, and behavior change strategies, which was followed by 30 minute group walking. Lent an Android smartphone with the ENGAGED app and also lent an accelerometer (SHIMMER). The app contains the Calorie King to count calories. Data were transmitted to their coach. Individuals could also view the other team members physical activity levels, post messages to the team, or messages other individuals. Received 2-4 personalized text messages per week for 6 months. Received 10-15 minute calls from a trained coach to review self-monitoring and goal achievement. Competition between the four 8-person Tech groups for financial incentives for weight loss.
Thomas et al. (2017)[32]	Control: Online newsletters available weekly for 3 months, then biweekly for 3 months, then monthly for 6 months. These contained general educational information on the benefits of losing weight and healthy eating and physical activity.	Weight Watchers Online: 12 months of access to the website, resources for tracking daily food intake and weekly tracking of body weight via a mobile app. They recorded food and beverage consumption using the app. All data were manual-entry.	Weight Watchers Online plus Active Link: Received all of the resources of the Weight Watchers Online group, and in addition received an Activelink accelerometer to wear on the waist or chest or wrist, with accompanying software to track physical activity. Also provided physical activity goals and encouraging messages as they monitored progress.

Study	Treatment 1	Other Treatment Groups
Turner-McGrievy et al. (2017)[25,26]	Diet App: Received the Calorie Counter App, and instructions. Told to record all foods and beverages consumed each day to track energy intake. Received a calorie goal, and encouraged to self-monitor their exercise using one of a list of free pedometer apps (all but 3 patients; study did not report the pedometer app choices) or they were given a pedometer (PedUSA CW Step Pedometer) (3 patients).	Bite: Received a BiteCounter device and how to use it. Wristwatch that detects when you are taking a bite (it is currently an app available on iphone or android). Tracked their data using software. Instructed to wear the device on their dominant hand and use the non-dominant hand to drink with. Received a bites per day goal, similar to the calorie goal of the other group. The BiteCounter also has a built in pedometer to track steps per day and they were encouraged to use this feature.
VanWormer et al. (2009)[630,631]	Waitlist: No intervention.	Intervention: Received a program manual with 10 lessons involving calorie reduction, increased physical activity (goal 10,000 steps/day), stress management, cognitive reframing, problem solving. Also included behavioral change tools such as a food/activity diary, weekly weight chart, action planner. They received up to 10 counseling calls from either a registered dietician or a health educator, occurring every other week for 20 weeks, and lasting about 15 minutes. These calls addressed the program lessons, reviewed progress on weight and activity and eating behavior. They also received a pedometer (DigiWalker SW 200 by Yamax) and their step/day were recorded manually in the diary. They also received a combined home scale and tele-monitoring device (Thin Link from www.cardio.com) which provided visual and auditory feedback on weight and prompted them to answer 3 or 4 basic questions each day (e.g., Are you choosing healthy foods). Think Link transmitted their data to the study staff directly. The system alerted counselor of the person gained 4+ pounds or failed to self-weigh at least once within a 3 day period.

Study	Treatment 1	Other Treatment Groups
Vorrink et al. (2016)[50,58]	Usual care: All participants continued to receive usual care according to the guidelines of the Dutch College of General Practitioners.	Intervention: 2 components: 1) a smartphone application and 2) a website for the physiotherapists. The application showed physical activity in real time in quantitative and qualitative form, measured by the accelerometer embedded in the smartphone (HTC desire A8181; HTC, Taoyuan, Taiwan). Subjects were persuaded to achieve their personalized physical activity goal by automated persuasive messages and an emoticon. The physiotherapists could monitor their patients via the (secure) website, which showed a detailed view of individual patients. The physiotherapist was able to adjust each patient's physical activity goal and send group or individual text messages. No automated adjustments of the physical activity goal were performed. Physiotherapists received individual face-to-face (and written) instruction on the functionalities of the website. Patients received a smartphone, a phone/ internet contract and an individual face-to-face (and written) instruction on the use of the smartphone and the application. They were instructed to wear the smartphone in a pouch on their belt and use it as their usual phone. They were to transfer the SIM card from their personal mobile phone into the study smartphone. For the first week of the study, physical activity goals were not set, and subjects were instructed to perform their day-to-day activities as usual. Afterwards, initial personal physical activity goals were calculated using data from this baseline week as follows. 1) Average steps per day +20% as daily step goal; 2) daily, the number of steps during the 30 most intensive minutes were counted and averaged into a value for a week. This latter value +20% was set as the minimum required number of steps in 1 min to account for an intensive minute of physical activity; and 3) 30 intensive minutes performed per day, according to the Dutch healthy exercise norm. After this initial physical activity goal setting, physiotherapists were given responsibility for physical activity goal adjustment. They could reduce or increase the amount and intensity of the physical activity goal via the website, based on the individual ability of their patient over time.
West et al. (2016)[22]	Control: Received HPV vaccination awareness education, with separate private Facebook group, to build social support for completing the full vaccination series.. Matched in duration and contact schedule to the intervention group, but received no weight management content OR monitoring devices.	Healthy Weight intervention: Special weight loss program, weekly electronic newsletters and Facebook postings. Patients were encouraged to weigh themselves daily using the WiFi scale (Fitbit Aria). They were given an accelerometer (Fitbit Zip) which provided personalized real time feedback on steps taken and miles walked and also cumulative personal reports on activity level. Given graded goals to increase steps to at least 10,000 per day. Also education about healthy dietary intake.

Study	Treatment 1	Other Treatment Groups
Yoo et al. (2009)[23]	Control: Visited their clinic according to their routine schedule and received the usual outpatient treatment from physicians.	Intervention: Received a cellular phone (LG SV280), blood glucose monitoring device (Anycheck from Insung) including strips and lancets, BP monitor (Omron T5M) and scale (HD308 from Tanita). The phone sent reminders to measure blood glucose, BP twice a day, and weight once a day. The glucometer sent the reading automatically to the study database. After transmitting their glucose reading, the phone sent messages of encouragement and reminders according to a guideline-based algorithm. These reminders alerted the patient if their BP or glucose were high, and how to avoid high readings in the future. The system also recorded exercise time by asking patients via text about exercise. The system also sent 3 texts a day about healthy diet and exercise methods. Physicians could use the website to track trends in BP or glucose or weight, allowing physicians to send additional personalized messages.

NR = not reported

Table C-7. Obesity and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Arbillaga-Etxarri et al. (2018)[52]	+	+	+	−	+	+	−	+	+	Moderate
Bennett et al. (2018)[18,72,73]	+	?	+	−	+	+	+	−	+	Moderate
Biddle et al. (2015)[57]	+	?	+	−	+	+	−	+	+	Moderate
Cadmus-Bertram et al. (2015)[19,20]	+	+	+	−	?	+	+	−	+	Moderate
Carr et al. (2013)[31]	?	?	−	−	+	+	−	+	+	High
Chen et al. (2017)[56,615]	+	?	+	−	?	+	+	+	+	Moderate

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Cho et al. (2018)[62]	?	?	+	−	+	+	−	−	+	High
Creel et al. (2016)[45]	?	+	+	+	?	+	−	−	+	Moderate
Dorough et al. (2014)[126]	?	?	?	−	?	+	?	?	+	High
Edney et al. (2020)[53-55]	+	+	+	−	+	+	+	−	+	Moderate
Ferrante et al. (2018)[48]	+	+	−	−	?	+	+	−	+	High
Fukuoka et al. (2019)[33-38]	+	+	+	+	+	+	+	−	+	Low
Goulis et al. (2004)[51]	?	?	+	−	?	+	+	−	+	High
Green et al. (2014)[24]	?	?	+	−	+	+	+	−	+	High
Haggerty et al. (2017)[49]	?	+	?	−	?	+	+	−	+	High
Jakicic et al. (2016)[30]	+	+	+	+	+	+	−	+	+	Low
Jospe et al. (2017)[622]	+	+	+	−	+	+	−	+	+	Moderate

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Katzmarzyk et al. (2011)[17]	+	+	+	+	+	+	−	−	+	Moderate
Kim et al. (2019)[61]	?	?	+	+	+	+	−	−	+	High
Mameli et al. (2018)[29]	?	?	+	−	+	+	−	−	+	High
Martin et al. (2015)[625]	?	?	+	−	?	+	+	+	+	Moderate
Mendelson et al. (2014)[47]	?	?	+	−	+	+	−	−	+	High
Nakata et al. (2019)[628]	+	+	+	−	+	+	+	?	+	Moderate
Nanchahal et al. (2009)[626,627]	+	?	+	−	+	+	−	+	+	Moderate
Nicklas et al. (2014)[43]	?	?	+	+	?	+	+	?	+	Moderate
Oh et al. (2015)[27,28]	+	?	+	−	+	+	−	−	+	High
Peyer et al. (2017)[59]	?	?	−	+	?	+	+	−	+	High
Polzien et al. (2007)[614]	?	?	+	+	?	+	+	−	+	Moderate

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Richardson et al. (2016)[39]	?	?	+	+	+	+	−	−	+	High
Rogers et al. (2016)[616]	?	?	+	+	?	+	+	−	+	Moderate
Ross et al. (2016)[46]	+	?	−	+	+	+	+	?	+	Moderate
Ruotsalainen et al. (2015)[16]	?	+	−	+	?	+	+	−	+	Moderate
Shapiro et al. (2012)[629]	?	+	+	−	?	+	−	−	+	High
Shin et al. (2017)[41,42]	+	+	+	+	+	+	+	?	+	Low
Shuger et al. (2011)[44]	+	+	+	+	+	+	−	−	+	Moderate
Smith et al. (2019)[21]	?	?	+	+	?	+	+	−	+	Moderate
Spring et al. (2017)[617,618]	+	+	+	−	+	+	+	+	+	Low
Thomas et al. (2017)[32]	+	+	+	+	+	+	+	+	+	Low
Turner-McGrievy et al. (2017)[25,26]	+	?	+	+	?	+	−	+	+	Moderate

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
VanWormer et al. (2009)[630,631]	?	?	+	−	+	+	+	−	+	High
Vorrink et al. (2016)[50,58]	+	?	−	−	+	+	−	+	+	High
West et al. (2016)[22]	+	+	+	−	?	+	+	−	+	High
Yoo et al. (2009)[23]	?	?	+	−	?	+	+	−	+	High

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-8. Obesity and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Arbillaga-Etxarri et al. (2018)[52]	Guiding Question 2	Device usage	Urban Training: 90% used the pedometers	Not calculated
Bennett et al. (2018)[18,72,73]	Guiding Question 2	Device usage	Intervention: 36% weighed themselves at least 5 days a week on average	Not calculated
Cadmus-Bertram et al. (2015)[19,20]	Guiding Question 2	Device usage	Web-based tracking group: 96% reported wearing it at least 4 days a week, and this was corroborated by the Fitbit data which a median of 106 out of 112 possible days. 72% viewed the fitbit data at least once a day. The median participant logged 10 hours a day of wear time.	Not calculated
Carr et al. (2013)[31]	Guiding Question 2	Device usage	Intervention: Participants pedalled an average of 37.7% (22.6 days) of all days they had access to the pedal machine (excluding weekends). Participants pedalled an average of 31.1 +31.6 min/day on the days they used the pedal machines and an average of 16.1+17.2 min/pedalling bout.	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Carr et al. (2013)[31]	Guiding Question 2	Device usage	Intervention: Patients wore the FitBit ZIp an average of 14 hours a day	Not calculated
Chen et al. (2017)[56,615]	Guiding Question 2	Device usage	Mobile phone: Seventeen of 23 mobile phone-based intervention participants (75%) reported accessing the Fitbit program via the app or website several times a week, and five adolescents (20%) accessed the program once a week.	Not calculated
Chen et al. (2017)[56,615]	Guiding Question 2	Device usage	Mobile phone: The majority of adolescents (91%) shared their Fitbit data with their primary care providers.	Not calculated
Edney et al. (2020)[53-55]	Guiding Question 2	Device usage	Self-monitoring: Used the app an average of 120 times over 100 days. Specifically used the step calendar an average of 36 times. % of users who accessed it daily was 64% at day 7, 36% at day 49, and 21% at day 91.	Not calculated
Edney et al. (2020)[53-55]	Guiding Question 2	Device usage	Socially enhanced self-monitoring: Used the app an average of 239 times over 100 days. Specifically used the step calendar an average of 44 times. % of users who accessed it daily was 68% at day 7, 44% at day 49, and 31% at day 91.	Not calculated
Ferrante et al. (2018)[48]	Guiding Question 2	Device usage	Intervention: Adherence with Fitbit was high, with mean of 5–6 days of use per week throughout the study period with no difference between groups. Participants universally felt it was a “wonderful tool.” Eight participants needed extra training with the following: (a) using the computer dashboard; (b) syncing data; (c) updating the Fitbit app; and (d) connecting the tracker to a new phone.	Not calculated
Fukuoka et al. (2019)[33-38]	Guiding Question 2	Device usage	Plus: Adherence to daily messages or video clips or daily physical activity diary using the app was 86% across the two app groups. The plus group adhered to daily physical activity 68% during months 3-9.	Not calculated
Jakicic et al. (2016)[30]	Guiding Question 2	Device usage	Of the 237 participants randomized to enhanced intervention, 191 participants received the wearable device that was a component of the intervention starting after month 6 and wore the device for 1 day or longer (median days worn, 170.0 [25th - 75th percentile 68.0 - 347]). On days that the device was worn, the median wear time was 241.1 min/d (25th-75th percentile 99.3-579.1). Additional user experience with this technology is reported in eTable2 in Supplement 2 of the article.	Not calculated
Jospe et al. (2017)[622]	Guiding Question 2	Device usage	Daily weighing: Weighed themselves an average of 186/365 days (51%)	Not calculated
Jospe et al. (2017)[622]	Guiding Question 2	Device usage	Diet Monitoring App: Entered food intake on 57 of 98 days (58%)	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Kim et al. (2019)[61]	Guiding Question 2	Device usage	App only: Physical activity data collected on an average of 49.96% of days. Sleep data collected on an average of 32.45% of days. Weight data collected on an average of 31.87% of days.	Not calculated
Kim et al. (2019)[61]	Guiding Question 2	Device usage	App+wearable: Physical activity data collected on an average of 49.82% of days. Sleep data collected on an average of 32.01% of days. Weight data collected on an average of 32.82% of days.	Not calculated
Mameli et al. (2018)[29]	Guiding Question 2	Device usage	Experimental: The average app use was 24 of 30 days and the average wristband use was 11 of 30 days	Not calculated
Martin et al. (2015)[625]	Guiding Question 2	Device usage	SmartLoss: "Weight data were successfully wirelessly transmitted to counselors on 66 days (79% of the days in the study). Activity/step data were wirelessly transmitted on 54 days (64% of the days in the study). In case of transmission failure, participants occasionally self-reported body weight data and when these data are considered, weight data were received by counselors on 69 days (82% of the days in the study). On average, participants weighed 5.75 times per week.	Not calculated
Nakata et al. (2019)[628]	Guiding Question 2	Device usage	Web support: In the web-support group, the participants uploaded their body weight on a median (first–third quartile) of 75.6% (43.1%–83.4%) of days during the 24-month weight-maintenance phase. More specifically, in months 4–9, 10–15, 16–21, and 22–27, the equivalent proportions were 80.2% (53.9%–92.6%), 81.0% (48.8%–91.0%), 61.5% (31.8%–83.3%), and 71.4% (12.8%–84.2%), respectively. Similarly, the participants in the web-support group uploaded their step count on a median of 69.4% (55.5%–79.8%) of days during the 24-month weight-loss maintenance phase. The equivalent proportions were 68.1% (58.2%–78.9%), 70.7% (61.3%–85.6%), 77.5% (58.5%–86.6%), and 69.4% (29.8%–81.4%) in months 4–9, 10–15, 16–21, and 22–27, respectively.	Not calculated
Nicklas et al. (2014)[43]	Guiding Question 2	Device usage	DIET + EX + SRI: Of the 20 participants who completed the DIET + EX + SRI intervention, 17 (85%) provided accelerometer process data for the entire 10 months; the remaining three stopped providing accelerometry logs at 19, 21, and 31 weeks. Participants reported wearing the accelerometer at least 10 hours/day for an average of 87% of the days and the daily spontaneous physical activity (SPA) goal was met for 81% of the days. The average number of SPA minutes recorded (39 min) was higher than the average SPA goal ($p<0.0001$). The most common reported barriers to full accelerometer compliance (10 hours/ day, every day for 10 months) were: device malfunction/ need for battery change (13%), illness or health reason (9%), forgot to wear (7%), and too busy or time conflict (7%).	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Polzien et al. (2007)[614]	Guiding Question 2	Device usage	Continuous Tech: Average armband time 71 hours/week (42% of the week), and average # of meals per week logged 24	Not calculated
Polzien et al. (2007)[614]	Guiding Question 2	Device usage	Intermittent Tech: Average armband time 64 hours/week (38% of the week), and average # of meals per week logged 18	Not calculated
Rogers et al. (2016)[616]	Guiding Question 2	Device usage	Enhanced technology-based system: Wore the Jawbone device an average of 106 days out of 182 (58%). Average of 9.5 hours/day.	Not calculated
Rogers et al. (2016)[616]	Guiding Question 2	Device usage	Technology-based system: Wore the Jawbone device an average of 118 days out of 182 (64%). Average of 11 hours/day.	Not calculated
Ross et al. (2016)[46]	Guiding Question 2	Device usage	Technology (TECH): Wore the Fitbit an average of 137/180 days (76%). Used the scale an average of 102/180 days (56%).	Not calculated
Ross et al. (2016)[46]	Guiding Question 2	Device usage	Technology + Phone: Wore the Fitbit an average of 154/180 days (86%). Used the scale an average of 132/180 days (73%).	Not calculated
Shapiro et al. (2012)[629]	Guiding Question 2	Device usage	Intervention: 33% response to text message about weight, attempt #2	Not calculated
Shapiro et al. (2012)[629]	Guiding Question 2	Device usage	Intervention: 47% response to text message about pedometer steps, attempt #2	Not calculated
Shapiro et al. (2012)[629]	Guiding Question 2	Device usage	Intervention: 51% response to text message about pedometer steps, daily message #1	Not calculated
Shapiro et al. (2012)[629]	Guiding Question 2	Device usage	Intervention: 55% response to text message about weight, daily message #1	Not calculated
Shapiro et al. (2012)[629]	Guiding Question 2	Device usage	Intervention: 60% response to knowledge-testing text messages	Not calculated
Shin et al. (2017)[41,42]	Guiding Question 2	Device usage	Smartcare plus financial incentives: For the two smartcare groups, when interviewed 1 months after the 3 month study, only 4/66 said they maintained their weight loss and used the activity tracker. Two participants reported that switching to usual smartphone applications without incentive had caused them to cease using the device. Two participants changed their activity tracking to other activity trackers (such as smartwatches or smartphone pedometers).	Not calculated
Thomas et al. (2017)[32]	Guiding Question 2	Device usage	Weight Watchers Online plus Active Link: The active link group rated their frequency wearing the ActiveLink device on a 0-5 scale where 0=never, 1=1-3 times/month, 2=once/week, 3=several days per week, 4=daily, and 5=several times a day. The average was 3.1 at 3 months and 2.3 at one year. They also rated their frequency of accessing ActiveLink resources on the web using the same scale: average 2.1 at 3 months and 1.4 at one year.	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Thomas et al. (2017)[32]	Guiding Question 2	Device usage	Weight Watchers Online plus Active Link: The two WW groups rated their frequency of app engagement on a 0-5 scale where 0-never, 1=1-3 times/month, 2=once/week, 3=several days per week, 4=daily, and 5=several times a day. Their engagement was low for tracking diet with the app (average 1.1 at 3 months and 0.5 at one year), exercise with the app (average 0.6 at 3 months and 0.,4 at one year), and weight with the app (0.7 at 3 months and 0.4 at one year).	Not calculated
Turner-McGrievy et al. (2017)[25,26]	Guiding Question 2	Device usage	Bite: The number of days per week on which any dietary tracking occurred averaged 3.6 days for the Bite group. The number of eating occasions tracked per day averaged 1.9 for the bite group.	Not calculated
Turner-McGrievy et al. (2017)[25,26]	Guiding Question 2	Device usage	Diet App: The number of days per week on which any dietary tracking occurred averaged 4.1 days for the App group. The number of eating occasions tracked per day averaged 1.9 for the app group.	Not calculated
VanWormer et al. (2009)[630,631]	Guiding Question 2	Device usage	Intervention: Participants self-weighed on 50% of days during the 6 months	Not calculated
Vorrink et al. (2016)[50,58]	Guiding Question 2	Device usage	Intervention: The app was used an average of 89% of the study days (authors did not report if this meant the device usage or other aspect of the intervention)	Not calculated
West et al. (2016)[22]	Guiding Question 2	Device usage	Healthy Weight intervention: The percentage of students who used the Fitbit at least one day a week ranged from 24% during the week of spring break to 83% during week 2 of the study. They used fitbit to record step counts for an average of 23.7 days during the 63-day study period. The percentage of students who used the Aria WifiScale at least one day a week ranged from 38% during week 1 to 76% during week 2 of the study. They used the scale to record weight for an average of 14.1 days during the 63-day study period.	Not calculated
Yoo et al. (2009)[23]	Guiding Question 2	Device usage	Intervention: Participants in the intervention group sent blood glucose recordings an average of 1.84 times per day (compliance rate 92.2%) and blood pressure an average of 1.72 times per day (compliance rate 86.0%). Body weight measurements were sent an average of 0.87 times per day (compliance rate 87.4%).	Not calculated
Arbillaga-Etxarri et al. (2018)[52]	Guiding Question 2	Ease of use	Urban Training: Satisfaction with pedometers (0-10 scale) was an average of 9 on a scale from 1 to 10. Satisfaction with text messages was 9.4.	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Cadmus-Bertram et al. (2015)[19,20]	Guiding Question 2	Ease of use	Web-based tracking group: 100% liked the fitbit one and 76% would recommend to a friend. 56% preferred a clip-on, 29% preferred wrist-worn, and 24% had no preference. 96% rated the fitbit one as either somewhat or very helpful for increasing physical activity. By contrast, in the control gorup that received a basic pedometer (specific device NR), only 32% found it somewhat or very helpful.	Not calculated
Carr et al. (2013)[31]	Guiding Question 2	Ease of use	Intervention: When asked to rate the helpfulness of each intervention feature for reducing their sedentary time (Likert scale 1-5 where 5 means extremely helpful), participants rated the pedal machine biofeedback display a median of 5 (IQR 4 to 5) and wearing the pedometer a median of 5 (IQR 4 to 5).	Not calculated
Chen et al. (2017)[56,615]	Guiding Question 2	Ease of use	Mobile phone: All the adolescents (100%) who used the Fitbit Flex reported that the device was helpful in tracking physical activity level, and approximately 88% of adolescents found the device helpful in tracking physical activity food intake. All adolescents (100%) in the intervention group would recommend this program to others.	Not calculated
Edney et al. (2020)[53-55]	Guiding Question 2	Ease of use	Socially enhanced self-monitoring: 70% liked the self-monitoring feature, and 61% liked the leaderboard feature.	Not calculated
Edney et al. (2020)[53-55]	Guiding Question 2	Ease of use	Socially enhanced self-monitoring: Average usability score of 66 (scale range not reported, but >80 is considered high quality and 68 is considered average, so this is "Average"). 14% rated it as high quality, 30% said average quality, 28% said below average, and 28% said low quality.	Not calculated
Ferrante et al. (2018)[48]	Guiding Question 2	Ease of use	Intervention: Patients rated FitBit ease of use on a 1-4 scale where 1 is "Very difficult" and 4 is "Very easy". Average 3.46 for months 1-3, 3.76 for months 4-6, 3.75 for months 7-9, and 3.41 for months 10-12.	Not calculated
Green et al. (2014)[24]	Guiding Question 2	Ease of use	Web dietician: Intervention participants were asked to rate the parts of the intervention they thought were most useful in managing their health since enrolling in the study. More than 60% reported that measuring BP at home, sharing BP measures with providers, e-mailing or talking with a dietitian, and getting a “list of medications and things I should do” were extremely helpful.	Not calculated
Kim et al. (2019)[61]	Guiding Question 2	Ease of use	App only: Satisfaction scores range from 3.1 to 4.2 out of 7	Not calculated
Kim et al. (2019)[61]	Guiding Question 2	Ease of use	App+wearable: Satisfaction scores range from 3.7 to 4.7 out of 7	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Oh et al. (2015)[27,28]	Guiding Question 2	Ease of use	Intervention: The convenience of device usage, satisfaction with the SmartCare center service, and overall satisfaction of the remote monitoring were determined at weeks 12 and 24, based on a 5-point scale where 5 corresponded to highly satisfied. At week 12, the convenience of device usage, satisfaction with the SmartCare center service, and overall satisfaction of the remote monitoring were found to be 3.54 (SD: 1.02), 4.08 (SD: 0.86), and 3.93 (SD: 0.86), respectively. At week 24, the satisfaction with the convenience of device usage was 3.52 (SD: 0.99), SmartCare center service was 4.14 (SD: 0.88), and overall satisfaction of the remote monitoring was 3.92 (SD: 0.85).	Not calculated
Smith et al. (2019)[21]	Guiding Question 2	Ease of use	Exercise plus fitness tracker: 67% (16/24) reported a positive impact of the device, enjoyed the feedback on their activity levels, and were interested in the technology. The other 33% negatively viewed the device and did not think the information was useful, and reported forgetting to wear the device frequently, and not liking technology in general.	Not calculated
West et al. (2016)[22]	Guiding Question 2	Ease of use	Healthy Weight intervention: 83% (24/29) rated the Fitbit as helpful (response scale not reported). 66% (19 of 29) rated the Aria scale as helpful (response scale not reported).	Not calculated
Cadmus-Bertram et al. (2015)[19,20]	Guiding Question 2	Technical problems	Web-based tracking group: 20% had computer issues, 20% had technical difficulty with the Fitbit One, 16% had issues with a lost or broken Fitbit One.	Not calculated
Edney et al. (2020)[53-55]	Guiding Question 2	Technical problems	Socially enhanced self-monitoring: 25% reported intermittent technical areas, typically related to logging in or saving step data.	Not calculated
Ferrante et al. (2018)[48]	Guiding Question 2	Technical problems	Intervention: Problems included broken wristbands (replacement Fitbits were given) and incompatibility with certain smartphones (the one participant was able to use her computer to sync data).	Not calculated
Katzmarzyk et al. (2011)[17]	Guiding Question 2	Technical problems	Education+pedometer: 9 of 63 patients eligible for the trial (14%) did not provide enough baseline accelerometer data due to either equipment malfunction or have less than 3 days of 10 hours wear time (study did not report % equipment malfunctions).	Not calculated
Mameli et al. (2018)[29]	Guiding Question 2	Technical problems	Experimental: The only technical difficulty reported was the inability to download the app for 3 of 16 patients.	Not calculated
Nakata et al. (2019)[628]	Guiding Question 2	Technical problems	Web support: During phase 2, some technical issues were raised about the activity monitor (n=14), network (n=8), personal computer (n=6), SD: card (n=5), USB cable (n=2), and weight scale (n=2). Consultation and/or exchange of devices were made as necessary.	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
West et al. (2016)[22]	Guiding Question 2	Technical problems	Healthy Weight intervention: 26 of 29 participants initialized the Fitbit (did not report reasons for noninitialization). 26 of 29 initialized the Aria Wifi scale (2 said problems with campus internet explained their noninitialization).	Not calculated
Arbillaga-Etxarri et al. (2018)[52]	Health	Adverse events: any	Urban Training: 52 wks (N=) 77% (99/128) Usual care: 52 wks (N=) 73% (103/142)	p=0.363 between groups
Bennett et al. (2018)[18,72,73]	Health	Adverse events: any	Intervention: 9 of 170	No between-group statistics reported
Bennett et al. (2018)[18,72,73]	Health	Adverse events: any	Usual care: 10 of 167	No between-group statistics reported
Fukuoka et al. (2019)[33-38]	Health	Adverse events: # of emergency room or urgent care visits	Control: 8 events in 69 people	No between-group statistics reported
Fukuoka et al. (2019)[33-38]	Health	Adverse events: # of emergency room or urgent care visits	Regular and plus combined: 19 events in 140 people	No between-group statistics reported
Fukuoka et al. (2019)[33-38]	Health	Adverse events: % of patients who experienced significant medical/mental problems that restricted walking at least 7 consecutive days	First 3 months: Control: 6/69 (9%) Next 6 months: Control: 21/69 (26.9%)	Between groups p=0.05 at 3 months favoring the control group, and p=0.71 for the next 6 months
Fukuoka et al. (2019)[33-38]	Health	Adverse events: % of patients who experienced significant medical/mental problems that restricted walking at least 7 consecutive days	First 3 months: Regular and plus combined: 29/140 (20%) Next 6 months: Regular and plus combined: 47/138 (34%)	Between groups p=0.05 at 3 months favoring the control group, and p=0.71 for the next 6 months
Fukuoka et al. (2019)[33-38]	Health	Adverse events: number of events	First 3 months: Control: 35 Next 6 months: Control: 49	Between groups p=0.23 at 3 months and p=0.46 for the next 6 months
Fukuoka et al. (2019)[33-38]	Health	Adverse events: number of events	First 3 months: Regular and plus combined: 89 Next 6 months: Regular and plus combined: 110	Between groups p=0.23 at 3 months and p=0.46 for the next 6 months

Study	Outcome Category	Outcome	Results	Statistical Significance
Fukuoka et al. (2019)[33-38]	Health	Adverse events requiring hospitalization	Control: 5 events in 69 people	No between-group statistics reported
Fukuoka et al. (2019)[33-38]	Health	Adverse events requiring hospitalization	Regular and plus combined: 2 events in 140 people	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of depression alerts (This was triggered when the patient had a score of 13 or greater on the CES-D questionnaire)	Enhanced intervention: 32	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of depression alerts (This was triggered when the patient had a score of 13 or greater on the CES-D questionnaire)	Standard intervention: 19	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of non-serious event alerts (Study did not report when this was triggered)	Enhanced intervention: 147	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of non-serious event alerts (Study did not report when this was triggered)	Standard intervention: 121	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of serious event alerts (This was triggered when the patient had an overnight hospitalization or surgery)	Enhanced intervention: 11	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of serious event alerts (This was triggered when the patient had an overnight hospitalization or surgery)	Standard intervention: 6	No between-group statistics reported

Study	Outcome Category	Outcome	Results	Statistical Significance
Jakicic et al. (2016)[30]	Health	Adverse events: number of rapid weight loss alerts (This was triggered when the patient experienced 6% or greater weight loss during a 4 weeks period)	Enhanced intervention: 18	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of rapid weight loss alerts (This was triggered when the patient experienced 6% or greater weight loss during a 4 weeks period)	Standard intervention: 25	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of resting blood pressure alerts (This was triggered when resting SPB ≥140 or resting DBP ≥90)	Enhanced intervention: 13	No between-group statistics reported
Jakicic et al. (2016)[30]	Health	Adverse events: number of resting blood pressure alerts (This was triggered when resting SPB ≥140 or resting DBP ≥90)	Standard intervention: 7	No between-group statistics reported
Oh et al. (2015)[27,28]	Health	Adverse events: nonserious	Control: 23 of 210	No between-group statistics reported
Oh et al. (2015)[27,28]	Health	Adverse events: nonserious	Intervention: 27 of 212	No between-group statistics reported
Oh et al. (2015)[27,28]	Health	Adverse events: serious events	Control: 5 of 210	No between-group statistics reported
Oh et al. (2015)[27,28]	Health	Adverse events: serious events	Intervention: 3 of 212	No between-group statistics reported

Study	Outcome Category	Outcome	Results	Statistical Significance
Arbillaga-Etxarri et al. (2018)[52]	Health	Quality of life as measured by the Clinical COPD Questionnaire	Urban Training: Baseline (N=88): 1 (SD: 1) Urban Training: 52 wks (N=88): 1 (SD: 1) Usual care: Baseline (N=145): 1 (SD: 1) Usual care: 52 wks (N=145): 1 (SD: 1)	NS all comparisons
Arbillaga-Etxarri et al. (2018)[52]	Health	Quality of life as measured by the COPD Assessment Test	Urban Training: Baseline (N=88): 12 (SD: 7) Urban Training: 52 wks (N=88): 11 (SD: 7) Usual care: Baseline (N=145): 12 (SD: 8) Usual care: 52 wks (N=145): 11 (SD: 7)	NS all comparisons
Chen et al. (2017)[56,615]	Health	Quality of life as measured by the Pediatric quality of life scale: Physical component (Higher scores are better)	Control: Baseline (N=17): 78.13 (SD: 11.89) Control: 13 wks (N=17): 77.53 (SD: 13.44) Control: 26 wks (N=17): 80.08 (SD: 14.49) Mobile phone: Baseline (N=23): 78.99 (SD: 14.79) Mobile phone: 13 wks (N=23): 78.11 (SD: 15.23) Mobile phone: 26 wks (N=23): 84.69 (SD: 13.99)	NS all comparisons
Chen et al. (2017)[56,615]	Health	Quality of life as measured by the Pediatric quality of life scale: Psychosocial component (Higher scores are better)	Control: Baseline (N=17): 78.13 (SD: 11.89) Control: 13 wks (N=17): 77.53 (SD: 13.44) Control: 26 wks (N=17): 80.07 (SD: 14.49) Mobile phone: Baseline (N=23): 81.2 (SD: 10.3) Mobile phone: 13 wks (N=23): 84.79 (SD: 10.3) Mobile phone: 26 wks (N=23): 89.18 (SD: 8.75)	NS all comparisons
Edney et al. (2020)[53-55]	Health	Quality of life as measured by the SF-12 mental component (Higher scores are better)	Self-monitoring: Baseline (N=160): 47.8 (SD: 8.9) Self-monitoring: 13 wks (N=143): 47.4 (SD: 11.1) Self-monitoring: 39 wks (N=141): 48.5 (SD: 9.4) Socially enhanced self-monitoring: Baseline (N=141): 47.6 (SD: 8.7) Socially enhanced self-monitoring: 13 wks (N=129): 49.1 (SD: 9.4) Socially enhanced self-monitoring: 39 wks (N=120): 48.8 (SD: 9.2) Waitlist: Baseline (N=143): 47.3 (SD: 9) Waitlist: 13 wks (N=139): 47.9 (SD: 10.4) Waitlist: 39 wks (N=122): 47.1 (SD: 11)	NS group x time interaction p=0.61 at 13 weeks and p=0.68 at 39 weeks

Study	Outcome Category	Outcome	Results	Statistical Significance
Edney et al. (2020)[53-55]	Health	Quality of life as measured by the SF-12 physical component (Higher scores are better)	Self-monitoring: Baseline (N=160): 45.9 (SD: 9) Self-monitoring: 13 wks (N=143): 46.6 (SD: 8.9) Self-monitoring: 39 wks (N=141): 46.8 (SD: 9.1) Socially enhanced self-monitoring: Baseline (N=141): 46.5 (SD: 8.5) Socially enhanced self-monitoring: 13 wks (N=129): 47.2 (SD: 8.5) Socially enhanced self-monitoring: 39 wks (N=120): 48.5 (SD: 7.6) Waitlist: Baseline (N=143): 46.3 (SD: 7.5) Waitlist: 13 wks (N=139): 46 (SD: 8.5) Waitlist: 39 wks (N=122): 46.8 (SD: 8.7)	NS group x time interaction p=0.92 at 13 weeks and p=0.85 at 39 weeks
Ferrante et al. (2018)[48]	Health	Quality of life as measure by scale range 1-7 (unclear why the reported outcomes are over 100) (Lower scores are better)	Intervention: Baseline (N=18): 109.78 (SD: 39.26) Intervention: 13 wks (N=18) change: -5.44 (SD: 18.11) Intervention: 26 wks (N=18) change: -9.44 (SD: 16.97) Waitlist: Baseline (N=17): 108.76 (DS 36.17) Waitlist: 13 wks (N=17) change: -4.35 (SD: 16.69) Waitlist: 26 wks (N=17) change: -4.65 (SD: 24.21)	p=0.854 between groups at 13 weeks and p=0.50 between groups at 26 weeks
Fukuoka et al. (2019)[33-38]	Health	Quality of life as measured by the SF-12 mental component (Higher scores are better)	Control: Baseline (N=69): 47.5 (SD: 9) Control: 13 wks (N=68): NR Control: 39 wks (N=68): NR Plus: Baseline (N=70): 49.1 (SD: 9.2) Plus: 13 wks (N=67): NR Plus: 39 wks (N=68): NR Regular: Baseline (N=71): 49 (SD: 8.8) Regular: 13 wks (N=69): NR Regular: 39 wks (N=69): NR	NS all comparisons

Study	Outcome Category	Outcome	Results	Statistical Significance
Fukuoka et al. (2019)[33-38]	Health	Quality of life as measured by the SF-12 physical component (Higher scores are better)	Control: Baseline (N=69): 51.5 (SD: 6.8) Control: 13 wks (N=68): NR Control: 39 wks (N=68): NR Plus: Baseline (N=70): 50.9 (SD: 6.1) Plus: 13 wks (N=67): NR Plus: 39 wks (N=68): NR Regular: Baseline (N=71): 52.1 (SD: 5.6) Regular: 13 wks (N=69): NR Regular: 39 wks (N=69): NR	At 13 weeks, a combined group (regular or plus) had better results than the control group (p=0.04), but p=0.60 at 39 weeks. Regular vs. plus p=0.64
Goulis et al. (2004)[51]	Health	Quality of life as measured by the mental component scale of the SF-36 (Higher scores are better)	Control: Baseline (N=77): 41.9 (SD: 13.1) Intervention: Baseline (N=45): 45.9 (SD: 11.1) Control: 26 wks (N=77): 43.3 (SD: 10.1) Intervention: 26 wks (N=45): 42.4 (SD: 12.4)	NS all comparisons
Goulis et al. (2004)[51]	Health	Quality of life as measured by the Obesity Assessment Survey (Lower scores are better)	Control: Baseline (N=77): 51.2 (SD: 12) Intervention: Baseline (N=45): 57.8 (SD: 14.6) Control: 26 wks (N=77): 50.8 (SD: 16.5) Intervention: 26 wks (N=45): 45.9 (SD: 19.6)	NS all comparisons
Goulis et al. (2004)[51]	Health	Quality of life as measured by the physical component scale of the SF-36 (Higher scores are better)	Control: Baseline (N=77): 43 (SD: 10.5) Intervention: Baseline (N=45): 44 (SD: 10.2) Control: 26 wks (N=77): 38.7 (SD: 15.2) Intervention: 26 wks (N=45): 40.7 (SD: 17.5)	NS all comparisons
Goulis et al. (2004)[51]	Health	Quality of life as measured by the VAS of the EuroQOL 5D (Higher scores are better)	Control: Baseline (N=77): 72.7 (SD: 21.8) Intervention: Baseline (N=45): 66.2 (SD: 20.4) Control: 26 wks (N=77): 72.1 (SD: 16.3) Intervention: 26 wks (N=45): 70.7 (SD: 15)	NS all comparisons
Green et al. (2014)[24]	Health	Quality of life as measured by Obesity and Weight Loss Quality o Life (Higher scores are better)	Usual care: 26 wks (N=46): 2.5 (95% CI: -0.4 to 5.3) Web dietician: 26 wks (N=44): 5.5 (95% CI: 2.7 to 8.3)	p=0.14 between groups

Study	Outcome Category	Outcome	Results	Statistical Significance
Haggerty et al. (2017)[49]	Health	Quality of life as measured by the SF-12 physical component (Higher scores are better)	Enhanced usual care: 26 wks (N=10) change: +7.4 (95% CI: 1.8 to 11) Telemedicine: 26 wks (N=11) change: +5.4 (95% CI: 3.8 to 15) Texting: 26 wks (N=11) change: +0.9 (95% CI: -0.7 to 4.8)	p=0.044 comparing texting-with-scale group to telemedicine group, favoring telemedicine. Also the no-device group must have had better quality of life than the texting-with-scale group, since the no-device group's mean improvement was even better than the telemedicine group.
Mendelson et al. (2014)[47]	Health	Quality of life as measured by the undefined "MCS" (likely the mental component score of either SF-36 or SF-12) (Likely higher scores are better)	Standard: Baseline (N=53): 44.8 (SD: 11.1) Standard: 17 wks (N=53): 46.4 (SD: 9.1) Telemedicine: Baseline (N=54): 45.8 (SD: 10.2) Telemedicine: 17 wks (N=54): 47.4 (SD: 10.7)	NS all comparisons
Mendelson et al. (2014)[47]	Health	Quality of life as measured by the undefined "PCS" (likely the physical component score of either SF-36 or SF-12) (Likely higher scores are better)	Standard: Baseline (N=53): 43 (SD: 9.3) Standard: 17 wks (N=53): 45.9 (SD: 8.5) Telemedicine: Baseline (N=54): 41.5 (SD: 9.7) Telemedicine: 17 wks (N=54): 44.6 (SD: 9.4)	NS all comparisons
Richardson et al. (2016)[39]	Health	Quality of life as measured by the SF-12 mental component (Higher scores are better)	Enhanced pedometer: Baseline (N=80): 37.3 (SD: 8.4) Enhanced pedometer: 26 wks (N=61) change: +3 (95% CI: 1.2 to 4.7) Simple pedometer: Baseline (N=78): 38.3 (SD: 9) Simple pedometer: 26 wks (N=60) change: +2.2 (95% CI: 0.4 to 4) Time-based walking goals: Baseline (N=79): 38.2 (SD: 9.2) Time-based walking goals: 26 wks (N=63) change: -1.2 (95% CI: -2.9 to 4.6)	p<0.001 favoring enhanced over time based, p=0.49 enhanced vs. simple, p=0.01 simple vs. time based favoring simple pedometer

Study	Outcome Category	Outcome	Results	Statistical Significance
Richardson et al. (2016)[39]	Health	Quality of life as measured by the SF-12 physical component (Higher scores are better)	Enhanced pedometer: Baseline (N=80): 38.8 (SD: 8.3) Enhanced pedometer: 26 wks (N=61) change: -0.1 (95% CI: -1.4 to 1.3) Simple pedometer: Baseline (N=78): 38.1 (SD: 9.5) Simple pedometer: 26 wks (N=60) change: 0.1 (95% CI: -1.2 to 1.5) Time-based walking goals: Baseline (N=79): 39.9 (SD: 8.6) Time-based walking goals: 26 wks (N=63) change: -0.2 (95% CI: -1.5 to 1.1)	p=0.94 enhanced vs. time based, p=0.82 enhanced vs. simple, p=0.75 simple vs. time based
Smith et al. (2019)[21]	Health	Quality of life as measured by the SF-36 (Higher scores are better)	Study reported that there was no statistically significant difference between groups, and only reported group-combined means.	NS all comparisons
Vorrink et al. (2016)[50,58]	Health	Quality of life as measured by the self administered chronic respiratory questionnaire: Dyspnea	Intervention: Baseline (N=84): 4.84 (SD: 0.15) Intervention: 13 wks (N=84) change: +0.17 (95% CI: -0.45 to 0.38) Intervention: 26 wks (N=84) change: 0.11 (95% CI: -0.14 to 0.35) Intervention: 52 wks (N=84) change: -0.17 (95% CI: -0.44 to 0.09) Usual care: Baseline (N=73): 4.79 (SD: 0.15) Usual care: 13 wks (N=73) change: +0.01 (95% CI: -0.21 to 0.23) Usual care: 26 wks (N=73) change: -0.13 (95% CI: -0.33 to 0.08) Usual care: 52 wks (N=73) change: -0.08 (95% CI: -0.3 to 0.14)	p=0.17 group x time interaction
Vorrink et al. (2016)[50,58]	Health	Quality of life as measured by the self administered chronic respiratory questionnaire: Fatigue	Intervention: Baseline (N=84): 4.35 (SD: 0.1) Intervention: 13 wks (N=84) change: 0.05 (95% CI: -0.15 to 0.26) Intervention: 26 wks (N=84) change: -0.19 (95% CI: -0.39 to 0.01) Intervention: 52 wks (N=84) change: -0.14 (95% CI: -0.35 to 0.07) Usual care: Baseline (N=73): 4.2 (SD: 0.13) Usual care: 13 wks (N=73) change: -0.06 (95% CI: -0.28 to 0.17) Usual care: 26 wks (N=73) change: 0.13 (95% CI: -0.12 to 0.37) Usual care: 52 wks (N=73) change: -0.12 (95% CI: -0.37 to 0.13)	Significant group x time interaction, but authors stated this was likely not due to an intervention difference but rather variability in the data. No single timepoint showed a between group difference.
Arbillaga-Etxarri et al. (2018)[52]	Surrogate	BMI	Urban Training: Baseline (N=88): 28.3 (SD: 4.5) Urban Training: 52 wks (N=88:): 28.5 (SD: 4.5) Usual care: Baseline (N=145): 28.2 (SD: 4.5) Usual care: 52 wks (N=145): 28.2 (SD: 4.5)	NS all comparisons

Study	Outcome Category	Outcome	Results	Statistical Significance
Bennett et al. (2018)[18,72,73]	Surrogate	BMI	Intervention: Baseline (N=176): 35.9 (SD: 4.1) Intervention: 26 wks (N=170) change: -1.4 (95% CI: -1.7 to -1.1) Intervention: 52 wks (N=170) change: -1.4 (95% CI: -1.7 to -1) Usual care: Baseline (N=175): 35.9 (SD: 3.7) Usual care: 26 wks (N=167) change: +0.2 (95% CI: -0.07 to 0.5) Usual care: 52 wks (N=167) change: -0.01 (95% CI: -0.3 to 0.3)	p<0.0001 between groups at both 26 weeks and 52 weeks, favoring intervention
Biddle et al. (2015)[57]	Surrogate	BMI	Control: Baseline (N=93): 34.5 (95% CI: 33.5 to 35.6) Control: 13 wks (N=76) change: -13.2 (95% CI: -38.1 to +11.7) Control: 52 wks (N=67) change: -0.3 (95% CI: -0.92 to 0.31) Intervention: Baseline (N=84): 34.6 (95% CI: 33.6 to 35.6) Intervention: 13 wks (N=70) change: +2.97 (95% CI: -10.5 to +16.4) Intervention: 52 wks (N=60) change: -0.21 (95% CI: -0.83 to +0.4)	p=0.353 between groups at 13 weeks, and p=0.609 between groups at 52 weeks
Cadmus-Bertram et al. (2015)[19,20]	Surrogate	Weight (kg)	Pedometer: Baseline (N=26): 79.3 (SD: 12.2) Pedometer: 16 wks (N=26): 0.01 (SD: 2.3) Web-based tracking group: Baseline (N=25): 82.4 (SD: 14.7) Web-based tracking group: 16 wks (N=25): -0.3 (SD: 2.4)	p=0.61 between groups
Carr et al. (2013)[31]	Surrogate	BMI	Intervention: Baseline (N=23): 31.8 (SD: 5) Intervention: 12 wks (N=23) change :-0.1 (95% CI: -0.3 to 5) Waitlist: Baseline (N=17): 33.2 (SD: 4.5) Waitlist: 12 wks (N=17) change: +0.2 (95% CI: -0.1 to 0.5)	p=0.76 between groups
Chen et al. (2017)[56,615]	Surrogate	BMI	Control: Baseline (N=17): 28.35 (SD: 4.36) Control: 13 wks (N=17): 28.81 (SD: 4.43) Control: 26 wks (N=17): 29.18 (SD: 3.88) Mobile phone: Baseline (N=23): 27.37 (SD: 3.26) Mobile phone: 13 wks (N=23): 26.91 (SD: 3.25) Mobile phone: 26 wks (N=23): 26.93 (SD: 3.43)	p=0.001 group x time interaction favoring intervention

Study	Outcome Category	Outcome	Results	Statistical Significance
Cho et al. (2018)[62]	Surrogate	BMI	App: Baseline (N=24): 28.4 (SD: 3.6) App: 4 wks (N=24): 27.7 (SD: 3.5) Control: Baseline (N=23): 27.3 (SD: 2.4) Control: 4 wks (N=23): 27.1 (SD: 2.4)	Reported as p<0.001 favoring the app group, however ECRI performed the statistical test using reported data and a conservative prepost correlation of 0.75 and found p=0.43.
Creel et al. (2016)[45]	Surrogate	BMI	Pedometer: Baseline BMI (N=52): 48.4 (SD: 9.5) Pedometer: 26 wks Weight (kg) (N=52) change: -38.4 (SD: 2.8) Pedometer plus Counseling: Baseline BMI (N=48): 46.9 (SD: 7.8) Pedometer plus Counseling: 26 wks Weight (kg) (N=48) change: -40 (SD: 2.7) Standard care: Baseline BMI (N=50): 47.6 (SD: 8) Standard care: 26 wks Weight (kg) (N=50) change: -39.5 (SD: 2.5)	NS all comparisons
Dorough et al. (2014)[126]	Surrogate	Weight (lbs)	DASH 2 wellness only: Baseline (N=11): 183 (SD: 32.48) DASH 2 wellness only: 10 wks (N=11) change: -3.23 (SD: 5.66) DASH 2 wellness plus: Baseline (N=12): 200.57 (SD: 40.27) DASH 2 wellness plus: 10 wks (N=12) change: -10.54 (SD: 8.39)	p=0.032 between groups, favoring intervention
Ferrante et al. (2018)[48]	Surrogate	BMI	Intervention: Baseline (N=18): 35.64 (SD: 6.64) Intervention: 13 wks (N=18) change: -0.74 (SD: 0.83) Intervention: 26 wks (N=18) change: -0.74 (SD: 0.99) Waitlist: Baseline (N=17): 37.88 (SD: 7.06) Waitlist: 13 wks (N=17) change: -0.69 (SD: 0.83) Waitlist: 26 wks (N=17) change: -0.91 (SD: 1.39)	p=0.868 between groups at 13 weeks and p=0.692 between groups at 26 weeks
Goulis et al. (2004)[51]	Surrogate	BMI	Control: Baseline (N=77): 37.8 (SD: 7.8) Control: 26 wks (N=77): 37.2 (SD: 8.7) Intervention: Baseline (N=45): 37.6 (SD: 8.39) Intervention: 26 wks (N=45): 33.7 (SD: 5.2)	p=0.06 between groups but the study used last observation carried forward (LOCF) to impute data, which artificially inflates the N, thus actual data likely was NS. Actual 26-week data available for 108 of 122 (88%).

Study	Outcome Category	Outcome	Results	Statistical Significance
Green et al. (2014)[24]	Surrogate	Weight (kg)	Usual care: Baseline (N=50): 99.4 (SD: 17.9) Usual care: 26 wks (N=46) change: -0.5 (95% CI: -1.6 to 0.7) Web dietician: Baseline (N=51): 100.7 (SD: 18.2) Web dietician: 26 wks (N=44) change: -3.7 (95% CI: -4.9 to -2.5)	p<0.001 between groups, favoring intervention
Haggerty et al. (2017)[49]	Surrogate	Weight (kg)	Enhanced usual care: 26 wks (N=10) change: -1.8 (95% CI: -5.2 to -0.5) Telemedicine: 26 wks (N=11) change: -3 (95% CI: -11.5 to -0.1) Texting: 26 wks (N=11) change: -4.4 (95% CI: -7.9 to -1.1)	NS all comparisons
Jakicic et al. (2016)[30]	Surrogate	BMI	Enhanced intervention: Baseline (N=237): 32.3 (95% CI: 31.4 to 33.2) Enhanced intervention: 26 wks (N=NR) change: -2.7 (95% CI: -3.4 to -1.9) Enhanced intervention: 52 wks (N=NR) change: -2.1 (95% CI: -2.9 to -1.4) Enhanced intervention: 78 wks (N=NR) change: -1.9 (95% CI: -2.7 to -1.1) Enhanced intervention: 104 wks (N=181) change: -1.1 (95% CI: -1.9 to -0.3) Standard intervention: Baseline (N=233): 32.4 (95% CI: 31.5 to 33.3) Standard intervention: 26 wks (N=NR) change: -2.9 (95% CI: -3.7 to -2.2) Standard intervention: 52 wks (N=NR) change: -2.8 (95% CI: -3.5 to -2) Standard intervention: 78 wks (N=NR) change: -2.5 (95% CI: -3.3 to -1.7) Standard intervention: 104 wks (N=170) change: -1.8 (95% CI: -2.6 to -1)	Group x time interaction p=0.63 (includes all time points). At 102 weeks, weight iloss (in kg) was greater in the standard intervention group (-5.9 kg, 95% CI: -6.8 to 5) than in the enhanced intervention group (-3.5 kg, 95% CI: -4.5 to -2.6)

Study	Outcome Category	Outcome	Results	Statistical Significance
Jospe et al. (2017)[622]	Surrogate	BMI	Biochemical hunger training: Baseline (N=37): 32.6 (SD: 4.1) Biochemical hunger training: 26 wks (N=36): 31.1 (SD: 4) Biochemical hunger training: 52 wks (N=28): 30.8 (SD: 4.4) Brief support: Baseline (N=48): 33.4 (SD: 4.9) Brief support: 26 wks (N=48): 32.4 (SD: 4.9) Brief support: 52 wks (N=39): 32.1 (SD: 5.5) Daily weighing: Baseline (N=42): 33.1 (SD: 4.4) Daily weighing: 26 wks (N=40): 32.3 (SD: 4.8) Daily weighing: 52 wks (N=36): 32.2 (SD: 4.8) Diet Monitoring App: Baseline (N=38): 32.6 (SD: 3.6) Diet Monitoring App: 26 wks (N=36): 32 (SD: 3.8) Diet Monitoring App: 52 wks (N=32): 31.9 (SD: 4.4) No support: Baseline (N=44): 32 (SD: 4.1) No support: 26 wks (N=44): 30.9 (SD: 4.3) No support: 52 wks (N=36): 30.9 (SD: 4.6)	NS all comparisons
Katzmarzyk et al. (2011)[17]	Surrogate	BMI	Education: Baseline (N=23): 31.6 Education: 1 wk (N=23) change: -0.08 (SD: 0.1) Education+pedometer: Baseline (N=20): 30.8 Education+pedometer: 1 wk (N=20) change: -0.002 (SD: 0.07)	NS all comparisons
Kim et al. (2019)[61]	Surrogate	BMI	App only: Baseline (N=15): 30.8 (SD: 6) App only: 4 wks (N=15): 30.1 (SD: 6.2) App+wearable: Baseline (N=15): 29.1 (SD: 2.8) App+wearable: 4 wks (N=15): 28.7 (SD: 3) Control: Baseline (N=13): 28.7 (SD: 2.8) Control: 4 wks (N=13): 28.6 (SD: 3)	NS all comparisons
Mameli et al. (2018)[29]	Surrogate	BMI	Control: Baseline (N=20): 28.6 (SD: 2.6) Control: 13 wks (N=20) change: -0.04 (95% CI: 0.16 to 0.18 [nonsensical]) Experimental: Baseline (N=23): 29.6 (SD: 3.3) Experimental: 13 wks (N=23) change: -0.03 (95% CI: 0.14 to 0.09 [nonsensical])	p=0.87 between groups

Study	Outcome Category	Outcome	Results	Statistical Significance
Martin et al. (2015)[625]	Surrogate	Weight (kg)	Health education control: Baseline (N=20): 80.6 (SD: 2.91) Health education control: 4 wks (N=19) change: -0.5 (SEM 0.47) Health education control: 8 wks (N=19) change: -0.4 (SEM 0.47) Health education control: 12 wks (N=19) change: -0.6 (SEM 0.46) SmartLoss: Baseline (N=20): 80 (SD: 2.28) SmartLoss: 4 wks (N=19) change: -3.5 (SEM 0.46) SmartLoss: 8 wks (N=19) change: -6.2 (SEM 0.47) SmartLoss: 12 wks (N=19) change: -7.8 (SEM 0.46)	p<0.001 between groups favoring intervention
Mendelson et al. (2014)[47]	Surrogate	BMI	Standard: Baseline (N=53): 30.2 (SD: 5.7) Standard: 17 wks (N=53): 29.9 (SD: 3.5) Telemedicine: Baseline (N=54): 29.6 (SD: 3.9) Telemedicine: 17 wks (N=54): 29.8 (SD: 2)	No between-group statistics reported
Nakata et al. (2019)[628]	Surrogate	BMI	Control: Baseline (N=48): 28.2 (SD: 2.4) Control: 116 wks (N=48) change: -1.97 (95% CI: -2.51 to 1.44) Web support: Baseline (N=47): 28.4 (SD: 3.1) Web support: 116 wks (N=47) change: -1.74 (95% CI: -2.28 to 1.19)	NS all comparisons
Nanchahal et al. (2009)[626,627]	Surrogate	BMI	Intervention: Baseline (N=191): 33.92 (SD: 5.64) Intervention: 26 wks (N=134) change: -0.6 (95% CI: -0.86 to -0.34) Intervention: 52 wks (N=103) change: -0.83 (95% CI: -1.22 to -0.44) Usual care: Baseline (N=190): 33.02 (SD: 5.4) Usual care: 26 wks (N=129) change: -0.36 (95% CI: -0.65 to -0.07) Usual care: 52 wks (N=114) change: -0.48 (95% CI: -0.82 to -0.13)	p=0.22 between groups at 26 weeks and p=0.18 between groups at 52 weeks
Nicklas et al. (2014)[43]	Surrogate	Weight (kg)	DIET + EX: Baseline (N=21): 90 (SD: 9.5) DIET + EX: 22 wks (N=21) change: -6.6 (SE: 0.9) DIET + EX: 44 wks (N=21) change: -5 (SE: 0.9) DIET + EX + SRI: Baseline (N=20): 89 (SD: 12.5) DIET + EX + SRI: 22 wks (N=20) change: -8.8 (SE: 0.7) DIET + EX + SRI: 44 wks (N=20) change: -8.5 (SE: 0.8)	Adjusted p value 0.06 between groups at 22 weeks, and at 44 weeks adjusted p value <0.01 between groups, favoring DIET + EX + SRI over DIET + EX

Study	Outcome Category	Outcome	Results	Statistical Significance
Oh et al. (2015)[27,28]	Surrogate	BMI	Control: Baseline (N=209): 29.4 (SD: 3.39) Control: 12 wks (N=179): 28.59 (SD: 2.84) Control: 24 wks (N=181) change: -0.28 (SD: 1.03) Intervention: Baseline (N=212): 29.42 (SD: 3.53) Intervention: 12 wks (N=196): 28.35 (SD: 3.25) Intervention: 24 wks (N=196) change: -0.83 (SD: 1.31)	p value between groups p<0.001 after adjusting for site and baseline weight, favoring intervention
Peyer et al. (2017)[59]	Surrogate	Weight (kg)	Combined: Baseline (N=29): 114.1 (SD: 24.6) Combined: 8 wks (N=26) change: -4.88 (95% CI: 3.6 to 6.2) Combined: 26 wks (N=17) change: -5.57 (95% CI: 2.9 to 8.2) Guided weight loss: Baseline (N=31): 103.8 (SD: 15.5) Guided weight loss: 8 wks (N=26) change: -3.69 (95% CI: 2.4 to 5) Guided weight loss: 26 wks (N=21) change: -3.94 (95% CI: 2 to 5.9) Physical activity monitor: Baseline (N=29): 111.9 (SD: 20) Physical activity monitor: 8 wks (N=26) change: -4.05 (95% CI: 2.9 to 5.2) Physical activity monitor: 26 wks (N=15) change: -5.2 (95% CI: 2.3 to 8.1)	NS all comparisons
Polzien et al. (2007)[614]	Surrogate	Weight (kg)	Continuous Tech: Baseline (N=19): 86.6 (SD: 9.5) Continuous Tech: 12 wks (N=NR) change: -6.2 (SD: 4) Intermittent Tech: Baseline (N=19): 91 (SD: 8.8) Intermittent Tech: 12 wks (N=NR) change: -3.4 (SD: 3.4) Standard: Baseline (N=19): 89.1 (SD: 9) Standard: 12 wks (N=NR) change: -4.1 (SD: 2.8)	Statistically greater weight loss with continuous technology than intermittent technology. NS other comparisons.
Richardson et al. (2016)[39]	Surrogate	Weight (kg)	Enhanced pedometer: Baseline (N=84): 115.7 (SD: 21.3) Enhanced pedometer: 26 wks (N=61) change: -1.9 (95% CI: -2.7 to -1.1) Simple pedometer: Baseline (N=86): 111.8 (SD: 17.1) Simple pedometer: 26 wks (N=60) change: -0.6 (95% CI: -1.4 to 0.2) Time-based walking goals: Baseline (N=85): 113.8 (SD: 19.5) Time-based walking goals: 26 wks (N=63) change: -0.74 (95% CI: -1.5 to 0.005)	Enhanced pedometer group had greater weight loss than the other two groups (p=0.04 vs. time based, and p=0.02 vs. simple pedometer. p=0.24 simple pedometer vs. time based

Study	Outcome Category	Outcome	Results	Statistical Significance
Rogers et al. (2016)[616]	Surrogate	BMI	Enhanced technology-based system: Baseline (N=13): 39.3 (SD: 0.8) Enhanced technology-based system: 13 wks (N=9): 37.6 (SD: 0.9) Standard behavioral weight loss: Baseline (N=14): 39.5 (SD: 0.7) Standard behavioral weight loss: 13 wks (N=13): 38.3 (SD: 0.9) Technology-based system: Baseline (N=12): 39.7 (SD: 0.8) Technology-based system: 13 wks (N=12): 37.9 (SD: 0.9)	p=0.154 between groups
Ross et al. (2016)[46]	Surrogate	Weight (kg)	Standard treatment (ST): Baseline (N=23): 91.6 (SD: 14.54) Standard treatment (ST): 26 wks (N=23) change: -1.28 (SD: 1.19) Technology (TECH): Baseline (N=25): 89.23 (SD: 15.57) Technology (TECH): 26 wks (N=25) change: -4.04 (SD: 1.37) Technology + Phone: Baseline (N=24): 87.1 (SD: 12.39) Technology + Phone: 26 wks (N=24) change: -6.4 (SD: 1.17)	p=0.035 comparing TECH+PHONE to STD (favoring TECH + PHONE). NS other comparisons.
Ruotsalainen et al. (2015)[16]	Surrogate	BMI	Control: Baseline (N=14): 27 (SD: 3.8) Control: 12 wks (N=14) change: 0 (SD: 0.9) Facebook: Baseline (N=16): 27.5 (SD: 4.2) Facebook: 12 wks (N=16) change: -0.6 (SD: 0.9) Facebook plus self-monitoring: Baseline (N=16): 29.8 (SD: 8) Facebook plus self-monitoring: 12 wks (N=16) change: -0.1 (SD: 0.9)	NS all comparisons
Shapiro et al. (2012)[629]	Surrogate	Weight (lbs)	Control: Baseline (N=NR): 204.9 Control: 52 wks (N=73) change: -2.27 (SD: 9.39) Intervention: Baseline (N=NR): 202 Intervention: 52 wks (N=57) change: -3.64 (SD: 12.01)	p=0.12 for the group x time interaction after adjusting for sex, age, and time
Shin et al. (2017)[41,42]	Surrogate	BMI	Education: Baseline (N=32): 29.7 (SD: 2.2) Education: 12 wks (N=32) change: -0.2 (SD: 0.7) Smartcare: Baseline (N=34): 29.7 (SD: 2.5) Smartcare: 12 wks (N=34) change: -0.5 (SD: 0.8) Smartcare plus financial incentives: Baseline (N=32): 30 (SD: 3.4) Smartcare plus financial incentives: 12 wks (N=32) change: -1 (SD: 1.2)	Smartcare plus financial incentives had greater BMI reduction than education alone (p<0.01) and the Smartcare alone group (p=0.02). NS Smartcare alone vs. control

Study	Outcome Category	Outcome	Results	Statistical Significance
Shuger et al. (2011)[44]	Surrogate	BMI	Standard care: Baseline (N=50): 34.52 (SD: 0.91) Standard care: 17 wks (N=30): 34.12 (SD: 0.93) Standard care: 39 wks (N=26): 34.16 (SD: 0.94) Armband alone: Baseline (N=49): 34.73 (SD: 0.9) Armband alone: 17 wks (N=41): 33.83 (SD: 0.91) Armband alone: 39 wks (N=37): 33.56 (SD: 0.92) Group based behavioral weight loss education: Baseline (N=49): 34.54 (SD: 0.9) Group based behavioral weight loss education: 17 wks (N=32): 34.21 (SD: 0.92) Group based behavioral weight loss education: 39 wks (N=28): 33.84 (SD: 0.92) Combined intervention: Baseline (N=49): 34.39 (SD: 0.91) Combined intervention: 17 wks (N=37): 33.13 (SD: 0.91) Combined intervention: 39 wks (N=32): 32.11 (SD: 0.92)	NS all comparisons
Smith et al. (2019)[21]	Surrogate	BMI	Study reported that there was no statistically significant difference between groups, and only reported group-combined means.	NS all comparisons
Spring et al. (2017)[617,618]	Surrogate	Weight (kg)	Self: Baseline (N=32): 93.5 (SD: 11) Self: 13 wks (N=26) change: -1.8 (95% CI: -3.4 to -0.1) Self: 26 wks (N=26) change: -2.7 (95% CI: -5.1 to -0.3) Self: 52 wks (N=24) change: -2.7 (95% CI: -5.7 to 0.4) Standard: Baseline (N=32): 96 (SD: 14.6) Standard: 13 wks (N=31) change: -5.9 (95% CI: -7.5 to -4.4) Standard: 26 wks (N=30) change: -6.6 (95% CI: -8.8 to -4.4) Standard: 52 wks (N=28) change: -5.6 (95% CI: -8.5 to -2.8) Tech: Baseline (N=32): 94.7 (SD: 11.6) Tech: 13 wks (N=31) change: -4.1 (95% CI: -5.7 to -2.6) Tech: 26 wks (N=30) change: -4.7 (95% CI: -6.7 to -2.5) Tech: 52 wks (N=31) change: -3.1 (95% CI: -5.9 to -0.3)	NS all comparisons

Study	Outcome Category	Outcome	Results	Statistical Significance
Thomas et al. (2017)[32]	Surrogate	Weight (kg)	Control: Baseline (N=86): 88.8 (SD: 13.8) Control: 13 wks (N=76) change: -1.3 (95% CI: -2 to -0.5) Control: 52 wks (N=75) change: -1.2 (95% CI: -2.3 to -0.2) Weight Watchers Online: Baseline (N=94): 93.4 (SD: 14) Weight Watchers Online: 13 wks (N=83) change: -2.7 (95% CI: -3.5 to -2) Weight Watchers Online: 52 wks (N=84) change: -2.1 (95% CI: -3 to -1.1) Weight Watchers Online plus Active Link: Baseline (N=91): 91.9 (SD: 14.1) Weight Watchers Online plus Active Link: 13 wks (N=81) change: -2 (95% CI: -2.7 to -1.3) Weight Watchers Online plus Active Link: 52 wks (N=75) change: -1.6 (95% CI: -2.6 to -0.6)	At 13 weeks, p=0.01 favoring WW alone vs. control but NS WW plus vs. WW alone and NS WW alone vs. control. At 52 weeks, NS all comparisons
Turner-McGrievy et al. (2017)[25,26]	Surrogate	BMI	Bite: Baseline (N=39): 33.4 (SD: 5.7) Bite: 13 wks (N=39) change: -2.8 (SE: 0.8) Bite: 26 wks (N=39) change: -3 (SE: 0.8) Diet App: Baseline (N=42): 33.4 (SD: 4.8) Diet App: 13 wks (N=42) change: -4.7 (SE: 0.7) Diet App: 26 wks (N=42) change: -6.8 (SE: 0.8)	p=0.07 between groups at 13 weeks and p=0.001 at 26 weeks, favoring app group over Bite group
VanWormer et al. (2009)[630,631]	Surrogate	Weight (kg)	Intervention: Baseline (N=45): 238.2 (SE: 5.2) Intervention: 26 wks (N=39) change: -7.5 (SE: 1.5) Intervention: 52 wks (N=26) change: -8.1 (SE: 2.1) Waitlist: Baseline (N=55): 227.5 (SE: 4.7) Waitlist: 26 wks (N=46) change: +1.3 (SE: 1.4) Waitlist: 52 wks (N=39) change: -1.6 (SE: 1.9)	p<0.001 between groups favoring intervention at 26 weeks, and p=0.023 between groups favoring intervention at 52 weeks

Study	Outcome Category	Outcome	Results	Statistical Significance
Vorrink et al. (2016)[50,58]	Surrogate	BMI	Intervention: Baseline (N=84): 27.7 (SD: 0.58) Intervention: 13 wks (N=84) change: 0.08 (95% CI: -0.11 to 0.26) Intervention: 26 wks (N=84) change: 0.12 (95% CI: -0.14 to 0.37) Intervention: 52 wks (N=84) change: -0.04 (95% CI: -0.37 to 0.27) Usual care: Baseline (N=73): 26.7 (SD: 0.6) Usual care: 13 wks (N=73) change: 0.06 (95% CI: -0.13 to 0.26) Usual care: 26 wks (N=73) change: 0.32 (95% CI: 0.07 to 0.57) Usual care: 52 wks (N=73) change: 0.09 (95% CI: -0.2 to 0.39)	NS all comparisons
West et al. (2016)[22]	Surrogate	Weight (kg)	Control: Baseline (N=29): 66.6 (SD: 19.4) Control: 9 wks (N=27) change: -0.45 (SD: 1.4) Healthy Weight intervention: Baseline (N=29): 67.3 (SD: 11.3) Healthy Weight intervention: 9 wks (N=29) change: -0.48 (SD: 1.9)	p=0.94 between groups
Yoo et al. (2009)[23]	Surrogate	BMI	Control: Baseline (N=54): 25.5 (SD: 3.3) Control: 13 wks (N=54): 25 (SD: 3.3) Intervention: Baseline (N=57): 25.6 (SD: 3.5) Intervention: 13 wks (N=57): 25.1 (SD: 3.5)	NS all comparisons

CI = confidence interval; SD = standard deviation; SE = standard error; NR = not reported; NS = not statistically significant; wks = weeks

Table C-9. Usability findings for the Weight Watchers app

Nature of comment	Aspects of the Weight Watchers App
Positive	*Any screen*: The app is very good with being able to go back, as there is always arrow on the top left of the screen.
Positive	There is a 24/7 chat which is very helpful in getting immediate answers, coaching and concerns.
Positive	*Home screen* is easy to navigate and organized.
Positive	*Bar Code Scanner*: I love how there is a bar code scanner to track the foods, because some foods may be difficult to find using the search bar.
Positive	Ability to see previous days/history of meals.
Positive	*WellnessWins Screen*: I love the idea of having this page because it keeps people motivated to continue paying attention to their diet and exercise.
Positive	Food entry portion of the app is well-organized and does a good job of dividing the meals and searching up all possible brands and items.
Positive	I like how after using the app for a while, it records consistency in the meals you eat, which makes it easy to press on the foods you usually eat because it is recorded.
Positive	It is easy for users to update the food they ate, as well as putting it in the appropriate meal period if that mistake is made.
Positive	I like the ability to add foods using Siri rather than having the user go through the app to input. Siri shortcut integration is useful - if I was cooking or constantly eating the same thing, much easier than having to open up the app.
Positive	The Connect screen is very similar to most of the conventional social media apps, making it very easy to use.
Positive	I like how you are able to browse groups based on interest.
Positive	Good way for users to connect with one another.
Positive	I like that there is a tutorial (but it was not easy to find).
Positive	Success Checklist was easy to navigate (once found).
Positive	I like how it ties exercise with diet.
Positive	FAQs page is embedded in the app and not in a webpage or outside tab.
Positive	I like how the weight input is under this account information/settings, so that it is not as open on the other screens. It makes it more private for the user.
Positive	I love the Recipes feature because it allows users to add variation into their diet and already includes the daily points for that recipe.
Positive	I like how there are activities and training videos to better help users incorporate exercise in their habits, as well as being included in the fitness tracker.
Positive	I like the whole database of information of restaurants and stores relating to keywords to help reduce the stress of having to calculate each individual ingredient - also makes me feel more conscious of what I'm going to purchase - the power of being informed.
Positive	SmartPoint system is effective.
Positive	I like the idea of how you can prepare for meals ahead of time by spending SmartPoints through the weekly calendar to create a healthy diet.

Nature of comment	Aspects of the Weight Watchers App
Positive	Recipe suggestions/finder is useful (but would be better if you could specify special diet, e.g., low salt).
Negative	Problem description: Recipes never change regardless of potential user allergies or dietary restrictions. Suggestion: Allow for personalization for different commonly seen diets that will in turn exclude recipes containing those ingredients (vegetarian, gluten free, peanut butter allergy). (3)
Negative	Problem description: When putting in a food, the search assumes that it is whole wheat or a specific brand, making it harder to select what you actually ate. Suggestion: I would suggest for items such as bread or pasta, to indicate what kind of bread it is when clicking it, rather than already having it separated into specific options. Adjust keyword filtering – allow a generic selection rather than forcing a specific option. (2.5)
Negative	Problem description: Recording food: When clicking on the meal period, there is nothing to indicate to add foods except for the search bar. Using this app is a little challenging in regards to a college setting because not all the available food is implemented into the WW database of foods; one has to search through the meal plans to see what they are eating and their calories, etc. Suggestion: Add a + sign to add food rather than the search bar alone. (2.5)
Negative	Problem description: For novice users, getting started is a bit awkward. A more straightforward, clear tutorial or set of instructions or guide would increase usability from the start and make it easier to remember what to do later (especially after a break from use.) In particular, when initially landing on the home page, it is not immediately obvious how to begin or access tutorial. Also unclear what the difference will be when forced to choose between “weight loss and healthy habits” and “healthy habits”. Suggestion: Have a tutorial open automatically when a new user first logs in and/or move information needed to get familiar with the app up towards the top of home screen. (2)
Negative	Problem description: For novice users, it is unclear what the daily remaining number represents. It takes a bit of exploration to learn that it is Smart Points but at first glance, this isn’t evident. Suggestion: Consider labeling ‘weekly/daily points remaining’. (2)
Negative	Problem description: Use of buttons to navigate between weeks is unconventional for mobile apps. Suggestion: Display arrows at the ends of the weeks to show the user that they have the ability to swipe between different weeks. (2)
Negative	Problem description: WellnessWins screen: Button to get to the screen has a notification number but does not lead to a notification. Suggestion: Recommendations: Make notifications more obvious or remove the number if clicking will not lead to a notification for the user to see. Connect messages and notifications. Make it clearer whether user is expected to click on notification icon/symbol to dismiss or to access the message/information. (2)
Negative	Problem description: Going on the Success Checklist page and pressing an item led to a tutorial that users are not able to leave before going through all of it. Suggestion: Add a “skip tutorial” button on the bottom right. (2)
Negative	Problem description: Usually when opening a new app or initially subscribing, a checklist is shown in setting up on the top of the home screen so to explain how an application can best be used. The Success Checklist was towards the middle of the screen with nothing special to distinguish it. Suggestion: I would move the Success Checklist toward the top of the screen with a completion bar, so that users are oriented towards finishing the app set up before using the app. (2)
Negative	Problem description: The FAQ section is very disorganized, and I believe it should be organized by subject topic while still keeping the search bar for general searches. Suggestion: I would just make it more organized. Organize by relevant topics. Don’t expand answers to questions unless user clicks to get answer. (2)
Negative	Problem description: Supplementation needed for SmartPoint system to be a more complete diet. Suggestion: Allow users to access their total nutritional intake, or provide tips connected to specific aspects of diet since WW has this data from the user, e.g., watch sodium, need vitamin C, etc. (2)

Nature of comment	Aspects of the Weight Watchers App
Negative	Problem description: Home screen has a lot of information such as articles, connect to a Group, and share with friends; this distracts users/takes the attention away from the Food input section. Clicking on these items leads to a lot more information. Suggestion: Recommendations: Put articles, connect to group, share w/friends all under the Explore tab on the bottom of the home screen. (1) Have clear headings and subsections for that screen. (1)
Negative	Problem description: It is unclear what the clock with the arrow means when selecting mealtime. Suggestion: Provide a more recognizable symbol or explain what it means. (1)
Negative	Problem description: Home page scrolling is the same after a while, health tips are stagnant. Suggestion: Consider sharing new articles or reminders of how healthy foods improve your basic aspects of the user's health (carrots improve vision). This would enable research to explore if the articles actually influence users' behavior and adapt accordingly. (1)
Other	Problem description: After reviewing the "Color" assigned to me (BLUE) the button says "Get to know more about Blue", but upon proceeding it does not explain what it means to be BLUE. I didn't understand the meaning of being "Blue" until I scrolled to the bottom where the explore tab is. (2)
Other	Problem description: After answering questions, you are given a review of your Daily SmartPoints; upon defining what SmartPoints are, there are numbers connecting to different food groups - not sure what that is. (2)
Other	Problem description: Why do I have to set my goal weight in the settings section? Why wouldn't prompt in the beginning? Unless I had to select the "Weight loss and healthy habits" focus first in order to fill that in? (2)
Other	Problem description: The explore section of the application should have its own tab - similar to how Instagram has its own Explore Tab section. (2)
Other	Problem description: Consider adding negative points rather than having unhealthy foods count as zero. (1)
Other	Problem description: Definition of "little extra support" in question "What time of day would you like a little extra support?" can be confusing. (1)
Other	Problem description: What is the difference between "Measuring and tracking most foods" and "Limited measuring and tracking" in the question "What's most important to you?" (1)
Other	Problem description: Why can I adjust the Daily and Weekly Target values? What is their purpose, especially if I can adjust them? (1)
Other	Problem description: Definition of "Intensity of Activity" is weird - (Low intensity - little sweating; can talk easily) what does being able to talk easily mean? (1)

Table C-10. Diabetes prevention and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Improving Physical Activity Through a mHealth Intervention in Cardio-metabolic Risk Patients https://ClinicalTrials.gov/show/NCT02551640	Active, not recruiting	Diabetes Mellitus, Type 2, Prediabetic State, Hypertension, Prehypertension, Obesity	Other: FeatForward App (on study smartphone)	Mass General: Charlestown Healthcare Center, Charlestown, Massachusetts, United States Mass General Revere HealthCare Center, Revere, Massachusetts, United States
Preventing Risk for Metabolic Syndrome in Workaholics: An Intervention https://ClinicalTrials.gov/show/NCT04183907	Not yet recruiting	Prediabetes	Behavioral: Transform	Fraser Health, Surrey, British Columbia, Canada

Table C-11. Diabetes prevention and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Biddle et al. (2015)[57]	RCT	UK	Mar 2011 to Oct 2011	The minimum reduction in sedentary behaviour which would yield beneficial metabolic effects has not been determined. Cross-sectional data suggests that a 10% increase in sedentary time is associated with a 3.1 cm increase in waist circumference, and that sedentary time is positively associated with clustered metabolic risk [27]. Using the same dataset, the mean sedentary time is 56.7 hours/week (8.1 hours/day). Assuming a minimum clinically important difference of 10% (5.67 hours/week) and a standard deviation of 12.1 hours/week [27], authors required 72 individuals to complete the study per arm assuming an alpha of 0.05 and 80% power. Target recruitment was set at 90 individuals per arm to allow for an estimated dropout rate of 20%.	177	52
Petrella et al. (2014)[60]	Non-randomized study	Canada	Nov 2009 to Dec 2010	The sample size was calculated based on an estimated difference in mean change between the intervention and active control groups in SBP (primary outcome measure) of 6 mmHg at 12 weeks. A common standard deviation of 12 mmHg was assumed. The sample size calculation assumed 80% power and two-sided significance level of 0.05. It was determined that 63 participants would be required per group and by assuming a 15% drop-out rate, the required sample size increased to 73 participants per group.	149	52
Peyer et al. (2017)[59]	RCT	USA	Fall 2010 to Spring 2011	NR	89	26

NR = not reported; RCT = randomized controlled trial

Table C-12. Diabetes prevention and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity (FPG or HbA1c)	Rural Population
Biddle et al. (2015)[57]	Young obese adults at risk of type 2 diabetes	32.8	68.5	FPG 4.8 mmol/L, HbA1c 5.48	No
Petrella et al. (2014)[60]	Rural adults without current metabolic syndrome, but at risk for developing it (at least 2 risk factors)	57	74	FPG 5.2 mmol/L, HbA1c 5.8	Yes. Participants were at a community-based research centre called the Gateway Rural Health Research Institute. Study was conducted in small rural communities.
Peyer et al. (2017)[59]	Obese adults in central Iowa (95% Caucasian)	39	60	FPG 94 mg/dL	No

NR = not reported

Table C-13. Diabetes prevention and PGHD: treatment details

Study	Treatment 1	Other Treatment Groups	
Biddle et al. (2015)[57]	Control: Received an information leaflet for education.	Intervention: Attended a 3-hour educational workshop, given a Gruve accelerometer (Gruve Technologies) to monitor physical activity and sedentary behavior, and received a follow-up call 6 weeks after the workshop.	
Petrella et al. (2014)[60]	Active control: Prescribed a tailored exercise program by an exercise physiologist and the plan was updated at 12 and 24 weeks. Instructed to record all planned exercise in a paper diary.	Intervention: Same exercise prescriptions as the active control group. Also received a smartphone (Blackberry Curve 8300 or 8530) equipped with the Healthanywhere app (Biosign Technologies), a BP monitor (A&D UA-767PBT), a glucometer (Lifescan One Touch Ultra2), a pedometer (Omron HJ-150) and a heart rate monitor (Suunto Memory Belt, Vantaa Finland). They were educated on the devices in a 2-hour session, provided information on normal values, and encouraged to use these devices to monitor their health. Required to input pedometer steps daily, enter exercise daily, measure BP and FPG three times a week, and measure weight (using their own scale) once a month.	
Peyer et al. (2017)[59]	Guided weight loss: Weekly meetings with a health coach lasting one hour each. Provided a booklet on diet and weight loss strategies and encouraged to make self-directed changes in lifestyle.	Physical activity monitor: Received a SenseWear armband (Jawbone, San Francisco) and instructions on use of its connected online system. Encouraged to use it daily and view real-time estimates of caloric expenditure, minutes of moderate and vigorous physical activity, and steps per day. Also encouraged to enter dietary intake into the online system and view reports. Weekly contact with coaches addressed technical issues with the online system, not on substantive weight loss advice.	Combined: Received both of the other two groups' interventions.

NR = not reported

Table C-14. Diabetes prevention and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Biddle et al. (2015)[57]	+	?	+	−	+	+	−	+	+	Moderate
Petrella et al. (2014)[60]	−	−	+	−	+	+	+	−	+	High
Peyer et al. (2017)[59]	?	?	−	+	?	+	+	−	+	High

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-15. Diabetes prevention and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Petrella et al. (2014)[60]	Guiding Question 2	Device usage	Intervention: Completed 82.7% of BP measurements, 82.2% of FPG measurements, 70.9% of pedometer measurements, and 41.5% of body weight measurements. BP monitoring decreased from 91.5% in weeks 1-12 to 86.7% in weeks 13-24 to 77.6% in weeks 25-52. FPG monitoring decreased from 90.3% in weeks 1-12 to 87.2% in weeks 13-24 to 77% in weeks 25-52. Pedometer monitoring decreased from 83.6% in weeks 1-12 to 77.2% in weeks 13-24 to 63.1% in weeks 25-52. Body weight monitoring decreased from 63.6% in weeks 1-12 to 38.2% in weeks 13-24 to 28.4% in weeks 25-52.	Not calculated
Petrella et al. (2014)[60]	Health	Adverse event: Any	Active control: Four AEs in 3 participants in the active control group (2 angina, 1 stroke, 1 arm/shoulder pain)	No between-group statistics reported
Petrella et al. (2014)[60]	Health	Adverse event: Any	Intervention: No AEs in the intervention group	No between-group statistics reported

Study	Outcome Category	Outcome	Results	Statistical Significance
Petrella et al. (2014)[60]	Health	Adverse events: High DBP alarm (This was triggered when DBP went below 40 or above 110)	Intervention: 7 DBP alarms overall during the one-year follow-up	No between-group statistics reported
Petrella et al. (2014)[60]	Health	Adverse events: High glucose alarm (This was triggered when FPG went below 3 mmol/L or above 15)	Intervention: 12 FPG alarms overall during the one-year follow-up, but 11 of the 12 were from a single patient who was then diagnosed with type 2 diabetes	No between-group statistics reported
Petrella et al. (2014)[60]	Health	Adverse events: High SBP alarm (This was triggered when SBP went below 60 or above 220)	Intervention: No SBP alarms overall during the one-year follow-up	No between-group statistics reported
Biddle et al. (2015)[57]	Health	Quality of life as measured by EuroQOl 5D VAS (Higher scores are better)	Control: Baseline (N=82): 62 (95% CI: 58.3 to 65.8) Control: 13 wks (N=61) change: +3 (95% CI: -1.4 to +7.6) Control: 52 wks (N=56) change: +4.7 (95% CI: -0.2 to +9.5) Intervention: Baseline (N=88): 65 (95% CI: 61 to 69) Intervention: 13 wks (N=59) change: 6 (95% CI: 2 to 10) Intervention: 52 wks (N=55) change: 2 (95% CI: -2 to 7)	p=0.384 between groups at 13 weeks, and p=0.585 between groups at 52 weeks
Biddle et al. (2015)[57]	Surrogate	Fasting glucose (mmol/L)	Control: Baseline (N=93): 4.8 (95% CI: 4.7 to 4.9) Control: 13 wks (N=76) change: 0.17 (95% CI: 0.07 to 0.28) Control: 52 wks (N=67) change: 0.16 (95% CI: 0.07 to 0.26) Intervention: Baseline (N=94): 4.8 (95% CI: 4.7 to 4.9) Intervention: 13 wks (N=69) change: 0.17 (95% CI: 0.07 to 0.28) Intervention: 52 wks (N=59) change: 0.16 (95% CI: 0.07 to 0.26)	p=0.040 between groups at 13 weeks, (but the two groups' means were identical, and data were not discussed in the text, thus one cannot determine the direction of effect); p=0.947 between groups at 52 weeks

Study	Outcome Category	Outcome	Results	Statistical Significance
Petrella et al. (2014)[60]	Surrogate	FPG	Active control: Baseline (N=60): 4.87 (SD: 0.5) Active control: 12 wks (N=60): 4.94 (SD: 0.51) Active control: 24 wks (N=NR): NR (NR) Active control: 52 wks (N=NR): NR (NR) Intervention: Baseline (N=67): 5.29 (SD: 1.11) Intervention: 12 wks (N=67): 5.33 (SD: 1.03) Intervention: 24 wks (N=NR): NR (NR) Intervention: 52 wks (N=NR): NR (NR)	p=0.47 between groups at 12 weeks. Group x time interaction (Figure 3 of the article) over 52 weeks showing that the active control group got worse from time 0 to time 52 weeks, whereas the intervention group stayed stable, thus results favor intervention group.
Biddle et al. (2015)[57]	Surrogate	HbA1c	Control: Baseline (N=92): 5.58 (95% CI: 5.51 to 5.64) Control: 13 wks (N=73) change: -0.05 (95% CI: -0.1 to -0.004) Control: 52 wks (N=63) change: 0.06 (95% CI: 0.01 to 0.11) Intervention: Baseline (N=93): 5.58 (95% CI: 5.51 to 5.46) Intervention: 13 wks (N=68) change: -0.05 (95% CI: -0.1 to -0.004) Intervention: 52 wks (N=58) change: 0.06 (95% CI: 0.01 to 0.11)	p=0.773 between groups at 13 weeks, and p=0.207 between groups at 52 weeks
Petrella et al. (2014)[60]	Surrogate	HbA1c	Active control: Baseline (N=60): 5.77 (SD: 0.33) Active control: 12 wks (N=60): 5.75 (SD: 0.36) Active control: 24 wks (N=NR): NR (NR) Active control: 52 wks (N=NR): NR (NR) Intervention: Baseline (N=67): 5.86 (SD: 0.75) Intervention: 12 wks (N=67): 5.8 (SD: 0.68) Intervention: 24 wks (N=NR): NR (NR) Intervention: 52 wks (N=NR): NR (NR)	p=0.65 between groups at 12 weeks. Group x time interaction (Figure 3 of the article) over 52 weeks showed NS.
Peyer et al. (2017)[59]	Surrogate	Metabolic syndrome score (This is the sum of z scores of five risk factors: waist circumference, mean arterial pressure, triglycerides, glucose, and HDL)	Combined: Baseline (N=29): 0.71 (SD: 3.4) Combined: 8 wks (N=26) change: -2.08 (95% CI: -1.3 to -2.8) Guided weight loss: Baseline (N=31): -0.4 (SD: 2.6) Guided weight loss: 8 wks (N=26) change: -0.78 (95% CI: -0.2 to -1.4) Physical activity monitor: Baseline (N=29): -0.2 (SD: 2.7) Physical activity monitor: 8 wks (N=26) change: -1.06 (95% CI: -0.3 to -1.8)	Larger improvements in Mets score in the combined group than in the guided weight loss group. NS for other comparisons.

Study	Outcome Category	Outcome	Results	Statistical Significance
Biddle et al. (2015)[57]	Surrogate	Two-hour glucose (mmol/L)	Control: Baseline (N=92): 5.41 (95% CI: 5.13 to 5.69) Control: 13 wks (N=72) change: -0.24 (95% CI: -0.58 to 0.1) Control: 52 wks (N=60) change: 0.25 (95% CI: -0.34 to 0.57) Intervention: Baseline (N=93): 5.41 (95% CI: 5.13 to 5.69) Intervention: 13 wks (N=64) change: -0.24 (95% CI: -0.58 to 0.1) Intervention: 52 wks (N=51) change: 0.25 (95% CI: -0.34 to 0.57)	p=0.761 between groups at 13 weeks, and p=0.796 between groups at 52 weeks

CI: confidence interval; SD: standard deviation; SE: standard error; NR: not reported; NS: not statistically significant; wks: weeks

Table C-16. Sleep apnea and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Validation of the Dayzz Digital Sleep Training App in Insomnia and Sleep Apnea https://ClinicalTrials.gov/show/NCT03955120	Active, not recruiting	Insomnia, Sleep Apnea	Behavioral: Dayzz mobile sleep training Other: Treatment as usual	Carmel Hospital, Haifa, Israel
Global Self-management Telematic Support for Patients With Obstructive Sleep Apnea https://ClinicalTrials.gov/show/NCT03792880	Recruiting	Obstructive Sleep Apnea, Telemedicine, Compliance, Patient	Behavioral: Telematic control and self-management program Behavioral: Habitual follow-up in Healthcare System	Virgen del Puerto Hospital, Plasencia, Caceres, Spain San Pedro de Alcántara, Caceres, Spain
A Personalized Behavioral Intervention to Improve Physical Activity, Sleep and Cognition in Sedentary Older Adults https://ClinicalTrials.gov/show/NCT03959202	Recruiting	Sleep	Behavioral: ELDERFITNESS Other: Control	Johns Hopkins University, Baltimore, Maryland, United States

Table C-17. Sleep apnea and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Cho et al. (2018)[62]	RCT	South Korea	Jul 2016 to Nov 2016	NR	47	4
Kim et al. (2019)[61]	RCT	South Korea	Jul 2017 to Aug 2017	NR	43	4
Mendelson et al. (2014)[47]	RCT	France	Jul 2009 to Jan 2012	Based on the decrease in arterial BP after CPAP treatment reported in the meta-analysis of Bazzano et al. (-2.46±0.94 mmHg), authors supposed that BP would decrease by an additional 15% (i.e., -2.83 mmHg) when patients benefited from telemedicine. Authors expected a difference of 0.37 and a standard error of 0.94. Inclusion rate was set at 100 patients per group, based on statistical significance set at 0.05, and power at 80%. To account for a 10% dropout rate in the telemedicine arm, authors set inclusion at 110 patients per group. One blinded interim analysis of home self-measured BP was planned halfway through the inclusion process to look for premature evidence of benefits in the telemedicine versus standard care group, or of harm in any group. The results of this analysis showed that even if the set inclusion rate was met, no benefits would be found on the primary outcome measure (home self-measured BP); thus recruitment was interrupted at 107 patients.	107	17

NR = not reported; RCT = randomized controlled trial

Table C-18. Sleep apnea and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity (Apnea/Hypopnea Index)	Rural Population
Cho et al. (2018)[62]	Obese/overweight adults with habitual snoring or witnessed sleep apnea but not using CPAP or similar device	43	11	Apnea/Hypopnea Index: 22	No
Kim et al. (2019)[61]	Obese/overweight adults with sleep apnea who could use a mobile app and a wearable device	42	15	Apnea witnessed mean: 3.9 days/week	No
Mendelson et al. (2014)[47]	Adults with sleep apnea and BMI <40 with a high cardiovascular risk score or history of cardiovascular disease	63	17	Apnea/Hypopnea Index: 39	No

NR = not reported

Table C-19. Sleep apnea and PGHD: treatment details

Study	Treatment 1	Other Treatment Groups	
Cho et al. (2018)[62]	Control: Educated to modify their lifestyle to lose weight during the following 4 weeks. At two weeks into the study, patients met with physicians and the physicians could use self reported lifestyle and diet reports to set goals.	App: Educated to modify their lifestyle to lose weight during the following 4 weeks using a smartphone app. The app had two modules: diet and physical activity. In the diet module, the participant recorded daily dietary intake. The app showed food intake allowances remaining for the day. The physical activity module gathered physical activity (daily steps) from a wrist-worn activity tracker (Misfit Shine). At two weeks into the study, app users' data was shown to the physician for discussion. Physician counseling set individualized goals for diet and physical activity.	
Kim et al. (2019)[61]	Control: Conventional care for lifestyle modification, verbal advice from clinician to lose weight.	App only: Used an app called MyHealthKeeper, which collected automatic data on step counts (using the person's mobile phone, internal accelerometers of their phones NR) and patients' manually entered data on weight, food intake, sleep hours, and subjective daily stress. Clinicians viewed the data and gave weekly feedback.	App + wearable: Used the app, and also received a wearable activity monitor (Samsung Charm). Study did not report whether the wearable device provided any additional data that was not already being captured by the mobile phones of the App only group.
Mendelson et al. (2014)[47]	Standard: Fitted with a nasal mask and given an autotitrating machine. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was transferred from their machines (adherence, mask leak, residual respiratory events). After 4 months of treatment, data were downloaded from the machine, and patients saw their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.	Telemedicine: Patients assigned to telemedicine were oriented to CPAP, fitted with a nasal mask, and given an autotitrating machine. Patients received a smartphone with an application designed to transmit clinical information. The patients transmitted self-measured morning and evening BP (3-day measurements using the Omron 705CP), CPAP adherence, and subjective sleepiness weekly through a questionnaire-based application. Quality of life questionnaires were transmitted monthly. Patients received daily pictograms with diet and physical-activity related messages on their smartphones. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was reviewed. After 4 months of treatment, patients consulted their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.	

NR = not reported

Table C-20. Sleep apnea and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Cho et al. (2018)[62]	?	?	+	−	+	+	−	−	+	High
Kim et al. (2019)[61]	?	?	+	+	+	+	−	−	+	High
Mendelson et al. (2014)[47]	?	?	+	−	+	+	−	−	+	High

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-21. Sleep apnea and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Kim et al. (2019)[61]	Guiding Question 2	Ease of use	App only: Satisfaction scores range from 3.1 to 4.2 out of 7	Not calculated
Kim et al. (2019)[61]	Guiding Question 2	Ease of use	App+wearable: Satisfaction scores range from 3.7 to 4.7 out of 7	Not calculated
Kim et al. (2019)[61]	Guiding Question 2	Data transmission	App only: Physical activity data collected on an average of 49.96% of days. Sleep data collected on an average of 32.45% of days. Weight data collected on an average of 31.87% of days.	Not calculated
Kim et al. (2019)[61]	Guiding Question 2	Data transmission	App+wearable: Physical activity data collected on an average of 49.82% of days. Sleep data collected on an average of 32.01% of days. Weight data collected on an average of 32.82% of days.	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Mendelson et al. (2014)[47]	Health	Quality of life as measured by the undefined "MCS" (likely the mental component score of either SF-36 or SF-12) (Likely higher scores are better)	Standard: Baseline (N=53): 44.8 (SD: 11.1) Standard: 17 wks (N=53): 46.4 (SD: 9.1) Telemedicine: Baseline (N=54): 45.8 (SD: 10.2) Telemedicine: 17 wks (N=54): 47.4 (SD: 10.7)	NS all comparisons
Mendelson et al. (2014)[47]	Health	Quality of life as measured by the undefined "PCS" (likely the physical component score of either SF-36 or SF-12) (Likely higher scores are better)	Standard: Baseline (N=53): 43 (SD: 9.3) Standard: 17 wks (N=53): 45.9 (SD: 8.5) Telemedicine: Baseline (N=54): 41.5 (SD: 9.7) Telemedicine: 17 wks (N=54): 44.6 (SD: 9.4)	NS all comparisons
Cho et al. (2018)[62]	Surrogate	Apnea hypopnea index (number per hour)	App: Baseline (N=24): 23.5 (SD: 15.5) App: 4 wks (N=24): 20.6 (SD: 15.6) Control: Baseline (N=23): 20.2 (SD: 16.3) Control: 4 wks (N=23): 18.8 (SD: 16.7)	NS all comparisons
Kim et al. (2019)[61]	Surrogate	Apnea witnessed (# days/week)	App only: Baseline (N=15): 3.9 (SD: 2.6) App only: 4 wks (N=15): 3 (SD: 2.7) App+wearable: Baseline (N=15): 3.7 (SD: 2.7) App+wearable: 4 wks (N=15): 2.9 (SD: 2.8) Control: Baseline (N=13): 4.2 (SD: 2.7) Control: 4 wks (N=13): 2.8 (SD: 2.7)	NS all comparisons
Mendelson et al. (2014)[47]	Surrogate	Epworth sleepiness score (Scale 0-24 where lower is better)	Standard: Baseline (N=53): 7.2 (SD: 4.3) Standard: 17 wks (N=53): 5.1 (SD: 3.3) Telemedicine: Baseline (N=54): 8.7 (SD: 4.5) Telemedicine: 17 wks (N=54): 6.4 (SD: 4.4)	NS all comparisons
Cho et al. (2018)[62]	Surrogate	Lowest oxygen saturation %	App: Baseline (N=24): 80 (SD: 7.2) App: 4 wks (N=24): 82.9 (SD: 6) Control: Baseline (N=23): 84.1 (SD: 8.2) Control: 4 wks (N=23): 78.6 (SD: 19.3)	Reported as p=0.011 favoring the app group, and ECRI verified this with our statistical test assuming prepost correlation 0.75
Cho et al. (2018)[62]	Surrogate	Oxygen desaturation index (number per hour)	App: Baseline (N=24): 17.2 (SD: 13.1) App: 4 wks (N=24): 14.9 (SD: 13.3) Control: Baseline (N=23): 14.2 (SD: 15.2) Control: 4 wks (N=23): 14.1 (SD: 15.7)	NS all comparisons

Study	Outcome Category	Outcome	Results	Statistical Significance
Cho et al. (2018)[62]	Surrogate	Percentage of sleep spent snorting at least 45 dB	App: Baseline (N=24): 16.7 (SD: 14.9) App: 4 wks (N=24): 10.2 (SD: 9.3) Control: Baseline (N=23): 15.9 (SD: 18.4) Control: 4 wks (N=23): 13.2 (SD: 19.2)	NS all comparisons

CI = confidence interval; SD = standard deviation; SE = standard error; NR = not reported; NS = not statistically significant; wks = weeks

Table C-22. Hypertension and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Improving Physical Activity Through a mHealth Intervention in Cardio-metabolic Risk Patients https://ClinicalTrials.gov/show/NCT02551640	Active, not recruiting	Diabetes Mellitus, Type 2, Prediabetic State, Hypertension, Prehypertension, Obesity	Other: FeatForward App (on study smartphone)	Mass General: Charlestown Healthcare Center, Charlestown, Massachusetts, United States Mass General Revere HealthCare Center, Revere, Massachusetts, United States
Tailored Home-Based Exercise Program for Multiple Chronic Conditions https://ClinicalTrials.gov/show/NCT03874754	Recruiting	Cancer, Hypertension, Diabetes	Other: Tailored Technology-Enhance Home-based Exercise Program (iHBE)	The Sidney Kimmel Comprehensive Cancer Center, Baltimore, Maryland, United States
mGlide RCT: A Clinical Glide Path To Close The Guideline-to-Practice Gap In HTN Management https://ClinicalTrials.gov/show/NCT03612271	Recruiting	Hypertension	Behavioral: mGlide	Epidemiology Clinical Research Center, Minneapolis, Minnesota, United States
Smart Phone Medication Adherence Saves Kidneys–SMASK https://ClinicalTrials.gov/show/NCT02827695	Active, not recruiting	Kidney Transplantation, Medication Adherence, Hypertension	Behavioral: SMASK Behavioral: Enhanced SC	Medical University of South Carolina, Charleston, South Carolina, United States
The PCORnet Blood Pressure Home Monitoring Study https://ClinicalTrials.gov/show/NCT03796689	Recruiting	Hypertension	Device: Smartphone-linked HBPM and Associated App Device: Standard HBPM	University of Florida Health, Gainesville, Florida, United States University Medical Center, New Orleans, Louisiana, United States Mayo Clinic, Rochester, Minnesota, United States
Patient Centered Health Technology Medication Adherence Program for African American Hypertensives https://ClinicalTrials.gov/show/NCT03454308	Active, not recruiting	Hypertension, Medication Non-Adherence	Behavioral: SMASH Behavioral: Enhanced SC	Medical University of South Carolina, Charleston, South Carolina, United States

Title	Status	Conditions	Interventions	Locations
Targeting of UnControlled Hypertension in Emergency Department https://ClinicalTrials.gov/show/NCT03749499	Active, not recruiting	Hypertension, Cardiovascular Diseases, Vascular Diseases	Other: HTN Educational Video Other: Visual Echocardiogram Image Clips Other: Mobile Health and Remote BP Monitoring Other: Post-Acute Care HTN Transition Consultation (PACHT-c)	University of Illinois at Chicago, Chicago, Illinois, United States
Fight Hypertension in the Digital Age https://ClinicalTrials.gov/show/NCT03659656	Not yet recruiting	Pre Hypertension, Hypertension	Behavioral: Lifestyle Coaching Device: Fitbit Usage	University of Vermont, Burlington, Vermont, United States
Feasibility and Usability of a Pedometer in a Cardiovascular Disease Prevention Program for French-speaking Canadians https://ClinicalTrials.gov/show/NCT02837471	Active, not recruiting	Cardiovascular Disease	Device: PiezoRx Medical Grade Pedometer	University of Ottawa Heart Institute, Ottawa, Ontario, Canada

Table C-23. Hypertension and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Aekplakorn et al. (2016)[88]	RCT	Thailand	05/2013 to 06/2014	Sample size determination was based on the comparison of usual and intervention group with an estimated difference of mean SBP over 12 months of 5 mmHg, at 0.05 of alpha error and 80% of power, which required a sample size of 110 patients per group (allowance for 10% loss to follow up).	224	12 months
Bennett et al. (2018)[18,72,73]	RCT	USA	Jun 2013 to Sep 2015	Using data from previous work, mean weight was estimated at 81 kg with a standard deviation of 8 kg. Twelve months post-intervention, the authors hypothesized that there would be no change in the usual care group and a 2.6-kg reduction in the treatment group and that there will be an autocorrelation between baseline and follow-up weight values of 0.55. From these values, using a two-tailed test of differences at the α=0.05 level, it was estimated 80% power to detect a difference of 2.36 kg with 140 complete cases per group. From previous trials, the sample was inflated by 20% to accommodate projected attrition.	351	52 weeks

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Bernocchi et al. (2014)[125]	NRS	Italy	September 2009 to September 2011	NR	168	Mean of 80 days
Bosworth et al. (2009)[63]	RCT	USA	05/2004 to 12/2005	Sample size estimation was based on the primary hypothesis that patients assigned to an intervention group would have improved BP control at 24 months compared with the usual care group. A linear change in BP control was assumed, so the comparison was a difference in slopes (the treatment-by-time interaction in a logistic mixed effects regression model. Sample size and power estimates were generated empirically in a simulation study by using PROC NLMIXED in SAS, version 9.1 (SAS Institute, Cary, North Carolina). On the basis of previous studies, authors estimated baseline BP control as 40% and the 24-month dropout rate as 15%. The random intercept variance component was assumed to be 0.7 (equivalent to a patient interclass correlation of 0.18). To detect a difference in slopes resulting in 10% improvement in BP control at 24 months with 80% power and a type I error rate of 5%, 570 patients were needed; however, to account for dropout, authors enrolled 636 individuals.	636	2 years
Bosworth et al. (2011)[66-68]	RCT	USA	May 2006 to NR	Sample size estimation was based on the primary hypothesis that patients randomized to an intervention arm would have improved BP control at 18 months compared with the usual care group. A common intercept and a linear change in BP control were assumed, so the comparison was a difference in slopes (the treatment by time interaction in a logistic mixed-effects regression model). Sample size and power estimates were generated empirically via a simulation study using PROC NLMIXED statistical software. Baseline BP control at a single measurement was estimated as 30% and the 18-month dropout rate as 15%. The random intercept variance component was assumed to be 1.7. To detect a difference in slopes resulting in a 15% improvement in BP control at 18 months relative to the control group with 80% power and a type-I error rate of 5%, 600 patients were needed.	591	18 months
Bosworth et al. (2011)[89-91]	RCT	USA	NR	For a type-I error of 0.05, study authors estimated a total of n=570 patients were required to be able to detect a 10% increase in probability of BP control at 80% power.	636	24 months

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Bove et al. (2013)[92]	RCT	USA	NR	Study authors compared the proportion of control and telemedicine patients who reached goal systolic BP and compared the absolute changes in BP between control and telemedicine subjects.They hypothesized that 50% of telemedicine and 35% of control subjects would reach goal based on BP measured at the initial and final visit. To achieve a power of 0.8 with α value of 0.05, they aimed to recruit 252 subjects to accommodate a dropout rate of 20% and an expected 30% incidence of diabetes.	241	6 months
Broege et al. (2001)[79]	RCT	USA	NR	NR	40	3 months
Chandler et al. (2020)[74]	RCT	USA	November 2016 to November 2018	NR	30	12 months
Dorough et al. (2014)[126]	RCT	USA	NR	NR	23	10 weeks
Earle et al. (2010)[70,71]	RCT	UK	December 2006 to July 2007	Study authors aimed to recruit 60 patients in each group in anticipation of a 10–20% dropout over 6 months. This strategy meant the study would have at least 80% power to detect a 7 mmHg difference in SBP after 6 months.	137	6 months
Fuchs et al. (2012)[93]	RCT	Brazil	2008 to 2009	For an effect size of 2 mmHg (+/- 3 mmHg) in 24-h ambulatory BP monitoring SBP between intervention and control, with 90% power and p-value of 0.05, the sample size was 48 individuals.	121	60 days
Green et al. (2008)[80,81]	RCT	USA	June 2005 to NR	The study was designed to enroll 780 patients equally to each of the 3 intervention groups. The sample size was powered to detect clinically meaningful differences in mean changes in systolic BP of 4 mmHg and diastolic BP of 3 mmHg between usual care and home BP monitoring and Web training plus pharmacist care at 12-month follow-up.	778	1 year
Green et al. (2014)[24]	RCT	USA	2010 to 2011	The planned sample size of 100 randomized subjects provided 80% power to detect an effect size of 0.6 SD for the continuous outcomes, assuming 90% follow-up at the 6-month visit. This effect size corresponded to a detectable difference between groups of 9.3 mmHg for systolic BP (assuming SD=15.5), 5.1 mmHg for diastolic BP (assuming SD=5.1), and 2.7 kg for weight change (assuming SD=4.5).	101	26 weeks

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Halme et al. (2005)[127]	RCT	Finland	NR	Study authors assumed originally a clinically significant difference in diastolic home BP to be 3 mmHg, standard deviation to be 7 mmHg, alpha error to be 0.05, and beta error 0.2, which would give a mandatory sample size of 83 patients/group.	232	6 months
He et al. (2017)[128]	RCT	Argentina	June 2013 to April 2015	The trial was designed to provide 80% statistical power to detect a 4.0-mmHg or more reduction in SBP at a significance level of 0.05 using a 2-tailed test. Eighteen centers (9 in each group) with an average cluster size of 62 patients with hypertension, an 85% follow-up rate, an intracluster correlation of 0.06, and a standard deviation of 10.0 mmHg were assumed. The cluster design was taken into consideration in the power calculation.	1432	18 months
Hebert et al. (2012)[82]	RCT	USA	NR	Study authors calculated that a sample size of 120 patients per treatment arm would have 80% power to detect a 5 mmHg difference in the SBP between treatment arms at 9 months, assuming a rate of loss-to-follow-up of 20%.	416	18 months
Hoffmann-Petersen et al. (2017)[94]	RCT	Denmark	March 2011 and September 2014	A power calculation indicated that a sample of 169 patients in each group was necessary to detect a 2-mmHg difference in daytime ABPM with an assumed SD of 8 mmHg and a power of 90% at a significance level of 5%.	356	3 months
Hosseininasab et al. (2014)[129]	RCT	Iran	February 2012 to NR	Study sample size was calculated based on the assumptions of an expected difference of 5 mmHg, SD of 10 mmHg, significance level of 0.05, and power of 90% (n=170 participants). However, authors assumed a 15% loss to follow-up and planned to recruit 196 patients.	194	24 weeks
Kaihara et al. (2014)[95]	RCT	Japan	NR	A retrospective analysis determined that at least 26 subjects for each group were needed in the study on the condition that effect size was 0.8, alpha error probability was 0.05, and the power was 0.80.	57	2 weeks
Kao et al. (2019)[102]	RCT	Taiwan	NR	We estimated the sample size using G*Power version 3.1. According to a previous study, a sample size of 80 patients per group was estimated for 90% power (two-tailed and at a 5% significance level) to detect a difference of at least 5 mmHg in systolic blood pressure between the intervention and control groups and assuming an SD of 17 mmHg. Allowing for a 20% dropout rate during follow-up, the sample size was increased to at least 96 patients for each group.	222	6 months
Kauric-Klein et al. (2007)[96]	RCT	USA	NR	Not performed, "Because of funding limitations and the need to purchase home BP monitors, only 36 participants were enrolled in the study."	34	12 weeks

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Kerry et al. (2013)[103-105]	RCT	UK	Mar 2007 to Aug 2009	A sample of 322 was required to detect a difference of 5 mmHg in change in mean systolic blood pressure over 12 months between the intervention and control groups, with 80% power using a 5% significance level, assuming the SD was 16 mmHg. Allowing for a 10% loss to follow-up, authors needed to recruit 360 participants. In March 2009, the Data Monitoring Committee agreed that the sample size needed to be increased to 380 to allow for a 5% death rate.	381	52 weeks
Kim et al. (2015)[130]	RCT	South Korea	12/2010 to 11/2012	The study was initially designed to enroll 564 patients (under the assumption of a 25% dropout rate), which was later revised to enroll 495 patients equally to each of the three intervention groups, under the assumption of a 20% dropout rate because the dropout rate was lower than expected. With a sample size of 165 patients per group, the trial had 80% power to detect (α=0.05; two-sided test) a between-treatment difference between the group 1 and groups 2 and 3 of 3.8 mmHg in the SBP change from baseline with a SD for the SBP of 11.43 mmHg, with a 20% dropout rate. The between-treatment difference of 3.8mmHg and an SD of 11.43 mmHg were estimated from similar hypertension trials.	374	6 months
Kim et al. (2016)[97,101]	RCT	USA	July 2013 to July 2014	The study was designed to be powered to detect a one office visit difference between the control and monitoring arm (assuming a standard deviation of two office visits).	160	6 months
Klarskov et al. (2018)[131]	RCT	Denmark	NR	A power calculation showed that inclusion of 800 patients (400 in each group) would permit the detection of a 3.5 mmHg difference with a power of 90% at a 5% significance level, assuming a standard deviation of 15 mmHg.	1048	12 months
Lakshminarayan et al. (2018)[69]	RCT	USA	NR	No *a priori* power statement but in the discussion they said: a sample size of 135–150 / treatment arm would detect a 15% difference in the intent-to-treat analysis with 80% power and a type I error rate (alpha) of 0.05.	50	13 weeks
Logan et al. (2012)[132]	RCT	Canada	NR	The study was designed to have a statistical power of 80% to detect a 4-mmHg reduction in mean daytime systolic BP in the self-care support group, as compared with control group, using a 2-tailed test with an alpha level of 5%. Assuming a 10% dropout rate, study authors estimated a total sample size of 113 patients (56 per group).	110	1 year
Magid et al. (2011)[133]	RCT	USA	NR	NR	283	6 months

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Magid et al. (2013)[64]	RCT	USA	10/2008 and 12/2009	This study was designed to enroll up to 200 patients per group allocated equally to the HBPM and UC groups. Assuming a 15% dropout rate and a control rate of 30% in the UC group, this sample size provided 80% power to detect a 14% difference in BP control rate in the HBPM group compared with the UC group.	348	6 months
Margolis et al. (2013)[106-112]	RCT	USA	March 2009 to April 2011	The study was powered at 80% (2-sided test α level of 0.05) to detect a difference in the proportion of patients with controlled BP at both 6 and 12 months in 40% receiving usual care and 60% receiving the telemonitoring intervention. The sample size was based on recruitment of 450 patients from 16 clinics, of whom 405 (90%) would complete the 6-month clinic visit and 360 (80%) would complete both the 6- and 12-month clinic visits.	450	18 months
Marquez-Contreras et al. (2006)[98]	RCT	Spain	NR	Determined that 250 patients to detect a 4% difference in medication compliance between the groups with 95% power.	250	6 months
McKinstry et al. (2013)[113-115]	RCT	UK	02/2009 to 10/2010	The sample size was based on the mean daytime systolic ambulatory blood pressure (142 mmHg) and its standard deviation (14 mmHg) measured in a similar group of participants at the end of our pilot work. The likely effect size was based on a systematic review of non-drug interventions to reduce hypertension in which there was an average reduction of 4.5 mmHg in SBP. Such a reduction is considered clinically significant in that if it were to be sustained over 10 years it would be expected to lead to a greater than 15% reduction in risk of stroke and a greater than 10% reduction in risk of coronary heart disease.22 To have 80% power to identify a difference between telemonitoring and usual care of 4.5 mmHg in systolic ambulatory blood pressure in a two tailed test with α set at 0.05, authors needed 155 participants in each arm. Allowing for a 20% dropout, authors aimed to recruit a total of 400 participants.	401	6 months
McManus et al. (2010)[116-120]	RCT	UK	March 2007 to May 2008	On the assumption of an SD of 15 mmHg, and 20% dropout based on the results of our previous self-monitoring trial, a sample size of 239 participants per group was required to detect a BP difference of at least 5 mmHg between groups with 90% power.	480	12 months
McManus et al. (2014)[121]	RCT	UK	March 2011 and December 2011	A sample size of 243 patients per group was estimated for 90% power assuming a standard deviation of 17 mmHg and a difference of at least 5 mmHg in SBP between intervention and control groups based on previous research.	555	12 months

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
McManus et al. (2018)[83-86]	RCT	UK	Nov 13, 2014 to Feb 3, 2016	It was estimated that 1110 patients (370 per group, allowing for 15% attrition) would be required to detect a 5 mmHg SBP difference between the groups with 90% power and an adjusted alpha of 0·017 (two-sided) to account for all three pairwise comparisons. This calculation was based on an assumption of a common SD of 17 mmHg and a three-way pairwise comparison.	1173	12 months
Mehos et al. (2000)[122]	RCT	USA	NR	NR	41	6 months
Mendelson et al. (2014)[47]	RCT	France	Jul 2009 to Jan 2012	Based on the decrease in arterial BP after CPAP treatment reported in the meta-analysis of Bazzano et al. (-2.46±0.94 mmHg), authors supposed that BP would decrease by an additional 15% (i.e., -2.83 mmHg) when patients benefited from telemedicine. Study authors expected a difference of 0.37 and a standard error of 0.94. Inclusion rate was set at 100 patients per group, based on statistical significance set at 0.05, and power at 80%. To account for a 10% dropout rate in the telemedicine arm, authors set inclusion at 110 patients per group. One blinded interim analysis of home self-measured BP was planned halfway through the inclusion process to look for premature evidence of benefits in the telemedicine versus standard care group, or of harm in any group. The results of this analysis showed that even if the set inclusion rate was met, no benefits would be found on the primary outcome measure (home self-measured BP); thus recruitment was interrupted at 107 patients.	107	17 weeks
Neumann et al. (2011)[134,135]	RCT	Germany	NR	NR	60	3 months
Niiranen et al. (2014)[136]	RCT	Finland	NR	With significance set at 5% and power at 85%, approximately 110–115 patients per treatment group had to be randomized to detect systolic/diastolic BP differences of 5/3 mmHg, assuming an SD of 12.6/7.4, based on previous research.	220	12 months
Ogedegbe et al. (2014)[123]	RCT	USA	10/2004 to 2/2009	Authors anticipated 12-month treatment effects of ≥4 mmHg for SBP and ≥3 mmHg for DBP. With 30 sites, and 30 patients per site, authors estimated a power of 91% and 96%, respectively, to detect treatment effects of these magnitudes (using a 2-tailed, 0.05-level test). Allowing for a 15% attrition rate, the enrollment target was set at 1059 patients, for a final sample of 900 patients who would complete the study.	1039	12 months

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Petrella et al. (2014)[60]	Non-randomized comparative study	Canada	Nov 2009 to Dec 2010	The sample size was calculated based on an estimated difference in mean change between the intervention and active control groups in SBP (primary outcome measure) of 6 mmHg at 12 weeks. A common standard deviation of 12 mmHg was assumed. The sample size calculation assumed 80% power and two-sided significance level of 0.05. It was determined that 63 participants would be required per group and by assuming a 15% drop-out rate, the required sample size increased to 73 participants per group.	149	52 weeks
Qi et al. (2017)[99]	RCT	China	July 2010 and December 2015	NR	1032	5 years
Rifkin et al. (2013)[65]	RCT	USA	NR	Study authors planned to enroll 30 individuals in the intervention and 15 in the control arms in the study. The primary pre-specified aim was to detect a difference in the sum total of the number of BP readings from outside the clinic to assess the quantity of BP data exchanged. They calculated they had more than 90% power at an alpha of 5% to detect a clinically significant average difference of four readings per month, assuming an average of two readings per month shared in the control group and six readings per month shared in the intervention group. An *a priori* power calculation for the secondary endpoint of difference in BP between groups was also performed. Study authors calculated they had about 60% power at alpha of 5% to detect a 10-point difference in SBP between groups, assuming a SD of 15 mmHg.	43	6 months
Rogers et al. (2001)[137]	RCT	USA	May 1999 to April 2000	*A priori* sample size was calculated to detect a mean (+/- SD) difference in blood pressure of 3 +/- 5 mmHg between the two study groups. This yielded 60 patients per group with 90% power (alpha=0.05 [two-tailed]).	121	Median 11 weeks
Sarfo et al. (2018)[138,139]	RCT	Ghana	January 6, 2017 to June 14, 2017	Study was not powered to detect significant differences between the groups.	60	9 months
Stewart et al. (2014)[140]	RCT	Australia	NR	To detect an improvement in adherence from 50% to 65% with 80% power and a two-sided p-value of 0.05, 182 patients were required per study group. To allow for potential dropouts (approximately 25% over 6 months), the intent was to recruit 225 patients per group.	395	6 months

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Yoo et al. (2009)[23]	RCT	South Korea	NR	NR	111	13 weeks
Zaleski et al. (2019)[100]	RCT	USA	10/2016 to 2/2018	Sample size calculations estimated a sample mean and SD difference of approximately 11%, therefore a minimum of 12 subjects in each group would reject the null hypothesis with 93% power at P of 0.05 or less.	24	4 months
Zarnke et al. (1997)[124]	RCT	Canada	NR	NR	31	8 weeks
Zha et al. (2019)[87]	RCT	USA	NR	NR	25	6 months

ABPM = ambulatory blood pressure monitoring; BP = blood pressure; CPAP = continuous positive airway pressure; DBP = diastolic blood pressure; HBPM = home blood pressure monitoring; mmHg = millimeters of mercury; NR = not reported; NRS = nonrandomized study; RCT = randomized controlled trial; SBP = systolic blood pressure; SD = standard deviation; UC = usual care; UK = United Kingdom; USA = United States of America

Table C-24. Hypertension and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Aekplakorn et al. (2016)[88]	The inclusion criteria were patients with SBP ≥140 mmHg or diastolic BP (DBP) ≥90 mmHg based on average of the prior 12 months from community hospital registry and living in Bang phli district, Samutprakarn province. Patients were excluded due to age <35 years old, immigrants, or having deficiencies in communication skills.	59 (SD: 9.2)	66	SBP UC: 147.2 (SD: 14.9), PGHD: 149.4 (SD: 11.4), DBP UC: 82.2 (SD: 11.7), PGHD: 83.4 (SD: 9.9)	NR
Bennett et al. (2018)[18,72,73]	Aged 21 to 65 years, with a BMI of 30.0 to 44.9 and the aforementioned diagnoses (captured via ICD-9 codes). Additional inclusion criteria were as follows: at least two visits to the health center in the last 12 months, English fluency, ownership of a mobile phone, and willingness to send/receive three to nine text messages per week. Exclusion criteria included pregnancy or ≤12 months postpartum, cohabitation with another participant, participation in a related trial, or plans to move outside of the region within 2 years. The trial also excluded participants with a cardiovascular event in ≤6 months; a condition/medication that would affect weight; profound cognitive, developmental, or psychiatric disorders; or psychiatric hospitalization in ≤12 months.	51	68	NR	Yes

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Bernocchi et al. (2014)[125]	Inclusion: new finding of BP values >140/90 mmHg or history of 24-h ambulatory BP monitoring values ≥125/80 mmHg, age >18 years, having an in-home analog telephone line. Exclusion: residing in long-term care facilities, severe cognitive impairments or poor prognosis.	59.4	48	Mean SBP: 154.7 mmHg Mean DBP: 86.0 mmHg	Yes
Bosworth et al. (2009)[63]	Initial inclusion criteria were hypertension diagnosed at least 12 months before the data extraction date (ICD 9th revision, codes 401.0, 401.1, or 401.9), enrollment with a primary care physician at the included clinic for at least 12 months before data extraction, self-report of current antihypertensive medication use, a scheduled appointment with a non-laboratory primary care provider during the next 30 days, and residence in 1 of 32 specified ZIP codes in the areas around Duke University Health System. Exclusion criteria were a diagnosis of dementia, Parkinson disease, atrial fibrillation, or end-stage renal disease; patient of a study investigator or physician not expected to remain at the practice during the entire study period; resident in nursing home or receiving home health care; hospitalization for stroke or heart attack, surgery for blocked arteries, or diagnosis of metastatic cancer in the previous 3 months; poor vision or difficulty hearing on the telephone; difficulty understanding English on the telephone; participant in another BP study; spouse participating in current study; arm circumference greater than 17 inches and wrist circumference greater than 8.5 inches; pregnant or planning to become pregnant in the next 2 years; or not receiving most medical care from Duke clinics. Patients also were excluded after randomization because they were no longer receiving medical care at the Duke clinics, had initiated dialysis, had received an organ transplant in the previous 6 months, resided in a nursing home or receiving home health care, had no telephone, or received a diagnosis of pulmonary hypertension in the previous 6 months.	61 (SD: 12)	66	BP controlled at baseline 73%, mean SBP: 125 (SD: 18) and mean DBP: 71 (SD: 11)	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Bosworth et al. (2011)[66-68]	Inclusion: a diagnosis of hypertension, use of a BP-lowering medication, had inadequate BP control based on the average of the prior 12 months of clinic BP recordings obtained from electronic medical records. Exclusion: patients who received hemodialysis; had a serum creatinine level greater than 2.5 mg/dL or no documentation of renal function; had ever had an organ transplant; had been hospitalized for stroke, myocardial infarction, or coronary artery revascularization within 3 months of contact; had a diagnosis of metastatic cancer or dementia; did not have a home telephone; resided in a nursing home; received home health care; or had severely impaired hearing or speech.	64	8	Mean SBP: 129 mmHg Mean DBP: 77 mmHg	NR
Bosworth et al. (2011)[89-91]	Inclusion: diagnosis of hypertension, being enrolled with a primary care physician at the clinic of interest, having received a hypertensive medication prescription. Exclusion: having a diagnosis of dementia, Parkinson's disease, atrial fibrillation, or end stage renal disease; residing in a nursing home or receiving home health care; recently being hospitalized for a stroke, heart attack, surgery for blocked arteries or being diagnosed with metastatic cancer.	61	64	Mean SBP: 125 mmHg Mean DBP: 71 mmHg	NR
Bove et al. (2013)[92]	The authors studied an urban population comprised mainly of African Americans with a high incidence of both hypertension and diabetes. Subjects were recruited from Temple University Medical Center in Philadelphia, Pennsylvania, and Christiana Health Care Center in Wilmington, Delaware. Eligible subjects had a SBP of 140 mmHg or above and no overt CVD. Subjects were excluded if they had a history of coronary disease, did not have a telephone, could not read, were pregnant, or were younger than 18 years.	59.6	65	SBP UC: 154.4 (SD: 16.3), PGHD: 155.9 (SD: 13.7). DBP UC: 87.6 (SD: 10.9), PGHD: 88.9 (SD: 11.2)	No
Broege et al. (2001)[79]	Inclusion: aged 65 years or older; clinic SBP <150 mmHg and DBP <90 mmHg on antihypertensive medication; clinic SBP >150 mmHg and DBP >90 mmHg off antihypertensive medication; no previous cardiovascular morbid events; physically and mentally capable of using an automatic home monitor; ECG within normal limits; and body-mass index <31. Exclusion: NR	73	70	Mean ambulatory awake SBP: 147 mmHg Mean ambulatory awake DBP: 82 mmHg	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Chandler et al. (2020)[74]	Inclusion: Non-Hispanic White or African American men or women, aged 18–90 years old, and systolic BP 121 to 139 mmHg on 3 consecutive visits. Exclusion: Presence of any chronic illness or medical condition requiring regular pharmacological intervention that may affect BP, unwillingness to be randomized; inability to use smartphone; participating in another research study; pregnant, lactating, or have intention of becoming pregnant.	45.0	51.0	Mean SBP: 132.6 mmHg Mean DBP: 76.3 mmHg	NR
Dorough et al. (2014)[126]	Aged 45 to 65, met criteria set forth by the JNC-VII for prehypertension, having an SBP between 120 and 139 mmHg or a DBP of 80 to 89 mmHg. Participants were overweight to obese, BMI of ≥25 and ≤40, did not have any major chronic diseases, were not taking medications known to influence BP, body weight, or food intake; they were nonsmokers, were not clinically depressed, and did not meet criteria for an eating disorder.	54	70	NR	No
Earle et al. (2010)[70,71]	Inclusion: >18 years of age, diagnosis of diabetes, receiving pharmacological therapy for hypertension or who had an untreated sitting SBP or DBP of ≥130 or ≥80 mmHg. Exclusion: physical inability to self-monitor blood glucose or BP, pregnancy, severe life-threatening or terminal illness.	58.4	NR	Mean SBP: 131.1 mmHg Mean DBP: 76.8 mmHg	No
Fuchs et al. (2012)[93]	Inclusion: aged 18 to 80 years, with hypertension in office BP, on antihypertensive treatment, with uncontrolled office BP and 24-h ABPM. Exclusion: BP of at least 180/110 mmHg; recent severe acute or chronic illnesses, major cardiovascular event; masked hypertension; white-coat hypertension; secondary hypertension; pregnant or breast-feeding women.	59.0	60.3	Mean office SBP: 158.6 Mean office DBP: 89.5 Mean 24-hour systolic ABPM: 148.8 Mean 24-hour diastolic ABPM: 87.5	NR
Green et al. (2008)[80,81]	Inclusion: aged 25 to 75 years; with diagnosis of hypertension and taking antihypertensive medication; with no diagnoses of diabetes, cardiovascular or renal disease, or other serious conditions. Exclusion: NR	59.1	52.2	Mean SBP: 151.9 mmHg Mean DBP: 89.1 mmHg	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Green et al. (2014)[24]	Age 35–69 years with at least 2 years of enrollment and one primary care visit in the previous 2 years, BP >140 mmHg systolic or >90 mmHg diastolic at the most recent primary care visit, BMI >26, and Framingham CVD risk score between 10% and 25%. Patients with a history of CVD, diabetes, severe illnesses (e.g., renal failure or dementia), or illnesses that would make participation difficult (e.g., pregnancy, schizophrenia, or alcohol dependence) were excluded.	57	42	NR	No
Halme et al. (2005)[127]	Inclusion: 20 to 75 years old, suffered from essential hypertension. Exclusion: malignant or secondary hypertension, atrial fibrillation, flutter, obesity.	57.3	67.2	Mean office SBP: 159.3 mmHg Mean office DBP: 94.4 mmHg	NR
He et al. (2017)[128]	Inclusion: aged 21 years or older, diagnosis of hypertension, have a spouse with or without hypertension or another adult living in the same household with hypertension, patient at a participating Center for Primary Health Care. Exclusion: pregnancy	55.8	53.0	Mean SBP: 150.8 mmHg Mean DBP: 91.2 mmHg	No
Hebert et al. (2012)[82]	Inclusion: aged ≥18 years; uncontrolled hypertension recorded in the medical chart for their last two clinic visits; ≥150/95 mmHg at recruitment; black or Hispanic; community-dwelling; had received care for at least 6 months in a general medicine, geriatrics, or cardiology clinic or office at a participating site. Exclusion: pregnancy; renal dialysis; terminal illness; and medical conditions that prevented a patient's interacting with the nurse.	60.8	70.9	Mean SBP: 153 mmHg Mean DBP: 86.0 mmHg	No
Hoffmann-Petersen et al. (2017)[94]	Inclusion: for original prevalence study: age 55–64 years, registered address in the municipality of Holstebro, enrollment at a practice with a participating physician. For RCT: sufficient number of telemedical BP recordings, telemedicine BP recording ≥135/85 mmHg, confirmed hypertension, sinus rhythm. Exclusion: incapability to do telemedical BP recordings, normotension.	60.5	46	Mean office SBP: 154.6 mmHg Mean office DBP: 93.2 mmHg	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Hosseininasab et al. (2014)[129]	Inclusion: patients aged >18 years; new cases with a diagnosis of mild to moderate hypertension or uncontrolled with antihypertensive treatment; no electronic device for measuring home BP. Exclusion: patients with secondary hypertension, severe cardiovascular comorbidities, contraindication for antihypertensive drugs, or serum creatinine >1.5mg/dl.	58.7	61.3	Mean SBP: 145.2 mmHg Mean DBP: 85.3 mmHg	NR
Kaihara et al. (2014)[95]	Inclusion: aged 20 or older; diabetes mellitus or impaired glucose metabolism, dyslipidemia, hypertension, current smoking, kidney disease, atrial fibrillation, metabolic syndrome, chronic obstructive pulmonary disease, or sleep apnea.	64.4	65	Mean SBP: 144 mmHg Mean DBP: 83 mmHg	Yes
Kao et al. (2019)[102]	Patients with primary hypertension from a cardiovascular outpatient clinic of a medical center in northern Taiwan were enrolled. The inclusion criteria were as follows: age of 20 to 79 years, diagnosis of primary hypertension with SBP ≥130 mmHg or DBP ≥80 mmHg, intake of less than four antihypertensive agents, access to a sphygmomanometer at home, ownership of a smart phone or personal computer to use, ability to read and understand Chinese or Taiwanese, and willing to participate. The exclusion criteria were as follows: SBP ≥180 mmHg or DBP ≥100 mmHg; pregnancy; receipt of a heart transplant, permanent pacemaker, or implantable cardioverter defibrillator; diagnosis of arrhythmia, stroke, thyroid disease, major psychiatric disorder, renal disease, heart failure, acute myocardial infarction, cancer, or terminal disease; intake of antidepressants; or addiction to drugs or alcohol.	62.7 (SD: 9.3)	49	Total sample baseline SBP: 143.2 (SD: 13.6) and DBP: 84.2 (SD: 10.8). Average length of hypertension diagnosis was 6 years.	NR
Kauric-Klein et al. (2007)[96]	The study was conducted in a 170-chair hemodialysis unit in Detroit, Michigan. Eligible patients were between the ages of 20 and 65 years, with an average pre-hemodialysis systolic BP >150 mmHg and a diastolic BP >90 mmHg. Exclusion criteria included: on hemodialysis less than six months, scheduled for renal transplantation, history of illicit drug use, mental illness or dementia, lack of orientation to person, time or place, or having a major health problem such as terminal cancer or human immunodeficiency virus.	48.7 (SD: 10.8)	68	SBP was 161 (SD: 14) in the PGHD group and 162 (SD: 12) in the UC group. DBP was 94 (SD: 7) in the PGHD group and 100 (SD: 10) in the UC group. Patients were chronic hemodialysis patients.	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Kerry et al. (2013)[103-105]	Participants were eligible for inclusion if they had a history of stroke or transient ischemic attack within the 9 months before enrollment and had hypertension. Authors defined hypertension as a BP reading greater than 140/85 mmHg at the last clinic visit or treatment with antihypertensive medications, which was similar to definitions used in other studies. Authors excluded patients who were already enrolled in a trial; were severely ill or too frail; were already using a blood pressure monitor; had severe cognitive impairment (Abbreviated Mental Test score 13<7); lived within about an hour's travel from the study center, as defined by a list of postal codes; and did not speak English.	72	43	Mean SBP: 138 mmHg Mean DBP: 74 mmHg	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Kim et al. (2015)[130]	Inclusion criteria: 1. Hypertensive patients over 20 years of age whose office BP was uncontrolled with one or more antihypertensive medications SBP ≥140 mmHg; for DM or chronic kidney disease (CKD), SBP ≥130mmHg). Exclusion criteria: 1. The patients with an average sitting SBP of 4200mmHg at the screening visit. 2. Secondary hypertension. 3. HbA1c4 11%. 4. Hypertensive patients requiring admission care. 5. CKD with a serum creatinine level of 41.5 times the upper limit of normal. 6. Chronic liver disease with aspartate aminotransferase/ alanine aminotransferase over three times the upper limit of normal. 7. History of acute myocardial infarction, acute coronary syndrome, congestive heart failure and/or valvular heart disease within the last 6 months. 8. Chronic debilitating illness. 9. Autoimmune disease. 10. Patients taking medications that might influence BP (sedatives, hypnotics, lithium, selective serotonin reuptake inhibitors, tricyclic antidepressants, nonsteroidal anti-inflammatory drugs, oral contraceptives, alpha agonists, steroids). 11. Patients with known allergies to angiotensin-converting-enzyme inhibitors or angiotensin receptor blockers. 12. Patients with a history of alcoholism.	57.1	42	Hypertension duration was 8.4 (SD: 6.8) in group 1 (A&D medical BP monitoring/no remote monitoring/office visits every 8 weeks) 8.9 (SD: 8) in group 2 (LG Smartcare System without remote physician care/in-office visit every 8 weeks) 7.2 (SD: 6.4) for group 3 (LG SmartCare and remote physician care/no in person visits) SBP baseline: Group 1: 143.2 (SD: 13) Group 2: 142.9 (SD: 14.5) Group 3: 143.1 (SD: 14.7)	NR
Kim et al. (2016)[97,101]	Inclusion: a history of billing insurance for diagnostic codes consistent with diabetes, hypertension, and/or cardiac arrhythmia, Scripps Health insured employee or adult family member covered by Scripps Health plan, ability to attend two visits at a Scripps facility, within the past 12 months, aged 18 years or older. Exclusion: change in situation which will result in patient not being covered by Scripps Health plan, major surgery or trip in next 6 months which may interfere with device usage, BP cuff does not fit patient, pregnancy.	57.6	65	Mean SBP: 140.6 mmHg Mean DBP: 89.4 mmHg Number of antihypertensive medications: 2	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Klarskov et al. (2018)[131]	Inclusion: diagnosis of essential hypertension Exclusion: <18 years, pregnant	61.8	48	Mean daytime systolic ABPM: 137.7 mmHg Mean daytime diastolic ABPM: 82.1 mmHg Mean nighttime systolic ABPM: 122.8 mmHg Mean nighttime diastolic ABPM: 70.4 mmHg	NR
Lakshminarayan et al. (2018)[69]	Included were acute stroke survivors aged 40 to 85 years, with a neurologist validated ischemic stroke or intra-parenchymal hemorrhage. Participants had to be able to communicate in English, able to use or learn to use the wireless equipment and smart phone, answer survey questions and, have either a new diagnosis or history of hypertension. Participants were excluded if they were unable to give consent or complete the required trial tasks. Excluded participants with end stage renal disease.	66	28	Mean SBP: 140 mmHg Mean DBP: NR	No
Logan et al. (2012)[132]	Inclusion: diabetic patients with uncontrolled systolic hypertension. Exclusion: severe or end-stage organ disease, a history of diabetic ketoacidosis; any illness with expected survival <1 year; severe cognitive impairment, mental illness or disability; clinically significant cardiac arrhythmia; symptomatic orthostatic hypotension; or were pregnant.	62.9	44	Mean 24-hour SBP: 139.7 mmHg Mean 24-hour DBP: 74.7 mmHg	No
Magid et al. (2011)[133]	Inclusion: patients with hypertension, taking 4 or fewer antihypertensive medications, had elevations in 2 of the 3 most recent electronic BP measurements. Exclusion: NR	62	33	Mean SBP: 147.1 mmHg Mean DBP: 87.3 mmHg	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Magid et al. (2013)[64]	Adults 18 to 79 years of age were eligible if they (1) had a diagnosis of hypertension and their 2 most recent clinic BP readings were above goal (SBP ≥140 mmHg or DBP ≥90 mmHg or, for those with DM or CKD, SBP ≥130 mmHg or DBP ≥80 mmHg); (2) were prescribed ≤3 antihypertensive medications; (3) had a primary care provider who worked at 1 of the 10 participating clinics; and (4) were registered on the Kaiser Permanente Colorado My Chart Web site (which suggested that they had access to a computer and the Internet). Patients were excluded if they (1) had a limited life expectancy (e.g., patients in hospice or palliative care); (2) were ≥80 years of age because aggressive BP reduction may not be appropriate for these patients; (3) had a recent myocardial infarction, stroke, percutaneous coronary intervention, or coronary artery bypass graft surgery because Kaiser Permanente Colorado patients receive enhanced hypertension care as part of intensive cardiac rehabilitation in the year after the event; (4) had end-stage renal disease because hypertension care for these patients is provided by nephrology specialists instead of primary care providers; or (5) did not speak English. Patients were also excluded if they did not have access to the Internet and a computer with a USB port and Internet Explorer 6.0 or higher, if their BP measured at the baseline enrollment visit was already at goal, or if the home BP cuff could not be validated (e.g., the home BP reading was not within 5 mmHg of the baseline BP).	59.5	39.7	SBP UC: 145.5 (SD: 14.5), PGHD: 148.8 (16.2), DBP UC: 88.0 (SD: 9.9), PGHD: 89.6 (10.2)	No
Margolis et al. (2013)[106-112]	Inclusion: adult, elevated BP at 2 most recent primary care visits. Exclusion: NR	61.1	44.7	Mean SBP: 147.9 mmHg Mean DBP: 84.7 mmHg	No
Marquez-Contreras et al. (2006)[98]	Inclusion: 18 to 80 years old, newly diagnosed or uncontrolled hypertension, and did not have an electronic home BP monitor. Exclusion: Requiring multiple antihypertensive drugs, secondary arterial hypertension, pregnant, comorbidities which may interfere with the study.	59.1	49	Baseline SBP: 157.4 mmHg Baseline DBP: 91.7 mmHg	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
McKinstry et al. (2013)[113-115]	Patients aged 18 or more with a diagnosis of hypertension whose last surgery blood pressure measurement was >145 mmHg systolic or >85 mmHg diastolic were invited to attend a screening assessment. Exclusion criteria were inability to consent, atrial fibrillation, being on the stroke or diabetes registers, treatment for a cardiac event or other life threatening illness in the past six months, major surgery within the past three months, renal failure, or hypertension managed in secondary care.	60.6	40.5	Mean clinic BP: SBP PGHD: 152.9 (SD: 15.1), UC: 152.4 (SD: 14.3), DBP PGHD: 92.1 (SD: 11.5), UC: 89.9 (SD: 11.3) Mean daytime ambulatory BP: SBP PGHD: 146.2 (SD: 10.6) and UC: 146.2 (SD: 10.5) and DBP PGHD: 87.1 (SD: 10.0), UC: 85.4 (SD: 9.6)	NR
McManus et al. (2010)[116-120]	Inclusion: aged 35 to 85 years, receiving treatment for hypertension with two or fewer antihypertensive drugs, baseline BP >140/90 mmHg, willingness to monitor own BP and self-titrate medication. Exclusion: baseline BP >200/100 mmHg, postural hypotension terminal disease, dementia, score >10 on the short orientation memory concentration test, hypertension not managed by family doctor.	66.4	53	Mean SBP: 152.0 mmHg Mean DBP: 84.8 mmHg	NR
McManus et al. (2014)[121]	Inclusion: aged 35 years or older, have at least 1 of 3 high-risk conditions (cardiovascular disease, diabetes, stage 3 chronic kidney disease, or coronary heart disease), and have a blood pressure reading during the baseline examination of at least 130/80 mmHg. Exclusion: could not self-monitor because of dementia or if they had a score of more than 10 on the short-orientation memory concentration test; had blood pressure greater than 180/100 mmHg; had postural hypotension, SBP drop of more than 20 mmHg; took more than 3 antihypertensive medications.	69.5	40	Mean DBP: 143.4 mmHg Mean SBP: 80.1 mmHg	NR
McManus et al. (2018)[83-86]	Inclusion: age older than 35 years, with a diagnosis of hypertension, taking no more than three antihypertensive agents, clinic BP not controlled below 140/90 mmHg. Exclusion: NR	66.9	46	Mean SBP: 153.1 mmHg Mean DBP: 85.5 mmHg	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Mehos et al. (2000)[122]	Inclusion criteria: age 35 years or older, current therapy with at least one antihypertensive drug, stage 1 or 2 hypertension, ability to measure blood pressure with a home monitor. Exclusion criteria: stage 3 hypertension (systolic ≥180 mmHg and/or diastolic pressure ≥110 mmHg based on JNC-VI criteria), an identified secondary cause of hypertension, atrial fibrillation, pregnancy, current home blood pressure monitoring, failure to demonstrate correct use of monitoring device, and drug or alcohol abuse.	57.6 (control) vs. 60.0 (PGHD)	69.4	Systolic blood pressure (mmHg) 153.9±14.6 vs. 157.9±16.4 Diastolic blood pressure (mmHg) 89.6±9.8 vs. 91.1±10.8 Mean arterial pressure (mmHg) 111.0±6.4 vs. 113.4±8.0	No
Mendelson et al. (2014)[47]	Patients were eligible for the study if they were between 18 and 85 years old, diagnosed obstructive sleep apena on the diagnostic sleep study with apnea-hypopnea index >15 events/h, BMI <40 kg/m2, cardiovascular risk SCORE >5%, or being in secondary prevention with a past history of cardiovascular disease (transient ischemic attack, stroke, cerebral hemorrhage, myocardial infarction, angina, coronary revascularization, arteriopathy, aortic aneurism). Non-inclusion criteria were the following: central sleep apnea syndrome, cardiovascular score <5%, cardiac failure, history of hypercapnic chronic respiratory failure, incapacitated patients, and pregnancy in accordance with article L 1121-6 of the French public health code, or patients taking part in another clinical trial.	63	17	Mean SBP: 139 mmHg Mean DBP: 81 mmHg	No
Neumann et al. (2011)[134,135]	Inclusion: aged 18 to 80, ABPM mean value >130/80 mmHg (>125/75 mmHg if diabetes or renal insufficiency), no treatment with an angiotensin receptor blocker. Exclusion: secondary hypertension, malignant hypertension, cerebrovascular incidents or hypertensive encephalopathy, stroke within the last 6 months, pheochromocytoma, acute or endstage renal failure, potassium <3.5 mmol/L or >5.5 mmol/L, untreated diabetes, untreated hyperthyroidism or hypothyroidism, pregnancy, contraindication against treatment with an AT1-receptor antagonist.	55.5	52	Mean 24-hour systolic ABPM: 143.4 mmHg	NR
Niiranen et al. (2014)[136]	Inclusion: aged 35 to 74 years, untreated office blood pressure of ≥160/100 mmHg or on active antihypertensive treatment. Exclusion: severe psychiatric or neurologic illnesses, heart failure, hemodynamically significant valvular disease, unstable coronary heart disease, chronic kidney disease.	62.2	50	Mean SBP: 147 mmHg Mean DBP: 87 mmHg	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Ogedegbe et al. (2014)[123]	Patients were eligible for the study if they: self-identified as black or African American; were at least 18 years old, were receiving care at the participating CHC for at least six months prior to enrollment; had a diagnosis of hypertension, were taking at least one antihypertensive medication, and had uncontrolled BP at the time of enrollment based on standardized measurement at study visit (SBP ≥140 mmHg or DBP ≥90 mmHg; for those with diabetes or kidney disease, SBP ≥130 mmHg or DBP ≥80 mmHg).	56.5 (SD: 12.1)	72	Mean blood pressure: SBP: 151: (SD: 17) and DBP: 91 (SD: 11) for all patients combined	No
Petrella et al. (2014)[60]	Participants with at least two metabolic syndrome risk factors as defined by the National Cholesterol Education Program Adult Treatment Panel III [waist circumference ≥88 cm (women) or 102 cm (men); SBP ≥135 mmHg and/or DBP ≥85 mmHg; fasting plasma glucose ≥6.1 mmol/L; fasting triglycerides ≥1.7 mmol/L; fasting HDL ≤1.29 mmol/L (women) or 1.02 mmol/L (men)] presented to a community-based research center (Gateway Rural Health Research Institute, Seaforth, Ontario, Canada) and voluntarily provided informed consent to participate in this parallel-group, randomized controlled trial. Exclusion criteria, evaluated by self-report during a screening phone call and verified in-person were: SBP >180 mmHg and/or DBP >110 mmHg; type 1 diabetes; history of myocardial infarction, angioplasty, coronary artery bypass or cerebrovascular ischemia; symptomatic congestive heart failure; atrial flutter; unstable angina; unstable pulmonary disease; use of medications known to affect heart rate; second or third degree heart block; history of alcoholism, drug abuse or other emotional cognitive or psychiatric problems; pacemaker; unstable metabolic disease; and orthopedic or rheumatologic problems that could impair the ability to exercise.	57	74	Mean SBP: 141 mmHg Mean DBP: 85 mmHg	Yes
Qi et al. (2017)[99]	Inclusion: diagnosis of essential hypertension were registered in the hypertension management center of the community, age over 18 years, stable condition with or without antihypertensive drug in maximum tolerable doses of different classes. Exclusion: substantial valvular heart disease, pregnancy, recent history of myocardial infarction, unstable angina or cerebral vascular event, renal artery stenosis and/or previous renal artery intervention, secondary hypertension.	64.0	45	Mean SBP: 140.0 mmHg Mean DBP: 92.5 mmHg	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Rifkin et al. (2013)[65]	Inclusion: stage 3 CKD, established hypertension, age 50 years, community-dwelling, self-managing medications. Exclusion: secondary hypertension, clinical estimation of requiring dialysis or mortality within next 6 months.	68.3	5	Mean SBP: 148 mmHg Mean DBP: 79 mmHg	NR
Rogers et al. (2001)[137]	Inclusion: adults; previous diagnosis of hypertension; under evaluation for a change in antihypertensive therapy due to elevated BP, undesirable side effects of current treatment, or high BP with no current treatment. Exclusion: <18 years of age, pregnant, secondary hypertension.	61.5	50	NR	NR
Sarfo et al. (2018)[138,139]	Inclusion: aged at least 18 years with a recent CT-scan confirmed stroke of <1 month and uncontrolled hypertension SBP at least 140 mmHg. Exclusion: Severe cognitive impairment/dementia, severe global disability, renal dialysis, recent cancer diagnosis or treatment, planned pregnancy, or vulnerable population.	55.1	35	SBP Mean: 143.8 DBP Mean: 90.5 Number of antihypertensive medications: Mean 2.7	No
Stewart et al. (2014)[140]	Inclusion: used conventional antihypertensive medication within the last 6 months, diagnosis of primary hypertension, aged 18 years or older. Exclusion: participation in other adherence promotion programs, having had a recent pharmacist-conducted medicine review, not self-administering antihypertensive medication.	66.7	49	Mean SBP: 141.0 mmHg Mean DBP: 83.8 mmHg	NR
Yoo et al. (2009)[23]	Between 30 and 70 years of age, who met the following criteria: (i) a diagnosis of both Type 2 diabetes and hypertension at least 1 year previously by a physician; (ii) HbA1c 6.5–10.0%; (iii) blood pressure >130/80 mmHg; and (iv) BMI >=23.0 kg/m2 (overweight according to Asia-Pacific criteria) [15]. Exclusion criteria included (i) severe diabetic complications (e.g., diabetic foot or severe diabetic retinopathy); (ii) liver dysfunction with aspartate aminotransferase or alanine aminotransferase >2.5 times the reference level, or renal dysfunction (serum creatinine >132 lmol/l); (iii) medical history of congestive heart failure, angina pectoris, myocardial infarction, or stroke based on a physician's diagnosis; (iv) pregnancy or lactation; or (v) other medical problems that could affect study results or trial participation.	58	41	NR	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Zaleski et al. (2019)[100]	Patients at least 18 years with elevated BP to established hypertension defined by the updated ACC/AHA criteria as SBP at least 130 to less than 160 mmHg or DBP at least 80 to less than 100 mmHg or taking antihypertensive medication regardless of BP were enrolled. Ambulatory BP was also used to determine further study inclusion if BP values met the definition of being a 'postexercise hypotension responder' such that average 24-h ambulatory SBP or DBP was at least 2 mmHg lower after Visit 2 than after Visit 1 (i.e., orientation session). Participants were free of diagnosed cardiovascular, pulmonary, renal, metabolic, or other chronic diseases and depression; were nonsmokers for at least 6 months prior to entry; consumed less than two alcoholic drinks daily; and were physically inactive defined as engaging in formal exercise of 2 days/week or less. Other than antihypertensive medications, participants taking medications or supplements that influenced BP were asked to discontinue these medications for the duration of the study. Prescription medications were discontinued only after receiving the prescribing physician's approval. Study participants using antihypertensive medications were included if they reported taking the same medication for at least 3 months. Participants with osteoarthritis and orthopedic problems were not enrolled if these conditions compromised their ability to exercise. Participants with a past medical history of cancer-related lymphedema were not enrolled due to the increased risk of infection and/or pain experienced with repeated BP assessment. Participants were also not enrolled if that they were seeking to gain or lose weight due to the confounding influence of weight loss and dietary intake on BP. Women confirmed that they were not pregnant, lactating, or planning to become pregnant. Women using hormone-altering contraception that was administered in a bolus (e.g., Depo-Provera) with a 'tapering' dose effect (i.e., peak hormone concentrations followed by slow elimination) were excluded due to the potential influence of variable circulating estrogen levels on BP.	52.3 (SD: 10.8)	54	Resting SBP: 136.2 (SD: 11.2) and resting DBP: 85.2 (SD: 8.9) mmHg for total sample and duration of hypertension 6.2 (SD: 5.9) years	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Zarnke et al. (1997)[124]	Inclusion: aged between 18 and 80 years of age, had controlled mild to moderate essential hypertension for at least 6 months. Exclusion: BP >160/95 mmHg; current use of home BP monitoring device, secondary causes of hypertension; current use or adverse events from calcium channel blockers; recent myocardial infarction, stroke, or transient ischemic attack.	55	65	Mean arterial BP: 97 mmHg	NR
Zha et al. (2019)[87]	Inclusion: between 18 and 64 years of age, resided in one of the four public housing units near the study center, had been diagnosed with uncontrolled hypertension, on antihypertension medication, owned and used a compatible Apple or Android, device. Exclusion: pregnant women, patients with a serious arrhythmia or preeclampsia.	52.2	88	Mean SBP: 145.72 mmHg Mean DBP: 90.57 mmHg	No

ABPM = ambulatory blood pressure monitoring; ACC/AHA = American College of Cardiology/American Heart Association; BMI = body mass index; BP = blood pressure; CKD = chronic kidney disease; CPAP = continuous positive airway pressure; CT = computed tomography; CVD = cardiovascular disease; DBP = diastolic blood pressure; DM = diabetes mellitus; ECG = electrocardiogram; HbA1c = hemoglobin A1c; HBPM = home blood pressure monitoring; HDL = high-density lipoproteins; ICD = International Classification of Diseases; JNC = Joint National Committee; mmHg = millimeters of mercury; NR = not reported; NRS = nonrandomized study; PGHD = patient-generated health data; RCT = randomized controlled trial; SBP = systolic blood pressure; SCORE = Systematic Coronary Risk Evaluation; SD = standard deviation; UC = usual care; USB = Universal Serial Bus

Table C-25. Hypertension and PGHD: treatment details

Study	Treatment 1	Other Treatment Groups
Aekplakorn et al. (2016)[88]	Usual care: UC patients were treated at the discretion of the physician. The patients did not receive the home BP monitor. They were informed about their BP status at time of visit and advised about medication usage and healthy lifestyle practice, including healthy diet and exercise as usual.	PGHD (Omron HEM 7117): PGHD patients received a BP monitor. Each participant was instructed individually about how to use the monitor, record, and interpret the BP data whether they were in optimal level. They were trained to measure their BP at home every day for 6 months using the provided oscillometric BP monitor (Omron model HEM-7117, Kyoto, Japan). Blood pressures were measured 2 times aday (3 readings for each time), once in the morning within 1 hour after waking up, after urination, before breakfast and medication, and after 5 minutes of resting and another in the evening before going to bed according to the Japanese Society of Hypertension guideline 2003. The patients were asked to bring their BP records when they came to follow-up for physician review at the hypertension clinic. Any of 3 physicians in the community hospital assessed the recorded BP and communicated with the patients on their BP status and provided advice on medication and healthy lifestyle.

Study	Treatment 1	Other Treatment Groups
Bennett et al. (2018)[18,72,73]	Usual care: Received care from their primary care providers, self-help materials, list of community resources for healthy eating, physical activity, weight management, received quarterly with health tips newsletter.	Intervention: Based on social cognitive theory, with 6 components: 1 tailored behavioral goals using a pedometer (Yamax SW 650-651 Digi Walker), 2 self-monitoring of goals via phone and text messages, 3 daily self-weighing using a cellular-connected scale (specific device NR but the manufacturer was BodyTrace) 4 skills training materials 5 18 weight loss counseling phone calls and 6 brief primary careprivded weight loss counseling at medical visits.
Bernocchi et al. (2014)[125]	Usual care: Patients were followed by their general practitioners without any structured program.	Home-Based Telemedicine: The home-based medicine service consisted of a structured physician-directed, nurse-managed telephone support added to a BP telemonitoring. The staff included hypertension specialists, cardiologists, and trained nurses. Support consisted of scheduled and unscheduled telephone appointments. Scheduled appointments occurred approximately every 15 days. During these contacts, the nurse carried out a standardized interview on general clinical condition of the patients. The patient was also counseled on weight management and physical activity, smoking cessation, dietary changes and stress management. The patients were asked information about their prescribed drugs and whether they took them regularly. If drug compliance was poor, the nurse offered strategies to improve patient's compliance. Unscheduled appointments were initiated by the patient when they experienced signs and symptoms or had questions about their therapy. The patient had the opportunity to contact the nurse at any time of the day through the service center and report any clinical problems. Patients were supplied with an A&D UA-767 Plus BT and a mobile phone which had a Java 2 Platform Micro Edition. The A&D sensor could transmit the BP values to a mobile through Bluetooth connection and it could send them to a server via secure data connection. At the beginning of the study an educational meeting was held where the nurse explained the study to the patients and taught them the correct way to use the home BP instruments and the mobile phone and the correct way to measure BP based on published guidelines. The nurse could retrieve the BP values which were automatically updated with out-of-range values highlighted. In case of abnormal readings, the nurse could contact the patient through a service center. The nurse could also verify that the patient measured their BP with the agreed frequency. In case of no measurement for at least three days, the nurse contacted the patient.

Study	Treatment 1	Other Treatment Groups		
Bosworth et al. (2009)[63]	Usual care: Patients assigned to usual care received hypertension care from their primary care provider. They were not provided home BP monitors and did not have access to the nurse-administered behavioral intervention. They underwent the same 6-month outcome assessment measurements as the other groups.	PGHD (Omron 773AC or 637): Home BP Monitoring Intervention: Patients assigned to home BP monitoring received an Omron HEM 773AC arm monitor (OMRON Healthcare, Bannockburn, Illinois) if arm circumference was 17 inches or less or an Omron HEM 637 wrist monitor if arm circumference was greater than 17 inches and wrist circumference was less than 8.5 inches. Two research assistants trained patients in proper use of the home BP devices. At each 6-month assessment, patients were retrained if their BP assessment procedure was incorrect. Patients were asked to measure their BP 3 times weekly on 3 separate days, at the same time of day, and record their values in a log. Patients were asked to mail their logs in every 2 months by using study-provided, preaddressed, stamped envelopes.	Combination (PGHD plus behavior self-management): Patients assigned to the combined intervention received a home BP monitor, training on its use, and the behavioral self-management intervention. The nurse did not examine home BP values and did not use the home BP values to adjust the intervention.	Behavioral intervention: Tailored Behavioral Self-management Intervention: Patient factors targeted in the behavioral intervention included perceived risk for hypertension, memory, literacy, social support, patients' relationships with their health care providers, and side effects of antihypertension medication. In addition, the intervention focused on improving adherence to the Dietary Approaches to Stop Hypertension (DASH) dietary pattern, weight loss, reduced sodium intake, regular moderate-intensity physical activity, smoking cessation, and moderation of alcohol intake. The intervention was delivered by 1 nurse during bimonthly telephone calls. All information was presented in an easily understood format with a Flesch-Kincaid readability score of less than 9th grade. Each encounter included a core group of modules potentially implemented during each call (for example, medication and side effects) plus additional modules activated at specific intervals (for example, diet and social support).

Bosworth et al. (2011)[66-68]	Usual care: Patients treated received no contact with the intervention nurses and did not receive home telemonitoring equipment.	Combination (PGHD, behavioral management): Patients received an A&D model UA-767PC wireless home BP monitor and a Carematix model 102 telemedicine device and were advised to measure their BP every other day. The telemedicine device connected to a telephone line like an answering machine. Patients' BP measurements were transmitted automatically to a secure server. When 2-week average home BP was >135/85 mmHg or, for those with diabetes, >135/80 mmHg, an alert was triggered initiating the assigned management approach. Patients who maintained adequate BP control did not activate the intervention but triggered a contact every 6 months to reinforce their positive behavior. A safety alert was activated if 2 consecutive home BP measurements recorded at least 12 hours apart were greater than 175/105 mmHg. In this instance, a nurse contacted the patient and initiated an approved safety protocol. If an alert was triggered, patients received a behavioral management intervention consisting of 11 tailored health behavior modules focused on improving hypertension self-management, including hypertension knowledge, including medication adverse effects and medication memory; resources to improve health care access; and the patient–health care provider relationship.	Combination (PGHD, medication management): Patients received an A&D model UA-767PC wireless home BP monitor and a Carematix model 102 telemedicine device and were advised to measure their BP every other day. The telemedicine device connected to a telephone line like an answering machine. Patients' BP measurements were transmitted automatically to a secure server. When 2-week average home BP was >135/85 mmHg or, for those with diabetes, >135/80 mmHg, an alert was triggered initiating the assigned management approach. Patients who maintained adequate BP control did not activate the intervention but triggered a contact every 6 months to reinforce their positive behavior. A safety alert was activated if 2 consecutive home BP measurements recorded at least 12 hours apart were greater than 175/105 mmHg. In this instance, a nurse contacted the patient and initiated an approved safety protocol. If an alert was triggered, patients received a medication management intervention. A nurse notified a study physician and provided the physician with a medication change recommendation based on the decision support software. The study physician reviewed the patient's BP,	Combination (PGHD, behavioral management, medication management): Patients received an A&D model UA-767PC wireless home BP monitor and a Carematix model 102 telemedicine device and were advised to measure their BP every other day. The telemedicine device connected to a telephone line like an answering machine. Patients' BP measurements were transmitted automatically to a secure server. When 2-week average home BP was >135/85 mmHg or, for those with diabetes, >135/80 mmHg, an alert was triggered initiating the assigned management approach. Patients who maintained adequate BP control did not activate the intervention but triggered a contact every 6 months to reinforce their positive behavior. A safety alert was activated if 2 consecutive home BP measurements recorded at least 12 hours apart were greater than 175/105 mmHg. In this instance, a nurse contacted the patient and initiated an approved safety protocol. If an alert was triggered, patients received both the behavioral and medication management intervention.

Study	Treatment 1	Other Treatment Groups		
		Patients were also provided evidence-based recommendations regarding hypertension related behaviors, including salt intake, weight, stress reduction, smoking cessation, and alcohol use. Verbal information was reinforced with mailed handouts. The nurse used an intervention software application that contained predetermined scripts and patient-specific tailored algorithms for the modules. Each encounter consisted of 3 or 4 modules and lasted 12 to 14 minutes.	medication, and adherence (based on patient report and prescription refill data) with the nurse and decided whether to change hypertension medication. The nurse communicated recommended changes to the patient, while the study physician electronically prescribed the medication and generated a note in the patient's medical record that was co-signed by the patient's primary care physician. The nurse called the patient 3 weeks after the medication change to obtain reports of adverse effects and address patient questions.	
Bosworth et al. (2011)[89-91]	Usual care: Patients assigned to usual care received hypertension care from their primary care provider. They were not provided home BP monitors and did not have access to the nurse-administered behavioral intervention.	PGHD (Omron 773AC or 637): Patients received an Omron HEM 773AC arm monitor if arm circumference was 17 inches or less or an Omron HEM 637 wrist monitor if arm circumference was greater than 17 inches and wrist circumference was less than 8.5 inches. Two research assistants trained patients in proper use of the home BP devices. At each 6-month assessment, patients were retrained if their BP assessment procedure was incorrect. Patients were asked to measure their BP 3 times weekly on 3 separate days, at the same time of day, and record their values in a log. Patients were asked to mail their logs in every 2 months by using study-provided, preaddressed, stamped envelopes.	Behavioral intervention: Targeted patient factors including perceived risk of hypertension, memory, literacy, social support, patients' relationships with their health care providers, and side effects of hypertension medication therapy on an individualized basis. The intervention also focused on improving adherence to standard hypertension recommendations. The intervention was delivered by a nurse during bi-monthly telephone calls. These encounters included a core group of modules potentially implemented during each call (e.g., medication) plus additional modules activated at specific intervals.	Combination (PGHD plus behavior self-management): Patients received a home BP monitor, training on its use, and the behavioral self-management intervention. The nurse did not examine home BP values and did not use the home BP values to adjust the intervention.

Study	Treatment 1	Other Treatment Groups
Bove et al. (2013)[92]	Usual care: Eligible subjects had their medical history, medications, physical examination, electrocardiogram, blood studies, urinalysis, height, weight, and waist circumference recorded. Two BP measurements were recorded in the sitting position 5 minutes apart and were averaged. A fasting blood sample was obtained to determine cholesterol, LDL, HDL, triglycerides, glucose, and hemoglobin A1c. The subjects completed a cardiovascular health knowledge questionnaire, a medication compliance questionnaire, and the CAHPS Clinician & Group Survey. Control subjects were provided with the data from their initial assessment and instructed to contact their primary care provider for further care. No further intervention was provided to the control subjects.	PGHD (BP, pedometer, scale): Eligible subjects had their medical history, medications, physical examination, electrocardiogram, blood studies, urinalysis, height, weight, and waist circumference recorded. Two BP measurements were recorded in the sitting position 5 minutes apart and were averaged. A fasting blood sample was obtained to determine cholesterol, LDL, HDL, triglycerides, glucose, and hemoglobin A1c. The subjects completed a cardiovascular health knowledge questionnaire, a medication compliance questionnaire, and the CAHPS Clinician & Group Survey. Telemedicine subjects were trained on use of a computer and the Internet and were introduced to the Web site at the research center. Telemedicine subjects received instructions on use of an optional telephone communication system. The subjects were provided with a password and log-in name for access to the secure Web site, a personal identification number, and a toll-free telephone number to access the telephone system. Subjects in the Telemedicine arm were given a sphygmomanometer (Micro life USA Inc; 3AC1-AP, Clearwater, FL), a scale if needed (Taylor Digital LCD Scale, 7006, Oak Brook, IL), and a pedometer (Digi-Walker SW-200; Yamax Inc, Tokyo, Japan) and instructions on their use. Physicians caring for telemedicine patients received a monthly report via fax on the patient's BP status and a reminder of BP goals. Patients received the same report and were instructed to bring the report to their physician's office for discussion with their provider. Subjects were instructed to report their health data through a Web form or through the telephone and received an automatically generated e-mail or telephone call from the database program as a reminder to report. After 2 weeks of absent reports, the study nurse was informed to call the patient by telephone to provide motivation. Telemedicine subjects were provided with BP education through the Internet or via voice messages on the telephone. The communication system allowed patients to enter BP, pulse, weight, steps per day by either a Web screen or by voice or telephone keypad. Voice data were processed using automatic voice recognition, converted into digital form, and stored in a database. We instructed the telemedicine subjects to send their data at least twice a week. If the SBP was >140 mmHg, the telemedicine system automatically sent a short message to the patient stating that the measures were acceptable, a short message on health care, and instructions to continue with the scheduled transmission of data. The research nurses reviewed data from subjects who reported elevated BP and transmitted responses to the patient through the Internet system or by telephone. The system is a Health Insurance Portability and Accountability Act compliant, secure, encrypted Web system (Itsmyhealthrecord.com; Insight Telehealth Systems, Valley Forge, PA) that allows bidirectional data transfer between patient and practice. The system is adapted to convert text messages to voice messages for telephone users. Data, text, and voice messages are recorded in a database that provides the patient with their information in the form of a personal health record.
Broege et al. (2001)[79]	Clinic group: Patients were seen in the clinic every 2 weeks and had their blood pressure taken at each visit by a trained nurse.	PGHD (Omron HEM-702): Patients received an Omron HEM-702 semi-automatic BP monitor and were trained to measure and record their own BP three times in the morning and three times in the evening at approximately the same time every other day. Every 2 weeks these patients were telephoned by the project nurse who obtained their home measured BP. These measurements were used to make treatment decisions. Patients were also seen in the clinic every month three additional times from the initial visit, but the nurse and physician BP readings taken at these visits were not used to make medication decisions.

Study	Treatment 1	Other Treatment Groups
Chandler et al. (2020)[74]	PGHD (Runkeeper app): A research assistant downloaded the Runkeeper app to the patient's phone, demonstrated all features of the app, and ensured the participants' understanding of the app. The app was used to enable tracking and provide feedback of the duration of daily planned physical activities participants performed the amount of total daily activity using the phone's built in accelerometer (steps/day) and GPS software for distance tracking. Patients received healthy lifestyle-behaviorrelated educational messages associated with their heart-healthy diet, low sodium intake, non-smoking, physical activity, sun exposure, and other factors. Messages were not tailored. Participants were instructed to complete two 15-minute daily sessions for the first month, decrease to two 10-minute daily sessions for months 2 and 3, and then decrease to 5-minute sessions for the remainder of the trial.	PGHD (Tension Tamer app): A trained team member downloaded the Tension Tamer app to the participant's phone and instructed them in navigating each module of the app. The app utilizes a smartphone's camera lens to acquire continuous measures of heart rate via detection of fingertip pulsatile blood flow changes via reflective photoplethysmography software. The participant must keep the tip of their index finger on the camera lens during meditation sessions. Within 20 to 30 seconds, the app acquires a stable heart rate and continuously displays heart rate presented on a 4 beat rolling average. Additionally, there is a video clip guide, in which a moderate describes how to engage in breathing awareness meditation while showing an individual engaging in breating awareness medication with attention to the explansion of the abdominal region when inhaling through the nose. There is also an audio guide, which automatically plays on the initial meditation session. A brief chime activates midway and at completion of the session. The app provides a timer on the screen, which displays the duration of each session. Immediately following the completion of a session, users receive a feedback graph displaying average heart rate each minute and maximum decrease observed. The app sends encrypted heart rate data to a relational database management system managed by the study institution. Users also received tailored motivational and social reinforcement text messages based upon levels of adherence. Participants were instructed to complete two 15-minute daily sessions for the first month, decrease to two 10-minute daily sessions for months 2 and 3, and then decrease to 5-minute sessions for the remainder of the trial.
Dorough et al. (2014)[126]	DASH 2 wellness only: Received eating plan guide, recommended low sodium diet, counseling from registered dietician, walking and weight program, digital weight scale (Tanita Digital Weight Scale), pedometer (Accusplit 120 XL).	DASH 2 wellness plus: Received all the interventions of the DASH 2 wellness group, and in addition received an Omron Automatic BP monitor (HEM-712C). They were instructed about how to use the BP monitor, how to complete weekly tracking forms online, and weekly electronic visits over 10 weeks from their assigned project director, who supported the patient in lifestyle changes, information on the eating plan, and in an exercise walking program.

Study	Treatment 1	Other Treatment Groups
Earle et al. (2010)[70,71]	Usual care: Patients did not receive any equipment. They were not required to report their BP and did not receive any support from the research nurses. All of their management was provided by their local practitioners who were not involved in the study.	Combination (PGHD, treatment management): Patients received the One Touch Ultra Glucose Meter to self-measure capillary blood sugar. The monitor was adapted to transmit their recordings wirelessly by Bluetooth to a Motorola A-100 mobile phone. Patients also received the model UA-767BT and were trained to measure their own BP and transmit the recordings via Bluetooth wireless technology to a Motorola A-100 mobile phone. The mobile phone alerted the patient when a measurement was due. Data were sent from the patient's mobile phone to a server at the study center. The research clinicians reviewed the recordings via a web-based application. Letters were sent from the clinician to the patients and their physicians with details of the amalgamated readings and treatment recommendations. Patients could also use the mobile phones free of charge to contact the research team for clinical and technical support.
Fuchs et al. (2012)[93]	Usual care: At follow-up visits, patients received the same non-pharmacological recommendations as the intervention group and were also instructed to keep on their current medication doses. There was also a pharmacist care group, but for the purposes of the analysis, that group was combined with the usual care group.	PGHD (Omron HEM-705 CP): Patients received an Omron HEM-705 BP measuring device and a BP diary. Participants were trained to use the device, to measure BP according to the standardized technique, and to fill the BP diary. Patients were instructed to perform six measurements per day. In addition, they were instructed to maintain their current antihypertensive medication during the trial, including drugs and doses, which were not modified in the follow-up visits. The goal to control BP was explained to the patients. At each follow-up visit, apart from checking the BP diary records, patients were recommended to follow non-pharmacological interventions. There was also a PGHD plus pharmacist care group, but for the purposes of the analysis, that group was combined with the PGHD group.

Study	Treatment 1	Other Treatment Groups	
Green et al. (2008)[80,81]	Usual care: Patients were told their BP was not in control and were encouraged to work with their physician to improve it.	PGHD (Omron HEM-705 CP): Patients received an Omron Hem-705-CP BP monitor and were trained on how to use it. They were instructed to use this monitor to check their BP at least 2 days per week with 2 measurements each time. They were told the goal for average home systolic and diastolic BP was 135 and 85 mmHg or less. They also received training on how to use the website.	Combination (PGHD, Pharmacist Care): Patients received an Omron Hem-705-CP BP monitor and were trained on how to use it. They were instructed to use this monitor to check their BP at least 2 days per week with 2 measurements each time. They were told the goal for average home systolic and diastolic BP was 135 and 85 mmHg or less. They also received training on how to use the website. A pharmacist scheduled a phone call with the patient to obtain a more detailed medication history and review allergies, intolerances, and cardiovascular risk factors. At the end of the telephone call, the pharmacist introduced the patient to the action plan. The action plan was a template with the following 5 components: instructions for home BP monitoring; a list of current medications; at least 1 patient-selected lifestyle goal from the list in the Group Health hypertension pamphlet; recommended medication changes based on the stepped medication protocols; and the follow-up plan. All planned communications then occurred over the Web every 2 weeks until BP was controlled and less often thereafter. Patients were asked to provide BP measurements, concerns about medications, and progress related to their lifestyle goal. Pharmacists responded with specific recommendations (including medication changes) and patients were encouraged to provide feedback and collaboratively change the action plan.
Green et al. (2014)[24]	Usual care: Told that their BP was high and encouraged to follow-up with their physician. Also received a copy of their lab results including their 10 year CVD risk.	Web dietician: Received the same information as the usual care group, and in addition received a scale (device NR), a pedometer, (device NR), and a home BP monitor (Omron 711-DLX) and trained to use those 3 devices. They met with a dietician and asked to complete a questionnaire about dietary habits, physical activity, prior attempts to lose weight, tobacco/alcohol use, and a standard 3-day food diary. Received education about the DASH diet from the dietician, and created a five-component action plan. They communicated via the web throughout the study.	

Study	Treatment 1	Other Treatment Groups
Halme et al. (2005)[127]	Usual care: Patients used the Omron M4 BP monitor to measure home BP at baseline and follow-up.	Combination (PGHD, Physician management): Patients received an Omron M4 home BP measurement device. Physicians or nurses instructed the patients on how to measure BP at home. Blood pressure was measured twice daily, in the morning and in the evening. The measurements were performed in relaxed surroundings with the patient first sitting with the cuff around the arm for 5 min and then measuring the BP twice at 1- to 2-min intervals. Both readings were recorded by the patient. The measurements were performed on 7 consecutive days. Patients kept a diary on their BP values and returned it to the physician who could freely decide whether to take further measurements to intensify the antihypertensive treatment. The physicians could freely ask the patients for additional appointments, as well as the patients could themselves contact the physician. The participating physicians were educated to follow the recent Finnish BP guidelines, according to which the target BP for office measurements is ≤140/85 mmHg and for home measurements ≤135/80 mmHg. They were also given general instructions on the benefits of combination therapy and specifically instructed to intensify the treatment if the BP target was not met.
He et al. (2017)[128]	Usual care: Neither physicians nor community health workers were trained to conduct study interventions. Additionally, participants did not receive home visits, home BP monitors, or text messages. Participants were encouraged to follow the clinical visit schedule of the Remediar+Redes Program: monthly among patients after pharmacological treatment initiation and every 3 to 6 months among patients who had controlled BP.	Combination (health coaching, PGHD, and BP audit): Multi-component intervention program consisting of health coaching, home BP monitoring, BP audit, physician education, BP feedback, and text messaging. Community health workers were trained to coach patients and their family members on lifestyle modification, home BP-monitoring, and medication adherence during a 2-day interactive training session followed by onsite field testing and certification. They were also trained to function as case managers for the patients and their families by coordinating intervention activities and facilitating patient care. They visited participants' homes monthly for the first 6 months and every other month thereafter. The family-based intervention started with an initial 90-minute home visit at a time when all family members in the household were available to discuss general knowledge about hypertension prevention and treatment. During subsequent 60-minute monthly or bimonthly follow-up visits, the community health workers provided tailored counseling to participants and their families on lifestyle modification, home BP monitoring, and medication adherence skills. All patients with hypertension in the intervention group were given an Omron HEM-737 automatic home BP monitor and log and were trained to record their BP weekly. Additionally, they were provided 7-day pill organizers and counseled on techniques for improving medication adherence. Primary care physicians took part in an online education course on hypertension management followed by an onsite, in-person, half-day intensive training and certification. The physician training program focused on standard treatment algorithms for stepped-care BP management based on clinical guidelines. Individualized text messages to promote lifestyle changes and reinforce medication adherence were sent out weekly to participants' mobile phones by an eHealth platform at the Institute for Clinical Effectiveness and Health Policy in Buenos Aires, Argentina. Messages were based on hypertension status and perceived barriers to behavioral change identified during home visits and consisted of motivational statements and behavioral change techniques to reinforce in-person education interventions. The community health workers also collected information on participants' receipt of text messages.

Study	Treatment 1	Other Treatment Groups	
Hebert et al. (2012)[82]	Usual care: Patients received a pamphlet on strategies for controlling BP.	PGHD (Omron HEM-712C): Patients received an Omron HEM-712C BP monitor, information on its use, and a pamphlet on strategies for controlling BP.	Combination (PGHD, nurse management): Patients received an Omron HEM-712C BP monitor. A registered nurse provided face-to-face counseling with the patient. This counseling stressed vigilance in BP monitoring using the home BP monitor and BP diaries, gave strategies to improve medication adherence, and provided instructions to patients on how to read food labels on important foods to better monitor salt and fat intake. Counseling was also provided on reducing smoking and alcohol intake. Regular telephone follow-up reinforced these messages. Nurses also contacted patients' clinicians to discuss problems with specific medications, especially those with side-effects that affected adherence, and arranged any prescription changes. A cardiologist monitored the nurse's work, initially in weekly and then biweekly meetings.
Hoffmann-Petersen et al. (2017)[94]	Usual care: Patients had their BP measured by their physician as close to the normal routine as possible. Physicians were instructed to follow current guidelines regarding BP levels and treatments.	PGHD (A&D 767PlusBT or Omron 705IT): Patients received either the A&D 767PlusBT or the Omron 705IT BP Monitor. The A&D 767PlusBT was used at the beginning of the study, but was switched to the Omron 705IT to support integration of electronic health records at the clinic. Patients measured their BP for 3 days every second week. With the A&D 767PlusBT, data were sent using a Tunstall RTX3371 telehealth monitor, with Global System for Mobile communication/General Packet Radio Service communication with a central server. A summary report was extracted from the Tunstall Triagemanager software. With the Omron 705IT, data were sent using a Numera telehealth monitor with Global System for Mobile Communication/General Packet Radio Service with a central server. The mean of BP measurements was sent to the electronic health record using the Danish MedCom standard. A summary report could be extracted from the Columna Citizen Platform. Physicians were instructed to follow current guidelines regarding BP levels and treatments.	
Hosseininasab et al. (2014)[129]	Usual care: Patients received usual care as suggested by the physician.	PGHD (Samsung SHB-200w): Patients received a Samsung SHB-200w wrist blood pressure measurement device. They were instructed how to use the device and document their measurements in a logbook. They were advised to measure their blood pressure once daily at a specific time every day. The logbook was checked at each visit by the investigator and was collected at the final visit for data analysis.	

Study	Treatment 1	Other Treatment Groups
Kaihara et al. (2014)[95]	Conventional BP monitor: Patients used the Omron HEM-7080IC to monitor their BP for 2 weeks. Patients manually recorded their home BP data at the same time that their home BP data were input into their device.	PGHD (Omron HEM-7251G): Patients used the Omron HEM-7251G to monitor their BP for 2 weeks. The HEM-7251G received acquired physiological data (BP, pulse rate) wirelessly and transmitted them to the central Web server via the Internet.

Kao et al. (2019)[102]	Usual care: Included routine follow-up treatments for medication, lifestyle modification consultations, and a blood pressure check. Medications were adjusted depending on evaluations from their physicians at each clinical visit.	PGHD: PGHD participants received a 4-week training course before receiving the Web-based self-titration program. First, participants were given a secure account and a unique password of the website platform. Investigators assisted participants with any set-up required on their smartphones or tablets. A stepwise instruction booklet was provided to guide log-in and use the platform. Second, the physicians of these participants set individualized blood pressure targets and explained the tailored medication titration instructions to each participant, who were then asked to rely on their home blood pressure recordings to titrate their medication doses. Third, participants were trained to measure their blood pressure by using automated electronic sphygmomanometers correctly. Finally, all participants received education about the management of hypertension. When participants began the Web-based self-titration program, they were asked to measure their blood pressure before taking their medications and to report the data on the platform every day. Investigators reviewed the data daily and provided a consultation through a phone call or website platform as needed for each individual participant. The physicians provided instructions to participants for any medication dosage change (increase or decrease), based on the self-monitoring data, through the website platform or clinical visit every month. The participants learned how to modify their lifestyle and manage hypertension by visiting the website repeatedly. Blood pressure monitoring device was Omron Colin JPN1.The investigators determined that patients able to titrate medications by themselves should be proficient in three areas: the ability to measure blood pressure correctly, the ability to record and understand the blood pressure recordings, and the ability to adjust their dose (add, maintain, or decrease) or adopt emergency interventions based on the instructions. A secure website was designed to assist patients in performing safe self-titration. The website includes five sections: (1) personal information collection, (2) individual physical data recordings, (3) blood pressure recordings, (4) patient education in hypertension, and (5) consultations. In the personal information section, investigators required patients to provide the following data: age, gender, education status, employment status, contact information, comorbidity, current medications, and next visit date. In the individual physical data section, investigators input hematology test data such as low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, and serum creatinine levels through a chart review. Patients were able to access their blood test data through the website. In the blood pressure recording section, investigators set up individual blood pressure targets for each patient. The patients measured their blood pressure and recorded the data through the Web. An alarm and reminder system was designed and set up to allow patients to clearly understand the meaning of their current blood pressure readings and how to deal with them. When patients filled in their blood pressure data on the website, reminders popped up according to the blood pressure readings. If a blood pressure reading was below or above normal, the system automatically triggered an alert for the study team to contact the patient. If the blood pressure readings were not entered by 9 PM, the system was designed to send an email notification to remind the study team and either the patient or his/her caregiver to enter the readings. The database was automatically backed up at 12 PM each day. Outputs of blood pressure data were displayed as curve diagrams showing the 1-month or 3-month trends to patients. In the patient education section, a video provided information about the management of hypertension and instructions about blood pressure measurements, a healthy diet, and exercise. The video content was designed based on the guidance of five experts from among the cardiologists and nurses. Finally, the patients were able to directly contact the research team through the consultation section.

Study	Treatment 1	Other Treatment Groups
Kauric-Klein et al. (2007)[96]	Usual care: Usual care involved BP assessment during each hemodialysis treatment, as well as having health care providers deliver ad hoc information and education about BP. After initiation of the study, both study groups were seen weekly by the principal investigator, who answered questions and ensured the HBPM was working correctly (for those assigned to HBPM).	PGHD blood pressure monitoring Omron IC: The HBPM group received usual care plus a memory equipped Omron IC automatic home BP monitor. Patients in the HBPM group were asked to monitor and record their BP twice a day between 6 a.m. and 10 a.m. and then between 6 p.m. and 10 p.m. The first author trained patients on how to use the BP monitor and the patients performed a return demonstration of proper use. After initiation of the study, both study groups were seen weekly by the principal investigator, who answered questions and ensured the HBPM was working correctly (for those assigned to HBPM). Usual care involved BP assessment during each hemodialysis treatment, as well as having health care providers deliver ad hoc information and education about BP.
Kerry et al. (2013)[103-105]	Usual care: Received usual care from their physician, in addition to a well check phone call from the study administrator at 3 and 9 months.	Monitoring: Received a BP monitor (Omron M6) and taught how to use it. Advised to take 3 readings (1 minute apart) daily for the first week and record readings in a booklet. Advised that it should be less than 130/80. BP readings were taken in the arm unaffected by the stroke. Study did not report the frequency of BP readings after the first week. Received monthly calls from the nurse to check technique and review blood pressure readings. If the readings were high they were advised to see their physician and to take their booklet. Patients also received a well check phone call from the study administrator at 3 and 9 months.

Study	Treatment 1	Other Treatment Groups	
Kim et al. (2015)[130]	Home BP monitoring only: UC plus home BP monitoring validated with the BHS protocol (UA 767PBT, A&D medical, Tokyo, Japan) with no remote monitoring and office follow-up visits at 8-week intervals for 24 weeks. The subjects were instructed to measure and record their home BP measurement in their diary and bring the data to each office visit. The subjects were instructed on the proper intake of their medications, as well as maintenance of their usual healthy lifestyle modifications of their dietary and exercise habits. The patients were instructed to measure the BP at home in the dominant arm, once in the morning and once in the evening.	LG Smartcare System/without remote physician care: Patients received remote monitoring of home BP through the LG Smart Care system; however, they did not receive remote physician care. These patients receive in-office physician care at FU appointments every 8 weeks for 24 weeks. The patients were instructed to measure the BP at home in the dominant arm, once in the morning and once in the evening. The patients were educated regarding the use of the supplied netbook computer and the LG Smart Care system. All the data were uploaded onto the server by Bluetooth and constantly monitored by healthcare professionals (physicians, nurses, a nutritionist, an exercise trainer) involved in the study. In addition to the BP data that was obtained, the patients were instructed to upload the records of their daily dietary intake, as well as the types and duration of the exercise programs, which were monitored by the nutritionist and the exercise trainer.	LG Smartcare System/with remote physician visits: Patients received remote monitoring of home BP and remote physician care without in-office physician care. Remote physician care was provided every 8 weeks for 24 weeks by the attending physician. For the remote monitoring, routine contact was made with the patient every week from the 1st to 9th week and once every 4 weeks from the 10th to the 24th week. In addition, the patient was contacted in the following cases: (i) when the 1-week average home BP was ≥160/100 mmHg; (ii) when the measured BP was ≥180/120 mmHg; and (iii) if the patient did not measure the BP at home for 3 consecutive days. The patients were instructed to measure the BP at home in the dominant arm, once in the morning and once in the evening. The patients were educated regarding the use of the supplied netbook computer and the LG Smart Care system. All the data were uploaded onto the server by Bluetooth and constantly monitored by healthcare professionals (physicians, nurses, a nutritionist, an exercise trainer) involved in the study. In addition to the BP data that was obtained, the patients were instructed to upload the records of their daily dietary intake, as well as the types and duration of the exercise programs, which were monitored by the nutritionist and the exercise trainer.

Study	Treatment 1	Other Treatment Groups
Kim et al. (2016)[97,101]	Usual care: Patients were enrolled in the HealthComp disease management program, and HealthComp nursing staff could reach out to all participants for the purpose of relaying medical education and wellness information with regard to disease prevention and chronic disease management.	PGHD (Withings BP monitor): Hypertension patients received a Withings Blood Pressure Monitor, an iPhone with corresponding apps and were enrolled in the HealthyCircles Platform—an online disease management program featuring educational materials, consumer portals, and a dashboard to link with their families, caregivers, and health care professionals. HealthComp (a third-party administrator) nursing staff had access to the HealthyCircles care management dashboard that showed the participant's device monitoring results and trends over time. Readings recorded on the devices were wirelessly uploaded to the HealthyCircles account and were accessible to the patient as well as the HealthComp nurses via an iPhone or computer. Patients were trained on how to use their mobile phone, the HealthyCircles mobile app, portal, and their device. They were encouraged to use the device 3 times a week, taking 2 measurements per day, with the first in the morning. If their monitoring frequency fell below 3 times per week for 2 consecutive weeks, participants received an email on their HealthyCircles Platform reminding them of the monitoring schedule. If participants were recommended more frequent monitoring by their physician than that asked through the study, they were encouraged to follow the physician's instructions.
Klarskov et al. (2018)[131]	Usual care: The frequency of office visits and extent of BP monitoring was decided by patients' physicians. Physicians were blinded to baseline ABPM measurements. Office BP measurements were recorded following routine practice. The choice of antihypertensive medication and the use of non-pharmacological intervention were entirely decided by the individual physician.	Combination (PGHD, intensive monitoring): Patients received a Microlife BP3AC1 BP monitor and were instructed on how to use it orally and in writing by their physician. Home BP monitoring was done in the sitting position after 5 minutes of rest on 3 consecutive days. Each day, six measurements were performed with three before breakfast and three before dinner. Physicians were aware of baseline ABPM and home BP monitoring measurements. Patients received written information about hypertension including importance of blood pressure monitoring, life style interventions to reduce blood pressure and pharmacological management. Patients also had a supplementary ABPM. The choice of antihypertensive medication and the use of non-pharmacological intervention were entirely decided by the individual physician.
Lakshminarayan et al. (2018)[69]	Control: Received education on the importance of hypertension control, advice to self-monitor BP daily and share with primary care provided at clinic visits, and encouragement to follow-up with physician. Given an Omron digital BP monitor (specific device NR) which did not automatically transfer data to the physician.	Intervention: Received education from a nurse coordinator about the importance of hypertension control. They were given a smart phone and an upper arm Withings (Nikia) wireless BP monitor. Instructed to measure their own BP prior to breakfast, coffee, or medications. The smart phone transmitted their daily BP automatically to a database. Study staff received it weekly and adjusted medication as necessary in order to reach BP goal. Medication changes were communicated to patients via telephone.

Study	Treatment 1	Other Treatment Groups
Logan et al. (2012)[132]	Control Group: Patients received a device that was "identical appearing" to the intervention device without built-in Bluetooth capability to transmit data. Patients were taught how to measure their BP correctly, instructed to measure their BP 2 days per week twice in the morning and twice in the evening, and given a booklet with detailed information on the self-measurement of BP, treatment of hypertension, and goals of therapy. Treatment decisions, including medication adjustments and changes in lifestyle, were made by the patients' primary care physician.	Combination (PGHD, Self-Care Support System): Patients received the A&D Life Source UA-767 arm BP device paired with a Blackberry smartphone that automatically transmitted every reading to a central server for processing and storage. Patients were taught how to measure their BP correctly, instructed to measure their BP 2 days per week twice in the morning and twice in the evening, and given a booklet with detailed information on the self-measurement of BP, treatment of hypertension, and goals of therapy. Treatment decisions, including medication adjustments and changes in lifestyle, were made by the patients' primary care physician. Patients were also taught how to use the telemonitoring system and review past readings on their smartphone and the study-specific Web site. BP readings were automatically transmitted by the smartphone to application servers, which processed the information for trends and applied decision rules. The reporting and alerting component of the system sent a self-care message to the screen of the patients' smartphone immediately after each reading. Messages related to the control of hypertension were based on care paths defined by running averages of transmitted readings. They instructed patients whose BP fell outside the target range (predefined low and high values) to take additional BP readings, which were then used to provide advice on the urgency to make a follow-up visit with their physician. The message to patients whose BP was within the target range indicated that their hypertension was under control and that they should continue to monitor their BP as recommended. Non-adherence to the preset home BP measurement schedule triggered an automated voice message that was sent to the patients' home telephone, requesting them to check the smartphone for a message. Critical alerts were automatically sent to their physician's office by fax whenever BP readings exceeded predetermined threshold values. Simultaneously an automated voice message was left on the patients' home telephone advising them to check their smartphone for a message, which instructed them to contact their doctor immediately for advice. On the day before the office visit to their physician, patients called a dedicated telephone number to initiate the automated process to fax a 1-page patient summary report to their physician.
Magid et al. (2011)[133]	Usual care: Patients were educated about hypertension using a National Institutes of Health booklet on hypertension and were instructed to follow up with their primary care provider to get their BP under control.	Combination (PGHD, BP Reporting, Education, Pharmacist Management): Patients were educated about hypertension using a National Institutes of Health booklet on hypertension, instructed about use of the interactive voice response phone system, and trained on using a LifeSource UA-767 BP electronic cuff to monitor home BP Patients were instructed to measure their BP 3 to 4 times per week and were encouraged to measure their BP on different days of the week and at various times of the day. Patients were asked to report their BP measurements to the phone system on a weekly basis. During the call, patients were prompted to input their systolic and diastolic BP readings for the week using the touch-tone keypad of their phone. The average of the inputted measurements was calculated, and patients were given feedback on whether their BP measurements were at goal at the end of the call. In addition, patients were offered an opportunity to listen to educational messages or to request a call from the clinical pharmacist to answer questions. The clinical pharmacist reviewed the reported home BP measurements. For patients whose home BP measurements were above guideline-recommended treatment goals, clinical pharmacists reviewed medication adherence, made adjustments to antihypertensive medication regimens as appropriate, and provided counseling on healthy therapeutic lifestyle changes.

Study	Treatment 1	Other Treatment Groups
Magid et al. (2013)[64]	Usual care: Patients assigned to the UC group were advised that their BP was elevated; received written educational materials on managing high BP, diet, and physical activity; and were instructed to follow up with their primary care physician. In addition, the patient's physician was notified of the patient's elevated BP via a note sent to the EHR in-box of the physicians.	PGHD (Omron HEM 790 IT): In addition to receiving the same educational materials as the UC group, PGHD patients were provided a properly fitted home BP cuff (Omron HEM-790IT) and were trained on how to use it. Patients were assisted in establishing an account at the Heart360 Web site and were shown how to automatically upload BPs stored on their home BP device into their Heart360 account. Patients in the HBPM group also met with a clinical pharmacy specialist who reviewed their current BP medication regimen, provided counseling on lifestyle changes, and adjusted or changed antihypertensive medications as needed. Patients were asked to measure their BP at least 3 times per week and to upload their BPs to their Heart360 account weekly. From the Heart360 account, BPs were automatically uploaded nightly to Kaiser Permanente Colorado and organized into BP summary reports that were viewed by the clinical pharmacy specialists managing their care. The reports summarized weekly BP averages and flagged patients with averages above their goal. The clinical pharmacy specialist reviewed the home BP measurements and adherence to antihypertensive medications of the patients, made medication adjustments as needed, and communicated with patients via telephone or secure e-mail. Any medication changes were communicated to the primary care physician of the patient through the EHR. Patients who neglected to upload their BP readings as instructed received up to 3 reminder phone calls through an automated interactive voice response system. If a patient still failed to upload readings, he or she received a call from a clinic staff member.
Margolis et al. (2013)[106-112]	Usual care: Patients worked with their primary care physicians as they had in the past. This could include referral to a medication therapy management pharmacist for consultation and conventional home BP measurement.	Combination (PGHD, Pharmacist Care): Patients received an A&D Medical 767PC automated oscillometric arm BP monitor that stored and transmitted data to a secure website via modem (AMC Health). Pharmacists met with patients for a 1-hour, in-person visit, during which they reviewed the patient's relevant history, covered general teaching points about hypertension, instructed the patients on using the home BP telemonitoring system, and provided patients with an individualized home BP goal 5 mmHg lower than their clinic BP goal. Patients were instructed to transmit at least 6 BP measurements weekly (3 in the morning and 3 in the evening). During the first 6 months of the intervention, patients and pharmacists met every 2 weeks via telephone until BP control was sustained for 6 weeks, and then frequency was reduced to monthly. During intervention months 7 through 12, telephone visits occurred every 2 months. After 12 months, patients discontinued use of the telemonitors, returned to the care of their primary physicians, and no longer received support from a study pharmacist. During telephone visits, pharmacists emphasized lifestyle changes and medication adherence. They assessed and adjusted antihypertensive drug therapy based on an algorithm using the percentage of home BP readings meeting goal. If at least 75% of readings since the last visit met the BP goal, no medication changes were generally suggested. If fewer than 75% of readings met the BP goal, the algorithm recommended treatment intensification. Regardless of BP control, if patients experienced adverse effects, the dosage would be lowered or the drug was switched. Pharmacists communicated with patients' primary care teams through the electronic medical record following each visit.

Study	Treatment 1	Other Treatment Groups
Marquez-Contreras et al. (2006)[98]	Usual care: Received usual care from their general practitioners.	PGHD (OMRON M4 automatic monitor): In addition to usual care from their general practitioners, the PGHD group received OMRON automatic monitor for HBPM. The patients received a kit in their home containing the monitor, an instruction manual, a summary of the functions, and a card on which to note the measurements. They were advised to follow the HBPM, which consisted of measuring BP 3 days a week, twice before breakfast, and twice before supper and record these results on the card. The patients received a phone call to explain how to use the monitor and follow the HBPM program.

McKinstry et al. (2013)[113-115]	Usual care: Participants allocated to the usual care group were asked to continue to attend the practice for BP checks according to the usual routine of the practice. If they were already monitoring their blood pressure at home they were not discouraged. All participants: The general practitioner or practice nurse was informed that the ambulatory monitoring used to screen for eligibility for the current trial had shown that their average BP for all participants was above the target range, but they were not given the actual reading. All participants were given an information pack containing a range of publicly available leaflets on the management of hypertension and lifestyle modification. Clinical care in both groups: All participating doctors and nurses were already using a local guideline for hypertension management derived from national hypertension guidelines but were given additional guidance on timelines for escalating therapy. Participating practices were offered an educational session with a member of the research team who specializes in the management of hypertension. All participants received written information outlining drug and non-drug interventions to reduce blood pressure. Members of the research team did not provide any ongoing monitoring or clinical care.	PGHD (Stabil-O-graph mobile): Research nurses gave participants assigned to the PGHD group a 20 minute training session on how to use the telemonitoring equipment. Participants were asked to monitor their own BP twice each morning and twice each evening for the first week and then at least weekly thereafter or as often as they wished. They used a validated automated sphygmomanometer(Stabil-O-Graph mobil; IEM, Stuttgart, Germany).This was linked by a short range wireless connection to a mobile phone, which automatically transmitted readings to a central server managed by IEM. Participants and clinicians could log on to a website to see the data, and automated SMS texts or emails could be sent to participants with feedback on their blood pressure control. Participants could contact their clinicians if they were concerned about their BP control and clinicians could contact the participants if needed to arrange modification of therapy. The target home monitored BP was <135/85 mmHg based on contemporaneous UK guidelines, subsequently endorsed by the National Institute for Health and Clinical Excellence. Participants allocated to both the PGHD and the UC groups were told that the ambulatory blood pressure showed that their blood pressure was uncontrolled. All participants: The general practitioner or practice nurse was informed that the ambulatory monitoring used to screen for eligibility for the current trial had shown that their average BP for all participants was above the target range, but they were not given the actual reading. All participants were given an information pack containing a range of publicly available leaflets on the management of hypertension and lifestyle modification. Clinical care in both groups: All participating doctors and nurses were already using a local guideline for hypertension management derived from national hypertension guidelines but were given additional guidance on timelines for escalating therapy. Participating practices were offered an educational session with a member of the research team who specializes in the management of hypertension. All participants received written information outlining drug and non-drug interventions to reduce blood pressure. Members of the research team did not provide any ongoing monitoring or clinical care. Feedback to PGHD patients (closed loop feedback): In addition to optionally accessing their BP record on-line, participants could also opt to receive reports via text message or email. These gave advice on the current status of their BP based on the average of the last 10 readings, and whether they should contact their doctor or nurse. Reports were generated every 10 readings or weekly, whichever was sooner, with a reminder to check BP if this had not been done. These reports could reassure them that their average BP was within target (<135/85 mmHg) or tell them that their BP average was improved on the last report, but not yet to target and to maintain current therapy, or that their BP was not at target and that they should contact their clinician. If an individual BP reading was very high (>220/120 mmHg) an immediate text or email report was generated reinforcing the written advice in the patient information leaflet to rest for 30 min, check again and contact the practice if BP remained very high.Sharing the readings with the healthcare team: Members of the healthcare team were able to access the records of their patients online via a secure login to a summary screen which listed their patients, their average BP over the last 10 readings and the date of their last reading. Average BPs outside the recommended limits (set at 135/85 mmHg for the study) were highlighted. Clicking on the each individual patient led to lists or graphs of all their readings. Clinicians could then check their patients' electronic general practitioner (GP) record to see if there had been recent advice regarding medication or lifestyle change and if not, could

Study	Treatment 1	Other Treatment Groups
		contact the patient to make a change. Clinicians were recommended to check the website weekly, but the frequency of log-on could be chosen by them.
McManus et al. (2010)[116-120]	Usual care: Patients were asked to attend for a review by their family doctor. No specific instructions were given to the clinicians about the content of this visit other than to review medication. Thereafter, care was at the discretion of the family doctor.	Combination (PGHD, medication management): Patients were invited to two training sessions run by the research team. Participants were trained to monitor their own BP for the first week of each month with an Omron 705IT BP monitor and to transmit BP readings to the research team by means of an automated modem device (i-modem) which was connected to the BP monitor used the telephone line to transmit readings. Two self-measurements were made each morning with a 5-min interval and the second reading acted upon. A color traffic light system was used by participants to code these readings as green (below target but above safety limit), amber (above target but below safety limits) and red (outside of safety limits). A month was deemed to be "above target" if the readings on 4 or more days were above target. Titration schedules consisting of two changes or increases in medication were agreed between patients and their family doctor at a review visit after training. The family doctor received no specific instruction from the research team about suitable medication changes other than receiving national guidelines. If patients had two consecutive months of readings above target, they were instructed to make medication changes in accordance with the titration schedule by requesting a new prescription without seeing their family doctor. After each set of two changes had been implemented, patients returned to their family doctor for a further titration schedule if BP remained above target. Monthly summaries of each patient's BP readings were sent to their family doctor. Patients with internet access could view their own readings via a dedicated internet site. Home targets were 130/85 mmHg for patients without diabetes and 130/75 mmHg for patients with diabetes.
McManus et al. (2014)[121]	Usual care: Patients booked an appointment for a routine blood pressure check and medication review (including dose adjustment if required) with the participating family physician. Thereafter, blood pressure measurement, blood pressure targets, or adjustment of medication for patients receiving usual care were at the discretion of the family physician.	PGHD (Microlife Watch BP Home): Patients were trained to self-monitor blood pressure using Microlife Watch BP Home with self-titration of medication following a predetermined plan, in 2 or 3 sessions, each lasting approximately an hour. Following training, intervention patients went to their family physician to agree with the individualized 3-step plan to increase or add antihypertensive medications. This was operationalized in a paper-based algorithm including the option for additional blood tests if required. Patients took their blood pressure twice each morning for the first week of each month using color-coded instructions. Four or more blood pressure readings recorded during the measurement week for 2 consecutive months that were higher than the target necessitated a change in medication pursuant to the predetermined plan. Very high or very low readings required the participant to contact his/her practice. When a medication change was needed, patients sent a paper form to their family physicians without any need for a consultation. Medication choice remained at the discretion of the family physician. If patients used all 3 steps of their management plan, they returned to their general practitioner for additional instructions.

Study	Treatment 1	Other Treatment Groups	
McManus et al. (2018)[83-86]	Usual care: Patients were managed with titration of antihypertensive treatment based on clinic BP measurements at the discretion of their attending health-care professional.	PGHD (Omron M10-IT): Patients received an Omron M10-IT BP monitor and were taught how to use it. They were asked to monitor their own blood pressure in their non-dominant arm, twice each morning and evening, for the first week of every month using standard recommendations and their physicians were asked to use the self-monitored measurements for titration of antihypertensive medication. A simple color chart was used to train patients to attend their practice for BP checks in the case of very high or very low readings. At the end of each monitoring week they were asked to record their readings on paper and send them for review to their practice in a reply-paid envelope. Clinicians were asked to review readings on a monthly basis and had the freedom to adjust antihypertensive and other medication as they sought fit.	Combination (PGHD, telemonitoring): Patients received an Omron M10-IT BP monitor and were taught how to use it. They were asked to monitor their own blood pressure in their non-dominant arm, twice each morning and evening, for the first week of every month using standard recommendations and their physicians were asked to use the self-monitored measurements for titration of antihypertensive medication. Patients were trained to send readings via a simple free SMS text-based telemonitoring service with web-based data entry back-up. The telemonitoring system incorporated an algorithm that alerted participants to contact their surgery in the light of very high or very low readings, reminded them if insufficient readings were transmitted, prompted them to make contact with their practice if their average BP was above target, and presented readings to attending clinicians via a web interface. This web page automatically calculated mean blood pressure for each monitoring week, highlighted very high or very low readings, and presented a graphical display of BP measurements. Clinicians had the freedom to adjust antihypertensive and other medication as they sought fit.

Study	Treatment 1	Other Treatment Groups
Mehos et al. (2000)[122]	Control Group: All subjects received counseling on antihypertensive drug therapy and lifestyle modification by one of three investigators using an identical format according to study protocol. During a 30-minute appointment, the pharmacist provided all subjects with written pamphlets from the American Heart Association that explained hypertension and cardiovascular risks. Subjects were counseled on the importance of exercise and salt and alcohol reduction.	PGHD (A&D UA-702 manual electronic blood pressure monitor): Subjects were instructed to monitor blood pressure with arm device each morning, before food, coffee, or drugs, after a 5-minute rest in a seated position, and again after 2 to 5 minutes. Each subject was given a predated diary in which they documented the two morning values, changes in antihypertensive drug therapy, and missed doses. A clinical pharmacist contacted each intervention subject by telephone after 1 month to evaluate blood pressure response. If mean monthly home values were above 140/90 mmHg (as calculated by an investigator), primary care physicians were informed and therapy recommendations were made as necessary. These subjects were contacted again by telephone at monthly intervals to evaluate average blood pressure measurements and response to therapy. If mean monthly blood pressure remained above 140/90 mmHg, they were contacted at 2-month intervals for follow-up evaluations.
Mendelson et al. (2014)[47]	Usual care: Fitted with a nasal mask and given an auto-titrating machine. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was transferred from their machines (adherence, mask leak, residual respiratory events). After 4 months of treatment, data were downloaded from the machine, and patients saw their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.	PGHD (Telemedicine): Patients assigned to telemedicine were oriented to CPAP, fitted with a nasal mask, and given an auto-titrating machine. Patients received a smartphone with an application designed to transmit clinical information. The patients transmitted self-measured morning and evening BP (3-day measurements using the Omron 705CP), CPAP adherence, and subjective sleepiness weekly through a questionnaire-based application. Quality of life questionnaires were transmitted monthly. Patients received daily pictograms with diet and physical-activity related messages on their smartphones. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was reviewed. After 4 months of treatment, patients consulted their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.

Study	Treatment 1	Other Treatment Groups
Neumann et al. (2011)[134,135]	Usual care: Patients were advised to contact the treating physician by phone or visit the office in case of side effects or a not sufficient BP reduction.	Combination (PGHD, Physician management): Patients received the IEM Stabil-O-Graph automatic BP monitor with an upper arm cuff and Bluetooth interface as well as a Bluetooth-compatible mobile phone. As soon as a patient completed successfully a measurement with the Stabil-O-Graph, the patients' BP data were transmitted from the mobile phone via short message service remote operating system, which decoded the contents and transmitted them by TCP/IP via a secured channel to the central database server. If alarm criteria were met an alarm report was generated automatically and sent via e-mail to the physician who contacted the patient by phone to discuss the future treatment. The physician had full access to all BP data from the individual patients stored in the database server. Every month patients received a report with all BP values and alarms stored in the database.
Niiranen et al. (2014)[136]	Usual care: The patients and the staff of the control health center did not receive any intervention. Hypertension treatment continued according to conventional practice.	Combination (PGHD, behavioral, pharmaceutical): Patients received lifestyle guidance from an investigator-educated nurse during two 30-minute individual counseling sessions held at 4-week intervals and at a 60-minute group session of 10–12 participants held 4 weeks later. In addition, written instructions were distributed to the participants. The participants were instructed to avoid added salt, use low-salt food ingredients, increase intake of fruits, vegetables, and berries, favor unsaturated fat over saturated fat, use low-fat dairy products, eat fish for 1–2 meals per week, exercise at least 3 hours per week, lose weight if necessary, and use no more than moderate amounts of alcohol. Patients were also given an Omron HEM-722C monitor to measure home BP, with a target home BP of <135/83 mmHg. BP readings were mailed to the treating physician, and the patient was contacted by telephone. A face-to-face appointment was scheduled, if deemed necessary. If home BP was greater than the target pressure, the drug therapy was intensified. Physicians had free choice of which medications to use, but they had been educated on rational drug choices and combinations.
Ogedegbe et al. (2014)[123]	Usual care: patients received printed education materials and the physicians at sites randomized to UC received hypertension treatment guidelines.	PGHD (Microlife model BP 3AC1-1PC): Patients at the IC sites received the following: (1) 4 modules of interactive, computerized patient education focused on the causes, complications, and treatment of hypertension; expected medication adverse effects; and methods for adoption of healthy lifestyle behaviors; (2) 6 behavioral lifestyle telephone/group counseling sessions; and (3) free validated automated home BP monitors (model BP 3AC1-1 PC; Microlife USA, Inc., Dunedin, FL). They were encouraged to record their weekly BP readings (twice daily, 3 days per week) in a diary and bring it to each study visit. The primary care clinicians received monthly onsite continuing medical education based on the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure11; hypertension case rounds, and quarterly chart audits of their patient office BP readings. They were also provided quarterly feedback on the values of their patients' home BP readings, which were obtained from the patient diaries. Patients at the enhanced UC sites received a single hypertension patient education session plus printed versions of the National Heart, Lung, and Blood Institute patient education material, "Your Guide to Lowering Blood Pressure" and "Facts about the DASH Eating Plan," whereas the primary care clinicians received print versions of Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines.

Study	Treatment 1	Other Treatment Groups
Petrella et al. (2014)[60]	Active control: Prescribed a tailored exercise program by an exercise physiologist, and the plan was updated at 12 and 24 weeks. Instructed to record all planned exercise in a paper diary.	Intervention: Same exercise prescriptions as the active control group. Also received a smartphone (Blackberry Curve 8300 or 8530) equipped with the Healthanywhere app (Biosign Technologies), and an BP monitor (A&D UA-767PBT), and a glucometer (Lifescan One Touch Ultra2), and a pedometer (Omron HJ-150) and a heart rate monitor (Suunto Memory Belt, Vantaa Finland). They were educated on the devices in a 2 hour session, and provided information on normal values, and encouraged to use these devices to monitor their health. Required to input pedometer steps daily, enter exercise daily, measure BP and FPG three times a week, and measure weight (using their own scale) once a month.
Qi et al. (2017)[99]	Control Group: Patients had their BP measured at the hypertension management center at the beginning of each month.	PGHD (Omron HEM-7121): Patients received an Omron HEM-7121 to measure home BP twice a day.

Study	Treatment 1	Other Treatment Groups
Rifkin et al. (2013)[65]	Usual care: Patients were asked to measure and record their BP at home according to their physicians' instructions.	Combination (PGHD, Physician management): Patients received an A&D Medical UA-767PBT fully automatic oscillometric BP unit and the home health hub. The BP units have a BP measuring range spread over 20–280mmHg and a pulse range of 40–200 beats/min. The home health hub receives BP and pulse data through Bluetooth from the BP unit, and relayed that data through the Internet (using study-provided cellular modem) to a secure website, which was accessible through password to study personnel. The study device used its own cellular modem connection to transmit data. The website allowed for viewing of BP data sorted by participant, using unique study ID numbers. Also, each device sent a regular signal through the home health hub even if BP was not being checked, so that study personnel could differentiate equipment failure from an absence of BP readings without additional calls to the participant. Patients were educated about appropriate use of the cuff, and those assigned to the device arm had BP checked before study initiation using a standard cuff as well as the device to ensure accuracy. Patients were instructed in proper use of the BP cuff. They were told that BP readings would be checked by study personnel on a weekly basis, and that they could expect to be contacted by telephone if their BP was out of range. They were further counseled that they would not be contacted if BP was at goal. Finally, they were told that although the device transmitted on a continuous basis, it would not be checked continuously, and was not a substitute for contacting medical personnel in case of severe hypertension or hypotension or other symptoms. Patients were asked to measure and record their BP at home according to their physicians' instructions. On a weekly basis, the study physicians and pharmacist met to review BP logs of each participant. If a patient had consistently above-goal readings during the prior week, one of the study physicians or pharmacist called to discuss the readings, provide counseling, or adjust medications as indicated. Each telephone encounter was recorded in the medical chart. Additional in-person follow-up with clinic physicians or urgent care was scheduled at the discretion of the study team if it was felt that telephone counseling was not sufficient. If patients did not have any readings during a given time period, the study coordinator checked to ensure that the device was still transmitting a check-in signal; if so, no additional contact with the patient was made so as not to change the participant's usual behavior. Prior to scheduled in-person follow-up, the electronic medical record was updated by means of an addendum to the prior chronic kidney disorder clinic note with the full record of telemonitoring results since the prior visit, to allow clinic physicians to review these at the time of in-person visits. Treating physicians to fill out a post-visit form for each in-person visit detailing the amount of home BP data brought to that visit by the patient, the number of medication changes at the visit, and whether BP was at goal.

Study	Treatment 1	Other Treatment Groups
Rogers et al. (2001)[137]	Usual care: Patients were treated for hypertension according to the guidelines of the Joint National Committee on Prevention, Detection, and Treatment of High Blood Pressure.	Combination (PGHD, Physician management): Patients received a Welch Allyn Model 52500 BP monitoring device that transmitted data over analog telephone lines. Patients were instructed to take their blood pressure three times in the morning before eating or drinking and three times in the evening before going to bed. After each reading, the device automatically dialed the Service and Support Center at Welch Allyn and transmitted the data. Patients were asked to conduct this routine at least three days each week for a minimum of 8 weeks and could take additional readings if they desired. A computer program was developed to display the results in a report form, which was then faxed to each patient's physician. The report form contained information on the patient's BP. Both physicians and patients received a report form each week, as well as a summary report form at the end of the trial. When physicians received report forms that indicated elevated pressure, they adjusted antihypertensive medications through a telephone call, an office visit, or both.
Sarfo et al. (2018)[138,139]	Usual care: Patients received SMS messages dealing with healthy lifestyle behaviors but not with medication adherence.	PGHD (UA-767Plus BT BP): Patients received a Blue-toothed UA-767Plus BT arm BP device and a smartphone with embedded application for monitoring and reporting BP measurements and medication intake under nurse guidance for three months. Participants were instructed to monitor their own BP in their non-dominant arm, twice each morning and evening. A study nurse took each participant through a standardized operating procedure on how to measure blood pressure using the BP device and observed the participant/care giver perform the procedure satisfactorily. Participants who had difficulties with the protocol were re-trained until proficiency was attained. Tailored motivational text messages were delivered based upon levels of adherence to the medication intake regimen. A secure web page hosted at the Medical University of South Carolina automatically calculated the mean BP for each monitoring session, as well as daily medication intake adherence scores.
Stewart et al. (2014)[140]	Usual care: Patients continued to receive routine care.	Pharmacist Care: Received a package of interventions from a pharmacist trained to deliver the intervention. The package included: • An Omron HEM-790IT BP monitor with the capacity to store and download BP readings to be used for discussion at 3- and 6-month follow-ups; • Training by the pharmacist on self-monitoring of BP; • Motivational interviewing and education by the pharmacist to help patients improve their medication adherence and achieve target BP; • Pharmacy-based medicines review to identify and resolve, where necessary, possible medication-induced hypertension (e.g., due to non-steroidal anti-inflammatory drugs, cold preparations, complementary medicines); • Pharmacist-initiated dose administration aid, home-based medicines review and/or patient medication list, where necessary; • Referral to a general practitioner at the pharmacist's discretion; and • Optional refill reminders (by SMS, telephone, or mail) from their pharmacist 3 days before their antihypertensive medication was due to run out.

Study	Treatment 1	Other Treatment Groups
Yoo et al. (2009)[23]	Usual care: Visited their clinic according to their routine schedule and received the usual outpatient treatment from physicians.	Intervention: Received a cellular phone (LG SV280), blood glucose monitoring device (Anycheck from Insung) including strips and lancets, BP monotir (Omron T5M) and scale (HD308 from Tanita). The phone sent reminders to measure blood glucose, BP twice a day, and weight once a day. The glucometer sent the reading automatically to the study database. After transmitting their glucose reading, the phone sent messages of encouragement and reminders according to a guideline-based algorithm. These reminders alerted the patient if their BP or glucose were high, and how to avoid high readings in the future. The system also recorded exercise time by asking patients via text about exercise. The system also sent 3 texts a day about healthy diet and exercise methods. Physicians could use the website to track patients' trends in BP or glucose or weight, allowing physicians to send additional personalized messages.
Zaleski et al. (2019)[100]	Usual care: All participants began a progressive, supervised, moderate intensity aerobic exercise training for 40 to 50 min/session, 3 days/week for 12 weeks and encouraged to exercise unsupervised at home at least 30 min/day, 1 to 2 days/week. Briefly, participants were trained to log the details of each workout utilizing a Polar FT7 HR monitor (Polar Electro Oy, Kempele, Finland) and the timeline follow backlog, which was reviewed weekly by study investigators. Exercise training frequency, intensity, time, and type; subjective rating of intensity; training impulse, and adherence were recorded for supervised and supervised and unsupervised exercise training over the course of 12 weeks.	PGHD (BP Omron 705 CPN): All participants began a progressive, supervised, moderate intensity aerobic exercise training for 40 to 50 min/session, 3 days/week for 12 weeks and encouraged to exercise unsupervised at home at least 30 min/day, 1 to 2 days/week. Briefly, participants (in both groups) were trained to log the details of each workout utilizing a Polar FT7 HR monitor (Polar Electro Oy, Kempele, Finland) and the timeline follow back, which was reviewed weekly by study investigators. Exercise training frequency, intensity, time, and type; subjective rating of intensity; training impulse, and adherence were recorded for supervised and supervised and unsupervised exercise training over the course of 12 weeks. In addition to supervised exercise training and self-monitoring of exercise as described above, participants were given a home BP monitor (Omron MEM-705CPN; Omron Healthcare, Bannockburn, Illinois, USA) and trained in its use. Participants were instructed to measure BP upon waking and in the evening around the same time of day in the non-dominant arm following a 5 min period of seated rest. In addition, on unsupervised exercise days, participants were instructed to sit quietly and measure BP in their non-dominant arm, 10 min before and after the unsupervised exercise sessions performed at home. Participants recorded their BP readings using the AHA 'Check. Change. Control. Tracker' (previously known as Heart360) web-enabled, patient-centered BP monitoring tool (https://www.ccctracker.com/aha). Self-generated graphs of BP in the morning, evening, and before and after home exercise were reviewed with the study investigators on a weekly basis. In addition, researchers were trained with an Institutional Review Boards-approved standardized script to communicate and/or react to BP assessments taken after each exercise session to minimize the influence of individual and/or researcher verbal cues on the subjects' reaction to their BP responses to exercise.

Study	Treatment 1	Other Treatment Groups
Zarnke et al. (1997)[124]	Usual care: Treatment adjustments were made by the patients' physicians during office visits.	Combination (PGHD, treatment management): Patients received an Omron Marshall 85 oscillometric sphygmomanometer and were trained to monitor home BP twice daily, recording their values in a diary. Patients were instructed to make alterations in drug therapy when blood pressure values consistently exceeded specified limits according to an algorithm specific for each patient's medications. The algorithms specified increasing drug therapy in a stepwise fashion by standard dosage increments for sustained blood pressure above 160 mmHg systolic or above 95 mmHg diastolic for a 2-week period. They also specified decreasing therapy for sustained blood pressure less than 110 mmHg systolic and less than 70 mmHg diastolic for more than a one week period. If subjects found their blood pressure elevated over a sustained interval despite maximizing initial therapy, they were asked to visit their primary care physicians for consideration of adding a dihydropyridine calcium channel blocker. Once started, they were then asked to titrate the new drug according to directions in their individualized algorithm as necessary.
Zha et al. (2019)[87]	Usual care: Patients attended the community health center for management of their hypertension, which consisted of a weekly nursing assessment, medication management, patient education, and follow-up.	PGHD (iHealth BP7 Wireless Blood Pressure Wrist Monitor): Patients received the iHealth BP7 Wireless Blood Pressure Wrist Monitor. The monitor uses the oscillometric principle to measure BP and pulse rate with a Bluetooth synchronization system that can interphase with both Apple and Android devices. The monitor is paired with an iHealth MyVitals mobile app to test, track, and share BP data. The application automatically tracks and analyzes key health vital measurements. The measurements taken by the monitor are automatically synchronized and stored in an easy-to-read format on the iHealth MyVitals application. Patients receive instant feedback, which allows them to see how they are doing and set goals for ongoing improvement. With each monitor, the patient received a free cloud service account, where BP data were stored and securely backed up. The patient and their health care provider could log into the cloud account from any device and access the information, irrespective of where the measurement was taken. Patients were trained on how to use the monitor correctly and how to monitor their BP on their smartphone. The iHealth MyVitals app was downloaded on participants' smartphones and iHealth cloud accounts were created. In addition, patients attended the community health center for management of their hypertension, which consisted of a weekly nursing assessment, medication management, patient education, and follow-up.

ABPM = ambulatory blood pressure monitoring; BP = blood pressure; CPAP = continuous positive airway pressure; CVD = cardiovascular disease; DASH = dietary approaches to stop hypertension; DBP = diastolic blood pressure; EHR = electronic health record; HBPM = home blood pressure monitoring; HDL = high-density lipoproteins; ICD = International Classification of Diseases; JNC = Joint National Committee; mmHg = millimeters of mercury; LDL = low-density lipoproteins; NR = not reported; PGHD = patient-generated health data; SBP = systolic blood pressure; SMS = short message service; TCP/IP = transmission control protocol/internet protocol; UC = usual care

Table C-26. Hypertension and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Aekplakorn et al. (2016)[88]	+	+	+	+	+	+	+	?	+	Low
Bennett et al. (2018)[18,72,73]	+	?	+	−	+	+	+	−	+	Moderate
Bernocchi et al. (2014)[125]	−	−	+	−	?	+	+	+	+	High
Bosworth et al. (2009)[63]	+	+	−	+	−	+	−	+	+	Moderate
Bosworth et al. (2011)[66-68]	+	+	+	−	+	+	+	+	+	Low
Bosworth et al. (2011)[66-68]	+	+	+	−	+	?	+	+	+	Moderate
Bosworth et al. (2011)[89-91]	+	+	+	+	+	+	?	+	+	Low
Bove et al. (2013)[92]	+	?	+	+	+	+	+	?	+	Low
Broege et al. (2001)[79]	?	?	−	+	?	+	+	−	+	High
Chandler et al. (2020)[74]	?	?	+	−	+	+	+	?	+	Moderate
Dorough et al. (2014)[126]	?	?	?	−	?	+	?	?	+	High

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Earle et al. (2010)[70,71]	+	?	+	−	?	+	−	+	?	High
Fuchs et al. (2012)[93]	+	+	+	+	+	+	+	−	+	Low
Green et al. (2008)[80,81]	+	+	−	+	+	+	+	+	+	Low
Green et al. (2014)[24]	?	?	+	−	+	+	+	−	+	High
Halme et al. (2005)[127]	?	?	+	−	?	+	+	+	+	Moderate
He et al. (2017)[128]	?	?	+	−	+	+	+	+	+	Moderate
Hebert et al. (2012)[82]	+	+	+	+	+	+	−	+	+	Low
Hoffmann-Petersen et al. (2017)[94]	+	+	+	+	+	?	+	−	+	Moderate
Hosseininasab et al. (2014)[129]	+	+	+	?	?	+	+	?	+	Moderate
Kaihara et al. (2014)[95]	+	+	−	+	+	+	+	−	?	Moderate
Kao et al. (2019)[102]	+	+	+	−	+	+	+	+	+	Low

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Kauric-Klein et al. (2007)[96]	+	+	−	+	+	+	+	?	+	Moderate
Kerry et al. (2013)[103-105]	+	+	+	−	+	+	+	+	+	Low
Kim et al. (2015)[130]	+	?	+	−	+	+	+	−	+	High
Kim et al. (2016)[97,101]	?	?	+	+	?	+	−	−	+	High
Klarskov et al. (2018)[131]	+	?	+	−	+	+	+	?	+	Moderate
Lakshminarayan et al. (2018)[69]	+	+	+	+	?	+	−	−	+	Moderate
Logan et al. (2012)[132]	?	+	−	−	+	+	+	?	+	Moderate
Magid et al. (2011)[133]	+	+	−	−	+	+	+	+	+	Moderate
Magid et al. (2013)[64]	+	?	−	−	+	+	+	+	+	Moderate
Margolis et al. (2013)[106-112]	?	?	+	−	−	+	+	−	+	Moderate
Marquez-Contreras et al. (2006)[98]	+	+	+	+	?	?	+	−	+	Moderate

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
McKinstry et al. (2013)[113-115]	+	+	+	−	+	+	+	+	+	Low
McManus et al. (2010)[116-120]	+	?	+	−	−	+	+	−	+	High
McManus et al. (2014)[121]	+	?	+	−	+	+	+	+	+	Moderate
McManus et al. (2018)[83-86]	+	+	+	+	+	+	+	−	+	Low
Mehos et al. (2000)[122]	+	?	+	−	+	+	+	?	+	Moderate
Mendelson et al. (2014)[47]	?	?	+	−	+	+	−	−	+	High
Neumann et al. (2011)[134,135]	?	?	+	−	+	+	+	?	+	Moderate
Niiranen et al. (2014)[136]	+	?	+	−	+	+	+	+	+	Moderate
Ogedegbe et al. (2014)[123]	?	+	+	−	+	+	−	?	?	High
Petrella et al. (2014)[60]	−	−	+	−	+	+	+	−	+	High
Qi et al. (2017)[99]	?	?	+	+	?	+	+	?	+	Moderate

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Rifkin et al. (2013)[65]	+	?	+	−	+	+	+	+	+	Moderate
Rogers et al. (2001)[137]	+	+	−	−	+	+	+	−	+	Moderate
Sarfo et al. (2018)[138,139]	+	+	+	−	+	+	+	+	+	Low
Stewart et al. (2014)[140]	+	−	+	−	+	+	−	−	+	High
Stewart et al. (2014)[140]	+	−	+	−	+	+	+	?	+	Moderate
Yoo et al. (2009)[23]	?	?	+	−	?	+	+	−	+	High
Zaleski et al. (2019)[100]	+	?	−	+	+	+	+	−	+	High
Zarnke et al. (1997)[124]	+	?	?	−	+	+	+	−	+	High
Zha et al. (2019)[87]	?	?	?	+	?	+	+	−	+	Moderate

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-27. Hypertension and PGHD: economic evaluation risk of Bias

Study	1 Competing alternatives described?	2 Economic study design appropriate?	3 Important and relevant costs for alternatives identified?	4 Costs measured appropriately?	5 Costs valued appropriately?	6 Important and relevant outcomes for alternatives identified?	7 Outcomes measured appropriately?	8 Outcomes valued appropriately?	9 Incremental analysis of costs and outcomes of alternatives performed?	10 Future costs and outcomes discounted appropriately?	11 Sensitivity analysis?	Overall Risk of Bias
McManus et al. (2018)[83-86]	+	+	+	−	−	−	+	+	+	+	+	Moderate
Margolis et al. (2013)[106-112]	+	+	+	−	−	+	+	+	+	?	+	Moderate
McKinstry et al. (2013)[113-115]	+	+	+	?	+	+	+	?	+	?	+	Low
McManus et al. (2010)[116-120]	+	+	+	?	?	−	+	+	+	+	+	Moderate

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-28. Hypertension and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Aekplakorn et al. (2016)[88]	Guiding Question 2	PGHD device compliance	Usual care vs. PGHD (Omron HEM 7117) Adherence to the self-monitored practice was not complete. 84.1% of the PGHD subjects record their BP measurement with an average of 123.94 recorded days, and 54.7% of the subjects recorded their daily BP measurement more than 135 days. The proportion of regular recorders of their BP was slightly higher, but not significant among those aged ≥60 years compared with those aged <60 years (61% vs. 47%, p=0.24).	NA
Bennett et al. (2018)[18,72,73]	Guiding Question 2	Device usage	Intervention 36% weighed themselves at least 5 days a week on average.	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2009)[63]	Guiding Question 2	Adherence to PGHD	PGHD (Omron 773AC or 637) vs. Combination (PGHD plus behavior self-management) Of the 158 patients assigned to the PGHD group, 91% of patients in the first 2 months of the study and 64% of patients in the last 2 months turned in BP logs with at least 1 recorded BP reading. The percentage of patients who turned in their logs was higher among patients who completed the study. Combined Intervention. Of the 159 patients assigned to the combined intervention group, 89% and 59% turned in BP logs with at least 1 recorded BP reading for the first and last 2 months of the study, respectively; these proportions were 99% and 81%, respectively, for the 110 patients with a BP measurement at 24 months. Nurses completed 1589 telephone calls to 156 patients; the mean number of completed calls per patient was 10 (SD: 3) of a possible 12, and the mean call length was 16 minutes (SD: 7).	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[66-68]	Guiding Question 2	Number of alerts generated due to non-adherence to BP monitoring. Alerts were automatically generated when there were too few readings to make a determination of BP control. This occurred when the patient had not transmitted three or more readings on three or more different days during a two-week period. Patients had been asked to take six readings, one every other day over two weeks. Alerts were classified as due to patient non-adherence if the patient responded to a message from the research assistant mentioned that no readings had been transmitted and subsequently transmitted at least a single BP reading, the patient transmitted only a single BP reading after the alert creation date following instructions from the research assistant to carry out a system reset, or the patient admitted to not following the study protocol.	Combined data across intervention groups Over 6 months: 421 (61% of total alerts)	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[66-68]	Guiding Question 2	Number of alerts generated due to device problem. Alerts were automatically generated when there were too few readings to make a determination of BP control. This occurred when the patient had not transmitted three or more readings on three or more different days during a two-week period. Patients had been asked to take six readings, one every other day over two weeks. Alerts were classified as due to device problem if the patient indicated that they were unable to take readings because the devices were not working properly.	Combined data across intervention groups Over 6 months: 35 (5% of total alerts)	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[66-68]	Guiding Question 2	Number of alerts generated due to patient knowledge. Alerts were automatically generated when there were too few readings to make a determination of BP control. This occurred when the patient had not transmitted three or more readings on three or more different days during a two-week period. Patients had been asked to take six readings, one every other day over two weeks. Alerts were classified as due to patient knowledge if the research assistant decided that the patient had not fully understood what was needed to take and transmit BP readings.	Combined data across intervention groups Over 6 months: 35 (5% of total alerts)	NA
Bove et al. (2013)[92]	Guiding Question 2	Adherence to PGHD Chart review	PGHD (BP, pedometer, scale) vs. Usual care The telemedicine subjects used telephone communication 65% of the time. Average use was 1.8±1.6 communications per week (equivalent to 46.5 transmissions in 6 months). Frequency of use showed no correlation with education, income, or BP; however frequency of use increased with age (p=0.002).	NA
Broege et al. (2001)[79]	Guiding Question 2	Number of home measurements per patient	PGHD (Omron HEM-702) At 3 months: Ranged between 72 and 108 measurements/month	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Chandler et al. (2020)[74]	Guiding Question 2	Adherence to Protocol In the Tension Tamer group, encrypted time and date stamped heart rate data measured via the app's built-in photo plethysmograph were automatically relayed to the study institution's server infrastructure. Adherence was reported on a monthly percentage calculated as average of daily adherence scores across a number of days in the month. Those in the Runkeeper group had adherence scores derived from their Runkeeper app's daily output of the number and duration per session of physical activity for the previous 24 hours. Scores were calculated in the same manner as the Tension Tamer adherence scores.	PGHD (Tension Tamer app) vs. PGHD (Runkeeper app) At 1-month follow up Tension Tamer: 77.3% Runkeeper: 68.2% p-value for difference: 0.288 At 3-month follow up Tension Tamer: 77.1% Runkeeper: 67.1% p-value for difference: 0.408 At 6-month follow up Tension Tamer: 78.0% Runkeeper: 61.5% p-value for difference: 0.189 At 12-month follow up Tension Tamer: 69.8% Runkeeper: 65.2% p-value for difference: 0.760	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Chandler et al. (2020)[74]	Guiding Question 2	Meeting 75% Adherence Benchmark In the Tension Tamer group, encrypted time and date stamped heart rate data measured via the app's built-in photo plethysmograph were automatically relayed to the study institution's server infrastructure. Adherence was reported on a monthly percentage calculated as average of daily adherence scores across a number of days in the month. Those in the Runkeeper group had adherence scores derived from their Runkeeper app's daily output of the number and duration per session of physical activity for the previous 24 hours. Scores were calculated in the same manner as the Tension Tamer adherence scores.	PGHD (Tension Tamer app) vs. PGHD (Runkeeper app) At 1-month follow up Tension Tamer: 60.0% Runkeeper: 50.0% p-value for difference: 0.604 At 3-month follow up Tension Tamer: 64.3% Runkeeper: 57.1% p-value for difference: 0.712 At 6-month follow up Tension Tamer: 58.3% Runkeeper: 35.7% p-value for difference: 0.267 At 12-month follow up Tension Tamer: 385% Runkeeper: 27.3% p-value for difference: 0.582	No
Earle et al. (2010)[70,71]	Guiding Question 2	Number of BP readings	Combination (PGHD, treatment management) At 6 months: Total 1721 readings	NA
Earle et al. (2010)[70,71]	Guiding Question 2	Number of blood glucose readings	Combination (PGHD, treatment management) At 6 months: Total 4099 readings	NA
Earle et al. (2010)[70,71]	Guiding Question 2	Transmission rate of BP readings	Combination (PGHD, treatment management) At 6 months: 4.0 (SD: 3.8) readings/person/month	NA
Earle et al. (2010)[70,71]	Guiding Question 2	Transmission rate of blood glucose readings	Combination (PGHD, treatment management) At 6 months: 1.8 (SD: 1.1) readings/person/month	NA
Fuchs et al. (2012)[93]	Guiding Question 2	Adherence to home BP monitoring Evaluated by BP diary entries	PGHD (Omron HEM-705 CP) The adherence to home BP monitoring decreased from 94% during the first week after randomization to 84.6% at the end of the trial.	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Green et al. (2014)[24]	Guiding Question 2	Ease of use	Web dietician Intervention participants were asked to rate the parts of the intervention they thought were most useful in managing their health since enrolling in the study. More than 60% reported that measuring BP at home, sharing BP measures with providers, e-mailing or talking with a dietitian, and getting a "list of medications and things I should do" were extremely helpful.	NA
Kaihara et al. (2014)[95]	Guiding Question 2	Adherence to home BP measurement protocol The frequency of BP measurements in the latter half of the study (maximum frequency: 28) minus that in the first half (maximum frequency: 28).	PGHD (Omron HEM-7251G) vs. Conventional BP monitor Change from baseline to 2 weeks Intervention group: 0.03 (SD: 1.35) Control group: -0.81 (SD: 2.00) p-value for difference: 0.064	No
Kerry et al. (2013)[103-105]	Guiding Question 2	Device usage	Monitoring 30% of intervention patients (51/168) required the assistance of a care provider to take their blood pressure. 48% (80/168) recorded a full set of BP readings in the previous 4 weeks. Of 84 intervention patients answered questions at 18 months (after cessation of nurse support), 80 said they still used the monitor (95%), and 57 of these dais they used it at least once a month.	NA
Kim et al. (2015)[130]	Guiding Question 2	Device adherence Number of measurements for 1 week, home BP measurements in the week before the 24 week follow-up	Home BP monitoring only vs. LG Smartcare System/without remote physician care Group 1 7.5 (SD: 3.2) and Group 2 5.4 (SD: 3.5)	Yes
Kim et al. (2015)[130]	Guiding Question 2	Device adherence Number of measurements for 1 week, home BP measurements in the week before the 24 week followup.	Home BP motitoring only vs. LG Smartcare System/with remote physician visits Group 1 7.5 (SD: 3.2) and Group 3 4.7 (SD: 3.4)	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Kim et al. (2016)[97,101]	Guiding Question 2	Number of BP readings Device usage statistics were recorded for each study participant in the intervention group. Whenever a study participant used a device, the time, date, and user information of that particular reading was sent to a database managed by Qualcomm and available to participants through Healthy Circles.	PGHD (Withings BP monitor) Average readings per patient Intervention group: 151 (SD: 84) readings	NA
Lakshminarayan et al. (2018)[69]	Guiding Question 2	Data transmission	Intervention Transmitted day on an average of 89% of days	NA
Lakshminarayan et al. (2018)[69]	Guiding Question 2	Ease of use	Intervention Patients answered several 1-5 Likert scale items of agree/ disagree, and the ease of use of the mHealth system was favorable. For example, the average was 4.6 out of 5 on the item "I thought the system was easy to use". All items appear in Table 3 of the article.	NA
Lakshminarayan et al. (2018)[69]	Guiding Question 2	Technical problems	Intervention Phone charge ran out if not plugged in or monitor battery lost charge (n=4), having to play around with the phone to get the app to come up (n=6), wanting easier access to historic BP trends (n=2). There were no problems with cellular network access except for one participant who took the equipment with him when he went hunting, (n=1). There were no privacy breaches.	NA
Logan et al. (2012)[132]	Guiding Question 2	Number of readings per week per patient BP readings were automatically transmitted by the smartphone to application servers.	Combination (PGHD, Self-Care Support System) At 12 months: Intervention: 10.8 (SD: 6.7)	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Logan et al. (2012)[132]	Guiding Question 2	Number of patients with decreasing trend in self-measurement of BP BP readings were automatically transmitted by the smartphone to application servers.	Combination (PGHD, Self-Care Support System) At 12 months: Intervention: 40 (72.7%)	NA
Logan et al. (2012)[132]	Guiding Question 2	Adherence rate with home blood pressure measurement schedule Full adherence (100%) was defined as a minimum of 8 readings per week.	Combination (PGHD, Self-Care Support System) At 12 months: Intervention: 65.4%/week (SD: 30.0)	NA
Magid et al. (2013)[64]	Guiding Question 2	Ease of use of PGHD Questionnaire	PGHD (Omron HEM 790 IT) vs. Usual care 68% of PGHD patients reported that the home BP cuff and Heart360 monitoring system were very or extremely easy to use, and the majority of patients (52%) found their interactions with the clinical pharmacy specialist to be very or extremely helpful.	NA
Margolis et al. (2013)[106-112]	Guiding Question 2	Number of BP readings Patients were asked to measure their BP a minimum of 6 times per week.	Combination (PGHD, Pharmacist Care) Over 6 months: 31.5 measurements/week	NA
Margolis et al. (2013)[106-112]	Guiding Question 2	Percentage of weeks with at least 6 readings	Combination (PGHD, Pharmacist Care) Over 6 months: Median 81% (IQR: 62, 88)	NA
McKinstry et al. (2013)[113-115]	Guiding Question 2	Adherence to PGHD	Usual care vs. PGHD (Stabil-O-graph mobile) Compliance with the intervention: Participants in the PGHD arm took a median of 76 BP readings, and 178 (89%) completed more than 90% of the expected minimum number of readings during the trial. Five people requested to stop using the home monitor of whom three subsequently withdrew (with the other two continuing until the end of the trial).	NA
McManus et al. (2010)[116-120]	Guiding Question 2	Number of BP readings	Combination (PGHD, medication management) Over 11 months: Median 152 readings (IQR: 138 to 168)	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Mehos et al. (2000)[122]	Guiding Question 2	Completion of daily BP diary	PGHD (A&D UA-702 manual electronic blood pressure monitor) 12/18 (66%) completed 87% of days with 2 BP entries 89.9% of days with 1 BP entry	NA
Ogedegbe et al. (2014)[123]	Guiding Question 2	Adherence to PGHD/BP monitoring	PGHD (Microlife model BP 3AC1-1PC) vs. Usual care For PGHD patients only: Only 53% of patients completed all of the patient education modules, 38% returned home BP diaries for all 4 visits, and 45% received 4 to 6 lifestyle counseling sessions.	NA
Petrella et al. (2014)[60]	Guiding Question 2	Device usage	Intervention Completed 82.7% of BP measurements, 82.2% of fasting plasma glucose measurements, 70.9% of pedometer measurements, and 41.5% of body weight measurements. BP monitoring decreased from 91.5% in weeks 1-12 to 86.7% in weeks 13-24 to 77.6% in weeks 25-52. FPG monitoring decreased from 90.3% in weeks 1-12 to 87.2% in weeks 13-24 to 77% in weeks 25-52. Pedometer monitoring decreased from 83.6% in weeks 1-12 to 77.2% in weeks 13-24 to 63.1% in weeks 25-52. Body weight monitoring decreased from 63.6% in weeks 1-12 to 38.2% in weeks 13-24 to 28.4% in weeks 25-52.	NA
Rifkin et al. (2013)[65]	Guiding Question 2	Number of BP readings The number of BP readings transmitted by the system for each participant was totaled on a monthly basis.	Combination (PGHD, Physician management) At 1 month: Intervention: Median 36.5 (IQR: 26.5, 56.5) At 2 months: Intervention: Median 35.5 (IQR: 23.5, 59) At 3 months: Intervention: Median 30 (IQR: 19.5, 50) At 4 months: Intervention: Median 31 (IQR: 13, 51.5) At 5 months: Intervention: Median 35 (IQR: 23.5, 77) At 4 months: Intervention: Median 14 (IQR: 4, 28)	NA
Rifkin et al. (2013)[65]	Guiding Question 2	Patients with at least 4 BP readings The number of BP readings transmitted by the system for each participant was totaled on a monthly basis.	Combination (PGHD, Physician management) At 1 month: Intervention: 97% At 2 months: Intervention: 100% At 3 months: Intervention: 100% At 4 months: Intervention: 93% At 5 months: Intervention: 86% At 4 months: Intervention: 78%	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Rifkin et al. (2013)[65]	Guiding Question 2	User satisfaction	Combination (PGHD, Physician management) 96% reported they would continue to use BP device	NA
Sarfo et al. (2018)[138,139]	Guiding Question 2	Retention rate	PGHD (UA-767Plus BT BP) vs. Usual care At 3 months: Intervention group: 29/30 (97%) Control group: 27/30 (90%) p-value for difference: 0.30 At 9 months Intervention group: 28/30 (93%) Control group: 27/30 (90%) p-value for difference: 0.30	No
Sarfo et al. (2018)[138,139]	Guiding Question 2	Generally satisfied with mHealth system and BP monitor Used Telemedicine Satisfaction & Usefulness Questionnaire	PGHD (UA-767Plus BT BP) Levels of satisfaction Strongly disagree: 0 (0%) Disagree: 0 (0%) Neither agree nor disagree: 0 (0%) Agree: 2 (7%) Strongly agree: 26 (93%) Don't know: 0 (0%)	NA
Yoo et al. (2009)[23]	Guiding Question 2	Device usage	Intervention: Participants in the intervention group sent blood glucose recordings an average of 1.84 times per day (compliance rate 92.2%) and blood pressure an average of 1.72 times per day (compliance rate 86.0%). Body weight measurements were sent an average of 0.87 times per day (compliance rate 87.4%).	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Zaleski et al. (2019)[100]	Guiding Question 2	Patient experience/usability Investigators assessed the perceived acceptability, helpfulness, relevance, and satisfaction of EXERCISE and EXERCISE plus BP monitoring by interviewing participants using an Institutional Review Board approved standardized form that was developed in accordance with standard qualitative evaluation methodology for health interventions. Qualitative transcription data of the open ended responses obtained during process evaluation were synthesized independently by two investigators using a thematic mapping approach in Microsoft Excel. The response to each question was analyzed and summarized for content and coded as either positive, negative, or neutral towards EXERCISE and EXERCISE/BP self-monitoring with an inter-reliability of 100%.	PGHD (BP Omron 705 CPN) vs. Usual care BP monitoring group: A majority of participants (11 or 92%) found self-monitoring to be an extremely helpful, easy, and valid tool to increase exercise adherence and for overall health. In general, individuals actively engaged in prehypertension self-monitoring described increased awareness of the interrelatedness of exercise, daily BP, and PEH through daily, individualized feedback and reinforcement. Exploratory narrative analysis revealed three major themes: 1) Almost all participants (11 or 92%) stated that BP/prehypertension self-monitoring gave them reassurance and peace of mind that their chronic condition was under control. 2) Many (6 or 50%) participants noted that a unique aspect of prehypertension self-monitoring was the medical oversight component. Individuals found the American Heart Association web-enabled, patient-centered BP monitoring tool in combination with weekly BP review sessions with the study coordinator to be an extremely important component of prehypertension self-monitoring. 3) A third common theme was increased locus of control and the use of BP as a tool for cue to action. For example, one participant stated, “I liked taking my blood pressure daily and seeing it change after exercise. I would notice it creep up and the fact that I had control over that was reassuring to me”. Both treatment arms were given the opportunity to suggest areas of improvement or aspects of exercise/prehypertension self-monitoring that they disliked. Individuals among both groups found the timeline follow back log extremely easy to use, however, (10 or 42%) participants found it to be time consuming and 8 or 33% noted that a mobile, application-based tool (i.e., app) or wearable device would greatly improve likability and adherence for exercise self-monitoring. Similarly, 6 or 50% individuals in PGHD BP group found daily BP assessment to be very time consuming and 4 or 17% noted that they would continue to use BP self-monitoring only “once in a while as a check in”. Some (4 or 17%) individuals noted that a mobile app would improve usability and adherence to BP/prehypertension self-monitoring. For example, one participant stated, “I wouldn’t change anything unless there was a way my numbers could be transferred immediately to an app or something. Do they make that?” A second participant stated, “I think I would make the BP log electronic for those who are on-the-go.”	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Zaleski et al. (2019)[100]	Guiding Question 2	Adherence to BP monitoring Self-report	PGHD (BP Omron 705 CPN) vs. Usual care Among adults in PGHD/BP (n=12), 58%, or seven subjects, reported maintenance of BP self-monitoring. These individuals who reported maintenance of BP self-monitoring at follow-up (n=7) also reported greater maintenance of exercise (45.0 (SD: 7.1) min for 3.6 (SD1.3) days/week) compared with adults who did not report maintenance of BP self-monitoring (19.0 (SD: 18.8) min for 1.2 (SD: 1.3 days/week; p<0.01).	NA
Zha et al. (2019)[87]	Guiding Question 2	BP Monitoring Adherence BP monitoring adherence for the intervention group was calculated in two ways. For the first measure, the total number of times the monitor was used to measure BP was divided by the total number of expected times it should have been used (one BP measurement performed every day for 6 months) at home. For the second measure, the total number of office visits to measure BP was divided by the total number of expected visits (one office BP measurement every week for 6 months). BP monitoring adherence for the control group was calculated by the second measure that was used for the intervention group.	PGHD (iHealth BP7 Wireless Blood Pressure Wrist Monitor) vs. Usual care Over 6 months Home measurements Intervention: 71% (1,567/2,208 measures) Control: NA Office visits Intervention: 79% (227/288 visits) Control: 65% (203/312 visits)	NR
Bennett et al. (2018)[18,72,73]	Health	Adverse events	Intervention vs. Usual care Intervention: 9 Usual care: 10	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2009)[63]	Health	Adverse events Authors monitored for cardiovascular adverse events, such as myocardial infarction, death, and hospitalizations, through medical record and patient report. A data safety and monitoring board met annually to review all adverse events.	No AEs in any study group.	No
Bosworth et al. (2009)[63]	Health	Hospitalizations Electronic record	The proportion of hospitalized patients did not differ across groups (range 19.5% to 22.6%, p=0.91).	No
Bosworth et al. (2011)[66-68]	Health	Adverse events	No study-related adverse events occurred in any intervention group.	NA
Broege et al. (2001)[79]	Health	SF-36 QoL Questionnaire SF-36 QoL Questionnaire is a 36-item survey that measures health status from the patient's point of view in 8 categories: 1) physical functioning; 2) role limitations because of physical health problems; 3) bodily pain; 4) social functioning; 5) general mental health; 6) role limitations because of emotional problems; 7) vitality energy/fatigue, and 8) general health problems. The global score from the questionnaire was used to determine the patient's quality of life.	PGHD (Omron HEM-702) vs. Clinic group Change from baseline to 3 months Intervention: -6 points Control: -4 points p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Green et al. (2008)[80,81]	Health	SF-12 QoL Scores ranged from 1 to 100	PGHD (Omron HEM-705 CP) vs. Usual care At 12 months General health Intervention: 66.6 (SD: 20.9) Control: 67.1 (SD: 20.4) Difference between groups: -0.1 (95% CI: -4.0 to 3.7) Physical health Intervention: 77.7 (SD: 30.3) Control: 78.1 (SD: 27.7) Difference between groups: -0.4 (95% CI: -5.6 to 4.7) Emotional health Intervention: 72.1 (SD: 16.8) Control: 71.5 (SD: 17.7) Difference between groups: 0.5 (95% CI: -2.7 to 3.8)	No
Green et al. (2008)[80,81]	Health	SF-12 QoL Scores ranged from 1 to 100	Combination (PGHD, Pharmacist Care) vs. Usual care At 12 months General health Intervention: 66.6 (SD: 22.2) Control: 67.1 (SD: 20.4) Difference between groups: -0.1 (95% CI: -4.0 to 3.8) Physical health Intervention: 81.0 (SD: 26.5) Control: 78.1 (SD: 27.7) Difference between groups: 2.8 (95% CI: -2.3 to 8.0) Emotional health Intervention: 71.7 (SD: 19.7) Control: 71.5 (SD: 17.7) Difference between groups: 0.1 (95% CI: -3.1 to 3.4)	No
Green et al. (2008)[80,81]	Health	Serious adverse events	3 people died during the study; 2 died of cancer-related complications in the group receiving the PGHD only and 1 died of cardiac arrest in the PGHD plus Pharmacist Care group. 7 patients had nonfatal cardiovascular events: 2 in the usual care group, 4 in the PGHD only group, and 3 in the PGHD plus Pharmacist Care group.	NR
Hebert et al. (2012)[82]	Health	Mortality Measured via National Death Index plus deaths reported by patients' families.	8 overall over 18 months. No significant difference by treatment group (p=0.453).	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Kao et al. (2019)[102]	Health	QoL Health-Related Quality of Life Authors used the 3-level version of EuroQol five-dimension self-report questionnaire (EQ-5D-3L) to measure variables of health-related QoL. The EQ-5D-3L is composed of two parts: (1) the EQ-5D descriptive system and (2) the EuroQol visual analog scale (EQ-VAS). The EQ-5D descriptive system has five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on three levels: no problems (level 1), some problems (level 2), and extreme problems (level 3); the scores are converted into a single summary score, which describes a patient's health-related QoL. The EQ-VAS records the respondent's self-rated health status on a 20-cm vertical scale (visual analog scale) that ranges from 0, indicating the worst health status, to 100, indicating the best possible health state. The VAS is a quantitative measure of a patient's judgement about their health status. Authors used the Chinese version of EQ-5D-3L, which has been demonstrated to have adequate validity and reliability.	PGHD vs. Usual care EQ-5D PGHD baseline: 0.82, 3 months: 0.96 and 6 months: 0.99 vs. UC baseline: 0.89, 3 months: 0.81 and 6 months: 0.78 EQ-VAS PGHD baseline: 61.6, 3 months: 77.8 and 6 months: 85.7 vs. UC baseline: 71.9, 3 months: 63.6 and 6 months: 59.1	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Kerry et al. (2013)[103-105]	Health	Adverse event: Falls	Monitoring vs. Usual care At 52 weeks Monitoring: 19% Usual care: 17.20% p-value for difference: NS	No
Kerry et al. (2013)[103-105]	Health	Adverse event: Recurrent stroke	Monitoring vs. Usual care At 52 weeks Monitoring: 6% Usual care: 8.10% p-value for difference: NS	No
Kerry et al. (2013)[103-105]	Health	Quality of life as measured by the EuroQol 5D Lower scores are better	Monitoring vs. Usual care Change from baseline to 52 weeks Monitoring: -0.13 (95% CI: -0.09 to -0.15) Usual care: -0.12 (95% CI: -0.1 to -0.17) p-value for difference: NS	No
Magid et al. (2013)[64]	Health	Hospitalizations Chart review	Usual care vs. PGHD (Omron HEM 790 IT) Mean and SD: Hospitalizations : UC: 0.04 (0.20), PGHD: 0.03 (0.17), p=0.57	No
Magid et al. (2013)[64]	Health	ER visits Chart review	Usual care vs. PGHD (Omron HEM 790 IT) Mean and SD: ER visits UC: 0.05 (0.23), PGHD: 0.04 (0.19), p=0.44	No

Margolis et al. (2013)[106-112]	Health	SF-12 QoL score Medical Outcomes Study Short Form 12 survey. Items were scored on scale of 0 to 100, with 100 indicating highest levels of health.	Combination (PGHD, Pharmacist Care) vs. Usual care SF-12 physical At 6 months Intervention: 47.5 (95% CI: 45.2 to 49.8) Control: 46.2 (95% CI: 43.9 to 48.5) At 12 months Intervention: 47.2 (95% CI: 44.8 to 49.5) Control: 46.6 (95% CI: 44.3 to 49.0) At 18 months Intervention: 47.4 (95% CI: 45.1 to 49.7) Control: 46.6 (95% CI: 44.2 to 48.9) Change from baseline to 6 months Intervention: -0.50 (95% CI: -1.56 to 0.56) Control: -1.17 (95% CI: -2.26 to 0.07) Change from baseline to 12 months Intervention: -0.84 (95% CI: -2.00 to 0.32) Control: -0.72 (95% CI: -1.90 to 0.45) Change from baseline to 18 months Intervention: -0.85 (95% CI: -1.77 to 0.69) Control: -0.82 (95% CI: -2.09 to 0.45) SF-12 mental At 6 months Intervention: 52.5 (95% CI: 51.0 to 54.0) Control: 51.3 (95% CI: 49.8 to 52.9) At 12 months Intervention: 52.1 (95% CI: 50.4 to 53.8) Control: 50.5 (95% CI: 48.8 to 52.3) At 18 months Intervention: 53.7 (95% CI: 52.3 to 55.3) Control: 51.8 (95% CI: 50.3 to 53.2) Change from baseline to 6 months Intervention: 0.25 (95% CI: -0.88 to 1.38) Control: 0.09 (95% CI: -1.08 to 1.26) Change from baseline to 12 months Intervention: -0.05 (95% CI: -1.83 to 0.78) Control: -0.78 (95% CI: -2.11 to 0.55) Change from baseline to 18 months Intervention: 1.51 (95% CI: -0.18 to 2.40) Control: 0.50 (95% CI: -0.83 to 1.84)	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Margolis et al. (2013)[106-112]	Health	Adverse events Safety was assessed at each research visit by collecting all reports of hospitalizations and reports of emergency department, urgent care, and same-day medical visits for problems related to elevated BP, hypotension, fainting, loss of consciousness, and allergic reactions.	Combination (PGHD, Pharmacist Care) vs. Usual care Any adverse event Intervention: 49; Control: 60 Related to hypotension, dizziness, or loss of conciousness Intervention: 6; Control: 1 Related to hypertension Intervention: 1; Control: 4 Strokes Intervention: 2; Control: 5 Transient ischemic attacks Intervention: 0; Control: 3 Episodes of atrial fibrillation Intervention: 1; Control: 1 Myocardial infarction Intervention: 0; Control: 1 Angina Intervention: 1; Control: 0 Cardiac bypass surgeries Intervention: 0; Control: 2	NR
McKinstry et al. (2013)[113-115]	Health	Adverse events	Usual care vs. PGHD (Stabil-O-graph mobile) Adverse events In total, 43 adverse events were recorded. One death occurred in the intervention group and two in the usual care group, none of which were thought to be related to BP. The other events included three people who reported anxiety as a result of self-monitoring, one who had a fall, and two who fainted (which may have been related to BP control), and six seen in hospital because of cardiovascular problems (two atrial fibrillation, two chest pain, two very high BP). In addition, one patient had a rash thought to be due to antihypertensive drug therapy and one developed hyperkalaemia secondary to dehydration and a viral illness but that was possibly exacerbated by antihypertensive drug therapy. The remainder had hospital admissions thought to be unrelated to BP or the intervention. Apart from the three who had become anxious as a result of self-monitoring, adverse events were evenly distributed between the groups.	Only anxiety was different, higher for PGHD.

Study	Outcome Category	Outcome	Results	Statistical Significance
McKinstry et al. (2013)[113-115]	Health	Death	PGHD (Stabil-O-graph mobile) vs. Usual care One death occurred in the intervention group and two in the usual care group, none of which were thought to be related to BP.	No
McKinstry et al. (2013)[113-115]	Health	QOL (EQ-5D) Authors measured quality of life using index scores generated from standard algorithms for the EQ-5D. The EQ-5D index scores were tested using non-parametric bootstrap of differences in means between trial arms reporting confidence intervals and P values (two tailed) for each, with significance set at the 5% level.	PGHD (Stabil-O-graph mobile) vs. Usual care Mean (SD) PGHD: 0.864 (SD: 0.185) and UC: 0.824 (SD: 0.178)	No
McKinstry et al. (2013)[113-115]	Health	Hospitalization Resource use survey	PGHD (Stabil-O-graph mobile) vs. Usual care 21/177 in PGHD group and 15/177 in UC	NR: "authors say adverse events were evenly distributed between groups (with the exception of anxiety).
McKinstry et al. (2013)[113-115]	Health	ER visits Resource use survey	Usual care vs. PGHD (Stabil-O-graph mobile) 10/177 in PGHD and 14/177 in UC	NR "authors say AEs were evenly distributed between groups with the exception of anxiety".

Study	Outcome Category	Outcome	Results	Statistical Significance
McManus et al. (2010)[116-120]	Health	EQ-5D score EuroQol Group 5-Dimension Self-Report Questionnaire score. Value of 1.00 indicates "full health".	Combination (PGHD, medication management) vs. Usual care At 6 months Intervention: 0.819 (95% CI: 0.789 to 0.850) Control: 0.848 (95% CI: 0.818 to 0.877) At 12 months Intervention: 0.833 (95% CI: 0.805 to 0.861) Control: 0.844 (95% CI: 0.814 to 0.873) Change from baseline to 6 months Intervention: 0.010 (95% CI: -0.013 to 0.032) Control: 0.000 (95% CI: -0.028 to 0.026) Difference between the groups: 0.010 (95% CI: -0.024 to 0.043) Change from baseline to 12 months Intervention: 0.024 (95% CI: 0.002 to 0.047) Control: -0.004 (95% CI: -0.030 to 0.020) Difference between the groups: 0.028 (95% CI: -0.011 to 0.060)	No

McManus et al. (2010)[116-120]	Health	Adverse events Side-effects were measured by use of standard questionnaires. Most frequent side effects reported.	Combination (PGHD, medication management) vs. Usual care At 12 months Stiff joints Intervention: 95/234 (41%) Control: 104/246 (42%) p-value for difference: 0.709 Pain Intervention: 89/234 (38%) Control: 84/246 (34%) p-value for difference: 0.375 Fatigue Intervention: 84/234 (36%) Control: 78/246 (32%) p-value for difference: 0.332 Swelling of legs Intervention: 74/234 (32%) Control: 55/246 (22%) p-value for difference: 0.022 Sleeping difficulties Intervention: 72/234 (31%) Control: 80/246 (33%) p-value for difference: 0.680 Dry mouth Intervention: 68/234 (29%) Control: 59/246 (24%) p-value for difference: 0.208 Feeling flushed Intervention: 61/234 (26%) Control: 57/246 (23%) p-value for difference: 0.461 Cough Intervention: 61/234 (26%) Control: 60/246 (24%) p-value for difference: 0.672 Breathlessness Intervention: 53/234 (23%) Control: 59/246 (34%) p-value for difference: 0.730 Sore eyes Intervention: 48/234 (21%)	Yes, for swelling of legs.

Study	Outcome Category	Outcome	Results	Statistical Significance
			Control: 58/246 (24%) p-value for difference: 0.419	

McManus et al. (2014)[121]	Health	Adverse events Measured using standard questionnaires	PGHD (Microlife Watch BP Home) vs. Usual care Stiff joints Intervention group: 110/230 (48%) Usual care: 109/220 (50%) p-value for difference: 0.72 Pain Intervention group: 113/230 (49%) Usual care: 101/220 (46%) p-value for difference: 0.49 Fatigue Intervention group: 106/230 (46%) Usual care: 93/220 (42%) p-value for difference: 0.42 Swelling of legs and ankles Intervention group: 78 /230 (34%) Usual care: 81/220 (37%) p-value for difference: 0.52 Sleep difficulties Intervention group: 86/230 (37%) Usual care: 71/220 (32%) p-value for difference; 0.26 Breathlessness Intervention group: 66/230 (29%) Usual care: 68/220 (31%) p-value for difference: 0.61 Dry mouth Intervention group: 74/230 (32%) Usual care: 58/220 (26%) p-value for difference: 0.18 Cough Intervention group: 65/230 (28%) Usual care: 64/220 (29%) p-value for difference: 0.85 Pins and needles Intervention group: 61/230 (27%) Usual care: 52/220 (24%) p-value for difference: 0.48 Loss of libido Intervention group: 49/230 (21%) Usual care: 48/220 (22%) p-value for difference: 0.90	No

Study	Outcome Category	Outcome	Results	Statistical Significance
McManus et al. (2014)[121]	Health	EQ-5D QoL EuroQol Group 5-Dimension Self-report Questionnaire score: Utility values range from 1=perfect health, to 0=death to -0.59 (worse than death)	PGHD (Microlife Watch BP Home) vs. Usual care At 6 months Intervention group: 0.822 (95% CI: 0.794 to 0.850) Usual care: 0.798 (95% CI: 0.766 to 0.830) Between group difference: -0.018 (95% CI: -0.054 to 0.018) At 12 months Intervention group: 0.816 (95% CI: 0.786 to 0.846) Usual care: 0.806 (95% CI: 0.786 to 0.846) Between group difference: -0.004 (95% CI: -0.039 to 0.031)	No
McManus et al. (2018)[83-86]	Health	EQ-5D-5L QoL score	PGHD (Omron M10-IT) vs. Usual care At 12 months Difference between the groups: -0.01 (95% CI: -0.04 to 0.02); p-value: 0.4862	No
McManus et al. (2018)[83-86]	Health	EQ-5D-5L QoL score	Combination (PGHD, telemonitoring) vs. Usual care At 12 months Difference between the groups: -0.03 (95% CI: -0.06 to -0.001); p-value: 0.0384	Yes

McManus et al. (2018)[83-86]	Health	Adverse events Top 10 and hypertension-specific adverse events were reported.	PGHD (Omron M10-IT) vs. Usual care At 12 months Pain Intervention: 144/329 (44%) Control: 156/348 (45%) Odds ratio: 0.80 (95% CI: 0.51 to 1.25); p-value: 0.3328 Stiff joints Intervention: 134/329 (41%) Control: 152/348 (44%) Odds ratio: 0.67 (95% CI: 0.40 to 1.10); p-value: 0.1161 Sleep difficulties Intervention: 137/325 (42%) Control: 140/349 (40%) Odds ratio: 0.89 (95% CI: 0.52 to 1.53); p-value: 0.6797 Fatigue Intervention: 122/327 (37%) Control: 132/348 (38%) Odds ratio: 0.76 (95% CI: 0.45 to 1.27); p-value: 0.2949 Cough Intervention: 105/329 (32%) Control: 113/346 (34%) Odds ratio: 0.88 (95% CI: 0.55 to 1.41); p-value: 0.5865 Swelling of legs or ankles Intervention: 80/326 (25%) Control: 95/349 (27%) Odds ratio: 0.75 (95% CI: 0.40 to 1.41); p-value: 0.3763 Sore eyes Intervention: 71/325 (22%) Control: 80/348 (23%) Odds ratio: 0.83 (95% CI: 0.49 to 1.41); p-value: 0.4965 Dry mouth Intervention: 71/326 (22%) Control: 66/348 (19%) Odds ratio: 1.23 (95% CI: 0.63 to 2.39); p-value: 0.5427 Pins and needles Intervention: 71/326 (22%) Control: 69/346 (20%) Odds ratio: 1.00 (95% CI: 0.52 to 1.94); p-value: 0.9941 Loss of strength Intervention: 77/328 (23%)	No

Study	Outcome Category	Outcome	Results	Statistical Significance
			Control: 75/347 (22%) Odds ratio: 0.95 (95% CI: 0.52 to 1.74); p-value: 0.8678 Feeling flushed Intervention: 76/328 (23%) Control: 73/346 (21%) Odds ratio: 0.96 (95% CI: 0.52 to 1.76); p-value: 0.8854 Dizziness Intervention: 50/324 (15%) Control: 61/348 (18%) Odds ratio: 1.40 (95% CI: 0.72 to 2.74); p-value: 0.3212 Impotence Intervention: 43/274 (16%) Control: 37/310 (12%) Odds ratio: 1.01 (95% CI: 0.34 to 3.05); p-value: 0.9789	

McManus et al. (2018)[83-86]	Health	Adverse events Top 10 and hypertension-specific adverse events were reported.	PGHD (Omron M10-IT) vs. Usual care At 12 months Pain Intervention: 139/326 (43%) Control: 156/348 (45%) Odds ratio: 0.82 (95% CI: 0.52 to 1.28); p-value: 0.3816 Stiff joints Intervention: 146/325 (45%) Control: 152/348 (44%) Odds ratio: 1.02 (95% CI: 0.62 to 1.68); p-value: 0.9381 Sleep difficulties Intervention: 129/325 (40%) Control: 140/349 (40%) Fatigue Intervention: 123/324 (38%) Control: 132/348 (38%) Odds ratio: 0.93 (95% CI: 0.56 to 1.55); p-value: 0.7851 Cough Intervention: 108/326 (33%) Control: 113/346 (34%) Odds ratio: 0.99 (95% CI: 0.62 to 1.60); p-value: 0.9827 Swelling of legs or ankles Intervention: 89/324 (27%) Control: 95/349 (27%) Odds ratio: 1.22 (95% CI: 0.66 to 2.26); p-value: 0.5279 Sore eyes Intervention: 86/324 (27%) Control: 80/348 (23%) Odds ratio: 1.07 (95% CI: 0.64 to 1.79); p-value: 0.7861 Dry mouth Intervention: 87/324 (27%) Control: 66/348 (19%) Odds ratio: 2.64 (95% CI: 1.37 to 5.07); p-value: 0.0036 Pins and needles Intervention: 66/325 (20%) Control: 69/346 (20%) Odds ratio: 1.02 (95% CI: 0.53 to 1.98); p-value: 0.9542 Loss of strength Intervention: 76/325 (23%) Control: 75/347 (22%) Odds ratio: 0.70 (95% CI: 0.38 to 1.30); p-value: 0.2615	Yes, for dry mouth.

Study	Outcome Category	Outcome	Results	Statistical Significance
			Feeling flushed Intervention: 66/324 (20%) Control: 73/346 (21%) Odds ratio: 0.76 (95% CI: 0.41 to 1.41); p-value: 0.3776 Dizziness Intervention: 50/324 (15%) Control: 61/348 (18%) Odds ratio: 0.77 (95% CI: 0.38 to 1.54); p-value: 0.4546 Impotence Intervention: 43/288 (15%) Control: 37/310 (12%) Odds ratio: 1.85 (95% CI: 0.42 to 5.22); p-value: 0.2422	
Mehos et al. (2000)[122]	Health	SF-36 QOL scale	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) p>0.1	No
Mendelson et al. (2014)[47]	Health	MCS QoL MCS is undefined in paper, but is likely the mental component score of either SF-36 or SF-12. Likely higher scores are better.	PGHD (Telemedicine) vs. Usual care At 17 weeks Intervention: 47.4 (SD: 10.7) Control: 46.4 (SD: 9.1) p-value for difference: NS	No
Mendelson et al. (2014)[47]	Health	PCS QoL PCS is undefined in paper, but is likely the physical component score of either SF-36 or SF-12. Likely higher scores are better.	PGHD (Telemedicine) vs. Usual care At 17 weeks Intervention: 44.6 (SD: 9.4) Control: 45.9 (SD: 8.5) p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Ogedegbe et al. (2014)[123]	Health	Adverse events	Usual care vs. PGHD (Microlife model BP 3AC1-1PC) Mean per 100 patients: PGHD serious AE: 0.115, non-serious: 0.074, total: 0.189; UC serious AE: 0.139, non-serious: 0.075, total: 0.216; p values for serious AE: 0.28, non-serious: 0.96 and total: 0.34. Relation of AE to study: none 98% (n=102) for PGHD and 99% (n=112) for UC; possible 1% (n=1) for PGHD and 0 for UC; probable 0 for both groups; definite 1% (1) for PGHD and 1% (1) for UC. Action taken to resolve the AE: none 12% (n=13) for PGHD and 11% (n=13) for UC; hospitalization 52% (n=54) for PGHD and 58% (n=66) for UC, p=0.16; reported to medical director 15% (n=16) PGHD and 14% (n=16) for UC, p not calculated; study termination 0 for both groups.	No
Ogedegbe et al. (2014)[123]	Health	Death	Usual care vs. PGHD (Microlife model BP 3AC1-1PC) Among the 1039 participants, there were 11 deaths, 8 in the IC group and 3 in the UC group (p=0.22).	No
Petrella et al. (2014)[60]	Health	High SBP alarm This was triggered when SBP went below 60 or above 220 mmHg.	Intervention No SBP alarms overall during the one-year follow-up.	NA
Petrella et al. (2014)[60]	Health	High DBP alarm This was triggered when DBP went below 40 or above 110 mmHg.	Intervention 7 DBP alarms overall during the one-year follow-up.	NA
Petrella et al. (2014)[60]	Health	Adverse event: Any	Intervention vs. Active control Intervention: No AEs in the intervention group Active control: Four AEs in 3 participants in the active control group (2 angina, 1 stroke, 1 arm/shoulder pain)	NR
Zaleski et al. (2019)[100]	Health	Adverse events	Usual care vs. PGHD (BP Omron 705 CPN) There were no adverse exercise training-related injuries reported throughout the duration of the study.	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Zarnke et al. (1997)[124]	Health	MOS SF-36 Medical Outcomes Survey-Short Form 36. Positive values represent improved quality of life.	Combination (PGHD, treatment management) vs. Usual care Change from baseline to 8 weeks Physical function Intervention: -1.25 (SD: 7.8) Control: 0.50 (SD: 8.6) p-value for difference: NS Role—physical Intervention: -1.25 (SD: 20.6) Control: -5.0 (SD: 34.9) p-value for difference: NS Bodily pain Intervention: 4.35 (SD: 11.3) Control: 0.0 (SD: 21.0) p-value for difference: NS General health Intervention: -1.4 (SD: 17.3) Control: -4.0 (SD: 12.3) p-value for difference: NS Vitality Intervention: -25.0 (SD: 16.4) Control: -28.5 (SD: 8.8) p-value for difference: NS Social function Intervention: 0.63 (SD: 20.5) Control: -7.5 (17.9) p-value for difference: NS Social function Intervention: 0.63 (SD: 20.5) Control: -7.5 (17.9) p-value for difference: NS Role—emotional Intervention: 5.0 (SD: 31.1) Control: -16.7 (SD: 32.3) p-value for difference: NS Mental health Intervention: 1.8 (SD: 11.4) Control: -1.2 (SD: 11.3) p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Zarnke et al. (1997)[124]	Health	Multi-dimensional Health Locus of Control Positive values represent increased sense of self-control.	Combination (PGHD, treatment management) vs. Usual care Change from baseline to 8 weeks Internality Intervention: -0.60 (SD: 3.97) Control: -1.10 (SD: 4.09) p-value for difference: NS Powerful others Intervention: -0.55 (SD: 4.21) Control: -0.90 (SD: 3.84) p-value for difference: NS Chance Intervention: 0.20 (SD: 2.84) Control: 2.00 (SD: 5.91) p-value for difference: NS	No
Zarnke et al. (1997)[124]	Health	State Trait Anxiety Inventory Positive values represent increased anxiety state.	Combination (PGHD, treatment management) vs. Usual care Change from baseline to 8 weeks State anxiety Intervention: 0.91 (SD: 7.54) Control: 6.01 (SD: 13.3) p-value for difference: NS	No

Zha et al. (2019)[87]	Health	MOS SF-36 QoL The Medical Outcomes Study 36-item Short-Form Health Survey consists of the sum scores of eight subscales (physical functioning, physical role limitations, mental health, emotional role limitations, social functioning, vitality, pain, and general health perceptions). The eight subscales are then summarized into two composite scores (physical and psychological quality of life). Scores on the SF-36 generally range from 20 to 60, with higher scores representing increased health-related QoL.	PGHD (iHealth BP7 Wireless Blood Pressure Wrist Monitor) vs. Usual care At 6 months Physical function Intervention: 57.21 (SD: 23.97) Control: 56.82 (SD: 35.81) p-value for difference: 0.51 Role function Intervention: 60.00 (SD: 27.23) Control: 67.54 (SD: 29.3) p-value for difference: 0.53 Bodily pain Intervention: 43.69 (SD: 25.31) Control: 55.46 (SD: 33.84) p-value for difference: 0.84 General health Intervention: 42.38 (SD: 21.22) Control: 57.71 (SD: 20.49) p-value for difference: 0.08 Vitality Intervention: 45.71 (SD: 17.43) Control: 50.46 (SD: 15.95) p-value for difference: 0.08 Social foundation Intervention: 50.29 (SD: 31.78) Control: 60.50 (SD: 36.71) p-value for difference: 0.31 Role emotional Intervention: 48.62 (SD: 25.64) Control: 67.99 (SD: 27.35) p-value for difference: 0.07 Mental health Intervention: 54.49 (SD: 20.11) Control: 80.73 (SD: 18.73) p-value for difference: 0.003 Physical component summary Intervention: 42.63 (SD: 11.21) Control: 44.25 (SD: 11.17) p-value for difference: 0.72 Mental component summary Intervention: 43.11 (SD: 10.23)	Yes, for mental health subscale only.

Study	Outcome Category	Outcome	Results	Statistical Significance
			Control: 49.65 (SD: 11.87) p-value for difference: 0.18	
Aekplakorn et al. (2016)[88]	Surrogate	BP Uncontrolled BP defined as SBP ≥ 140 mmHg or DBP ≥ 90 mmHg	PGHD (Omron HEM 7117) vs. Usual care SBP UC baseline: 147.2 (95% CI: 144.5 to 150.0) 6 months: 137.9 (95% CI: 135.3 to 140.5) 12 months: 136.8 (95% CI: 133.6 to 140.0); SBP PGHD baseline: 149.4 (95% CI: 147.3 to 151.5), 6 months: 137.4 (95% CI: 135.0 to 139.7), 12 months: 136.4 (95% CI: 133.6 to 139.0). P for adjusted difference between groups at 6 months mean difference: -2.9 (95% CI: -7.8 to 1.8) and adjusted difference between groups mean difference for 12 months: -2.5 (95% CI: -7.3 to 2.2). DBP UC baseline: 82.2 (95% CI: 80.0 to 84.4), 6 months: 76.0 (95% CI: 74.0 to 78.0), 12 months: 78.1 (95% CI: 75.6 to 80.5); PGHD baseline: 83.4 (95% CI: 81.6 to 85.3), 6 months: 76.4 (95% CI: 74.6 to 78.2), 12 months: 78.1 (95% CI: 76.0 to 80.1). P for adjusted difference between groups at 6 months mean difference: -0.6 (95% CI: -3.9 to 2.7) and adjusted difference between groups mean difference for 12 months: -1.2 (95% CI: -4.5 to 2.0). Percent of uncontrolled BP data: UC baseline (77.9%), 6 months (40.2%); 12 months (46.4%). PGHD baseline (87.4%), 6 months (40.2%), and 12 months (46.4%), p 0.13 for difference between group change scores at 6 months and p=0.13 for difference between group change scores at 12 months.	No
Bennett et al. (2018)[18,72,73]	Surrogate	SBP	Intervention vs. Usual care Change from baseline to 26 weeks Intervention: -4.65 (95% CI: -7.5 to -1.7) mmHg Usual care: -3.4 (95% CI: -6.3 to -0.6) mmHg p-value for difference: 0.54 Change from baseline to 52 weeks Intervention: -8.4 (95% CI: -11.4 to -5.3) mmHg Usual care: 7.5 (95% CI: -10.4 to -4.5) mmHg p-value: 0.65	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Bennett et al. (2018)[18,72,73]	Surrogate	DBP	Intervention vs. Usual care Change from baseline to 26 weeks Intervention: -4.1 (95% CI: -5.9 to -2.4) mmHg Usual care: -2.5 (95% CI: -4.2 to -0.8) mmHg p-value for difference: 0.16 Change from baseline to 52 weeks Intervention: -5.2 (95% CI: -7.1 to -3.3) mmHg Usual care: -4.2 (95% CI: -6.1 to -2.4) mmHg p-value: 0.43	No
Bernocchi et al. (2014)[125]	Surrogate	SBP BP measurements were done using an oscillometric device measured the BP three times at intervals and the mean of three values was recorded as the BP for that visit	Home-Based Telemedicine vs. Usual care At end of follow-up (mean 80 days) Intervention group: 130 (SD: 15) mmHg Control group: 149 (SD: 17) mmHg Change from baseline to end of follow-up Intervention group: -22.3 (SD: 22.6) mmHg Control group: -6.8 (SD: 14.6) mmHg	NR
Bernocchi et al. (2014)[125]	Surrogate	DBP BP measurements were done using an oscillometric device measured the BP three times at intervals and the mean of three values was recorded as the BP for that visit.	Home-Based Telemedicine vs. Usual care At end of follow-up (mean 80 days) Intervention group: 76 (SD: 11) mmHg Control group: 86 (SD: 9) mmHg Change from baseline to end of follow-up Intervention group: -13 (SD: 12.2) mmHg Control group: -4 (SD: 8) mmHg	NR
Bernocchi et al. (2014)[125]	Surrogate	BP Control BP measurements were done using an oscillometric device measured the BP three times at intervals and the mean of three values was recorded as the BP for that visit.	Home-Based Telemedicine vs. Usual care At end of follow-up (mean 80 days) Uncontrolled SBP Intervention group: 26% Control group: 81% Uncontrolled DBP Intervention group: 8% Control group: 62%	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2009)[63]	Surrogate	BP Blood pressure control was defined as SBP less than 140 mmHg and DBP less than 90 mmHg for patients without diabetes, and SBP less than 130 mmHg and DBP less than 80 mmHg for patients with diabetes. Secondary outcomes were systolic and diastolic BP at each time point over 24 months. At each time point, a research assistant who was blinded to the patient's group assignment obtained 2 BP measurements with a digital sphygmomanometer (BPTRU Automated Non-invasive BP monitor, Model BPM-100, BpTRU Medical Devices Headquarters, Coquitlam, British Columbia, Canada); the first was obtained after patients were seated and had rested for at least 5 minutes, and the second was obtained 30 seconds after the first. The mean of the 2 values was used as the outcome for that time point.	Usual care vs. PGHD (Omron 773AC or 637) % controlled at 12 months: PGHD vs. UC (95% CI:): 3.8 (95% CI: -1.1 to 8.5); 24 months: PGHD vs. UC: 7.6 (95% CI: -1.9 to 17.0); SBP: 12 months: PGHD vs. UC: -3.7 (95% CI: -6.1 to -1.2) and 24 months: PGHD vs. UC: -0.6 (95% CI: -3.6 to 2.3); DBP: 12 months: PGHD vs. UC: -3.1 (95% CI: -4.4 to -1.8) and 24 months: PGHD vs. UC: -1.2 (-2.9 to 0.4).	No for percent controlled at 12 and 24 months. SBP yes for 12 months but no for 24-month follow-up. DBP yes for 12 months but no for 24-month follow-up.

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2009)[63]	Surrogate	BP Blood pressure control was defined as SBP less than 140 mmHg and DBP less than 90 mmHg for patients without diabetes, and SBP less than 130 mmHg and DBP less than 80 mmHg for patients with diabetes. Secondary outcomes were systolic and diastolic BP at each time point over 24 months. At each time point, a research assistant who was blinded to the patient's group assignment obtained 2 BP measurements with a digital sphygmomanometer (BPTRU Automated Non-invasive BP monitor, Model BPM-100, BpTRU Medical Devices Headquarters, Coquitlam, British Columbia, Canada); the first was obtained after patients were seated and had rested for at least 5 minutes, and the second was obtained 30 seconds after the first. The mean of the 2 values was used as the outcome for that time point.	Usual care vs. Combination (PGHD plus behavior self-management) % controlled 12 months combination vs. UC: 5.6 (95% CI: 0.9 to 10.2) and 24 months: 11.0 (95% CI: 1.9 to 19.8); SBP at 12 months combination vs. UC: -3.3 (-5.7 to -0.8) and 24 months: -3.9 (-6.9 to -0.9), DBP at 12 months combination vs. UC: -2.2 (-3.5 to -0.8) and 24 months combination vs. UC: -2.2 (-3.8 to -0.6).	Yes, for all.
Bosworth et al. (2011)[66-68]	Surrogate	BP Control BP control defined as <140/90 mmHg or, for those with diabetes, <130/80 mmHg.	Combination (PGHD, behavioral management) vs. Usual care At 6 months Difference between the groups: 3.3% (95% CI: -8.7 to 15.3) At 12 months Difference between the groups: 12.8% (95% CI: 1.6 to 24.1) At 18 months Difference between the groups: -2.9% (95% CI: -15.0 to 9.3)	Yes, at 12 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[66-68]	Surrogate	SBP A research assistant asked patients to rest for 5 minutes before obtaining 2 BP measurements using a digital sphygmomanometer.	Combination (PGHD, behavioral management) vs. Usual care At 6 months Difference between the groups: 1.3 (95% CI: -2.9 to 5.4) mmHg At 12 months Difference between the groups: -2.1 (95% CI: -6.2 to 2.1) mmHg At 18 months Difference between the groups: 2.2 (95% CI: -2.2 to 6.6) mmHg	No
Bosworth et al. (2011)[66-68]	Surrogate	SBP A research assistant asked patients to rest for 5 minutes before obtaining 2 BP measurements using a digital sphygmomanometer.	Combination (PGHD, medication management) vs. Usual care At 6 months Difference between the groups: -0.4 (95% CI: -4.6 to 3.7) mmHg At 12 months Difference between the groups: -2.4 (95% CI: -6.5 to 1.7) mmHg At 18 months Difference between the groups: -1.3 (95% CI: -5.7 to 3.2) mmHg	No
Bosworth et al. (2011)[66-68]	Surrogate	SBP A research assistant asked patients to rest for 5 minutes before obtaining 2 BP measurements using a digital sphygmomanometer.	Combination (PGHD, behavioral management, medication management) vs. Usual care At 6 months Difference between the groups: -0.9 (95% CI: -5.1 to 3.2) mmHg At 12 months Difference between the groups: -4.3 (95% CI: -8.5 to -0.2) mmHg At 18 months Difference between the groups: -3.6 (95% CI: -8.1 to 0.9) mmHg	Yes, at 12 months.
Bosworth et al. (2011)[66-68]	Surrogate	DBP A research assistant asked patients to rest for 5 minutes before obtaining 2 BP measurements using a digital sphygmomanometer.	Combination (PGHD, behavioral management) vs. Usual care At 6 months Difference between the groups: 0.5 (95% CI: -1.9 to 2.9) mmHg At 12 months Difference between the groups: -0.7 (95% CI: -3.2 to 1.9) mmHg At 18 months Difference between the groups: 0.6 (95% CI: -2.0 to 3.3) mmHg	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[66-68]	Surrogate	DBP A research assistant asked patients to rest for 5 minutes before obtaining 2 BP measurements using a digital sphygmomanometer.	Combination (PGHD, medication management) vs. Usual care At 6 months Difference between the groups: -1.2 (95% CI: -3.5 to 1.2) mmHg At 12 months Difference between the groups: -0.9 (95% CI: -3.5 to 1.6) mmHg At 18 months Difference between the groups: -0.5 (95% CI: -3.5 to 1.6) mmHg	No
Bosworth et al. (2011)[66-68]	Surrogate	DBP A research assistant asked patients to rest for 5 minutes before obtaining 2 BP measurements using a digital sphygmomanometer.	Combination (PGHD, medication management) vs. Usual care At 6 months Difference between the groups: -0.2 (95% CI: -2.5 to 2.2) mmHg At 12 months Difference between the groups: -0.01 (95% CI: -2.6 to 2.6) mmHg At 18 months Difference between the groups: -1.4 (95% CI: -4.0 to 1.3) mmHg	No
Bosworth et al. (2011)[66-68]	Surrogate	BP Control BP control defined as <140/90 mmHg or, for those with diabetes, <130/80 mmHg.	Combination (PGHD, behavioral management, medication management) vs. Usual care At 6 months Difference between the groups: 5.4% (95% CI: -6.5 to 17.3) At 12 months Difference between the groups: 8.3% (95% CI: -3.3 to 19.9) At 18 months Difference between the groups: 7.7% (95% CI: -4.1 to 19.5)	No
Bosworth et al. (2011)[66-68]	Surrogate	BP Control BP control defined as <140/90 mmHg or, for those with diabetes, <130/80 mmHg.	Combination (PGHD, medication management) vs. Usual care At 6 months Difference between the groups: 6.7% (95% CI: -5.1 to 18.5) At 12 months Difference between the groups: 12.5% (95% CI: 1.3 to 23.6) At 18 months Difference between the groups: -0.3% (95% CI: -12.4 to 11.9)	Yes, at 12 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[89-91]	Surrogate	SBP Blood pressure was measured using a digital sphygmanometer (BPTRU Automated Non-invasive blood pressure monitor, Model BPM-100). The readings were taken by a research assistant who was blinded to the patient's randomization assignment. Two blood pressure readings were taken; the first after patients were seated and had rested in a quiet room separate from the clinical practice site, for at least 5 minutes, and the second 30 seconds after the first. The mean blood pressure reading taken at each of the five visits was used as the outcome.	PGHD (Omron 773AC or 637) vs. Usual care At 12 months White Difference between groups: -1.5 (95% CI: -6.1 to 3.2) mmHg Non-white Difference between groups: -5.5 (95% CI: -10.3 to -0.8) mmHg At 24 months White Difference between groups: -0.8 (95% CI: -6.4 to 4.7) mmHg Non-white Difference between groups: 1.3 (95% CI: -4.4 to 7.1) mmHg	Yes, for non-white patients at 12 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[89-91]	Surrogate	DBP Blood pressure was measured using a digital sphygmanometer (BPTRU Automated Non-invasive blood pressure monitor, Model BPM-100). The readings were taken by a research assistant who was blinded to the patient's randomization assignment. Two blood pressure readings were taken; the first after patients were seated and had rested in a quiet room separate from the clinical practice site, for at least 5 minutes, and the second 30 seconds after the first. The mean blood pressure reading taken at each of the five visits was used as the outcome.	PGHD (Omron 773AC or 637) vs. Usual care At 12 months White Difference between groups: 0.1 (95% CI: -2.4 to 2.6) mmHg Non-white Difference between groups: -3.7 (95% CI: -6.2 to -1.1) mmHg At 24 months White Difference between groups: 0.1 (95% CI: -3.0 to 3.2) mmHg Non-white Difference between groups: -0.6 (95% CI: -3.9 to 2.6) mmHg	Yes, for non-white patients at 12 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[89-91]	Surrogate	SBP Blood pressure was measured using a digital sphygmanometer (BPTRU Automated Non-invasive blood pressure monitor, Model BPM-100). The readings were taken by a research assistant who was blinded to the patient's randomization assignment. Two blood pressure readings were taken; the first after patients were seated and had rested in a quiet room separate from the clinical practice site, for at least 5 minutes, and the second 30 seconds after the first. The mean blood pressure reading taken at each of the five visits was used as the outcome.	Combination (PGHD plus behavior self-management) vs. Usual care At 12 months White Difference between groups: -0.7 (95% CI: -5.2 to 3.9) mmHg Non-white Difference between groups: -5.3 (95% CI: -10.1 to -0.5) mmHg At 24 months White Difference between groups: -0.4 (95% CI: -5.9 to 5.0) mmHg Non-white Difference between groups: -7.5 (95% CI: -13.7 to -1.4) mmHg	Yes, for non-white patients at 12 and 24 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Bosworth et al. (2011)[89-91]	Surrogate	DBP Blood pressure was measured using a digital sphygmanometer (BPTRU Automated Non-invasive blood pressure monitor, Model BPM-100). The readings were taken by a research assistant who was blinded to the patient's randomization assignment. Two blood pressure readings were taken; the first after patients were seated and had rested in a quiet room separate from the clinical practice site, for at least 5 minutes, and the second 30 seconds after the first. The mean blood pressure reading taken at each of the five visits was used as the outcome.	Combination (PGHD plus behavior self-management) vs. Usual care At 12 months White Difference between groups: 1.3 (95% CI: -1.2 to 3.7) mmHg Non-white Difference between groups: -5.3 (95% CI: -10.1 to -0.5) mmHg At 24 months White Difference between groups: 0.5 (95% CI: -2.5 to 3.5) mmHg Non-white Difference between groups: -3.5 (95% CI: -7.0 to -0.1) mmHg	Yes, for non-white patients at 12 and 24 months.
Bove et al. (2013)[92]	Surrogate	BP Two BP measurements were recorded in the sitting position 5 minutes apart and were averaged.	Usual care vs. PGHD (BP, pedometer, scale) SBP change after 6 months: UC: -13.9 (SD: 18.2) and PGHD: -18.2 (SD: 20.3) p=0.12; DBP change after 6 months: UC: -4.9 (SD: 10.2), PGHD: -7.1 (SD: 11.8), p=0.17.	No
Bove et al. (2013)[92]	Surrogate	BP (% reaching goal) Two BP measurements were recorded in the sitting position 5 minutes apart and were averaged. Goal defined as SBP <140 mmHg.	Usual care vs. PGHD (BP, pedometer, scale) % at goal after 6 months: UC: 52.3% and PGHD: 54.5%, p=0.43	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Broege et al. (2001)[79]	Surrogate	Ambulatory Awake SBP Ambulatory blood pressure was measured with the SpaceLabs 90207 BP monitor. The monitor was preprogrammed to record BP every 15 minutes during the day while subjects were awake, and every half-hour during the night while they slept.	PGHD (Omron HEM-702) vs. Clinic group At 3 months Intervention: 146 (SD: 11) mmHg Control: 144 (SD: 19) mmHg Previously treated patients Intervention: 143 (SD: 9) mmHg Control: 138 (SD: 16) mmHg Previously untreated patients Intervention: 148 (SD: 12) mmHg Control: 151 (SD: 21) mmHg	NR
Broege et al. (2001)[79]	Surrogate	Ambulatory Awake DBP Ambulatory blood pressure was measured with the SpaceLabs 90207 BP monitor. The monitor was preprogrammed to record BP every 15 minutes during the day while subjects were awake, and every half-hour during the night while they slept.	PGHD (Omron HEM-702) vs. Clinic group At 3 months Intervention: 80 (SD: 8) mmHg Control: 83 (SD: 12) mmHg Previously treated patients Intervention: 78 (SD: 7) mmHg Control: 79 (SD: 10) mmHg Previously untreated patients Intervention: 81 (SD: 8) mmHg Control: 88 (SD: 13) mmHg	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Chandler et al. (2020)[74]	Surrogate	SBP	PGHD (Tension Tamer app) vs. PGHD (Runkeeper app) At 1-month follow up Tension Tamer: 125.2 mmHg Runkeeper: 128.9 mmHg p-value for difference: NS At 3-month follow up Tension Tamer: 125.3 mmHg Runkeeper: 130.1 mmHg p-value for difference: NS At 6-month follow up Tension Tamer: 123.2 mmHg Runkeeper: 131.3 mmHg p-value for difference: Significant At 12-month follow up Tension Tamer: 121.6 mmHg Runkeeper: 131.8 mmHg p-value for difference: Significant	Yes, at 6 and 12 months.
Chandler et al. (2020)[74]	Surrogate	DBP	PGHD (Tension Tamer app) vs. PGHD (Runkeeper app) At 1-month follow up Tension Tamer: 72.8 mmHg Runkeeper: 77.5 mmHg p-value for difference: NS At 3-month follow up Tension Tamer: 70.9 mmHg Runkeeper: 76.9 mmHg p-value for difference: NS At 6-month follow up Tension Tamer: 70.9 mmHg Runkeeper: 77.1 mmHg p-value for difference: NS At 12-month follow up Tension Tamer: 68.7 mmHg Runkeeper: 79.8 mmHg p-value for difference: Significant	Yes, at 12 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Chandler et al. (2020)[74]	Surrogate	SBP Control SBP control defined as SBP <130 mmHg.	PGHD (Tension Tamer app) vs. PGHD (Runkeeper app) At 1-month follow up Tension Tamer: 68.8% Runkeeper: 35.7% p-value for difference: 0.074 At 3-month follow up Tension Tamer: 73.3% Runkeeper: 57.1% p-value for difference: 0.377 At 6-month follow up Tension Tamer: 78.6% Runkeeper: 35.7% p-value for difference: 0.021 At 12-month follow up Tension Tamer: 91.7% Runkeeper: 35.7% p-value for difference: 0.029	Yes, at 6 and 12 months.
Chandler et al. (2020)[74]	Surrogate	DBP Control DBP control defined as DBP <80 mmHg.	PGHD (Tension Tamer app) vs. PGHD (Runkeeper app) At 1-month follow up Tension Tamer: NR Runkeeper: 87.5% p-value for difference: 0.642 At 3-month follow up Tension Tamer: NR Runkeeper: 86.7% p-value for difference: 0.642 At 6-month follow up Tension Tamer: NR Runkeeper: 85.7% p-value for difference: 0.571 At 12-month follow up Tension Tamer: NR Runkeeper: 83.3 p-value for difference: 0.600	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Dorough et al. (2014)[126]	Surrogate	SBP	DASH 2 wellness plus vs. DASH 2 wellness only Change from baseline to 10 weeks Intervention: -4.61 (SD: 8.28) Control: -15.14 (SD: 4.33) p-value for difference: 0.004; favors plus group	Yes
Earle et al. (2010)[70,71]	Surrogate	SBP After a 10-min rest, sitting BP was taken using an A&D model UA-767BT digital monitor in the non-dominant arm with an appropriately sized cuff positioned at heart level on three occasions. The mean of the last two measurements were recorded as the study blood pressure.	Combination (PGHD, treatment management) vs. Usual care Change from baseline to 6 months Intervention: -2.9 (95% CI: 0.6 to -5.1) mmHg Control: NR	NR
Fuchs et al. (2012)[93]	Surrogate	SBP Office BP was measured with aneroid sphygmomanometer (mean of six measurements in three visits) as well as with an Omron HEM-705 CP BP measuring device (mean of four measurements in two visits).	PGHD (Omron HEM-705 CP) vs. Usual care At 60 days Intervention: 145.6 (SD: 17.1) mmHg Control: 148.6 (SD: 18.7) mmHg Change from baseline to 60 days Intervention: -12.5 (SD: 16.2) mmHg Control: -10.8 (SD: 18.3) mmHg Difference between the groups: -1.2 (-7.6 to 5.2), p-value: 0.7	No
Fuchs et al. (2012)[93]	Surrogate	DBP Office BP was measured with aneroid sphygmomanometer (mean of six measurements in three visits) as well as with an Omron HEM-705 CP BP measuring device (mean of four measurements in two visits).	PGHD (Omron HEM-705 CP) vs. Usual care At 60 days Intervention: 83.9 (SD: 11.0) mmHg Control: 85.0 (SD: 14.3) mmHg Change from baseline to 60 days Intervention: -6.2 (SD: 8.3) mmHg Control: -4.3 (SD: 14.3) mmHg Difference between the groups: -2.3 (-5.7 to 1.1), p-value: 0.2	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Fuchs et al. (2012)[93]	Surrogate	ABPM A Spacelabs 90207 was used to to take measurements every 15 min from 0700 to 2300 h and every 20 min from 2300 to 0700 h.	PGHD (Omron HEM-705 CP) vs. Usual care 24-hour systolic ABPM At 60 days Intervention: 140.1 (SD: 14.7) mmHg Control: 145.0 (SD: 13.1) mmHg Change from baseline to 60 days Intervention: -8.8 (SD: 13.1) mmHg Control: -3.4 (SD: 11.6) mmHg p-value for difference: 0.02 24-hour diastolic ABPM At 60 days Intervention: 82.8 (SD: 11.6) mmHg Control: 85.7 (SD: 11.3) mmHg Change from baseline to 60 days Intervention: -5.6 (SD: 8.4) mmHg Control: -1.0 (SD: 7.9) mmHg p-value for difference: 0.002	Yes
Fuchs et al. (2012)[93]	Surrogate	BP control Office BP control: <140/90 mmHg 24-BP control: <130/80 mmHg	PGHD (Omron HEM-705 CP) vs. Usual care At 60 days Office BP Intervention: 42.6% Control: 41.2% p-value for difference: 0.9 24-hour BP Intervention: 32.4% Control: 16.2% p-value for difference: 0.03	Yes, for 24-hour BP control.
Green et al. (2008)[80,81]	Surrogate	SBP The Omron Hem-705-CP was used to measure clinic BP. BP was measured 3 times, with the mean of the last 2 measurements used as the BP value.	PGHD (Omron HEM-705 CP) vs. Usual care At 12 months Intervention: 143.8 (95% CI: 141.9 to 145.6) mmHg Control: 146.3 (95% CI: 144.5 to 148.2) mmHg Change from baseline to 12 months Intervention: -8.2 (95% CI: -10.0 to -6.4) mmHg Control: -5.3 (95% CI: -7.1 to -3.5) mmHg p-value for difference: 0.02	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Green et al. (2008)[80,81]	Surrogate	SBP The Omron Hem-705-CP was used to measure clinic BP. BP was measured 3 times, with the mean of the last 2 measurements used as the BP value.	Combination (PGHD, Pharmacist Care) vs. Usual care At 12 months Intervention: 137.9 (95% CI: 136.0 to 139.8) mmHg Control: 146.3 (95% CI: 144.5 to 148.2) mmHg Change from baseline to 12 months Intervention: -14.2 (95% CI: -16.0 to -12.4) mmHg Control: -5.3 (95% CI: -7.1 to -3.5) mmHg p-value for difference: <0.001	Yes
Green et al. (2008)[80,81]	Surrogate	DBP The Omron Hem-705-CP was used to measure clinic BP. BP was measured 3 times, with the mean of the last 2 measurements used as the BP value.	Combination (PGHD, Pharmacist Care) vs. Usual care At 12 months Intervention: 81.6 (95% CI: 80.4 to 82.9) mmHg Control: 85.7 (95% CI: 84.5 to 86.9) mmHg Change from baseline to 12 months Intervention: -7.0 (95% CI: -8.0 to -6.0) mmHg Control: -3.5 (95% CI: -4.5 to -2.5) mmHg p-value for difference: <0.001	Yes
Green et al. (2008)[80,81]	Surrogate	DBP The Omron Hem-705-CP was used to measure clinic BP. BP was measured 3 times, with the mean of the last 2 measurements used as the BP value.	PGHD (Omron HEM-705 CP) vs. Usual care At 12 months Intervention: 84.5 (95% CI: 83.3 to 85.7) mmHg Control: 85.7 (95% CI: 84.5 to 86.9) mmHg Change from baseline to 12 months Intervention: -4.4 (95% CI: -5.4 to -3.4) mmHg Control: -3.5 (95% CI: -4.5 to -2.5) mmHg p-value for difference: 0.21	No
Green et al. (2008)[80,81]	Surrogate	BP control The Omron Hem-705-CP was used to measure clinic BP. BP was measured 3 times, with the mean of the last 2 measurements used as the BP value. BP control was defined as <140/90 mmHg.	PGHD (Omron HEM-705 CP) vs. Usual care At 12 months Intervention: 36% (95% CI: 30 to 42) Control: 31% (95% CI: 25 to 37) p-value for difference: 0.20	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Green et al. (2008)[80,81]	Surrogate	BP control The Omron Hem-705-CP was used to measure clinic BP. BP was measured 3 times, with the mean of the last 2 measurements used as the BP value. BP control was defined as <140/90 mmHg.	Combination (PGHD, Pharmacist Care) vs. Usual care At 12 months Intervention: 56% (95% CI: 49 to 62) Control: 31% (95% CI: 25 to 37) p-value for difference: <0.001	Yes
Green et al. (2014)[24]	Surrogate	SBP	Web dietician vs. Usual care Change from baseline to 26 week Intervention: -13.9 (95% CI: -18.1 to -9.8) mmHg Usual care: -11.4 (95% CI: -15.4 to -7.3) mmHg	NR
Green et al. (2014)[24]	Surrogate	DBP	Web dietician vs. Usual care Change from baseline to 26 week Intervention: -8.5 (95% CI: -11.3 to -5.8) mmHg Usual care: -6.6 (95% CI: -9.2 to -3.9) mmHg	NR
Halme et al. (2005)[127]	Surrogate	BP Control Office BP target was <140/85 mmHg.	Combination (PGHD, Physician management) vs. Usual care Office At 6 months p-value for difference 0.28	No
Halme et al. (2005)[127]	Surrogate	SBP Office BP was measured with the Omron M4 device.	Combination (PGHD, Physician management) vs. Usual care Office At 6 months Intervention: 146.8 (SD: 17.8) mmHg Control: 149.5 (SD: 20.3) mmHg Change from baseline to 6 months Intervention: -12.7 (SD: 19.6) mmHg Control: -9.5 (SD: 19.5) mmHg p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Halme et al. (2005)[127]	Surrogate	DBP Office BP was measured with the Omron M4 device.	Combination (PGHD, Physician management) vs. Usual care Office At 6 months Intervention: 87.0 (SD: 9.3) mmHg Control: 89.1 (SD: 8.6) mmHg Change from baseline to 6 months Intervention: -7.1 (SD: 10.1) mmHg Control: -5.6 (SD: 8.9) mmHg p-value for difference: NS	No
He et al. (2017)[128]	Surrogate	SBP Blood pressure was measured according to a standard protocol recommended by the American Heart Association and was measured with participants in a seated position after 5 minutes of quiet rest. In addition, participants were required to avoid alcohol, cigarettes, coffee, tea, and exercise for at least 30 minutes before their BP measurement. An Omron HEM 907 XL BP Monitor was used, and cuff size was chosen based on each participant's arm circumference.	Combination (health coaching, PGHD, and BP audit) vs. Usual care Change from baseline to 6 months Intervention: -12.1 (95% CI: -13.5 to -10.7) mmHg Control: -7.4 (95% CI: -8.9 to -5.9) mmHg Difference between the groups: -4.7 (95% CI: -6.7 to -2.6) mmHg, p-value: <0.001 Change from baseline to 12 months Intervention: -15.7 (95% CI: -16.9 to -14.5) mmHg Control: -10.0 (95% CI: -11.2 to -8.8) mmHg Difference between the groups: -5.7 (95% CI: -7.4 to -4.0) mmHg, p-value: <0.001 Change from baseline to 18 months Intervention: -19.3 (95% CI: -20.7 to -17.9) mmHg Control: -12.6 (95% CI: -14.0 to -11.2) mmHg Difference between the groups: -6.7 (95% CI: -8.7 to -4.7) mmHg, p-value: <0.001	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
He et al. (2017)[128]	Surrogate	DBP Blood pressure was measured according to a standard protocol recommended by the American Heart Association and was measured with participants in a seated position after 5 minutes of quiet rest. In addition, participants were required to avoid alcohol, cigarettes, coffee, tea, and exercise for at least 30 minutes before their BP measurement. An Omron HEM 907 XL BP Monitor was used, and cuff size was chosen based on each participant's arm circumference.	Combination (health coaching, PGHD, and BP audit) vs. Usual care Change from baseline to 6 months Intervention: -6.6 (95% CI: -7.5 to -5.7) mmHg Control: -3.5 (95% CI: -4.4 to -2.6) mmHg Difference between the groups: -3.1 (95% CI: -4.4 to -1.8) mmHg, p-value: <0.001 Change from baseline to 12 months Intervention: -9.4 (95% CI: -10.2 to -8.6) mmHg Control: -5.3 (95% CI: -6.0 to -4.5) mmHg Difference between the groups: -4.1 (95% CI: -5.2 to -3.0) mmHg, p-value: <0.001 Change from baseline to 18 months Intervention: -12.1 (95% CI: -13.1 to -11.2) mmHg Control: -7.0 (95% CI: -7.9 to -6.1) mmHg Difference between the groups: -5.1 (95% CI: -6.5 to -3.8) mmHg, p-value: <0.001	Yes
He et al. (2017)[128]	Surrogate	BP Control Blood pressure was measured according to a standard protocol recommended by the American Heart Association and was measured with participants in a seated position after 5 minutes of quiet rest. In addition, participants were required to avoid alcohol, cigarettes, coffee, tea, and exercise for at least 30 minutes before their BP measurement. An Omron HEM 907 XL BP Monitor was used, and cuff size was chosen based on each participant's arm circumference. Target BP was <140/90 mmHg.	Combination (health coaching, PGHD, and BP audit) vs. Usual care At 6 months Intervention: 45.6% (95% CI: 42.0 to 49.3) Control: 40.8% (95% CI: 37.0 to 44.5) Difference between the groups: 4.8% (95% CI: -0.4 to 10.1), p-value: <0.07 At 12 months Intervention: 60.2% (95% CI: 56.5 to 63.9) Control: 44.7% (95% CI: 40.9 to 48.5) Difference between the groups: 15.5% (95% CI: 10.2 to 20.8), p-value: <0.001 At 18 months Intervention: 72.0% (95% CI: 68.6 to 75.3) Control: 52.8% (95% CI: 48.9 to 56.7) Difference between the groups: 19.2% (95% CI: 14.1 to 24.3), p-value: <0.001	Yes, at 12 and 18 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Hebert et al. (2012)[82]	Surrogate	SBP The Omron HEM-712C was used for BP measurement.	PGHD (Omron HEM-712C) vs. Usual care Change from baseline to 9 months Intervention: -13.1 (SD: 26.2) mmHg Control: -11.7 (SD: 22.8) mmHg p-value for difference: NS Change from baseline to 18 months Intervention: -10.4 (SD: 29.2) mmHg Control: -13.9 (SD: 24.5) mmHg p-value for difference: NS	No
Hebert et al. (2012)[82]	Surrogate	SBP The Omron HEM-712C was used for BP measurement.	Combination (PGHD, nurse management) vs. Usual care Change from baseline to 9 months Intervention: -15.8 (SD: 21.0) mmHg Control: -8.1 (SD: 21.7) mmHg p-value for difference: NS Change from baseline to 18 months Intervention: -14.5 (SD: 21.8) mmHg Control: -14.4 (SD: 19.7) mmHg p-value for difference: NS	No
Hebert et al. (2012)[82]	Surrogate	DBP The Omron HEM-712C was used for BP measurement.	PGHD (Omron HEM-712C) vs. Usual care Change from baseline to 9 months Intervention: -8.3 (SD: 12.2) mmHg Control: -6.6 (SD: 13.1) mmHg p-value for difference: NS Change from baseline to 18 months Intervention: -8.2 (SD: 13.6) mmHg Control: -6.8 (SD: 13.3) mmHg p-value for difference: NS	No
Hebert et al. (2012)[82]	Surrogate	DBP The Omron HEM-712C was used for BP measurement.	Combination (PGHD, nurse management) vs. Usual care Change from baseline to 9 months Intervention: -10.6 (SD: 14.9) mmHg Control: -9.1 (SD: 12.0) mmHg p-value for difference: NS Change from baseline to 18 months Intervention: -8.7 (SD: 12.8) mmHg Control: -8.4 (SD: 11.3) mmHg p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Hebert et al. (2012)[82]	Surrogate	BP control BP control defined as <140/90 or <130/80 for patients with diabetes or renal disease.	PGHD (Omron HEM-712C) vs. Usual care At 9 months Intervention: 44% Control: 41% p-value for difference: NS At 18 months Intervention: 42% Control: 49% p-value for difference: NS	No
Hebert et al. (2012)[82]	Surrogate	BP control BP control defined as <140/90 or <130/80 for patients with diabetes or renal disease.	Combination (PGHD, nurse management) vs. Usual care At 9 months Intervention: 47% Control: 41% p-value for difference: NS At 18 months Intervention: 56% Control: 48% p-value for difference: NS	No
Hoffmann-Petersen et al. (2017)[94]	Surrogate	SBP Daytime ABPM. measurements were taken every 15 min during daytime.	PGHD (A&D 767PlusBT or Omron 705IT) vs. Usual care At 3 months Intervention: 144 (SD: 11) mmHg Control: 144 (SD: 12) mmHg p-value for difference: NS Change from baseline to 3 months Intervention: -8 (SD: 12) mmHg Control: -8 (SD: 13) mmHg p-value for difference: NS	No
Hoffmann-Petersen et al. (2017)[94]	Surrogate	DBP Daytime ABPM. measurements were taken every 15 min during daytime.	PGHD (A&D 767PlusBT or Omron 705IT) vs. Usual care At 3 months Intervention: 85 (SD: 7) mmHg Control: 86 (SD: 7) mmHg p-value for difference: NS Change from baseline to 3 months Intervention: -4 (SD: 7) mmHg Control: -4 (SD: 13) mmHg p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Hoffmann-Petersen et al. (2017)[94]	Surrogate	BP Control Target blood pressure <135/85 mmHg (<130/80 mmHg if diabetic, history of stroke or chronic kidney disease) on daytime ABPM.	PGHD (A&D 767PlusBT or Omron 705IT) vs. Usual care At 3 months Intervention: 17% (31/175) Control: 21% (37/181) p-value for difference: NS	No
Hosseininasab et al. (2014)[129]	Surrogate	DBP BP was measured in the office with the BM 16 digital upper arm device. BP was measured twice with a 10-minute interval in resting position. The mean of the 2 measurements was documented.	PGHD (Samsung SHB-200w) vs. Usual care At 4 weeks Intervention: 77.4 (SD: 6.2) mmHg Control: 77.1 (SD: 7.9) mmHg At 12 weeks Intervention: 76.7 (SD: 6.0) mmHg Control: 76.6 (SD: 5.1) mmHg At 24 weeks Intervention: 76.1 (SD: 4.6) mmHg Control: 76.6 (SD: 4.0) mmHg Change from baseline to 4 weeks Intervention: 8.1 (SD: 6.7) mmHg Control: 7.9 (SD: 8.6) mmHg	NR
Hosseininasab et al. (2014)[129]	Surrogate	SBP BP was measured in the office with the BM 16 digital upper arm device. BP was measured twice with a 10-minute interval in resting position. The mean of the 2 measurements was documented.	PGHD (Samsung SHB-200w) vs. Usual care At 4 weeks Intervention: 132.6 (SD: 7.4) mmHg Control: 133.4 (SD: 7.0) mmHg At 12 weeks Intervention: 131.9 (SD: 5.8) mmHg Control: 132.0 (SD: 6.0) mmHg At 24 weeks Intervention: 132.0 (SD: 4.4) mmHg Control: 132.5 (SD: 3.8) mmHg Change from baseline to 4 weeks Intervention: 11.6 (SD: 8.6) mmHg Control: 12.5 (SD: 8.2) mmHg	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Kaihara et al. (2014)[95]	Surrogate	SBP Outcome BP was based on home BP monitoring results, so the intervention group used the HEM-7251G device while the control group used the HEM-7080IC device. Patients measured their home BP consecutively three times at about 15-second intervals in the morning and evening. In the morning they measured home BP within 1 hour after rising (after urination and breakfast and before taking medicine), and in the evening they measured their home BP in the sitting position before sleeping and after resting for 1 to 2 minutes. Post-baseline, home BP data were the average of 3 measurements.	PGHD (Omron HEM-7251G) vs. Conventional BP monitor Change from baseline to 2 weeks Morning SBP Intervention group: -5.5 (SD: 0.9) mmHg Control group: 0.7 (SD: 0.7) mmHg p-value for difference: <0.001 Evening SBP Intervention group: -4.5 (SD: 1.0) mmHg Control group: 1.0 (SD: 1.1) mmHg p-value for difference: <0.001	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Kaihara et al. (2014)[95]	Surrogate	DBP Outcome BP was based on home BP monitoring results, so the intervention group used the HEM-7251G device while the control group used the HEM-7080IC device. Patients measured their home BP consecutively three times at about 15-second intervals in the morning and evening. In the morning they measured home BP within 1 hour after rising (after urination and breakfast and before taking medicine), and in the evening they measured their home BP in the sitting position before sleeping and after resting for 1 to 2 minutes. Post-baseline, home BP data were the average of 3 measurements.	PGHD (Omron HEM-7251G) vs. Conventional BP monitor Change from baseline to 2 weeks Morning DBP p-value for difference: NS Evening DBP p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Kao et al. (2019)[102]	Surrogate	BP Blood pressure was measured with an automatic sphygmomanometer (JPN1; Omron Colin, Kyoto, Japan). According to the guidelines of the Taiwan Society of Cardiology and the Taiwan Hypertension Society, investigators asked the participants to sit in a quiet and comfortable room for at least 5 minutes before taking their blood pressure. The blood pressure was taken twice at intervals of 1-2 minutes. The average of these two readings was used in the data analysis. In addition, the researchers assisted all participants in checking the accuracy of their own automated electronic sphygmomanometers and evaluated whether the cuffs were appropriately sized for participants' upper arms.	Usual care vs. PGHD SBP PGHD group baseline: 143, 3 months: 127 and 6 months: 123 vs. UC baseline: 143, 3 months: 149 and 6 months: 151 DBP PGHD group baseline: 84, 3 months: 77 and 6 months: 75 vs. UC baseline: 84, 3 months: 82 and 6 months: 84	Yes. After adjusting for the baseline difference in education, the GEE model showed that the SBP and DBP decreased significantly more for the PGHD group than UC at both the 3- and 6-month follow-ups.
Kauric-Klein et al. (2007)[96]	Surrogate	BP Average weekly pre-hemodialysis BP and interdialytic fluid gains in between hemodialysis treatments were calculated for both groups over a 12-week period. Average BP and fluid gain was used in these analyses.	Usual care vs. PGHD blood pressure monitoring Omron IC In the PGHD group, SBP fell from 161 (SD: 14 mmHg) at baseline to 153 (16 mmHg) at three-month follow-up (p=0.003); DBP fell from 94 (SD: 7 mmHg) to 90 (SD: 5 mmHg) (p=0.06). In the UC group, SBP fell from 162 (SD: 12 mmHg) to 161 (SD: 14 mmHg) at three-month follow-up (p=0.68); DBP fell from 100 (SD: 10 mmHg) to 97 (10 mmHg) (p=0.35). A significant difference (p=0.018) was found between the two groups for SBP; the difference was not significant for DBP (p=0.195).	Yes, for SBP and no for DBP.

Study	Outcome Category	Outcome	Results	Statistical Significance
Kerry et al. (2013)[103-105]	Surrogate	SBP	Monitoring vs. Usual care Change from baseline to 26 weeks Monitoring: 2.8 (95% CI: -0.4 to 5.9) mmHg Usual care: 0.6 (95% CI:-2.4 to 3.5) mmHg p-value for difference: NS Change from baseline to 52 weeks Monitoring: 1.7 (95% CI: -1.4 to 4.8) Usual care: -0.7 (95% CI: -4 to 2.5) p-value for difference: NS	No
Kerry et al. (2013)[103-105]	Surrogate	DBP	Monitoring vs. Usual care Change from baseline to 26 weeks Monitoring: 1.8 (95% CI: 0.2 to 3.3) mmHg Usual care: 0.6 (95% CI: -1 to 2.2) mmHg p-value for difference: NS Change from baseline to 52 weeks Monitoring: 1.6 (95% CI: -0.1 to 3.3) Usual care: 0.2 (95% CI: -1.5 to 1.9) p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Kim et al. (2015)[130]	Surrogate	BP Ambulatory BP was measured in the non-dominant arm using a validated ABPM device (A&D TM-2430, A&D Medical, San Jose, CA, USA). The daytime average BP was defined as the average of the BP measurements obtained from 0700 hours to 2259 hours. The night time average BP was defined as the average of the BP measurements obtained from 2300 hours to 0659 hours. The primary end point was the difference in the sitting SBP at the 24th week of FU compared with the baseline measurement. BP control defined as ambulatory BP <135/85-mmHg, <130/80 for DM and/or CKD.	Home BP monitoring only vs. LG Smartcare System/without remote physician care Group 1 (PGHD A&D BP monitoring) baseline SBP: 143.2 (SD: 13), week 24: 134.2 (SD: 14.5), change: -8.9 (SD: 15.5) vs. Group 2 (LG Smartcare and in person visits) baseline SBP: 142.9 (SD: 14.5), week 24: 130.7 (SD: 15.0), change: -11.3 (SD: 15.9), p=0.11. Group 1 (PGHD A&D BP monitoring) baseline DBP: 88.2 (SD: 9.5), week 24: 83.8 (SD: 10.6), change: -4.4 (SD: 9.9) vs. Group 2 (LG Smartcare and in person visits) baseline DBP: 88.1 (SD: 8.8), week 24: 82.9 (SD: 9.8), change: -5.0 (SD: 9.2), p=0.66, % controlled: Group 1 (53.8%) vs. Group 2 (67.5%), p=0.04. Group 1 (PGHD A&D BP monitoring) systolic ABPM: 135.7 (SD: 13.2), week 24: 133.1 (SD: 12.5), change: -1.9 (SD: 12.4) vs. Group 2 (LG Smartcare and in person visits) systolic ABPM: 132.4 (SD: 12.4), week 24: 131.2 (SD: 12.2), change: -0.2 (SD: 11.7), p=0.98. Group 1 (PGHD A&D BP monitoring) diastolic ABPM: 82.3 (SD: 8.4), week 24: 80.5 (SD: 8.9), change: -1.8 (SD: 9.3) vs. Group 2 (LG Smartcare and in person visits) diastolic ABPM: 80.1 (SD: 7.6), week 24: 80.9 (SD: 8.1), change: 0.6 (SD: 7.9), p=0.07, % BP controlled: Group 1 (35.2%) vs. Group 2 (40.6%), p=0.46.	Yes, for in office measurement of % controlled by week 24; no for all others.

Study	Outcome Category	Outcome	Results	Statistical Significance
Kim et al. (2015)[130]	Surrogate	BP Ambulatory BP was measured in the non-dominant arm using a validated ABPM device (A&D TM-2430, A&D Medical, San Jose, CA, USA). The daytime average BP was defined as the average of the BP measurements obtained from 0700 hours to 2259 hours. The night time average BP was defined as the average of the BP measurements obtained from 2300 hours to 0659 hours. The primary end point was the difference in the sitting SBP at the 24th week of FU compared with the baseline measurement. BP control defined as ambulatory BP <135/85-mmHg, <130/80 for DM and/or CKD.	Home BP monitoring only vs. LG Smartcare System/with remote physician visits Group 1 (PGHD A&D BP monitoring) baseline SBP: 143.2 (SD: 13), week 24: 134.2 (SD: 14.5), change: -8.9 (SD: 15.5) vs. Group 3 (LG Smartcare and remote visits) baseline SBP: 143.1 (SD: 14.7), week 24: 132.0 (SD15.6), change: -11.6 (SD: 19.8), p=0.52. Group 1 (PGHD A&D BP monitoring) baseline DBP: 88.2 (SD: 9.5), week 24: 83.8 (SD: 10.6), change: -4.4 (SD: 9.9) vs. Group 3 baseline DBP: 87.9 (SD: 8.8), week 24: 82.8 (SD: 9.8), change: -5.3 (SD: 10.2), p=0.54. % controlled: Group 1 (53.8%) vs. Group 3 (58.9%), p=0.48. Group 1 (PGHD A&D BP monitoring) systolic ABPM: 135.7 (SD: 13.2), week 24: 133.1 (SD: 12.5), change: -1.9 (SD: 12.4) vs. Group 3 systolic ABPM: 133.6 (SD: 15.0), week 24: 130.9 (SD: 12.5), change: -2.0 (SD: 13.6), p=0.34. Group 1 (PGHD A&D BP monitoring) diastolic ABPM: 82.3 (SD: 8.4), week 24: 80.5 (SD: 8.9), change: -1.8 (SD: 9.3) vs. Group 3 diastolic ABPM: 80.8 (SD: 8.8), week 24: 79.2 (SD: 8.2), change: -1.2 (SD: 7.6), p=0.74, ABP % controlled: Group 1 (35.2%) vs. Group 3 (39.6%), p=0.53.	No
Kim et al. (2016)[97,101]	Surrogate	SBP Systolic and diastolic blood pressure outcomes were based on those measured by a research nurse using the Withings Blood Pressure Monitor at the baseline and study completion visits.	PGHD (Withings BP monitor) vs. Usual care At 6 months Intervention: 133.4 (SD: 12.9) mmHg Control: 140.2 (SD: 18.4) mmHg	NR
Kim et al. (2016)[97,101]	Surrogate	DBP Systolic and diastolic blood pressure outcomes were based on those measured by a research nurse using the Withings Blood Pressure Monitor at the baseline and study completion visits.	PGHD (Withings BP monitor) vs. Usual care At 6 months Intervention: 82.8 (SD: 11.2) mmHg Control: 85.3 (SD: 12.1) mmHg	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Kim et al. (2016)[97,101]	Surrogate	BP Control Systolic and diastolic blood pressure outcomes were based on those measured by a research nurse using the Withings Blood Pressure Monitor at the baseline and study completion visits. Adequate blood pressure control was determined based on recommendations from the Eighth Joint National Committee.	PGHD (Withings BP monitor) vs. Usual care At 6 months Intervention: 34/52 (65%) Control: 22/43 (51%)	NR
Klarskov et al. (2018)[131]	Surrogate	Ambulatory DBP Twenty four-hour ambulatory blood pressure (Spacelabs 90207 or 90217) included measurement every 15 minutes during daytime and every 30 minutes during night-time. Daytime was defined as 07:00 a.m. to 10:59 p.m. Twenty four-hour ambulatory blood pressure monitoring was performed on days with routine patient activities.	Combination (PGHD, intensive monitoring) vs. Usual care At 12 months Daytime Intervention: 79.1 (SD: 9.9) mmHg Control: 78.1 (SD: 9.9) mmHg p-value for difference: 0.14 Nighttime Intervention: 68.7 (SD: 9.6) mmHg Control: 68.0 (SD: 9.9) mmHg p-value for difference: 0.39 Change from baseline to 12 months Daytime Intervention: -3.5 (SD: 8.2) mmHg Control: -2.8 (SD: 8.2) mmHg p-value for difference: 0.20 Nighttime Intervention: -2.3 (SD: 8.8) mmHg Control: -1.8 (SD: 8.3) mmHg p-value for difference: 0.42	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Klarskov et al. (2018)[131]	Surrogate	Ambulatory SBP Twenty four-hour ambulatory blood pressure (Spacelabs 90207 or 90217) included measurement every 15 minutes during daytime and every 30 minutes during night-time. Daytime was defined as 07:00 a.m. to 10:59 p.m. Twenty four-hour ambulatory blood pressure monitoring was performed on days with routine patient activities.	Combination (PGHD, intensive monitoring) vs. Usual care At 12 months Daytime Intervention: 132.0 (SD: 11.7) mmHg Control: 131.9 (SD: 12.6) mmHg p-value for difference: 0.97 Nighttime Intervention: 118.9 (SD: 12.0) mmHg Control: 119.3 (SD: 13.9) mmHg p-value for difference: 0.73 Change from baseline to 12 months Daytime Intervention: -5.6 (SD: 13.0) mmHg Control: -4.6 (SD: 13.5) mmHg p-value for difference: 0.27 Nighttime Intervention: -3.9 (SD: 13.6) mmHg Control: -3.2 (SD: 13.5) mmHg p-value for difference: 0.31	No
Lakshminarayan et al. (2018)[69]	Surrogate	SBP	Intervention vs. Control At 13 weeks Intervention: 130.2 (SD: 11.4) mmHg Control: 133.9 (SD: 16.9) mmHg p-value for difference: 0.4	No
Logan et al. (2012)[132]	Surrogate	24-hour ambulatory SBP 24-hour ambulatory BP monitoring using oscillometric SpaceLabs 90207 recorders. The recorders were programmed to measure BP at 20-minute intervals during the day and every 30 minutes at night. Participants were instructed to record the time they went to sleep at night and awoke in the morning.	Combination (PGHD, Self-Care Support System) vs. Control Group Change from baseline to 12 months Intervention: -8.7 (SD: 14.7) mmHg Control: -1.7 (SD: 12.1) mmHg Difference between groups: -6.8 (SD: 2.4) mmHg, p-value: 0.005	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Logan et al. (2012)[132]	Surrogate	24-hour ambulatory DBP 24-hour ambulatory BP monitoring using oscillometric SpaceLabs 90207 recorders. The recorders were programmed to measure BP at 20-minute intervals during the day and every 30 minutes at night. Participants were instructed to record the time they went to sleep at night and awoke in the morning.	Combination (PGHD, Self-Care Support System) vs. Control Group Change from baseline to 12 months Intervention: -4.2 (SD: 9.3) mmHg Control: -1.1 (SD: 6.8) mmHg Difference between groups: -3.6 (SD: 1.3) mmHg, p-value: 0.006	Yes
Logan et al. (2012)[132]	Surrogate	BP Control 24-hour ambulatory BP monitoring using oscillometric SpaceLabs 90207 recorders. The recorders were programmed to measure BP at 20-minute intervals during the day and every 30 minutes at night. Participants were instructed to record the time they went to sleep at night and awoke in the morning. BP control was defined as <130/80 mmHg on 24-hour ambulatory BP monitoring.	Combination (PGHD, Self-Care Support System) vs. Control Group At 12 months Intervention: 51% Control: 31% p-value for difference: <0.05	Yes
Magid et al. (2011)[133]	Surrogate	SBP Three BP measurements were obtained 1 minute apart using an electronic BP cuff (BPM-100 professional BP monitor) and the average of the latter 2 BPs was calculated.	Combination (PGHD, BP Reporting , Education, Pharmacist Management) vs. Usual care Change from baseline to 6 months Intervention: -13.1 (95% CI: -16.5 to -9.7) mmHg Control: -7.1 (95% CI: -9.8 to -4.4) mmHg p-value for difference: 0.006	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Magid et al. (2011)[133]	Surrogate	DBP Three BP measurements were obtained 1 minute apart using an electronic BP cuff (BPM-100 professional BP monitor) and the average of the latter 2 BPs was calculated.	Combination (PGHD, BP Reporting , Education, Pharmacist Management) vs. Usual care Change from baseline to 6 months Intervention: -6.5 (95% CI: -8.5 to -4.6) mmHg Control: -4.2 (95% CI: -5.9 to -2.5) mmHg p-value for difference: 0.07	No
Magid et al. (2011)[133]	Surrogate	BP Control Three BP measurements were obtained 1 minute apart using an electronic BP cuff (BPM-100 professional BP monitor) and the average of the latter 2 BPs was calculated. BP control defined as <140/90 mmHg.	Combination (PGHD, BP Reporting , Education, Pharmacist Management) vs. Usual care Change from baseline to 6 months Intervention: 36.0% Control: 35.2% p-value for difference: 0.89	No
Magid et al. (2013)[64]	Surrogate	BP After the patient sat for at least 5 minutes, the nurse took the BP of the patient 3 times 2 minutes apart using an electronic BP cuff (VS.M MedTech BPM-100 Professional Blood Pressure Monitor: A/A grade from the British Hypertension Society). BP control defined as <140/90 mmHg for all patients except those with DM and CKD, whose goal was <130/80 mmHg.	Usual care vs. PGHD (Omron HEM 790 IT) After 6 months, the mean BPs were significantly lower in the PGHD group than in the UC group (128.1 versus 137.4 mmHg, p<0.001 for SBP; 79.1 versus 83.1 mmHg, p<0.01 for DBP). The proportion of patients achieving BP goal at 6 months was significantly higher in the PGHD group (54.1%) than in the UC group (35.4% adjusted risk ratio, 1.5; 95% CI: 1.2 to 1.9). Compared with the UC group, the PGHD group experienced a 12.4-mmHg larger drop in SBP (95% CI: -16.3 to -8.6) and a 5.7-mmHg larger drop in DBP (95% CI: -7.8 to -3.6).	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Margolis et al. (2013)[106-112]	Surrogate	BP Control BP control defined as <140/90 mmHg or, for those with diabetes or chronic kidney disease, <130/80 mmHg.	Combination (PGHD, Pharmacist Care) vs. Usual care At 6 months Intervention: 71.8% (95% CI: 65.6 to 77.3) Control: 45.2% (95% CI: 39.2 to 51.3) Difference between the groups: 26.6 (95% CI: 19.1 to 33.1), p-value: <0.001 At 12 months Intervention: 71.2% (95% CI: 62.0 to 78.9) Control: 52.8% (95% CI: 45.4 to 60.2) Difference between the groups: 18.4% (95% CI: 7.9 to 27.0), p-value: 0.005 At 18 months Intervention: 71.8% (95% CI: 65.0 to 77.8) Control: 57.1% (95% CI: 51.5 to 62.6) Difference between the groups: 14.7% (95% CI: 7.0 to 21.4), p-value: 0.003	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Margolis et al. (2013)[106-112]	Surrogate	SBP BP was measured at each research visit using a standardized technique with an automated monitor identical to the home BP device. Three measurements were averaged.	Combination (PGHD, Pharmacist Care) vs. Usual care At 6 months Intervention: 126.7 (95% CI:124.4 to 129.0) mmHg Control: 136.9 (95% CI: 134.6 to 139.2) mmHg At 12 months Intervention: 125.7 (95% CI: 123.4 to 128.0) mmHg Control: 134.8 (95% CI: 132.5 to 137.2) mmHg At 18 months Intervention: 126.9 (95% CI: 124.3 to 129.4) mmHg Control: 133.0 (95% CI: 130.4 to 135.5) mmHg At 54 months (post-study follow-up) Intervention: 130.6 (95% CI: 128.2 to 133.0) mmHg Control: 132.6 (95% CI: 130.2 to 134.9) mmHg Change from baseline to 6 months Intervention: -21.5 (95% CI: -23.9 to -19.1) mmHg Control: -10.8 (95% CI: -13.3 to -8.3) mmHg Difference between groups: -10.7 (95% CI: -14.3 to -7.3) mmHg, p-value: <0.001 Change from baseline to 12 months Intervention: -22.5 (95% CI: -25.1 to -19.9) mmHg Control: -14.7 (95% CI: -17.6 to -11.8) mmHg Difference between groups: -9.7 (95% CI: -13.4 to -6.0) mmHg, p-value: <0.001 Change from baseline to 18 months Intervention: -21.3 (95% CI: -24.2 to -18.4) mmHg Control: -12.9 (95% CI: -15.5 to -10.2) mmHg Difference between groups: -6.6 (95% CI: -10.7 to -2.5) mmHg, p-value: 0.004 Change from baseline to 54 months (post-study follow-up) Intervention: -17.6 (95% CI: -20.3 to -15.0) mmHg Control: -15.1 (95% CI: -17.7 to -12.5) mmHg Difference between groups: -2.5 (95% CI: -6.3 to 1.2) mmHg, p-value: 0.18	Yes, for change from baseline to 6, 12, and 18 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Margolis et al. (2013)[106-112]	Surrogate	DBP BP was measured at each research visit using a standardized technique with an automated monitor identical to the home BP device. Three measurements were averaged.	Combination (PGHD, Pharmacist Care) vs. Usual care At 6 months Intervention: 75.0 (95% CI: 72.9 to 77.2) mmHg Control: 81.7 (95% CI: 79.5 to 84.0) mmHg At 12 months Intervention: 75.1 (95% CI: 72.8 to 77.4) mmHg Control: 80.8 (95% CI: 78.5 to 83.2) mmHg At 18 months Intervention: 75.1 (95% CI: 73.0 to 77.2) mmHg Control: 78.7 (95% CI: 76.6 to 80.9) mmHg At 54 months (post-study follow-up) Intervention: 77.5 (95% CI: 75.6 to 79.4) mmHg Control: 79.1 (95% CI: 77.2 to 81.0) mmHg Change from baseline to 6 months Intervention: -9.4 (95% CI: -11.1 to -7.6) mmHg Control: -3.4 (95% CI: -5.2 to -1.5) mmHg Difference between groups: -6.0 (95% CI: -8.6 to -3.4) mmHg, p-value: <0.001 Change from baseline to 12 months Intervention: -9.3 (95% CI: -11.0 to -7.7) mmHg Control: -4.3 (95% CI: -5.9 to -2.7) mmHg Difference between groups: -5.1 (95% CI: -7.4 to -2.8) mmHg, p-value: <0.001 Change from baseline to 18 months Intervention: -9.3 (95% CI: -11.7 to -7.0) mmHg Control: -6.4 (95% CI: -8.7 to -3.9) mmHg Difference between groups: -3.0 (95% CI: -6.3 to 0.3) mmHg, p-value: 0.07 Change from baseline to 54 months (post-study follow-up) Intervention: -7.0 (95% CI: -8.5 to -5.4) mmHg Control: -6.0 (95% CI: -7.5 to -4.4) mmHg Difference between groups: -1.0 (95% CI: -3.2 to 1.2) mmHg, p-value: 0.37	Yes, for change from baseline to 12 and 18 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
Marquez-Contreras et al. (2006)[98]	Surrogate	SBP The BP was measured using the validated OMRON M4 automatic monitor, taking the BP as the mean of two measurements.	PGHD (OMRON M4 automatic monitor) vs. Usual care At 1-month follow up Intervention: 145.2 (SD: 17.9) mmHg Control: 142.2 (SD: 13) mmHg p-value for difference: NS At 3-month follow-up Intervention: 140.7 (SD: 18.4) mmHg Control: 139.1 (SD: 13.3) mmHg p-value for difference: NS At 6-month follow-up Intervention: 135.6 (SD: 13.8) mmHg Control: 136.7 (SD: 11.2) mmHg p-value for difference: NS Change from baseline to 6 months Intervention: 23.4 (SD: 15.9) mmHg Control: 18.9 (SD: 15.9) mmHg p-value for difference: 0.163	No
Marquez-Contreras et al. (2006)[98]	Surrogate	Hypertension Control Mean BP at the final visit <140/90 mmHg.	PGHD (OMRON M4 automatic monitor) vs. Usual care At 6-month follow-up Intervention: 67% (95% CI: 57.8 to 76.2%) Control: 56% (95% CI: 46.3 to 65.7%) p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Marquez-Contreras et al. (2006)[98]	Surrogate	DBP The BP was measured using the validated OMRON M4 automatic monitor, taking the BP as the mean of two measurements.	PGHD (OMRON M4 automatic monitor) vs. Usual care At 1-month follow up Intervention: 85.1 (SD: 10.2) mmHg Control: 83.7 (SD: 7.7) mmHg p-value for difference: NS At 3-month follow-up Intervention: 81.9 (SD: 9.4) mmHg Control: 81.6 (SD: 8) mmHg p-value for difference: NS At 6-month follow-up Intervention: 79.5 (SD: 8.4) mmHg Control: 81.3 (SD: 7.6) mmHg p-value for difference: NS Change from baseline to 6 months Intervention: 12.8 (SD: 9.9) mmHg Control: 9.7 (SD: 9.8) mmHg p-value for difference: <0.05	Yes, but only for the difference between the change from baseline to 6 month values.

Study	Outcome Category	Outcome	Results	Statistical Significance
McKinstry et al. (2013)[113-115]	Surrogate	BP Daytime ambulatory blood pressure monitoring were taken with the 90207 ABP Monitor (Spacelabs Healthcare, Washington). Readings were taken every 20 minutes for 14 hours. BP was also measured electronically in the clinic initially using the Stabil-O-Graph (IEM, Germany) device with an appropriately sized cuff and after a five minute rest, and then twice more using the ambulatory blood pressure monitor. The monitor was fitted on the non-dominant arm or, if there was a difference of >20/10 mmHg between the two arms, the arm with the higher systolic reading. At follow-up, the mean of the second two out of three office readings each were used.	Usual care vs. PGHD (Stabil-O-graph mobile) The mean daytime systolic ambulatory BP fell in both groups, from 146.0 (SD: 10.5) mmHg to 140.0 (SD: 11.3) mmHg in the PGHD arm and from 146.5 (SD: 10.7) mmHg to 144.3 (SD: 13.4) mmHg in the UC arm (The difference between the two arms at six months (that is, UC minus PGHD) was 4.3 mmHg (95% CI: 2.01 to 6.53, p=0.0002), adjusted for baseline mean daytime systolic ambulatory BP and minimization factors. The mean daytime diastolic ambulatory BP also fell in both arms, from 87.4 (SD: 10.1) mmHg to 83.4 (SD: 9.1) mmHg in the PGHD arm and from 85.7 (SD: 9.6) mmHg to 84.3 (SD: 10.4) mmHg in the UC arm. The difference in mean daytime diastolic ambulatory BP at six months between the two arms (UC minus PGHD) was 2.3 mmHg (95% CI: 0.92 to 3.61, p=0.001), adjusted for baseline mean daytime diastolic ambulatory BP and minimization factors. The difference in mean clinic measured SBP at six months between the two groups (UC minus PGHD) was 4.6 mmHg (95% CI: 1.74 to 7.51, p=0.0017) and for clinic measured DBP was 2.8 mmHg (95% CI: 1.01 to 4.63, p=0.0021), adjusted for baseline clinic BP and minimization factors. PGHD group went from baseline: 153.1 (SD: 15.2) to 144.7 (SD: 16.1) at 6 months while UC went from baseline: 152.5 (SD: 14.5) and 148.8 (SD: 14.7) at 6 months. The difference in mean clinic measured DBP at six months between the two groups (UC minus PGHD) was 2.83 mmHg (95% CI: 1.03 to 4.63, p=0.0021), adjusted for baseline clinic BP and minimization factors. PGHD group went from baseline: 92.4 (SD: 11.6) to 86.9 (SD: 11.8) at 6 months while UC went from baseline: 90.1 (SD: 11.4) and 88.3 (SD: 11.2) at 6 months.	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
McManus et al. (2010)[116-120]	Surrogate	SBP BP was measured systematically after 5 min rest with an electronic automated sphygmomanometer (BP TRU BPM 100 or 200; BP TRU Medical Devices). Six BP readings were taken at intervals of 1 min. The mean of the second and third readings was used for the primary outcome.	Combination (PGHD, medication management) vs. Usual care At 6 months Intervention: 139.0 (95% CI: 137.0 to 141.0) mmHg Control: 142.4 (95% CI: 140.2 to 144.6) mmHg At 12 months Intervention: 134.9 (95% CI: 132.6 to 137.1) mmHg Control: 140.1 (95% CI: 138.0 to 142.2) mmHg Change from baseline to 6 months Intervention: -13.1 (95% CI: -10.9 to -15.3) mmHg Control: -9.4 (95% CI: -7.2 to -13.9) mmHg Difference between groups: -3.7 (95% CI: -0.6 to -6.8) mmHg Change from baseline to 12 months Intervention: -17.2 (95% CI: -14.8 to -19.7) mmHg Control: -11.7 (95% CI: -9.5 to -13.9) mmHg Difference between groups: -5.5 (95% CI: -2.2 to -8.8) mmHg	Yes
McManus et al. (2010)[116-120]	Surrogate	DBP BP was measured systematically after 5 min rest with an electronic automated sphygmomanometer (BP TRU BPM 100 or 200; BP TRU Medical Devices). Six BP readings were taken at intervals of 1 min. The mean of the second and third readings was used for the primary outcome.	Combination (PGHD, medication management) vs. Usual care At 6 months Intervention: 79.6 (95% CI: 78.4 to 80.9) mmHg Control: 80.3 (95% CI: 79.0 to 81.7) mmHg At 12 months Intervention: 77.4 (95% CI: 76.1 to 78.6) mmHg Control: 79.5 (95% CI: 78.1 to 80.9) mmHg Change from baseline to 6 months Intervention: -5.4 (95% CI: -4.3 to -6.5) mmHg Control: -4.1 (95% CI: -3.0 to -5.3) mmHg Difference between groups: -1.3 (95% CI: 0.3 to -2.8) mmHg Change from baseline to 12 months Intervention: -7.6 (95% CI: -6.5 to -8.8) mmHg Control: -5.0 (95% CI: -3.8 to -6.1) mmHg Difference between groups: -2.7 (95% CI: -1.1 to -4.2) mmHg	Yes, for change from baseline to 12 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
McManus et al. (2014)[121]	Surrogate	DBP At both baseline and follow-up visits, blood pressure was measured by a research facilitator systematically after 5 minutes of rest using a Bp-TRU blood pressure M 100 or 200 electronic automated sphygmomanometer. Six blood pressure readings were taken at 1-minute intervals, using the mean of the second and third readings for analysis.	PGHD (Microlife Watch BP Home) vs. Usual care At 6 months Intervention group: 75.2 (95% CI: 73.9 to 76.4) mmHg Usual care: 77.6 (95% CI: 77.6 to 78.8) mmHg Between group difference: 2.7 (95% CI: 0.4 to 5.1) mmHg, favoring intervention At 12 months Intervention group: 73.6 (95% CI: 72.4 to 74.8) mmHg Usual care: 76.4 (95% CI: 75.1 to 77.7) mmHg Between group difference: 3.1 (95% CI: 0.7 to 5.5) mmHg, favoring intervention	Yes
McManus et al. (2014)[121]	Surrogate	SBP At both baseline and follow-up visits, blood pressure was measured by a research facilitator systematically after 5 minutes of rest using a Bp-TRU blood pressure M 100 or 200 electronic automated sphygmomanometer. Six blood pressure readings were taken at 1-minute intervals, using the mean of the second and third readings for analysis.	PGHD (Microlife Watch BP Home) vs. Usual care At 6 months Intervention group: 132.1 (95% CI: 129.8 to 134.4) mmHg Usual care: 138.4 (95% CI: 136.3 to 140.5) mmHg Between group difference: 5.5 (95% CI: 1.6 to 9.5) mmHg, favoring intervention At 12 months Intervention group: 128.6 (95% CI: 126.5 to 130.7) mmHg Usual care: 138.2 (95% CI: 136.1 to 140.2) mmHg Between group difference: 8.8 (95% CI: 4.9 to 12.7) mmHg, favoring intervention	Yes
McManus et al. (2018)[83-86]	Surrogate	SBP Blood pressure was measured by a research nurse using a validated monitor, six times at baseline and each follow-up appointment in a standardized fashion, using the same arm and cuff size each time, in a seated position after at least 5 min rest.19 The mean of the second and third readings was used.	PGHD (Omron M10-IT) vs. Usual care At 6 months Intervention: 140.4 (SD: 15.7) mmHg Control: 142.5 (SD: 15.7) mmHg Difference between the groups: -2.1 (95% CI: -4.3 to 0.1) p-value: 0.0584 At 12 months Intervention: 137.0 (SD: 16.7) mmHg Control: 140.4 (SD: 16.5) mmHg Difference between the groups: -3.5 (95% CI: -5.8 to -1.2), p-value: 0.05029	Yes, at 12 months.

Study	Outcome Category	Outcome	Results	Statistical Significance
McManus et al. (2018)[83-86]	Surrogate	SBP Blood pressure was measured by a research nurse using a validated monitor, six times at baseline and each follow-up appointment in a standardized fashion, using the same arm and cuff size each time, in a seated position after at least 5 min rest.19 The mean of the second and third readings was used.	Combination (PGHD, telemonitoring) vs. Usual care At 6 months Intervention: 139.0 (SD: 16.8) mmHg Control: 142.5 (SD: 15.7) mmHg Difference between the groups: -3.7 (95% CI: -5.9 to -1.5), p-value: 0.0012 At 12 months Intervention: 136.0 (SD: 16.1) mmHg Control: 140.4 (SD: 16.5) mmHg Difference between the groups: -4.7 (95% CI: -7.0 to -2.4), p-value: <0.0001	Yes
McManus et al. (2018)[83-86]	Surrogate	DBP Blood pressure was measured by a research nurse using a validated monitor, six times at baseline and each follow-up appointment in a standardized fashion, using the same arm and cuff size each time, in a seated position after at least 5 min rest. The mean of the second and third readings was used.	PGHD (Omron M10-IT) vs. Usual care At 6 months Intervention: 80.3 (SD: 10.7) mmHg Control: 81.1 (SD: 10.7) mmHg Difference between the groups: -0.1 (95% CI: -1.3 to 1.07), p-value: 0.8421 At 12 months Intervention: 77.8 (SD: 10.1) mmHg Control: 79.9 (SD: 10.7) mmHg Difference between the groups: -1.5 (95% CI: -2.7 to -0.2), p-value: 0.0209	Yes, at 12 months.
McManus et al. (2018)[83-86]	Surrogate	DBP Blood pressure was measured by a research nurse using a validated monitor, six times at baseline and each follow-up appointment in a standardized fashion, using the same arm and cuff size each time, in a seated position after at least 5 min rest. The mean of the second and third readings was used.	Combination (PGHD, telemonitoring) vs. Usual care At 6 months Intervention: 79.8 (SD: 9.9) mmHg Control: 78.7 (SD: 9.7) mmHg Difference between the groups: -1.2 (95% CI: -2.4 to -0.01), p-value: 0.0482 At 12 months Intervention: 78.7 (SD: 9.7) mmHg Control: 79.9 (SD: 10.7) mmHg Difference between the groups: -1.3 (95% CI: -2.5 to -0.02), p-value: 0.0482	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Mehos et al. (2000)[122]	Surrogate	Between group change in mean absolute DBP	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) Control: 3.8 decrease PGHD: 10.5 decrease p=0.022	Yes
Mehos et al. (2000)[122]	Surrogate	Between group change in mean absolute MAP	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) Control: 4.9 decrease PGHD: 12.7 decrease p=0.01	Yes
Mehos et al. (2000)[122]	Surrogate	BP control Mean of 2 BP at 6 months. BP control defined as <140/90 mmHg.	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) Control: 22% PGHD: 44% p>0.1	No
Mehos et al. (2000)[122]	Surrogate	Between group change in mean absolute SBP Difference in BP at 6 months from baseline. At this first appointment, as well as the final 6-month appointment, blood pressure was measured (two values separated by at least 30 seconds) using the same mercury sphygmomanometer (Tycos, Arden, NC).	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) Control: 7.0 decrease PGHD: 17.1 decrease p=0.069	No
Mendelson et al. (2014)[47]	Surrogate	SBP	PGHD (Telemedicine) vs. Usual care At 17 weeks Results only reported in figure. There do not appear to be substantial differences between groups.	NR
Mendelson et al. (2014)[47]	Surrogate	DBP	PGHD (Telemedicine) vs. Usual care At 17 weeks Results only reported in figure. There do not appear to be substantial differences between groups.	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Neumann et al. (2011)[134,135]	Surrogate	Systolic AMBP 24-h ABPM was collected using the IEM Mobil-O-Graph. BP measurement was automatically performed every 15 min during daytime (0700 to 2200 hours) and every 30 min during nighttime (2200 to 0700 hours).	Combination (PGHD, Physician management) vs. Usual care At 3 months Intervention: 126.3 (SD: 6.3) mmHg Control: 131.6 (SD: 11.8) mmHg p-value for difference: 0.045 At average of 2.6 years (long-term follow-up) Intervention: 130.7 (SD: 10,4) mmHg Control: 121.2 (SD: 11.2) mmHg p-value for difference: 0.008 Change from baseline to 3 months Intervention: -17.0 mmHg Control: -9.8 mmHg p-value for difference: 0.032	Yes
Neumann et al. (2011)[134,135]	Surrogate	Diastolic AMBP 24-h ABPM was collected using the IEM Mobil-O-Graph. BP measurement was automatically performed every 15 min during daytime (0700 to 2200 hours) and every 30 min during nighttime (2200 to 0700 hours).	Combination (PGHD, Physician management) vs. Usual care At 3 months Intervention: 73.6 (SD: 7.3) mmHg Control: 75.1 (SD: 8.2) mmHg p-value for difference: NS At average of 2.6 years (long-term follow-up) Intervention: 77.0 (SD: 7.1) mmHg Control: 72.8 (SD: 10.9) mmHg p-value for difference: NS Change from baseline to 3 months Intervention: -9.0 mmHg Control: -7.0 mmHg p-value for difference: 0.356	No
Neumann et al. (2011)[134,135]	Surrogate	BP control BP control defined as <130/80 mmHg (<125/75 mmHg for diabetes or renal insufficiency).	Combination (PGHD, Physician management) vs. Usual care At 3 months Intervention: 54% Control: 34% p-value for difference: 0.007 At average of 2.6 years (long-term follow-up) Intervention: 56% Control: 40% p-value for difference: 0.024	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Niiranen et al. (2014)[136]	Surrogate	SBP Nurses measured office BP with a mercury sphygmomanometer after a 10-minute rest from the right arm with an appropriately sized cuff. Three BP measurements separated by 1 minute were obtained. Office BP was the mean of all available measurements.	Combination (PGHD, behavioral, pharmaceutical) vs. Usual care Change from baseline to 12 months Intervention group: -8 (SD: 17) mmHg Control group: -11 (SD: 17) mmHg Difference between groups: 3 (SD: 17) mmHg, p-value: 0.25	No
Niiranen et al. (2014)[136]	Surrogate	DBP Nurses measured office BP with a mercury sphygmomanometer after a 10-minute rest from the right arm with an appropriately sized cuff. Three BP measurements separated by 1 minute were obtained. Office BP was the mean of all available measurements.	Combination (PGHD, behavioral, pharmaceutical) vs. Usual care Change from baseline to 12 months Intervention group: -6 (SD: 8) mmHg Control group: -7 (SD: 8) mmHg Difference between groups: 2 (SD: 8) mmHg, p-value: 0.16	No
Niiranen et al. (2014)[136]	Surrogate	BP control Nurses measured office BP with a mercury sphygmomanometer after a 10-minute rest from the right arm with an appropriately sized cuff. Three BP measurements separated by 1 minute were obtained. Office BP was the mean of all available measurements. Target office BP was <140/85 mmHg.	Combination (PGHD, behavioral, pharmaceutical) vs. Usual care At 12 months Reached target BP Intervention group: 52.7% Control group: 60.2% p-value for difference: 0.26	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Ogedegbe et al. (2014)[123]	Surrogate	BP control at 12 mos (LT 140/90 or LT 130/80 for DM and kidney disease At baseline, 3 readings were taken by trained research assistants using an automated BP monitor (BPTru) with the patient seated comfortably for 5 minutes before each measurement, following American Heart Association guidelines. The same procedure was repeated at each study visit. The average of the 3 readings was used as the outcome measure for each visit.	Usual care vs. PGHD (Microlife model BP 3AC1-1PC) PGHD baseline SBP (150 and SD: 17) and DBP (91 and SD: 10) UC baseline SBP (153 and SD: 17) and DBP (91 and SD: 11); in an unadjusted intent-to-treat analysis, BP control at 12 months was 50.2% at the IC sites and 45.3% at the UC sites (OR: 1.22, 95% CI: 0.92 to 1.63, p=0.18), with no significant intervention effect. After adjusting for baseline BP, comorbidity, DM, and resistant HTN status, the BP control rate at the PGHD sites was 49.3% versus 44.5% at the UC sites (OR: 1.21, 95% CI: 0.90 to 1.63, p=0.21). The between-group difference in BP control favored PGHD for 73% of the community health center pairs (11 of the 15 randomized pairs, p=0.06). Although the unadjusted within patient reduction in SBP and DBP from baseline to 12 months was statistically significant for both groups (-16.1/-9.3 mmHg, both p<0.0001), there was no significant intervention effect (SBP PGHD: -16.1 mmHg versus UC: -16.0 mmHg, p=0.96); and DBP PGHD: -9.6 mmHg versus UC: -8.9 mmHg, p=0.46). These differences were non-significant after adjusting for diabetes mellitus, comorbidity, and resistant hypertension status.	No
Petrella et al. (2014)[60]	Surrogate	SBP	Intervention vs. Active control At 12 weeks Intervention: 138.2 (SD: 17.8) mmHg Active control: 132.7 (SD: 18.4) mmHg p-value for difference: 0.03, favors control group At 24 weeks Intervention: NR Active control: NR At 52 weeks Intervention: NR Active control: NR	Yes, at 12 weeks.

Study	Outcome Category	Outcome	Results	Statistical Significance
Petrella et al. (2014)[60]	Surrogate	DBP	Intervention vs. Active control At 12 weeks Intervention: 84 (SD: 10.7) mmHg Active control: 80.9 (SD: 9) mmHg p-value for difference: 0.06 At 24 weeks Intervention: NR Active control: NR At 52 weeks Intervention: NR Active control: NR	No
Qi et al. (2017)[99]	Surrogate	SBP BP was measured 1 hour after waking up and after being seated and resting for 5 minutes.	PGHD (Omron HEM-7121) vs. Control Group At 1 year Intervention: 135 mmHg Control: 135 mmHg p-value for difference: NS At 2 years Intervention: 128 mmHg Control: 132 mmHg p-value for difference: NS At 3 years Intervention: 126 mmHg Control: 122 mmHg p-value for difference: NS At 4 years Intervention: 126 mmHg Control: 124 mmHg p-value for difference: NS At 5 years Intervention: 121 mmHg Control: 127 mmHg p-value for difference: <0.05 Change from baseline to 5 years Intervention: -4.3 (SD: 3.2) mmHg Control: -3.9 (SD: 3.1) mmHg p-value for difference: <0.05	Yes, for 5-year follow-up results.

Study	Outcome Category	Outcome	Results	Statistical Significance
Qi et al. (2017)[99]	Surrogate	DBP BP was measured 1 hour after waking up and after being seated and resting for 5 minutes.	PGHD (Omron HEM-7121) vs. Control Group At 1 year Intervention: 88 mmHg Control: 89 mmHg p-value for difference: NS At 2 years Intervention: 83 mmHg Control: 87 mmHg p-value for difference: NS At 3 years Intervention: 75 mmHg Control: 76 mmHg p-value for difference: NS At 4 years Intervention: 78 mmHg Control: 77 mmHg p-value for difference: NS At 5 years Intervention: 76 mmHg Control: 79 mmHg p-value for difference: NS Change from baseline to 5 years Intervention: -3.5 (SD: 2.5) mmHg Control: -3.0 (SD: 2.5) mmHg p-value for difference: <0.05	Yes, for 5-year follow-up results.
Qi et al. (2017)[99]	Surrogate	BP control BP was measured 1 hour after waking up and after being seated and resting for 5 minutes. Target BP was <140/90 mmHg.	PGHD (Omron HEM-7121) vs. Control Group At 5 years Intervention: 85.37% Control: 79.96%	Yes
Rifkin et al. (2013)[65]	Surrogate	SBP	Combination (PGHD, Physician management) vs. Usual care At 6 months: Intervention: 136 (SD: 15.6) mmHg Control: 140 (SD: 14.4) mmHg p-value for difference: 0.48	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Rifkin et al. (2013)[65]	Surrogate	DBP	Combination (PGHD, Physician management) vs. Usual care At 6 months: Intervention: 73 (SD: 12.6) mmHg Control: 73 (SD: 10.3) mmHg p-value for difference: 0.93	No
Rogers et al. (2001)[137]	Surrogate	DBP An ABPM device automatically recorded BP every half-hour from 7:00 a.m. to 11:00 p.m. and every hour from 11:00 p.m. to 7:00 a.m.	Combination (PGHD, Physician management) vs. Usual care Change from baseline to median 11 weeks Intervention: -2.0 (95% CI: -4.04 to 0.14) mmHg Control: 2.1 (95% CI: -0.21 to 4.37) mmHg Difference between groups: -4.1 (95% CI: -7.13 to -0.93) mmHg, p-value for difference: 0.012	Yes
Rogers et al. (2001)[137]	Surrogate	SBP An ABPM device automatically recorded BP every half-hour from 7:00 a.m. to 11:00 p.m. and every hour from 11:00 p.m. to 7:00 a.m.	Combination (PGHD, Physician management) vs. Usual care Change from baseline to median 11 weeks Intervention: -4.9 (95% CI: -8.12 to -1.61) mmHg Control: -0.1 (95% CI: -3.17 to 3.43) mmHg Difference between groups: -4.8 (95% CI: -9.37 to 0.10) mmHg, p-value for difference: 0.047	Yes
Rogers et al. (2001)[137]	Surrogate	BP control SBP control defined as <140 mmHg (<130 mmHg for patients with target organ damage). DBP control defined as <90 mmHg (<85 mmHg for patients with target organ damage).	Combination (PGHD, Physician management) vs. Usual care Change from baseline to median 11 weeks SBP Control Intervention: 8.1% Control: 0.5% Difference between groups: 7.6% (95% CI: -0.6 to 15.8) DBP Control Intervention: 6.3% Control: -5.6% Difference between groups: 11.9% (95% CI: 3.6 to 20.1), p-value: 0.006	Yes
Sarfo et al. (2018)[138,139]	Surrogate	SBP Clinic BP	PGHD (UA-767Plus BT BP) vs. Usual care At 9-month follow-up Intervention group: 132.3 (SD: 16.2) mmHg Control group: 138.8 (SD: 18.4) mmHg p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Sarfo et al. (2018)[138,139]	Surrogate	DBP Clinic BP	PGHD (UA-767Plus BT BP) vs. Usual care At 9-month follow-up Intervention group: 87.6 (SD: 12.1) mmHg Control group: 84.4 (SD: 10.1) mmHg p-value for difference: NS	No
Sarfo et al. (2018)[138,139]	Surrogate	BP Control Overall BP control: Clinic BP 140/90 mmHg SBP control: Clinic SBP <140 mmHg DBP control: Clinic DBP <90 mmHg	PGHD (UA-767Plus BT BP) vs. Usual care At 9-month follow-up Overall BP control Intervention group: 14/30 (47%) Control group: 12/30 (40%) p-value for difference: 0.79 SBP control Intervention group: 22/30 (70%) Control group: 13/30 (43%) p-value for difference: 0.035 DBP control Intervention group: 14/30 (70%) Control group: 23/30 (77%) p-value for difference: 0.03	Yes, significant differences in terms of SBP control and DBP control, but not for overall BP control.
Stewart et al. (2014)[140]	Surrogate	SBP Pharmacist measured the patient's BP with the Omron HEM-790IT digital BP monitor, using the average of two readings. If these differed by more than 10 mmHg for systolic or 5 mmHg for diastolic, a third reading was taken and the average of the two closest readings recorded.	Pharmacist Care vs. Usual care At 6 months Intervention group: 131.7 (SD: 22.0) mmHg Control group: 135.3 (SD: 22.3) mmHg Change from baseline to 6 months Intervention group: 10.0 (SD: 25.0) mmHg Control group: 4.6 (SD: 25.3) mmHg Difference between the groups: 5.3 (95% CI: 0.0 to 10.6), p-value: 0.05	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Stewart et al. (2014)[140]	Surrogate	DBP Pharmacist measured the patient's BP with the Omron HEM-790IT digital BP monitor, using the average of two readings. If these differed by more than 10 mmHg for systolic or 5 mmHg for diastolic, a third reading was taken and the average of the two closest readings recorded.	Pharmacist Care vs. Usual care At 6 months Intervention group: 80.2 (SD: 13.6) mmHg Control group: 78.8 (SD: 13.8) mmHg Change from baseline to 6 months Intervention group: 4.5 (SD: 14.5) mmHg Control group: 4.2 (SD: 14.7) mmHg Difference between the groups: 0.3 (95% CI: -2.8 to 3.4), p-value: 0.85	No
Yoo et al. (2009)[23]	Surrogate	SBP	Intervention vs. Usual care At 13 weeks Intervention: 132.7 (SD: 16.2) mmHg Control: 134 (SD: 13.64) mmHg	NR
Yoo et al. (2009)[23]	Surrogate	DBP	Intervention vs. Usual care At 13 weeks Intervention: 80.3 (SD: 9.2) mmHg Control: 83.8 (SD: 10) mmHg	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Zaleski et al. (2019)[100]	Surrogate	BP After a minimum of 15 min of seated rest, resting BP was measured in the laboratory according to AHA standards using a BPTRU monitor (BPTRU Medical Devices; Coquitlam, British Columbia, Canada) three times, 5 min apart in each arm. Ambulatory BP monitor (Oscar2 automatic noninvasive ambulatory BP monitor, Suntech Medical Instruments Inc., Raleigh, North Carolina, USA) was attached to the participant on their nondominant arm by a trained investigator using previously published standard protocols. The next morning the monitor was removed and returned to be reviewed by a study investigator.	Usual care vs. PGHD (BP Omron 705 CPN) There was no statistically significant difference in the change in resting SBP following versus before 12 weeks of exercise training between UC (-5.2 (SD: 13.3) mmHg) and PGHD/BP (-9.9 (SD: 11.3) mmHg, p=0.344). There was no statistically significant change in resting DBP either: DBP following versus before 12 weeks of exercise training between UC (-3.6 (SD: 12.5) mmHg) and PGHD/BP (-6.1 (SD: 6.9) mmHg, p=0.552). Ambulatory: average awake, sleep, and 19-hour ambulatory DBP were not significantly different following exercise training between groups (p>0.102).	No
Zarnke et al. (1997)[124]	Surrogate	Arterial BP An automatic ambulatory blood pressure device (model 90207, SpaceLabs) was used to measure 12-hour daytime BP (between 6am and 6pm).	Combination (PGHD, treatment management) vs. Usual care Change from baseline to 8 weeks Intervention: -0.95 (SD: 5.8) mmHg Control: 1.90 (SD: 4.6) mmHg p-value for difference: 0.039	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Zha et al. (2019)[87]	Surrogate	SBP Patients sat in an upright position with feet flat on the floor, resting for at least 5 min before BP was measured using the Welch Allyn Spot Vital Signs LXi electronic BP monitor. For each participant, BP was measured at least once in each arm, separated by 5 min. SBP, DBP, and pulse were measured and recorded by the community health center nurses or community health workers.	PGHD (iHealth BP7 Wireless Blood Pressure Wrist Monitor) vs. Usual care At 3 months Intervention: 140.55 (SD: 5.46) mmHg Control: 142.62 (SD: 5.69) mmHg p-value for difference: NS At 6 months Intervention: 137.38 (SD: 4.86) mmHg Control: 140.88 (SD: 5.01) mmHg p-value for difference: NS	No
Zha et al. (2019)[87]	Surrogate	DBP Patients sat in an upright position with feet flat on the floor, resting for at least 5 min before BP was measured using the Welch Allyn Spot Vital Signs LXi electronic BP monitor. For each participant, BP was measured at least once in each arm, separated by 5 min. SBP, DBP, and pulse were measured and recorded by the community health center nurses or community health workers.	PGHD (iHealth BP7 Wireless Blood Pressure Wrist Monitor) vs. Usual care At 3 months Intervention: 90.53 (SD: 7.62) mmHg Control: 88.95 (SD: 9.02) mmHg p-value for difference: NS At 6 months Intervention: 88.08 (SD: 7.45) mmHg Control: 88.10 (SD: 9.41) mmHg p-value for difference: NS	No
Bosworth et al. (2009)[63]	Process	Healthcare resource use Electronic record	Number of outpatient encounters was similar for the 4 groups, medians ranged from 13 to 15 (p=0.73).	No
Hebert et al. (2012)[82]	Process	Medication changes Patient survey	PGHD (Omron HEM-712C) vs. Usual care No changes in medication At 9 months Intervention: 44% (95% CI: 35 to 53) Control: 38% (95% CI: 30 to 47) p-value for difference: NS	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Hebert et al. (2012)[82]	Process	Medication changes Patient survey	Combination (PGHD, nurse management) vs. Usual care No changes in medication At 9 months Intervention: 32% (95% CI: 24 to 40) Control: 38% (95% CI: 29 to 47) p-value for difference: NS	No
Kao et al. (2019)[102]	Process	Medication adjustment Authors calculated the antihypertensive dosage based on the daily defined dose, a unit of measurement for assumed average maintenance doses per day for a drug according to its main indication in adults.	Usual care vs. PGHD Daily defined dose of antihypertensives: PGHD baseline: 1.84, 3 months: 1.61 and 6 months: 1.58 vs. UC baseline: 0.74, 3 months: 2.05 and 6 months: 2.05.	Yes
Kerry et al. (2013)[103-105]	Process	Number of primary care consultations	Monitoring vs. Usual care At 52 weeks Monitoring: 5.2 (SD: 4.6) Usual care: 5.4 (SD: 5.3) p-value for difference: NS	No
Magid et al. (2013)[64]	Process	Medication adjustments Medication intensity was measured by comparing the proportion of patients in each group with at least one antihypertensive medication added between the baseline and the 6-month visit and the proportion with at least 1 dose increase for an antihypertensive medication that they were taking at baseline.	Usual care vs. PGHD (Omron HEM 790 IT) Patients with 1 or more meds added, n(%): UC: 41 (25%) and PGHD: 113 (70%), p<0.001 Patients with 1 or more dose increases, n (%): UC: 20 (12%) and PGHD: 69 (43%), p<0.001 Change in medication intensity score from baseline to 6 months, mean (SD): UC: 0.15 (SD: 0.82) and PGHD: 1.35 (SD: 1.37), p<0.001	Yes
Magid et al. (2013)[64]	Process	Health care used Chart review	Usual care vs. PGHD (Omron HEM 790 IT) Means and SD: Clinic visits UC: 3.1 (SD: 2.3), PGHD: 3.3 (SD: 2.5), p=0.16; telephone encounters UC: 3.5 (SD: 3.8), PGHD: 5.3 (SD: 4.5) p=0.02; e-mail encounters UC: 2.4 (3.2), PGHD: 6.0 (5.5) p<0.01.	Yes for telephone encounters and emails but no for clinic visits.

Study	Outcome Category	Outcome	Results	Statistical Significance
Margolis et al. (2013)[106-112]	Process	Prescribed any hypertension medications	Combination (PGHD, Pharmacist Care) vs. Usual care At 6 months Intervention: 94.5% (95% CI: 88.9 to 97.4) Control: 79.3% (95% CI: 68.6 to 87.0 At 12 months Intervention: 94.6% (95% CI: 89.2 to 97.4) Control: 80.3% (95% CI: 70.6 to 87.3) At 18 months Intervention: 94.6% (95% CI: 89.4 to 97.6) Control: 81.1% (95% CI: 71.2 to 88.1) Change from baseline to 6 months Intervention: 17.7% (95% CI: 13.0 to 20.3) Control: 6.3% (95% CI: -2.1 to 12.7) Change from baseline to 12 months Intervention: 17.8% (95% CI: 13.3 to 20.7) Control: 7.3% (95% CI: -0.8 to 13.8) Change from baseline to 12 months Intervention: 18.1% (95% CI: 13.5 to 20.8) Control: 8.1% (95% CI: -0.3 to 14.2)	NR
McKinstry et al. (2013)[113-115]	Process	Medication adjustment Chart review	Usual care vs. PGHD (Stabil-O-graph mobile) Number of drugs and defined daily dosage At follow-up more participants in the PGHD arm than in the UC arm had an increase in the number of drugs (p<0.001). There were increases in drug use across all the main drug groups, with calcium antagonists showing the biggest rise. In a retrospective comparison authors found that the treatment intensity in the PGHD group also increased, with 76 (39%) of participants in the PGHD group increasing their defined daily dosage of antihypertensive drugs compared with 22 (12%) of participants in the UC group (p=0.0003). Change in hypertensive drugs (n [%]): decreased PGHD: 11 (6%), UC: 11 (5%), none PGHD: 108 (54%) and UC: 149 (74%), increased PGHD: 75 (38%) and UC: 26 (13%) and missing data PGHD: 6 (3%) and UC: 15 (7%).	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
McManus et al. (2014)[121]	Process	Number of prescribed antihypertensive drugs Prescribed medications were recorded from the electronic patient record.	PGHD (Microlife Watch BP Home) vs. Usual care At 6 months Intervention group: 2.07 (95% CI: 1.87 to 1.92) Usual care: 1.75 (95% CI: 1.58 to 1.92) Between group difference: 0.19 (95% CI: -0.01 to 0.39), NS At 12 months Intervention group: 2.22 (95% CI: 2.03 to 2.42) Usual care: 1.73 (95% CI: 1.56 to 1.91) Between group difference: 0.27 (95% CI: 0.07 to 0.47)	Yes, at 12 months.
McManus et al. (2018)[83-86]	Process	Number of antihypertensive drugs	PGHD (Omron M10-IT) vs. Usual care At 12 months Intervention: 1.63 (SD: 0.89) Control: 1.55 (SD: 0.85) Difference between the groups: 0.11 (95% CI: 0.02 to 0.19), p-value: 0.0129	Yes
McManus et al. (2018)[83-86]	Process	Number of antihypertensive drugs	Combination (PGHD, telemonitoring) vs. Usual care At 12 months Intervention: 1.70 (SD: 0.88) Control: 1.55 (SD: 0.85) Difference between the groups: 0.13 (95% CI: 0.04 to 0.21), p-value: 0.0038	Yes
Mehos et al. (2000)[122]	Process	Compliance with anti-HTN therapy	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) Control mean compliance: 89% Intervention: 82% p=0.29	No
Mehos et al. (2000)[122]	Process	Anti-HTN medication changes	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) Control: 33% Intervention: 83% p<0.01	Yes
Mehos et al. (2000)[122]	Process	Office visits with primary doctor during 6 month trial period.	Control Group vs. PGHD (A&D UA-702 manual electronic blood pressure monitor) Control: 4.44 mean office visits/patient Intervention: 2.72 p=0.08	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Ogedegbe et al. (2014)[123]	Process	Medication intensification Chart review	Usual care vs. PGHD (Microlife model BP 3AC1-1PC) Percent and 95% CI: Visit 1-2: UC: 22 (16 to 29), PGHD: 24 (18 to 29), p=0.73; Visit 2-3: UC: 16 (9 to 23), PGHD: 21 (16 to 27), p=0.26; Visit 3-4: UC: 14 (7 to 19), PGHD: 14 (9 to 19), p=0.88; and Visit 4-5: UC: 23 (16 to 31), PGHD: 18 (13 to 23), p=0.26.	No
Zarnke et al. (1997)[124]	Process	Change in total antihypertensive drug use Total antihypertensive drug use was defined as the sum of assigned proportional units for each prescribed antihypertensive drug according to recommended antihypertensive doses (Canadian Consensus on Hypertension Management recommendations)	Combination (PGHD, treatment management) vs. Usual care Over 8 weeks Intervention: 0.05 (SD: 0.46) proportional units Control: 0.05 (SD: 0.46) proportional units p-value for difference: NS	No
Zarnke et al. (1997)[124]	Process	Physician visits	Combination (PGHD, treatment management) vs. Usual care Over 8 weeks Intervention: 1.05 (SD: 1.23) per patient Control: 0.20 (SD: 0.42) per patient p-value for difference: 0.045	Yes
Zarnke et al. (1997)[124]	Process	Change in drug therapy	Combination (PGHD, treatment management) vs. Usual care Over 8 weeks Percentage of patients Intervention: 25% Control: 10% p-value for difference: NS	No
Margolis et al. (2013)[106-112]	Cost-effectiveness	Intervention cost-effectiveness Calculated as (Intervention costs + Net incremental medical care costs compared to usual care) Intervention effect.	Combination (PGHD, Pharmacist Care) vs. Usual care BP control Cost of $ $7337 (95% CI: $2278 to $26 329) per person achieving BP control SBP Cost of $139 (95% CI: $46 to $347) per mmHg of reduced SBP DBP Cost of $265 (95% CI: $83 to $743) per mmHg of reduced DBP	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
McKinstry et al. (2013)[113-115]	Cost-effectiveness	Economic evaluation	Usual care vs. PGHD (Stabil-O-graph mobile) Costs per patient were higher and mean ambulatory SBP per patient was lower in the PGHD group than the UC ($p<0.001$ for both variables). This indicates that PGHD was both more costly and more effective than UC in all replicates. The ICER was £25.60/mmHg (95% CI: £16.05 to £46.69).	Yes

McManus et al. (2010)[116-120]	Cost-effectiveness	QALYs	Combination (PGHD, medication management) vs. Usual care QALYs gained Men – Over lifetime (35 years) Intervention: 9.16 Control: 8.92 Difference between groups: 0.24 Men – Over 30 years Intervention: 9.11 Control: 8.88 Difference between groups: 0.23 Men – Over 25 years Intervention: 8.93 Control: 8.30 Difference between groups: 0.17 Men – Over 20 years Intervention: 8.46 Control: 8.30 Difference between groups: 0.17 Men – Over 15 years Intervention: 7.50 Control: 7.39 Difference between groups: 0.11 Men – Over 10 years Intervention: 5.88 Control: 5.83 Difference between groups: 0.06 Men – Over 5 years Intervention: 3.45 Control: 3.43 Difference between groups: 0.02 Women – Over lifetime (35 years) Intervention: 10.57 Control: 10.46 Difference between groups: 0.12 Women – Over 30 years Intervention: 10.44 Control: 10.33 Difference between groups: 0.11 Women – Over 25 years Intervention: 10.07	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
			Control: 9.98 Difference between groups: 0.09 Women – Over 20 years Intervention: 9.31 Control: 9.24 Difference between groups: 0.07 Women – Over 15 years Intervention: 8.02 Control: 7.97 Difference between groups: 0.04 Men – Over 10 years Intervention: 6.12 Control: 6.09 Difference between groups: 0.06 Women – Over 5 years Intervention: 3.50 Control: 3.50 Difference between groups: 0.01	
McManus et al. (2010)[116-120]	Cost-effectiveness	ICER	Combination (PGHD, medication management) vs. Usual care Men – Over lifetime (35 years): £1624 Men – Over 30 years: £1635 Men – Over 25 years: £1660 Men – Over 20 years: £1690 Men – Over 15 years: £1659 Men – Over 10 years: £1247 Men - Over 5 years: Intervention is less costly and more effective Women – Over lifetime (35 years): £4923 Women – Over 30 years: £5108 Women – Over 25 years: £5547 Women – Over 20 years: £6349 Women – Over 15 years: £7532 Women – Over 10 years: £8726 Women – Over 5 years: £1635	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
McManus et al. (2018)[83-86]	Cost-effectiveness	QALYs	PGHD (Omron M10-IT) vs. Usual care Intervention: 11.0447 Control: 11.0040	NR
McManus et al. (2018)[83-86]	Cost-effectiveness	QALYs	PGHD (Omron M10-IT) vs. Usual care Intervention: 11.0621 Control: 11.0040	NR
McManus et al. (2018)[83-86]	Cost-effectiveness	ICER	PGHD (Omron M10-IT) vs. Usual care Intervention: £3035	NR
Bernocchi et al. (2014)[125]	Cost	NA	NA	NA
Bosworth et al. (2009)[63]	Cost	NA	NA	NA
Bosworth et al. (2011)[66-68]	Cost	NA	NA	NA
Margolis et al. (2013)[106-112]	Cost	NA	NA	NA
McKinstry et al. (2013)[113-115]	Cost	NA	NA	NA
McManus et al. (2010)[116-120]	Cost	NA	NA	NA
McManus et al. (2018)[83-86]	Cost	NA	NA	NA
Rogers et al. (2001)[137]	Cost	NA	NA	NA

ABPM = ambulatory blood pressure monitoring; AE = adverse events; BMI = body mass index; BP = blood pressure; CI = confidence interval; CKD = chronic kidney disease; CPAP = continuous positive airway pressure; CT = computed tomography; CVD = cardiovascular disease = DBP = diastolic blood pressure; DM = diabetes mellitus; ECG = electrocardiogram; EQ-5D = EuroQol five-dimension questionnaire; EQ-VAS = EuroQoL visual analog scale; ER = emergency room; HBPM = home blood pressure monitoring; HDL = high-density lipoproteins; ICER = incremental cost-effectiveness ratio; IQR = interquartile range; mmHg = millimeters of mercury; NA = not applicable; NR = not reported; NS = not statistically significant; PGHD = patient-generated health data; QALY = quality-adjusted life years; QoL = quality of Life; SBP = systolic blood pressure; SCORE = Systematic Coronary Risk Evaluation; SD = standard deviation; SF-12/36 = short form 12/36; UC = usual care

Table C-29. Coronary artery disease and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Personalized Activity Intervention in Rehabilitation After Cardiac Operations (the PACO Trial) https://ClinicalTrials.gov/show/NCT03470246	Recruiting	Coronary Artery Disease | Aortic Valve Stenosis | Mitral Valve Insufficiency	Behavioral: PACO intervention for CABG patients | Behavioral: PACO intervention for AVR patients | Behavioral: PACO intervention for MVR patients	Kuopio University Hospital, Kuopio, Finland
Smartphone Delivered In-home Cardiopulmonary Rehabilitation https://ClinicalTrials.gov/show/NCT02791685	Recruiting	Cardiovascular Disease | Coronary Artery Disease	Behavioral: MULTIFIT Cardiac Rehabilitation | Behavioral: Movn Pulmonary Rehabilitation | Behavioral: Standard of Care Cardiac Rehabilitation	Atlanta VA Medical Center, Atlanta, Georgia, United States
Pre-habilitation of Patients Scheduled for Cardiac Valve Surgery https://ClinicalTrials.gov/show/NCT03571906	Not yet recruiting	Valvular Heart Disease	Behavioral: Tele – Cardiac Pre-Rehabilitation	NR
Tele-Cardiac Rehabilitation Program https://ClinicalTrials.gov/show/NCT03584828	Not yet recruiting	Heart Diseases	Behavioral: Tele Cardiac Rehabilitation	Sheba Medical Center, Cardiac Rehabilitation Institute, Tel Hashomer, Israel
Feasibility and Usability of a Pedometer in a Cardiovascular Disease Prevention Program for French-speaking Canadians https://ClinicalTrials.gov/show/NCT02837471	Active, not recruiting	Cardiovascular Disease	Device: PiezoRx medical grade pedometer	University of Ottawa Heart Insititue, Ottawa, Ontario, Canada | University of Ottawa Heart Institute, Ottawa, Ontario, Canada

Table C-30. Coronary artery disease and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Avila et al. 2020[623] Avila et al. 2018[145]	RCT	Belgium	February 2014 to August 2016	NR	90	12 (Avila 2018) 52 (Avila 2020)
Treskes et al. 2020[141]	RCT	The Netherlands	May 2016 to December 2018	A power calculation was performed in R statistical software version 3.2.0 for Windows (R Project for Statistical Computing). A comparison of 2 proportions is used. It was expected that 95% of patients in the intervention group would have regulated BP and that 75%of patients in the control group would have regulated BP. An α of 0.05, a β of 0.20, and a margin of 0.07 were chosen, yielding a sample size of 200 patients.	200	52

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Blasco et al. 2011[143]	RCT	Spain	December 2007 to January 2010	Authors estimated that a sample size of 196 patients, 98 in each group, was required to detect a cardiovascular risk profile improvement of 70% in the telemedicine group in contrast to 50% in the control group, with a statistical power of 80% and a level of significance less than .05, assuming a 10% loss to follow-up.	203	52
Frederix et al. 2015[144]	RCT	Belgium	January 2011 to December 2012	NR	80	18
Kraal et al. 2017[142]	RCT	The Netherlands	March 2013 to December 2014	Sample size calculation was performed for primary outcome measure PAEE after one year, using data from Bonomi et al. They found a PAEE in healthy subjects of 4.0 +/- 1.2 MJ/day. If the difference in improvement in PAEE between the control group and intervention group in this study was 20%, 36 participants in both groups were required to test the null hypothesis that the population means were equal (power=0.8 and alpha=0.05). To account for a loss of 20% follow-up after one year, 45 patients were included in both groups.	90	52
Lear et al. 2015[146]	RCT	Canada	NR	NR, but stated study was powered to detect a clinically relevant difference of 60 seconds between the groups.	78	68
Mendelson et al. 2014[47]	RCT	France	Jul 2009 to Jan 2012	Based on the decrease in arterial BP after CPAP treatment reported in the meta-analysis of Bazzano et al. (-2.46±0.94 mmHg), the authors supposed that BP would decrease by an additional 15% (i.e., -2.83 mmHg) when patients benefited from telemedicine. They expected a difference of 0.37 and a standard error of 0.94. Inclusion rate was set at 100 patients per group, based on statistical significance set at 0.05, and power at 80%. To account for a 10% dropout rate in the telemedicine arm, they set inclusion at 110 patients per group. One blinded interim analysis of home self-measured BP was planned halfway through the inclusion process to look for premature evidence of benefits in the telemedicine versus standard care group, or of harm in any group. The results of this analysis showed that even if the set inclusion rate was met, no benefits would be found on the primary outcome measure (home self-measured BP); thus recruitment was interrupted at 107 patients.	107	17

BP = blood pressure; CPAP = continuous positive airway pressure; NR = not reported; PAEE = physical activity energy expenditure

Table C-31. Coronary artery disease and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Avila et al. 2020[623] Avila et al. 2018[145]	The eligible patients included men and women (aged between 40 and 75 years) with angiographically-documented CAD or previous myocardial infarction, on optimal medical treatment for the last 6 weeks, who successfully completed a supervised ambulatory cardiac rehabilitation program and who had access to a computer with Internet connection. The exclusion criteria included known clinically significant ventricular arrhythmia or exercise-induced arrhythmia at screening, myocardial ischemia, other cardiac diseases (valve disease with significant hemodynamic consequences, hypertrophic cardiomyopathy, etc), significant illness for the last 6 weeks, co-morbidity that might represent a significant influence on 1-year prognosis (eg, cancer), and co-morbidity that limits exercise testing and/or training.	61.4 years	11.1	62.2% had prior CABG, 37.8% had prior PCI	NR
Treskes et al. 2020[141]	Patients admitted to the Department of Cardiology of the Leiden University Medical Center with acute MI were eligible for participation. Patients were excluded if they were younger than 18 years, pregnant, unwilling to sign informed consent, or unable to speak Dutch or English.	59.7 years (median)	22	79% had ST-elevation MI	NR
Blasco et al. 2011[143]	Patients admitted to the hospital for an acute coronary syndrome were eligible if they had at least 1 CRF, such as: (1) tobacco smoking, (2) low-density lipoprotein cholesterol 100 mg/dL, (3) hypertension, or (4) diabetes mellitus. Ineligible patients were those physically or mentally unable to use the technical equipment needed for telemonitoring and did not have a support person, and those who had previously participated in a telemedicine project.	60.8 years	19.7	97.5% of patients had an MI that led to hospital admission Baseline LVEF: 52.8% in telemedicine group, 50.8% in control group	No
Frederix et al.2015[144]	Included patients suffered from an acute coronary syndrome for which a percutaneous coronary intervention or coronary artery bypass graft was performed. All patients had access to a computer with internet connection. Patients that (i) were more than 80 years old, (ii) had an implantable cardioverter defibrillator or pacemaker, (iii) suffered from severe arrhythmias, or (iv) had persistent exertional ischaemia after revascularization therapy, were not invited to participate in this study. Patients with severe heart failure (NYHA class III and IV), or neurological or orthopaedic disability limiting their capability to exercise, were also excluded.	Intervention arm: 58 years, control arm: 63 years (p=0.033 between groups)	17.5	74% had prior PCI, 26% had prior CABG, 90% had hypercholesterolemia	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Kraal et al. 2017[142]	We included patients that entered cardiac rehabilitation at Maxima Medical Centre after an acute coronary syndrome (myocardial infarction or unstable angina) or a revascularisation procedure (percutaneous coronary intervention or coronary artery bypass grafting). Patients were eligible for participation when they were classified as low to moderate risk for further events by a cardiologist, based on the criteria described in the Dutch cardiac rehabilitation practice guideline. In addition, patients were required to have Internet access and a personal computer at home. Exclusion criteria were: (a) ventricular arrhythmias or myocardial ischaemia during the maximal exercise test at baseline; (b) left ventricular ejection fraction below 45%; and (c) psychological, physical or cognitive impairments that prevented participation in exercise-based cardiac rehabilitation.	59.1 years	11.1	At baseline, 22 patients received prior CABG, 44 received prior PCI, and 12 received prior medication only	NR
Lear et al. 2015[146]	Cardiac in-patients (admitted for either acute coronary syndrome or revascularization procedure) from two hospitals in British Columbia were screened for study eligibility. To be eligible, participants must have resided in either Northern British Columbia, or the Coast Garibaldi region, as these areas are geographically isolated from the metropolitan areas, comprised of significant rural areas and scattered communities and have no outpatient CRP. Patients must have been at low or moderate risk, had regular Internet access (home, work or other environment), no physical limitations to regular physical activity and were fluent in English. Patients with previous experience with cardiac rehabilitation, depression, uncontrolled diabetes and other significant comorbidities that may interfere with effective cardiovascular management, pregnant women and those who the attending physician thought were unsuitable for participation were excluded.	60 years	15.4	NR	Yes
Mendelson et al. 2014[47]	Patients were eligible for the study if they were between 18 and 85 years old, diagnosed OSA on the diagnostic sleep study with AHI >15 events/h, BMI <40 kg/m2, cardiovascular risk SCORE >5%, or being in secondary prevention with a past history of cardiovascular disease (transient ischemic attack, stroke, cerebral hemorrhage, myocardial infarction, angina, coronary revascularization, arteriopathy, aortic aneurism). Non-inclusion criteria were the following: central sleep apnea syndrome, cardiovascular score <5%, cardiac failure, history of hypercapnic chronic respiratory failure, incapacitated patients, and pregnancy in accordance with article L 1121-6 of the French public health code, or patients taking part in another clinical trial.	63 years	17	SBP: 139, DBP: 81	No

AHI = apnea hypopnea index; BMI = body mass index; CAD = coronary artery disease; CRF = cardiac risk factor; MI = myocardial infarction; OSA = obstructive sleep apnea

Table C-32. Coronary artery disease and PGHD: treatment details

Study	Treatment 1	Treatment 2	Treatment 3
Avila et al. 2020[623] Avila et al. 2018[145]	The home-based cardiac rehabilitation group received training for the first three sessions under the supervision of the investigator. During this period, the patients received an individualized aerobic exercise prescription recommending at least 150 min of exercise per week (preferably 6-7 days/week) at an individually determined target heart rate corresponding to a moderate intensity (ie, 70%-80% of heart rate reserve) in their home environment during the 12-week intervention. Furthermore, this group received instructions on how to use the heart rate monitor (Garmin Forerunner 210, Wichita USA) and how to upload their exercise data to the Garmin platform. This application was used to review the training data by both the patient and the investigator. Patients received feedback via phone or email once a week according to their preferences. These contact moments were used for the following purposes: 1) to check for adverse events and injuries, 2) to provide feedback on performed exercise during the preceding week, 3) to discuss the exercise program regarding duration and intensity, and 4) to discuss adherence and barriers to adherence if necessary.	Patients randomized to center-based cardiac rehabilitation continued their exercise program at the outpatient clinic of UZ Leuven under the direct supervision of physiotherapists. The patients were asked to perform three exercise sessions per week totaling approximately 150 min of endurance exercise. Each training session consisted of predominantly endurance training (2×7 min of cycling, 2×7 min of treadmill walking/ running, 7 min of arm ergometry or rowing, and 2×7 min of dynamic calisthenics) and was followed by relaxation. The endurance exercise workload was individually controlled by heart rate monitoring, which was performed by palpation by the physiotherapist during the last minute of each round of exercise. Exercise load was adjusted to maintain target heart rate (70%-80% of the HRR).	Patients randomized to the control group received usual care including the standard advice to remain physically active.

Treskes et al. 2020[141]	In the intervention group, the 1-month and 6-month follow-up visits were replaced by an electronic visit (e-visit). This e-visit consisted of a patient interview done via a secured video connection. Patients used a tablet, smartphone, or computer. Via internet, both nurse practitioner and patients logged into a virtual meeting room. The e-visits were performed by the same nurse practitioner as the regular outpatient clinic visits. The content of the patient interview was comparable to that of the regular outpatient clinic visit. The smart technology intervention included 4 smartphone-compatible devices: a BP monitor (Wireless Blood Pressure Monitor; Withings), a step counter (Pulse Ox; Withings), a weight scale (Smart Body Scale Analyzer; Withings), and a single-lead ECG device (Kardia; AliveCor Inc). The BP monitor is an oscillometric device. It is a preformed cuff that has to be applied to the bare upper arm. It communicates with the device-dedicated application (app) on the smartphone via Bluetooth. The inflation of the cuff has to be started in the app. Patients have to sit still with their upper arm on the same height as their chest. The measurement result is displayed in the app. As such, patients immediately can see their own BPs. Data are automatically transferred to and integrated in the department's electronic medical record. As such, results are available to any physician who is legally allowed to view an individual patient's electronic medical record. Devices have to be installed and synchronized the first time they are used. The step counter is a wristwatch that records the time and number of steps per day. These data, as well as data acquired by the weight scale, are sent to the app via Bluetooth. The single-lead ECG device is approximately the size of a credit card. It has 2 electrodes. To record a single-lead ECG, a patient has to position 2 fingers of the right hand to the right electrode and 2 fingers of the left hand to the left electrode. An ultrasound signal is generated and converted into an electrical signal in the smartphone, which is displayed as single-lead ECG on the smartphone screen. The ECG readings were sent to the hospital, where they were checked by a project dedicated health care professional with ample training, supervised by a consultant cardiologist. Patients were asked to record their steps continuously, their BP and weight daily, and their ECG daily and to record symptoms of possible cardiac origin. Data were reviewed daily by a project dedicated professional with ample training. Data were not	Regular follow-up (usual care)	

Study	Treatment 1	Treatment 2	Treatment 3
	continuously monitored. Therefore, the smart technology intervention was not a substitute for emergency care. Patients were contacted in case their systolic BP exceeded 139 mmHg or diastolic BP exceeded 89 mmHg. Patients were also contacted in case of newly diagnosed arrhythmias or at least 4 newly diagnosed symptomatic premature ventricular contractions on the single-lead ECG. All clinical data were stored in the departmental electronic patient files (EPD-Vision; Leiden University Medical Center).		
Blasco et al. 2011[143]	Patients randomized to the telemonitoring group were temporarily provided with an automatic sphygmomanometer (Omron M4-I; Omron Corporation, Kyoto, Japan), a glucose and lipid meter (Cardiochek, Polymer Technology System, Inc, Indianapolis, IN) and a cellular phone (Nokia 3510i, Nokia Corporation, Espoo, Finland). Patients, and support persons if needed, were taught to measure their blood pressure (BP), heart rate and weight (weekly), and glucose and lipids (monthly), and to send the results through their mobile phones following a structured questionnaire (Wireless Application Protocol session). A cardiologist accessed biological and clinical data via a secure Web application and, through this application, sent individualized short message service text messages with recommendations to the patients during the 12-month followup period. At exit, subjects in the telemedicine group completed an additional questionnaire to evaluate satisfaction with the program.	All patients received lifestyle counseling and usual-care treatment. Each patient met with his or her cardiologist for 3 clinical visits during the study period, and was provided with written recommendations and verbal information about CVD prevention.	

Study	Treatment 1	Treatment 2	Treatment 3
Frederix et al. 2015[144]	Patients were instructed to wear the accelerometer all day long during the study period and weekly upload their physical activity data on their personal computer by means of an USB-connection to their online patient account. Each patient received weekly personalised automated feedback on their physical activity by email or SMS. The program was designed to encourage the patient to increase his/her daily amount of steps with 10% each week from baseline.	All patients in the control group wore a modified motion sensor for seven consecutive days during te first, sixth and 18th week of the Telerehab II study period. These motion sensors were modified to hide all information from the patient. They wore the modified motion sensor all day long (also while exercising in the hospital's rehabilitation center) and were only allowed to take it off while asleep or bathing. All modalities of exercise training were allowed (walking, running, bicycle riding, etc.). The motion sensors registered activity data during all these exercise sessions. These patients did not upload their physical activity themselves, but they brought back their sensors to the hospital's rehabilitation center each time after these seven consecutive days where the medical staff uploaded the physical activity data. The patients did not receive feedback about their physical activity and had no access to the recorded physical activity.	

Study	Treatment 1	Treatment 2	Treatment 3
Kraal et al. 2017[142]	Patients in the home-based group received three supervised training sessions in the outpatient clinic, before they continued their training program in their home environment. During these sessions, patients were familiarised with training duration and intensity and their preferred training modality was discussed with a physical therapist and exercise specialist. In addition, they were instructed how to use a heart rate monitor with a chest strap (Garmin FR70) and how to upload recorded heart rate data to a web application (Garmin Connect) through the Internet. After the three training sessions, patients started their training program in the home environment. The heart rate monitor was used to record the exercise data and to evaluate training duration and intensity during the training. The web application was used by the patient, the physical therapist and the exercise specialist to review the data. Once a week the patient received feedback on training frequency, duration and intensity via telephone by the physical therapist. Motivational interviewing principles were used to enhance patients' motivation and encourage the development of self-management skills. After 12 weeks, the feedback was terminated, but the patients were encouraged to continue their training program with the heart rate monitor and web application.	Patients in the center-based group received group-based training in the outpatient clinic, supervised by two physical therapists specialised in cardiac rehabilitation. All patients received an individually tailored training program on a cycle ergometer and treadmill. During the final sessions of the training program, the physical therapist encouraged the participants to continue their physical activities in their home environment. Both groups participated in a training program of 12 weeks with at least two training sessions a week. Session duration was 45–60 min and all sessions were based on continuous training with an intensity of 70–85% of the maximal heart rate assessed during the cardiopulmonary exercise test at baseline.	
Lear et al. 2015[146]	vCRP: Participants randomized to the intervention were registered to the vCRP website with a unique username and password, and received an off-the-shelf heart rate monitor (Polar s610i) and a home blood pressure monitor (Lifesource UA779) for the intervention. Participants underwent a 30 minute in-person training session following their randomization on the use of the vCRP, heart rate monitor and blood pressure monitor. The vCRP included on-line intake forms (medical, risk factor and lifestyle forms), scheduled one-on-one chat sessions with the program nurse case manager, exercise specialist and dietitian (three times each during the 12 weeks), weekly education sessions in the form of interactive slide presentations, data capture for the exercise stress test and blood test results, progress notes (for health professionals), and monthly ask-an-expert group chat sessions.	Participants randomized to usual care (care from their primary care physician) were given simple guidelines for safe exercising and healthy eating habits, and a list of Internet-based resources. Apart from the study follow-up assessments, there was no contact between the study personnel and the usual care participants for the duration of the study, nor was there any attempt to control for the level of patient care.	

Study	Treatment 1	Treatment 2	Treatment 3
Mendelson et al. 2014[47]	Telemedicine: Patients assigned to telemedicine were oriented to CPAP, fitted with a nasal mask, and given an autotitrating machine. Patients received a smartphone with an application designed to transmit clinical information. The patients transmitted self-measured morning and evening BP (3-day measurements using the Omron 705CP), CPAP adherence, and subjective sleepiness weekly through a questionnaire-based application. Quality of life questionnaires were transmitted monthly. Patients received daily pictograms with diet and physical-activity related messages on their smartphones. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was reviewed. After 4 months of treatment, patients consulted their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.	Standard: Fitted with a nasal mask and given an autotitrating machine. Patients were contacted after 2 days to ask about adherence, side effects, and any problems encountered with the machine. After 4 weeks of treatment, patients met with their sleep specialist and information was transferred from their machines (adherence, mask leak, residual respiratory events). After 4 months of treatment, data were downloaded from the machine, and patients saw their sleep specialist and were re-evaluated. Patients also received a SenseWear Pro2 armband to measure daily physical activity.	

BP = blood pressure; CPAP = continuous positive airway pressure; CVD = cardiovascular disease; SMS = short message service; vCRP = virtual cardiac rehabilitation program

Table C-33. Coronary artery disease and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes prespecified and reported?	6 Were participants analyzed based on originally-assigned groups across timepoints?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Avila et al. 2020[623]; Avila et al. 2018[145]	+	?	?	?	+	?	+	-	+	High
Treskes et al. 2020[141]	?	?	+	+	+	+	?	-	+	Moderate
Blasco et al. 2011[143]	?	?	+	?	+	+	?	+	+	Moderate

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes prespecified and reported?	6 Were participants analyzed based on originally-assigned groups across timepoints?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Frederix et al.2015[144]	+	+	?	+	?	-	+	?	+	Moderate
Kraal et al. 2017[142]	+	+	?	+	+	+	?	-	+	Moderate
Lear et al. 2015[146]	?	?	?	-	+	+	?	+	+	High
Mendelson et al. 2014[47]	?	?	+	-	+	+	-	-	+	High

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; - solid red circle with a minus sign indicates high risk of bias

Table C-34. Coronary artery disease and PGHD: economic evaluation risk of bias

Study	1 Competing alternatives described?	2 Economic study design appropriate?	3 Important and relevant costs for alternatives identified?	4 Costs measured appropriately?	5 Costs valued appropriately?	6 Important and relevant outcomes for alternatives identified?	7 Outcomes measured appropriately?	8 Outcomes valued appropriately?	9 Incremental analysis of costs and outcomes of alternatives performed?	10 Future costs and outcomes discounted appropriately?	11 Sensitivity analysis?	Overall Risk of Bias
Kraal et al. 2017[142]	+	+	+	+	+	+	+	+	+	?	?	Low

 solid green circle with a plus sign indicates low risk of bias;  solid yellow circle with a question mark indicates unclear risk of bias;  solid red circle with a minus sign indicates high risk of bias

Table C-35. Coronary artery disease and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Avila et al. 2020[623] Avila et al. 2018[145]	Health	Quality of life	Short Form-36 total scores Home-based CR: baseline: 82.2 (SD: 13.3), 3 months: 82.6 (SD: 13), 12 months: 80 (SD: NR) Center-based CR: baseline: 79.8 (SD: 16.1), 3 months: 82.6 (SD: 15.8), 12 months: 83 (SD: NR) Usual Care: baseline: 73.3 (SD: 15.1), 3 months: 76.4 (SD: 16.4), 12 months: 77 (SD: NR) p-value for interaction (3 months) 0.57, (12 months) 0.70 p-value for group (3 months) 0.06, (12 months) NR	No
Treskes et al. 2020[141]	Health	Mortality (all-cause)	Intervention: 2 (2%); Control: 2 (2%); p>0.99	No
Treskes et al. 2020[141]	Health	Recurrent MI	Intervention: 2 (2%); Control: 2 (2%); p=0.62	No
Treskes et al. 2020[141]	Health	Hospitalization for heart failure	Intervention: 0 (0%;) Control: 1 (1%); p>0.99	No
Treskes et al. 2020[141]	Guiding Question 2	Adherence	Of all patients who finished the intervention, 32% sent measurements each week. In total, 63% sent measurements in more than 80% of all 52 weeks they participated in the trial.	Not applicable, only measured for intervention group.
Treskes et al. 2020[141]	Guiding Question 2	Acceptance	Of all patients in the intervention group, 90% indicated that they were satisfied with the smart technology intervention. Satisfaction with individual devices was 88%for the BP monitor, 88% for the weight scale, 4%for the step counter, and 89%for the ECG device.	Not applicable, only measured for intervention group.
Blasco et al. 2011[143]	Health	Mortality	Telemedicine arm: 0 deaths; Usual care arm: 5 deaths; p=0.029	Yes
Blasco et al. 2011[143]	Health	Quality of life	There were no significant differences between the scores obtained in SF-36 at the initial visit in the 2 groups and changes were not significant between groups. At 12 months, the SF-36 “physical health” scale showed a 2.8-point increase in the telemedicine arm (p=0.011) and a 1.5-point increase in the usual care arm (p=0.16). The change was smaller in the “mental health” scale, with a 0.5-point increase in the telemedicine arm (p=0.64) and a 0.5-point decrease (p=0.73) in the usual care arm.	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Blasco et al. 2011[143]	Guiding Question 2	Acceptability	Almost all patients (98%) completed more than 50% of wireless application protocol sessions and more than 83% completed more than 75% of them. Only 0.5 messages per patient were missed, due to the mobile phone being turned off. Familial support of the telemedicine group patients was analyzed in 4 different levels: never (58% of patients), only first week (10%), 1 month (7%), and always (25%).	Not applicable, only measured for telemedicine group.
Frederix et al.2015[144]	Health	Re-hospitalization	Intervention arm: 4 patients (12.5%); Control arm: 9 patients (26.5%); p=0.09	No
Kraal et al. 2017[142]	Health	Health-related quality of life	HRQOL total: mean (SD) Home-based CR: baseline: 5.62 (0.2), follow-up: 5.75 (0.10) Center-based CR: baseline: 5.45 (0.14), follow-up: 5.43 (0.12) p=0.609	No
Kraal et al. 2017[142]	Guiding Question 2	Adherence	After the three introductory sessions in the hospital, patients in the home-based group performed 22.0 +/- 6.8 sessions at home in the first 12 weeks (ranging from 13–41). Patients in the center-based group attended 20.6 +/- 4.3 training sessions (86% of the expected 24 sessions, ranging from 6–25) during CR at the outpatient clinic.	No
Kraal et al. 2017[142]	Guiding Question 2	Acceptability	Patients in the home-based group were more satisfied with their CR program compared to patients in the center-based group (home-based: 8.7/10, center-based: 8.1/10, p=0.02).	Yes
Kraal et al. 2017[142]	Cost-effectiveness	QALYs and societal costs	The QALYs calculated for the center-based group (0.78 +/- 0.08) were similar to the QALYs for the home-based group (0.77 +/- 0.13, p=0.73). From a societal perspective (i.e. the sum of healthcare and non-healthcare costs), costs per patient were 3160 lower for patients in the home-based group (95% CI: -460 to 6780, p=0.09).	No
Lear et al. 2015[146]	Health	Exercise capacity	Increase from baseline in total time on exercise stress test (seconds) vCRP arm: 45.7; Usual care: 0; p=0.045	Yes
Lear et al. 2015[146]	Health	Emergency room visit or major event	vCRP arm: 6 patients (18%); Usual care arm: 11 patients (30%); p=0.275	No
Mendelson et al. 2014[47]	Health	Quality of life	Telemedicine: 45.8±10.2 47.4±10.7 Standard: 44.8±11.1 46.4±9.1	No

CR = cardiac rehabilitation; HRQOL = health-related quality of life; MI = myocardial infarction; QALYs = quality associated life years; SD = standard deviation; SF-36 = short form 36; vCRP = virtual cardiac rehabilitation program

Table C-36. Heart failure and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Effects of Telemonitoring on the Outcome of Heart Failure Patients After an Incidence of Acute Decompensation https://ClinicalTrials.gov/show/NCT03358303	Recruiting	Heart Failure	Device: Medly	Michael Garron Hospital, Toronto, Ontario, Canada Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada Mt. Sinai Hospital, Toronto, Ontario, Canada
Daily Ambulatory Remote Monitoring System For Post-Dischage Management Of ADHF https://ClinicalTrials.gov/show/NCT03072693	Not yet recruiting	Heart Failure With Reduced Ejection Fraction	Procedure: Home-based remote heart failure management Procedure: Home-based physiological parameter recording only	NR

Table C-37. Heart failure and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Cichosz et al. 2019[151]	RCT	Denmark	NR	NR	299	52
Koehler et al. 2018[147]	RCT	Germany	August 13, 2013 to May 12, 2017	The authors used data for specific subgroups from the TIM-HF trial for sample size calculations. For the patient subgroup that mirrored the population they intended to include in the TIM-HF2 trial, 19 days were lost due to all-cause death or unplanned cardiovascular hospital admissions at 12 months in the usual care group, and 12 days were lost for patients in the remote patient management group, which corresponds to a 38% reduction. With an estimated pooled SD of 48, we calculated that 750 patients would be required in each group to detect this difference with a power of 80% and a two-sided α of 5%.	1571	52
Kulshreshtha et al. 2010[150]	RCT	USA	July 2006 to June 2007	NR	150	26
Ong et al. 2016[152]	RCT	USA	October 12, 2011 to September 30, 2013	Sample size was calculated based on the assumption that the control group would experience no change in the observed baseline 180-day readmission rate of 38%. A sample size of 1,500 (750 per arm) will provide 80% power to detect a relative reduction of 28% in the primary outcome with a significance level of 0.05, after adjusting for within-hospital clustering.	1437	26

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Scherr et al. 2009[148]	RCT	Austria	October 1, 2003 to April 29, 2008	The authors assumed that patients in the control arm would show an event rate of 30% over 6 months. For the telemedicine arm, they expected a 50% reduction of the event rate. To show a statistically significant difference at an error of 0.05 with a power of 80%, a sample size of 240 subjects was calculated.	120	26
Seto et al. 2012[149]	RCT	Canada	September 2009 to February 2010	A sample size calculation was based on the Self-Care of Heart Failure Index, using a population standard deviation of 20 and an effect size of 10 (effect size represents a clinically significant change of more than half a standard deviation) as determined in previous studies (alpha=0.05, power=0.8). We calculated the required sample size per group to be 34, and recruited 50 participants for the intervention group and 50 for the control group to compensate for the patients estimated as lost to follow-up, including due to mortality, over the six-month trial.	100	26

NR = not reported; RCT = randomized controlled trial; SD = standard deviation; TIM-HF = telemedical interventional management in patients with heart failure

Table C-38. Heart failure and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Cichosz et al. 2019[151]	Participants were qualified for inclusion if they had been diagnosed with HF according to national guidelines and were placed within the New York Heart Association (NYHA) class 2, 3, or 4. Patients should also have a permanent residence in Denmark and be motivated to use telehealth care. Motivation was assessed by the health care personnel by asking the patient prior to inclusion. Patients were excluded if they lacked a landline phone, a mobile phone or Global System for Mobile communications coverage. Patients not able to understand Danish adequately enough to complete the questionnaires and patients without the energy to participate were also excluded.	Median 69 years	19.1	Median NYHA score (IQR): 2 (2-3)	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Koehler et al. 2018[147]	Patients were eligible for inclusion if they had been admitted to hospital for worsening heart failure within 12 months before randomisation, were in functional New York Heart Association class II or III, had a left ventricular ejection fraction of 45% or lower (or if more than 45%, were being treated with oral diuretics). Patients were excluded if they had major depression (i.e., PHQ-9 score >9), were on haemodialysis, or had been admitted to hospital for any reason within 7 days before randomisation. In addition, patients with a left ventricular assist device or those who had undergone coronary revascularisation or cardiac resynchronisation therapy implantation within 28 days before randomisation were excluded, as were those who were scheduled for coronary revascularisation, transcatheter aortic valve implantation, mitral clip implantation, or cardiac resynchronisation therapy implantation 3 months after randomisation.	70 years	30	Mean LVEF: 41 (SD: 13) NYHA Class IV: 0.3%, Class III: 47.2%, Class II: 51.8%, Class I: 0.7%	No
Kulshreshtha et al. 2010[150]	Inclusion required current admission or recent discharge (within prior 2 weeks) from Massachusetts General Hospital with a primary diagnosis of HF, considered high risk for readmission (history of hospital readmissions for cardiac-related reasons or ejection fraction ≤20%), non-homebound, age over 18 years, not awaiting cardiac or renal transplant, English speaking, mentally competent (or willing primary caregiver), a working telephone line with a 3 prong electric outlet, and a Partners-affiliated physician or cardiologist (Partners HealthCare is an integrated health care system founded by Brigham and Women's Hospital and Massachusetts General Hospital in Boston).	66 years (remote monitoring arm), 70 years (usual care arm)	41.3	Mean ejection fraction (SD): RM participants: 0.39 (0.23) RM non-participants: 0.42 (0.21) Usual care: 0.37 (0.18)	No

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Ong et al. 2016[152]	Individuals admitted as hospital inpatients or on observation status were eligible if they were 50 years or older, were receiving active treatment for decompensated HF (defined as HF with the initiation of or an increase in diuretic treatment), were expected to be discharged to their home, and were capable of providing written informed consent in English, Spanish, Farsi, or Russian. Enrollment criteria were expanded in January 2012 to include all patients being actively treated for HF instead of just those having a principal diagnosis of HF. The study exclusions can be grouped into 3 main categories. First were patients who did not have the cognitive or physical ability (e.g., dementia or weight >204 kg) or access to resources (e.g., working telephone or usual source of care) required to participate fully in the BEAT-HF intervention. Second were patients already in a system of care providing more health professional contacts than the planned intervention (e.g., living in a skilled nursing facility, receiving chronic hemodialysis, or awaiting or having received an organ transplant). Third were patients whose HF was due to a cardiovascular condition that was expected to improve because of medical intervention (e.g., percutaneous coronary intervention or interventional valve procedure during hospitalization).	Median 73 years (intervention group), 74 years (usual care group)	46.9	Ejection fraction mean: 42.85%	No
Scherr et al. 2009[148]	Patients were eligible for the study if they met all of the following inclusion criteria: acute worsening of heart failure (acute cardiac decompensation) with hospital admission lasting >24 hours within the last 4 weeks, treatment according to the guidelines of the European Society of Cardiology with an angiotensin converting enzyme inhibitor or an angiotensin receptor blocker, diuretic, and beta-blocker (except in cases with documented intolerance to beta-blockers). Initially, patients older than 18 years and younger than 75 years were eligible; the latter was amended to 80 years after 4 months of recruitment. Patients with one of the following conditions were not eligible for MOBITEL: unstable coronary artery disease with revascularization within the last 6 months, planned revascularization (percutaneous or surgical) for coronary artery disease, planned heart valve surgery, planned or completed heart transplantation, uncontrolled arterial hypertension, acute myocarditis, inability to read the display of a handheld phone, or malignancy.	Median 66 years	29.2	Median LVEF (IQR): Telemedicine arm: 25 (20-38) Usual care arm: 29 (21-36) NYHA Class II: 13%, Class III: 64.8%, Class IV: 22.2%	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Seto et al. 2012[149]	Eligible participants were ambulatory patients diagnosed with heart failure. Other eligibility criteria included 18 years of age or older, ability to speak and read in English, not on the heart transplantation list, an expected survival of greater than one year, and a left ventricular ejection fraction (LVEF) less than 40%.	53.7 years	21	Mean LVEF: 27 NYHA Class II: 43%, Class II/III: 11%, Class III: 42%, Class IV: 4%	No

BEAT-HF = Better Effectiveness After Transition–Heart Failure; HF = heart failure; LVEF = left ventricular ejection fraction; MOBITEL = MOBIle TELemonitoring in Heart Failure Patients Study; NYHA = New York Heart Association; SD = standard deviation

Table C-39. Heart failure and PGHD: treatment details

Study	Treatment 1	Treatment 2	Treatment 3
Cichosz et al. 2019[151]	Patients in the intervention group received telehealth care in addition to usual practice. The telehealth care solution, the Telekits, consisted of a standard tablet (Samsung Galaxy Tab2) that facilitated data collection from a disease-specific questionnaire andBluetooth linkage with two external devices. The external devices included a digital blood pressure monitor (Model UA-767, plus BT-C, Nonin Medical, MN, USA) and a scale (Precision Health Scale, UC321PBT-C, A & D Medical, Tokyo, Japan) that collected disease-specific data (blood pressure, pulse and weight) and wirelessly transmitted these data to a central clinical system. In addition, the patients' responses to a disease-specific questionnaire, which was developed by clinical domain experts in the North Denmark Region, were set up in an application on the tablet and transmitted to the clinical system. The tablet actively reminded patients when it was time to take measurements and answer the questionnaire. Patients were asked to use the scale and blood pressure monitor daily during the first 2 weeks and one to two times weekly after the first 2 weeks. Specially trained nurses assessed all the data in the clinical system. Data assessment comprised the following elements: that the data were seen, interpreted and evaluated to determine whether there was a need for specific action.	Patients assigned to the control group received usual practice only. This involved usual treatment, monitoring, and care throughout the study period. The patients' general practitioners or the outpatient health care centres provided this treatment and monitoring. As part of usual care, HF patients in the North Denmark Region were offered rehabilitation involving dietary advice, training, closely monitored up-titration of medicine if necessary (ACE Inhibitors, beta-blocker, Spiron and more), screening for risk factors and conversation about lifestyle changes in relation to the disease. The rehabilitation took 3–6 months, based on the patient's needs. The intervention groups received usual care as well.	

Study	Treatment 1	Treatment 2	Treatment 3
Koehler et al. 2018[147]	The remote patient management intervention consisted of the following: a daily transmission of bodyweight, systolic and diastolic blood pressure, heart rate, analysis of the heart rhythm, peripheral capillary oxygen saturation (SpO2) and a self-rated health status (scale range one to five) to the telemedical centre; a definition of a patient's risk category using the baseline and followup visit biomarker data in combination with the daily transmitted data; patient education; and co-operation between the telemedical centre, and the patient's GP and cardiologist. The telemonitoring system, which was installed in the patient's home within 7 days after randomisation, was a multicomponent system with a three-channel electrocardiogram (ECG) device to collect either a 2 min or streaming ECG measurements (PhysioMem PM 1000,GETEMED Medizin und Informationstechnik AG, Teltow, Germany); a blood pressure measuring device (UA767PBT, A&D Company Ltd, Tokyo, Japan); and weighing scales (Seca 861, seca GmbH & Co KG, Hamburg, Germany). SpO2 was collected using Masimo Signal Extraction Technology (Masimo Europe Ltd, Puchheim, Germany).	Patients allocated to the usual care group were followed up in accordance with the current guidelines for the management and treatment of patients with heart failure. Throughout the study follow-up, the patient's GP and cardiologist were free to adjust or prescribe treatments in accordance with the patient's clinical condition.	
Kulshreshtha et al. 2010[150]	Remote monitoring participants. Patients were instructed to transmit monitor readings including weight, blood pressure, pulse, and pulse oximetry on a daily basis. The Remote monitoring equipment included VitelNet, FDA-approved devices: a UA 767PC Turtle 400 monitor, a LifeSource digital weight scale, an A&D blood pressure/pulse cuff and meter, and a BCI pulse oximeter device (UC-321PBT).Patient data were transferred securely via telephone service to the Internet. They also answered a set of symptom-related questions including changes in shortness of breath or swelling. The RM nurse made weekly phone calls to the patients to provide additional instruction as needed, monitor adherence to the RM program, and solicit patient feedback about the program. The skilled nursingportion of the telephone call included evaluation of the RM readings and a telephone assessment of the patient. The RM nurse further evaluated patients who experienced clinical signs or symptoms of a worsening condition.	Remote monitoring non-participants. Same as usual care. These patients were offered remote monitoring but refused it.	Usual care. Standard care was provided during the duration of the trial, but there was no description of standard care.

Study	Treatment 1	Treatment 2	Treatment 3
Ong et al. 2016[152]	The BEAT-HF intervention consists of three components: pre-discharge heart failure education, regularly scheduled telephone coaching, and home telemonitoring of weight, blood pressure, heart rate, and symptoms. The telemonitoring equipment consists of the FDA-approved Ideal Life PodTM, a Bluetooth enabled wireless gateway, the Ideal Life BodyManager (weight scale), and the Ideal Life BP-Manager, a blood pressure/heart rate monitor integrated with a device that displays text questions and sends simple text responses.	After randomization, the site nurse gives patients in the usual care (control) arm a study binder that contains a one page summary of the study, a checklist for completion of the 7-day, 30-day and 180-day telephone surveys, a copy of the upcoming 7-day survey, and copies of their consent and HIPAA authorization forms. Control patients have no further contact with site study nurses or call center nurses. However, they may be exposed to other readmission reduction or chronic disease management programs implemented by hospitals, physician groups, or health plans, such as education about heart failure, pharmacist consultation, and post-discharge telephone calls.	
Scherr et al. 2009[148]	The telemonitoring equipment consisted of three commercially available components: (1) a mobile phone (Nokia 3510, Finland), (2) a weight scale with 0.1 kg accuracy and electronic display (Soehnle creta, Germany), and (3) a sphygmomanometer for fully automated measurement of blood pressure and heart rate (BosoMedicus, Bosch&Sohn, Germany). Tele group patients were trained in measurement of blood pressure and weight using the equipment prior to discharge home. Furthermore, tele group patients were instructed by a study technician in the use of the mobile phone. Tele group patients were asked to measure vital parameters (blood pressure, heart rate, body weight) on a daily basis at the same time, preferably in the morning after emptying the bladder and before dressing and taking medication. Thereafter, patients were advised to enter these values as well as their dosage of heart failure medication into the mobile phone's Internet browser and send them to the monitoring center provided by the Austrian Institute of Technology – Information Management & eHealth, Graz. Study physicians had access to a secure website providing both numerical and graphical depiction of data for each patient. Whenever necessary, study physicians could contact patients using the mobile phone. Patients also received usual care (pharmacological treatment).	Pharmacological treatment.	

Study	Treatment 1	Treatment 2	Treatment 3
Seto et al. 2012[149]	The participants in the telemonitoring group received the telemonitoring system in addition to standard care. They were asked to use the telemonitoring system for 6 months to take daily morning weight and blood pressure readings as well as weekly single-lead ECGs if provided with an ECG recorder. They were also asked to answer daily morning symptom questions on a mobile phone. Only the 17 patients who did not have an implantable cardioverter defibrillator (ICD) were provided with an ECG recorder because the recorder was not certified for use with ICDs. Patients were also told to report their symptoms through the mobile phone if they did not feel well during the day. The patients in the telemonitoring group were given an individual training session on how to use the system during the recruitment session, and were provided with technical support by telephone throughout the study. The daily measurements took about 5 minutes each morning. The weight and blood pressure readings (UA UC-321PBTweight scale and UA-767PBT blood pressure monitor, A&D Medical, USA) and ECG recordings (SelfCheck ECG PMP4, CardGuard, Israel) were automatically sent wirelessly via Bluetooth to a mobile phone (BlackBerry Pearl 8130, Research in Motion, Canada) and then to the data repository at the hospital. Patients also answered symptom questions (mainly yes/no) through the mobile phones.	The standard care group received standard care at the UHN Heart Function Clinic, which includes visiting the clinic between once every 2 weeks to once every 3 to 6 months, depending on the severity of the patient's heart failure condition and the need for optimizing their medication. Standard care also includes heart failure education during preliminary visits at the Heart Function Clinic and the ability to telephone the clinic as necessary. Participants in the standard care group were not contacted again regarding the study until the end of the trial.	

ACE = angiotensin-converting enzyme; BEAT-HF = Better Effectiveness After Transition, Heart Failure; ECG = electrocardiogram; GP = general practitioner; HF = heart failure; HIPAA = Health Insurance Portability and Accountability Act; RM = remote monitoring

Table C-40. Heart failure and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes prespecified and reported?	6 Were participants analyzed based on originally-assigned groups across timepoints?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Cichosz et al. 2019[151]	?	?	+	+	+	+	−	−	+	High
Koehler et al. 2018[147]	+	+	+	−	+	?	+	?	+	Moderate
Kulshreshtha et al. 2010[150]	−	?	?	+	+	+	−	?	+	High
Ong et al. 2016[152]	+	?	+	−	+	+	−	+	+	Moderate
Scherr et al. 2009[148]	+	?	+	+	+	+	?	?	+	Moderate
Seto et al. 2012[149]	+	+	+	+	+	?	?	−	+	Moderate

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-41. Heart failure and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Cichosz et al. 2019[151]	Health	Quality of life (physical component summary)	SF-36 PCS mean (SD) change score Telekit arm: 0.45 (8.4) Usual care arm: 1.23 (7.1)	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Cichosz et al. 2019[151]	Health	Quality of life (mental component summary))	SF-36 MCS mean (SD) change score Telekit arm: 3.81 (10.7) Usual care arm: -0.96 (10.8) p<0.01	Yes
Cichosz et al. 2019[151]	Health	Quality of life (disease-specific instrument)	KCCQ12 mean (SD) change score Telekit arm: 4.19 (17) Usual care arm: 0.72 (17.7)	No
Koehler et al. 2018[147]	Health	All-cause mortality	Remote patient management: 61 (8%) Usual care: 89 (12%) p=0.028	Yes
Koehler et al. 2018[147]	Health	Cardiovascular mortality	Remote patient management: 39 (5%) Usual care: 59 (8%) p=0.056	No
Koehler et al. 2018[147]	Health	Quality of life	Change in MLHFQ global score (baseline to 12 months) Remote patient management: -3.08 (95% CI: -4.42 to -1.75) Usual care: -1.98 (95% CI: -3.34 to -0.61) p=0.26	No
Koehler et al. 2018[147]	Health	Hospitalization for unplanned cardiovascular cause or death	Remote patient management: 235 (35%) Usual care: 290 (38%) p=0.046	Yes
Koehler et al. 2018[147]	Guiding Question 2	Adherence	For patients randomly assigned to receive remote patient management, 743 (97%) were at least 70% compliant with the daily transfer of data to the telemedical centre.	Not applicable, reported only for PGHD arm.
Kulshreshtha et al. 2010[150]	Health	Hospital readmission (all-cause)	Remote monitoring (includes participants and non-participants): mean 0.69 (SD: 0.96) Usual care: mean 0.73 (SD: 1.51) p=0.46	No
Kulshreshtha et al. 2010[150]	Health	Hospital readmission (heart failure-related)	Remote monitoring (participants and non-participants): mean 0.30 (SD: 0.73) Usual care: mean 0.38 (SD: 1.06) p=0.50	No
Kulshreshtha et al. 2010[150]	Health	Emergency room visits (all cause)	Remote monitoring (participants and non-participants): mean 0.74 (SD: 1.04) Usual care: mean 0.57 (SD: 1.43) p=0.06	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Kulshreshtha et al. 2010[150]	Health	Emergency room visits (heart failure-related)	Remote monitoring (participants and non-participants): mean 0.30 (SD: 0.66) Usual care: mean 0.25 (SD: 1.02) p=0.12	No
Kulshreshtha et al. 2010[150]	Guiding Question 2	Acceptability	On completion of the program, 20 of 42 subjects in the RM arm returned the satisfaction survey (response rate 48%). All these participants reported high level of satisfaction, with 93% respondents agreeing that the equipment was easy to use; the program improved their HF control; the program helped them stay out of hospital. All (100%) respondents reported that the equipment was simple and easy to use and the program made them feel more in control of their health. The majority of respondents (80%) also believed that the program should continue longer.	Not applicable, only measured in the remote monitoring arm.
Ong et al. 2016[152]	Health	Hospital readmission	BEAT-HF: 180-day readmission: 363 patients (50.8%) Usual care: 180-day readmission: 355 (49.2%) p=0.39	No
Ong et al. 2016[152]	Health	Mortality	BEAT-HF: 180-day mortality: 100 patients (14%) Usual care: 180-day mortality: 114 patients (15.8%) p=0.30	No
Ong et al. 2016[152]	Health	Quality of life	MLHFQ score BEAT-HF: mean 28.5 Usual care: mean 32.63 p=0.02	Yes
Scherr et al. 2009[148]	Health	Cardiovascular mortality or rehospitalization for worsening heart failure	Intention-to-treat analysis MOBITEL arm: 11 (17%) Usual care arm: 18 (33%) p=0.06 (per-protocol analysis p-value 0.04)	No
Scherr et al. 2009[148]	Guiding Question 2	Adherence	On 7554 out of 7962 cumulative monitoring days, at least one set of values was sent, which indicates a patient adherence rate of 95%.	Not applicable, only measured in the MOBITEL group.
Scherr et al. 2009[148]	Process	Physician adjustment of medication	There were 375 alerts sent to study physicians in cases of exceeding predefined thresholds for body weight or exceeding the dynamic threshold of ±2 kg in 2 days. Consequently, tele group patients were contacted 170 times. In 55 of those times, an adjustment of heart failure medication was made.	Not applicable, only measured in the MOBITEL group.

Study	Outcome Category	Outcome	Results	Statistical Significance
Seto et al. 2012[149]	Health	Quality of life	Quality of life (MLHFQ mean score) Telemedicine: baseline: 50.3 (SD: 29.1), 6 months: 41.4 (SD: 26.7) Usual care: baseline: 47.8 (SD: 22.6), 6 months: 47.3 (SD: 23.4) p=0.05	Yes
Seto et al. 2012[149]	Health	Mortality	Telemedicine: 3 deaths Usual care: 0 deaths	No
Seto et al. 2012[149]	Health	Hospitalization	Mean (SD) hospital admissions Telemedicine: 0.5 (0.8) Usual care: 0.2 (0.4) p=0.10	No
Seto et al. 2012[149]	Health	Emergency department visits	Mean (SD) ED visits Telemedicine: 0.4 (0.9) Usual care: 0.3 (0.5) p=0.60	No
Seto et al. 2012[149]	Guiding Question 2	Adherence	About 42, 33, and 16 out of the 50 telemonitoring group patients (84%, 66%, and 32%) completed at least 91 (50%), 146 (80%), and 173 (95%) of possible daily readings over the six months, respectively.	Not applicable, only reported for telemedicine group.

BEAT-HF = Better Effectiveness After Transition–Heart Failure; CI = confidence interval; ED = emergency department; HF = heart failure; KCCQ = Kansas City Cardiomyopathy Questionnaire; MLHFQ = Minnesota Living with Heart Failure Questionnaire; MOBITEL = MOBIle TELemonitoring in Heart Failure Patients Study; SD = standard deviation; SF-36 MCS = short form 36 mental component score; SF-36 PCS = short form 36 physical component score

Table C-42. Cardiac arrhythmia and PGHD: Trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Pulsewatch: Smartwatch Monitoring for Atrial Fibrillation After Stroke https://ClinicalTrials.gov/show/NCT03761394	Recruiting	Stroke, Atrial Fibrillation	Device: Testing Devices Device: Cardea Solo by Cardiac Insight Device: Kardia Mobile by AliveCor	UMass Memorial Medical Center, Worcester, Massachusetts, United States
mHealth Screening to Prevent Strokes https://ClinicalTrials.gov/show/NCT02506244	Active, not recruiting	Atrial Fibrillation	Device: iRhythm ZIO XT Patch Device: Wristband by Amiigo	Scripps Translational Science Institute, La Jolla, California, United States
Feasibility Study to Improve AF Outcomes Using a Digital Application for CV Risk Reduction https://ClinicalTrials.gov/show/NCT04050982	Recruiting	Atrial Fibrillation	Device: AF CARE Behavioral: Usual Care	Stanford Health Care, Stanford, California, United States
CardioSenseSystem Compared Study Regarding Efficacy and Safety in the Monitoring of ECG https://ClinicalTrials.gov/show/NCT03610529	Not yet recruiting	Cardiac Arrythmias, Unstable Angina, Heart Valve Disorders, Disorder of Aorta	Device: CardioSenseSystem Device: Philips Intellivue	VO Thorax o Karl Region Skane, Lund, Entregatan 7, Sweden
The Application of Internet+ Home-based Cardiac Rehabilitation in Atrial Fibrillation Patients After RFCA https://ClinicalTrials.gov/show/NCT04414007	Recruiting	Atrial Fibrillation	Home-based cardiac rehabilitation program through Internet platform and intelligent wearable devices.	Nanjing Medical University, Nanjing, Jiangsu, China

Table C-43. Cardiac arrhythmia and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Caceres et al. 2020[621] Goldenthal et al. 2019[153]	RCT	USA	NR	The study was designed to have 80% power to detect a hazard ratio of 2 for recurrence detection (α=0.05). Analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).	238	24
Halcox et al. 2017[160]	RCT	UK	NR	The study sample size was based on the incidence of approximately 1.5 per 1000 per year reported in routine care of the 60/65 year group in a regional UK study**.** In comparison with this population, the authors assumed a four-fold increase due to selecting a high risk group, but also a 2-fold reduction in routine reporting in our study area, hence an expected 3 per 1000 in the routine arm. They expected considerable under-reporting overall, with an effect size leading to up to 30 per 1000 if the iECG was used. They recommended 500 participants per study arm based on these figures, which would generate 92% power to detect a significant different (at 5%) between the rates (calculated using PS: Power and Sample Size Calculation version 3.1.2, 2014). This sample size also generated high power under the scenarios of limited loss to follow up and/or the possibility of smaller than expected effect size (e.g., a 5-fold effect size would require 480 per group for 80% power).	1004	52
Reed et al. 2019[155]	RCT	UK	July 4, 2016 to January 9, 2018	Using a symptomatic rhythm detection rate at 90 days of 25% versus standard care (10%), the authors estimated that 110 participants in each group would have 80% power to determine an absolute 15 percentage point improvement in symptomatic rhythm detection. They aimed to recruit an extra 10% in each group to allow for drop out (i.e., 121 participants in each group).	242	12
Stavrakis et al. 2017[154]	RCT	USA	November 2013 until June 2015	NR	58	Median 80 (IQR 56 to 88)

ECG = electrocardiogram; IQR = interquartile range; NR = not reported; RCT = randomized controlled trial

Table C-44. Cardiac arrhythmia and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Caceres et al. 2020[621] Goldenthal et al. 2019[153]	Inclusion criteria were age 18 and older with a history of documented AF and at least one AF risk factor (sedentary lifestyle, obesity, hypertension, smoking, and diabetes). Patients also needed to express willingness to participate for the full 6-month duration of the trial and demonstrate an ability to use a smartphone, send and receive text messages, and successfully use the AliveCor KardiaMobile ECG monitor (AliveCor). Patients with a history of cognitive impairment and those unwilling to have their clinical data collected or receive text messages were excluded from the study.	61 years	22.7	Persistent AF: 34.5% of patients Paroxysmal AF: 65.5% of patients	No
Halcox et al. 2017[160]	Individuals >65 years of age with a CHADS-VASc score ≥2 not in receipt of OAC therapy without a known diagnosis of AF currently, a known contraindication to anticoagulation, or permanent cardiac pacing implantation were recruited. Participants were required to have access to the internet via WiFi and to be able to operate the AliveCor Kardia system (AliveCor Inc, Mountain View, CA) attached to an iPod (Apple Inc, Cupertino, CA) after simple instruction.	72.6 years	53.4	CHADS-VASc score mean: 3.0 (SD: 1.0)	No
Reed et al. 2019[155]	Inclusion criteria were: 1. Participant aged 16 years or over 2. Participant presenting with an episode of palpitations or pre-syncope with no obvious cause 3. Participant's underlying ECG rhythm during these episodes remains undiagnosed after clinical assessment Exclusion criteria were: 1. Prior diagnostic ECG 2. Palpitations or pre-syncope present during an admission ECG 3. Frequent episodes (i.e., at least once a day) 4. Participants under 16 years of age 5. Previous participation in the study 6. Alcohol/illicit drugs/seizure/stroke/transient ischaemic attack/head trauma/ hypoglycaemia as presumptive cause 7. Inability or unwilling to give informed consent 8. Participants with recent (i.e., within 3 months) myocardial infarction, severe heart failure (New York Heart Association class 4) or unstable angina 9. Participants unwilling or unable to use the AliveCor Heart Monitor and AliveECG app 10. Participants without a compatible smartphone or tablet 11. Participants with cardiac pacemakers or other implanted electronic devices 12. No telephone number for follow-up 13. Participant in custody	39.6 years	56.6	Number of episodes palpitations or pre-syncope in last 24 h/median (IQR): 1 (1 to 3)	NR

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Stavrakis et al. 2017[154]	Patients with paroxysmal AF, documented by ECG, implantable device electrogram, or Holter monitor, within 6 months of randomization on two separate occasions, at least 1 day apart, were eligible for enrollment. In addition, patients were required to have at least one additional risk factor for stroke, including left ventricular ejection fraction ≤40% or symptomatic heart failure, age ≥75, diabetes, hypertension, or age ≥65 with documented coronary artery disease. Patients were excluded if they had any of the following: prior stroke or transient ischemic attack, prosthetic valve or hemodynamically significant valve disease, reversible causes of AF, severe renal impairment (estimated creatinine clearance 30 mL/min or less), active liver disease, anemia (hemoglobin less than 10 g/dL) or thrombocytopenia (platelets less than 100 × 109/L), and pregnancy or nursing.	61.7 years	43	CHA2DS2-VASc score mean: 2.6±1.2	No

AF = atrial fibrillation; ECG = electrocardiogram; IQR = interquartile range; OAC = oral anticoagulation

Table C-45. Cardiac arrhythmia and PGHD: treatment details

Study	Treatment 1	Treatment 2	Treatment 3
Caceres et al. 2020[621] Goldenthal et al. 2019[153]	iHEART AliveCor KardiaMobile Patients randomized to the iHEART intervention received an iPhone and cellular service plan with unlimited data/text messaging, and the AliveCor KardiaMobile ECG monitor for 6 months. If they already owned a smartphone compatible with the KardiaMobile device, they had the option to use the KardiaMobile device with their own phone. Patients also received motivational text messages three times per week relating to management of AF and risk factors (e.g., obesity, sedentary lifestyle), for example, "Limit sugary drinks to no more than 36 oz a week." Patients were trained on how to use the phone; how to use the Kardia application, which connects to the KardiaMobile device to record ECGs; and how to record ECGs and symptoms using the KardiaMobile device. Patients were instructed to record a daily ECG and additional ECGs whenever they experienced symptoms perceived to be associated with an atrial arrhythmia. Upon discovery of any arrhythmia, patients contacted their health-care provider, and all treatment, management, and follow-up for the arrhythmia were determined by the patient's provider.	Standard of care (participants in the usual care group received guideline-directed medical care defined by the treating cardiologist and evidence-based clinical guidelines for the management of AF) with no additional monitoring.	
Halcox et al. 2017[160]	iPod ECG Participants in the intervention iECG arm were instructed to undertake twice-weekly recording and transmission of a 30-second single-lead iECG trace to a secure server (Monday and Wednesday recommended, plus additional submissions if symptomatic) over a 12-month period. iECG traces were analyzed by an automated analysis software algorithm (AliveCor version 2.2.0 [build 21]) and sent for offline analysis by a physiologist-led electrocardiographic reading service (Technomed Ltd UK). Abnormal ECGs were overread by a cardiologist. Clinical review and appropriate care was arranged for those with clinically significant arrhythmia.	Usual care. Patients in the usual care arm were followed up as normal by their general practitioner.	

Study	Treatment 1	Treatment 2	Treatment 3
Reed et al. 2019[155]	AliveCor Usual care plus the use of a smartphone-based event recorder. All intervention group participants were given an AliveCor Heart Monitor and trained in the use of the device and app in the ED or AMU by the research team. If a participant allocated to the intervention group had an episode of palpitations or pre-syncope and was able to record an AliveCor Heart Monitor ECG during the episode, the participant emailed the ECG at a convenient time to the secure (nhs.net) email address of the coordinating Edinburgh research team. This email included a Portable Document Format (pdf) file attachment of the ECG tracing along with the participant's AliveCor app login (which was their study number; no identifiable participant data left the local site). The AliveCor app rhythm analysis algorithm automatically reported any ECG recorded as Normal, Atrial Fibrillation or Unclassified. The duty Consultant Emergency Physician at the coordinating Edinburgh centre along with a trial team Emergency Physician reviewed the ECG. The central study team contacted the local study team to arrange follow-up if required. In cases of disagreement, the central cardiology team were contacted for further opinion. If specialist follow-up of the ECG tracing was not required, the local study team wrote to the participant informing them and asked them to arrange follow-up with their general practitioner (GP) who was also contacted with the report. Participants continued to record ECGs for the duration of the study period, but the participant and GP were not contacted again if participants recorded further ECGs that similarly did not require specialist follow-up. If the participant's ECG recorded a serious cardiac arrhythmia, (i.e., ventricular tachyarrhythmia, complete or 3rd degree heart block, second degree heart block type II (assumed to be symptomatic given the participant had chosen to record an ECG during the episode), pause N6 s, symptomatic bradycardia b40 beats/min) during the study period, the central study team contacted the local study team who alerted the participant immediately by telephone, and referred them urgently to their local ED or cardiac electrophysiology service (as per local protocol). Participants were asked to use a participant symptom diary to record any symptoms and include time and date, type of symptom and whether they were able to record an ECG during the symptoms. They returned this diary to the local study team along with the participant satisfaction and compliance questionnaire, and smartphone-based event recorder at the end of the 90 days in a pre-paid stamped, addressed envelope. Participants failing to do this were reminded by phone.	Standard care (not described).	

Study	Treatment 1	Treatment 2	Treatment 3
Stavrakis et al. 2017[154]	Intermittent anticoagulation (+ ECG monitoring) Patients in the intermittent anticoagulation group were provided with an iPhone-based rhythm monitoring device and were instructed to transmit a daily 30-s ECG rhythm strip at approximately the same time of the day, as well as when experiencing symptoms of AF. If AF was detected, as confirmed by one of the investigators, the patients were instructed to start anticoagulation immediately. By doing so, patients started anticoagulation within 24 h after the onset of AF. To increase compliance of the participants with daily rhythm monitoring, an automatic daily reminder was programmed through their iPhones. In addition, patients who did not transmit their rhythm for two consecutive days received a reminder call from one of the investigators. When AF was detected based on rhythm monitoring, patients received anticoagulation for 48 h to 1 week, according to a prespecified algorithm, depending on the duration of the AF episode, to account for atrial stunning.	Continuous anticoagulation. Patients in the continuous anticoagulation group received one of the NOACs, with the choice of the NOAC left to the discretion of the referring physician. Patients who were previously on warfarin were started on one of the NOACs after their INR fell to about 2.0.	

AF = atrial fibrillation; ECG = electrocardiogram; ED = emergency department; iHEART = iPhone Helping Evaluate Atrial fibrillation Rhythm through Technology; INR = international normalized ratio; NOAC = non-vitamin K antagonist oral anticoagulant

Table C-46. Cardiac arrhythmia and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes prespecified and reported?	6 Were participants analyzed based on originally-assigned groups across timepoints?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Caceres et al. 2020[621] Goldenthal et al. 2019[153]										High
Halcox et al. 2017[160]										Moderate
Reed et al. 2019[155]										Low
Stavrakis et al. 2017[154]										High

 solid green circle with a plus sign indicates low risk of bias;  solid yellow circle with a question mark indicates unclear risk of bias;  solid red circle with a minus sign indicates high risk of bias

Table C-47. cardiac arrhythmia and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Caceres et al. 2020[621];	Health	Health-related quality of life	Atrial Fibrillation Effect on Quality of Life-Global Difference between groups (baseline to 6 months): 7.3 (SE: 4.3), p=0.09 Short-Form Health Survey – Physical Component Difference between groups (baseline to 6 months): 1.2 (SE: 1.3), p=0.37 Short-Form Health Survey – Mental Component Difference between groups (baseline to 6 months): -0.5 (SE: 1.4), p=0.74 EuroQol-5D Index Difference between groups (baseline to 6 months): 0.0 (SE: 0.03), p=0.98	No
Goldenthal et al. 2019[153]	Health	Hospitalization (all-cause)	iHEART arm: 45; Usual care arm: 56	No
Goldenthal et al. 2019[153]	Health	Emergency room visits (all-cause)	iHEART arm: 3; Usual care arm: 13	No
Goldenthal et al. 2019[153]	Guiding Question 2	Adherence	41 patients (36%) recorded greater than 180 times, on average once per day, and 77 (67%) used the device in the last month of their study period. 93 (81%) averaged transmission at least once per week and 86 (75%) used the device in the second half of the study.	Not applicable, only measured for iHEART arm.
Halcox et al. 2017[160]*	Health	Mortality	iPod ECG arm: 3 deaths; Usual care arm: 5 deaths; p=0.51	No
Halcox et al. 2017[160]*	Health	Stroke/TIA	iPod ECG arm: 6 stroke/TIA events; Usual care arm: 10 stroke/TIA events; p=0.34	No
Halcox et al. 2017[160]*	Health	DVT/PE	iPod ECG arm: 3 DVT/PE; Usual Care arm: 1 DVT/PE; p=0.31	No
Halcox et al. 2017[160]*	Health	Clinically significant bleeding	iPod ECG arm: 2 bleeds; Usual Care arm: 1 bleed; p=0.56	No
Halcox et al. 2017[160]*	Surrogate	Time to arrhythmia detection	Log-rank p=0.004 (Mantel-Cox) favoring iPod ECG over Usual Care for shorter time to arrhythmia detection.	Yes
Halcox et al. 2017[160]*	Process	Medication changes	Patients diagnosed with AF in the iECG arm were all treated promptly with anticoagulation (9 with warfarin and 10 with a NOAC). In the control arm, 3 were treated with warfarin, 1 with NOAC, and 1 with clopidogrel.	Unclear, no statistical analysis reported.
Reed et al. 2019[155]	Health	Mortality (all-cause)	AliveCor arm: 0 deaths; Usual Care arm: 1 death	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Reed et al. 2019[155]	Health	Major adverse cardiac events	AliveCor arm: 0; Usual care arm: 1	No
Reed et al. 2019[155]	Health	ED visits	There were more ED presentations (after index visit) due to palpitations/pre-syncope in the AliveCor group (12/124, 9.7%, 95% CI: 4.5 to 14.9% with 1 or more non-index ED presentations) compared to the control group (3/116, 2.6%, 95% CI: 0.0 to 5.5%, p=0.031).	Yes
Reed et al. 2019[155]	Surrogate	Time to arrhythmia detection	Mean time to symptomatic arrhythmia detection: AliveCor arm: 9.5 days (SD 16.1 days); Usual care arm: 42.9 days (SD 16 days), p<0.0001.	Yes
Reed et al. 2019[155]	Guiding Question 2	Acceptability	Eighty of 92 (87.0%) participants found the AliveCor monitor easy to use.	Not applicable, only measured in AliveCor arm.
Reed et al. 2019[155]	Process	Medication initiation	At 90 days, 12 participants in the intervention group were subsequently undergoing (or planning to undergo) treatment for symptomatic cardiac arrhythmia versus 6 in the control group (p=0.192).	No
Stavrakis et al. 2017[154]	Health	Mortality	Intermittent arm: 2 non-cardiac deaths; Continuous arm:1 non-cardiac death, 1 cardiac death; p-value not reported	No
Stavrakis et al. 2017[154]	Health	Stroke	Intermittent arm: 0 strokes; Continuous arm: 1 stroke; p=0.32	No
Stavrakis et al. 2017[154]	Health	Major bleeding	Intermittent arm: 1 bleed; Continuous arm: 2 bleeds; p=0.61	No
Stavrakis et al. 2017[154]	Guiding Question 2	Fidelity to protocol	Among 29 patients in intermittent arm 4 (14%) crossed over to continuous arm due to failure to submit rhythm strips. Six patients crossed over to continuous arm due to development of persistent AF. Among the 29 patients, there was a median of 3 failed submissions of rhythm strips (IQR 0 to 5).	Not applicable, only measured for intermittent arm.

*reported cost information
AF = atrial fibrillation; CI = confidence interval; DVT = deep vein thrombosis; ECG = electrocardiogram; ED = emergency department; iHEART = iPhone Helping Evaluate Atrial fibrillation Rhythm through Technology; NOAC = non-vitamin K antagonist oral anticoagulant; PE = pulmonary embolism

Table C-48. Stroke and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Smartphone-based Balance Assessment System for Chronic Stroke https://ClinicalTrials.gov/show/NCT04040101	Recruiting	Stroke	Device: Smartphone-based balance training system	Tri-Service General Hospital, Taipei, Neihu District, Taiwan
Pulsewatch: Smartwatch Monitoring for Atrial Fibrillation After Stroke https://ClinicalTrials.gov/show/NCT03761394	Recruiting	Stroke, Atrial Fibrillation	Device: Testing Devices Device: Cardea Solo by Cardiac Insight Device: Kardia Mobile by AliveCor	UMass Memorial Medical Center, Worcester, Massachusetts, United States

Table C-49. Stroke and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration (weeks)
Kerry et al. (2013)[103-105]	RCT	UK	Mar 2007 to Aug 2009	A sample of 322 was required to detect a difference of 5 mmHg in change in mean systolic blood pressure over 12 months between the intervention and control groups, with 80% power using a 5% significance level, assuming the standard deviation (SD) was ±16 mmHg. Allowing for a 10% loss to follow-up, authors needed to recruit 360 participants. In March 2009, the Data Monitoring Committee agreed that the sample size needed to be increased to 380 to allow for a 5% death rate.	381	52

NR = not reported; RCT = randomized controlled trial

Table C-50. Stroke and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity (Rankin score)	Rural Population
Kerry et al. (2013)[103-105]	Hypertensive patients with a history of stroke or transient ischemic attack	72	43	28% had a Rankin score of 0, 27% had a score of 1, 27% had a score of 2, and 18% had a score of 3 or more.	No

NR = not reported

Table C-51. Stroke and PGHD: treatment details

Study	Treatment 1	Other Treatment Groups
Kerry et al. (2013)[103-105]	Usual care: Received usual care from their physician, in addition to a well check phone call from the study administrator at 3 and 9 months.	Monitoring: Received a BP monitor (Omron M6) and taught how to use it. Advised to take 3 readings (1 minute apart) daily for the first week and record readings in a booklet. Advised that it should be less than 130/80. BP readings were taken in the arm unaffected by the stroke. Study did not report the frequency of BP readings after the first week. Received monthly calls from the nurse to check technique and review blood pressure readings. If the readings were high they were advised to see their physician and to take their booklet. Patients also received a well check phone call from the study administrator at 3 and 9 months.

NR = not reported

Table C-52. Stroke and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes pre-specified and reported?	6 Were participants analyzed based on originally-assigned groups across time points?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Kerry et al. (2013)[103-105]	+	+	+	?	+	+	+	+	+	Low

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-53. Stroke and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Kerry et al. (2013)[103-105]	Guiding Question 2	Device usage	Monitoring: 30% of intervention patients (51/168) required the assistance of a care provider to take their blood pressure. 48% (80/168) recorded a full set of BP readings in the previous 4 weeks.	Not calculated
Kerry et al. (2013)[103-105]	Guiding Question 2	Device usage	Monitoring: Of 84 intervention patients answered questions at 18 months (after cessation of nurse support), 80 said they still used the monitor (95%), and 57 of these dais they used it at least once a month.	Not calculated
Kerry et al. (2013)[103-105]	Health	Adverse event: Falls	Monitoring: 52 wks (N=): 19% of 164 Usual care: 52 wks (N=): 17.2% of 164	NS between groups
Kerry et al. (2013)[103-105]	Health	Adverse event: Recurrent stroke	Monitoring: 52 wks (N=): 6.1% of 164 Usual care: 52 wks (N=): 8.1% of 164	NS between groups
Kerry et al. (2013)[103-105]	Health	Quality of life as measured by the EuroQol 5D (Lower scores are better)	Monitoring: Baseline (N=164): 0.8 (SD: 0.22) Monitoring: 52 wks (N=164) change: -0.13 (95% CI: -0.09 to -0.15) Usual care: Baseline (N=164): 0.79 (SD: 0.22) Usual care: 52 wks (N=164) change: -0.12 (95% CI: -0.1 to -0.17)	NS between groups
Kerry et al. (2013)[103-105]	Process	Number of primary care consultations	Monitoring: 5.2 (SD: 4.6)	NS between groups
Kerry et al. (2013)[103-105]	Process	Number of primary care consultations	Usual care: 5.4 (SD: 5.3)	NS between groups

CI = confidence interval; SD = standard deviation; SE = standard error; NR = not reported; NS = not statistically significant; wks = weeks

Table C-54. Parkinsons's disease and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
A Study to Analyze Symptoms Prevalent in Early PD (Dysphonia, Tremor) https://ClinicalTrials.gov/show/NCT04288804	Recruiting	Parkinson Disease	Device: Smartphone microphone sensor Device: Smartphone accelerometer sensor	Goalspal LLC, Pleasanton, California, United States
Improving Walking Ability in Parkinson Disease https://ClinicalTrials.gov/show/NCT03921697	Recruiting	Parkinson Disease	Device: Werable sensors	Fondazione Don Carlo Gnocchi Onlus, Roma, Italy
Patient-Centered PD Ambulatory Monitoring System https://ClinicalTrials.gov/show/NCT04142528	Enrolling by invitation	Parkinson Disease	Device: ParkinPal	David E. Riley, MD, Warrensville Heights, Ohio, United States
Bringing Parkinson Care Back Home https://ClinicalTrials.gov/show/NCT04288583	Not yet recruiting	Parkinson Disease	NR	NR

Table C-55. COPD and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
A Wearable and a Self-management Application for Chronic Obstructive Pulmonary Disease (COPD) Patients at Home https://ClinicalTrials.gov/show/NCT03857061	Recruiting	COPD	Device: smartwatch that passively senses heart rate, motion, audio Device: smartphone that can obtain oxygen saturation upon demand Device: use a self-management app on the smartwatch, smartphone and a webapp.	Toronto General Hospital, Toronto, Ontario, Canada
The Clinical Application and Popularization of Portable Home Noninvasive Ventilator https://ClinicalTrials.gov/show/NCT03238339	Recruiting	Pulmonary Disease, Chronic Obstructive, Hypercapnic Respiratory Failure	Device: Portable Home Noninvasive Ventilator and remote breathing data-monitoring platform based on mobile internet Comparator: routine home oxygen inhalation	Emergency Department, Xinqiao Hospital, Third Military Medical University, Chongqing, China

Table C-56. COPD and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Arbillaga-Etxarri et al. (2018)[52]	RCT	Spain	10/2013 to 1/2016	To detect a difference of 775 steps per day^{-1} (primary outcome) between groups (based on previous research about the effects of behavioral interventions in the elderly), with a two-sided alpha=0.05 and a power of 80%, assuming a standard deviation of 3000 steps per day^{-1} and a correlation between baseline and final steps ≥0.7 (based on authors' data in COPD patients), a sample size of 142 patients per group was necessary. To account for a 30% dropout rate during follow-up, we planned to recruit 202 participants per group (404 in total).	407	12 months
Boer et al. (2019)[166]	RCT	Netherlands	06/2015 to 07/2016	Sample size calculation using analysis of variance showed that we needed 43 participants in each group for 80% power (alpha=0.05, 2 sided) to detect an increase of 6 exacerbation-free weeks per year and anticipating a dropout rate of 20% (9/43). The calculation was based on a previous dataset in which we found a mean of 44 exacerbation-free weeks, with SD 4.5 weeks.	87	12 months

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Demeyer et al. (2017)[161]	RCT	Belgium	06/2014 to 12/2014	The sample size calculation prior to the study, based on previous interventions in the elderly or chronically ill patients, resulted in a need of 253 patients in each arm (total of 506) for 90% power using an alpha level of 0.05 (2-sided). During the inclusion period this sample size calculation was revised because more recent data came available using similar interventions in patients with COPD. This calculation of sample size was based on repeated measurements in two groups (i.e., intervention and control group). The minimum difference in daily steps to be identified as statistically significant has been obtained from previous interventions to increase physical activity (PA) in a 3-months period in COPD patients, and ranges between 1334 steps day^{-1} (S2) and 2984 $steps.day^{-1}$ (S3) as the difference in intervention versus control group; to be conservative we used a value of 1500 in our sample size calculation. A previous review of the levels of PA in COPD patients has shown an SD in daily steps of around 3400 (S4), which has been used in the sample size calculation. Based on (i) unpublished data from the PROactive observational study (NCT01388218 S5) with COPD patients from the same geographical areas and of similar severity distribution to this study showing a correlation of 0.88 in steps between baseline and 6-weeks follow-up, and (ii) unpublished data from an intervention study in Belgium (NCT00948623 S6) with very severe COPD patients showing a correlation of 0.73 in steps between pre and post-intervention after adjusting for seasonality, a correlation between baseline and final daily steps of 0.75 was assumed for this study. Lastly a dropout rate of 20% has been considered. Using these assumptions 68 patients are needed in each arm (total of 136) for 90% power using an alpha level of 0.05 (2-sided).	343	3 months
Jehn et al. (2013)[169]	RCT	Germany	1/12 to 4/12	NR	62	9 months
Jodar-Sanchez et al. (2013)[164,165]	RCT	Spain	09/2010 to 12/2010	NR	43	4 months
Kawagoshi et al. (2015)[162]	RCT	Japan	NR	NR	27	12 months
Mendes de Oliveira et al. 2010[167]	RCT	Brazil	NR	The sample size was calculated based on a study by Shahin, in which the standard deviation on the post-home rehabilitation 6MWT was 19 meters. Considering a clinically significant difference of 54 meters, α=5% and 90% power, it was determined that a minimum of 23 patients was needed for each group. This study had 3 arms, but only 2 are relevant to this report.	216	12 weeks

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Nolan et al. (2017)[168]	RCT	UK	7/12 to 6/14	Sample size was based on a previous study which demonstrated that a 3-month pulmonary rehabilitation (PR) program increased the average daily walking time assessed using an accelerometer by a mean (SD) of 7%. Authors assumed that an additional increase in moderate-intensity physical activity of 20% would represent a clinically relevant improvement. To detect this using a two-sample t test with 80% power at the 0.05 significance level (two-sided), assuming equal variances, a total of 50 participants per group was required. On the basis of PR studies of similar duration, authors allowed for attrition during PR (22%) and from PR to 6 months post-PR (33%) and planned to recruit 155 participants overall.	152	6 months
Tabak et al. (2014)[163]	RCT	Netherlands	10/2010 to NR	A sample size of 32 participants was expected to be feasible (16 participants in each group) owing to the limited availability of the activity coach.	30	1 month
Vorrink et al. (2016)[50,58]	RCT	Netherlands	NR	Power calculations were based on the raw data of a previous study with similar subjects and protocol. With effect sizes based on this previous study, analysis with the random intercept, random slope linear mixed 'linear up' model calculations were made in software program PASS 11 for 60, 70, and 80 subjects per group. The power for the time-group interaction for these group sizes was ~72%, ~76%, and ~84% respectively (two-sided test, level of statistical significance: p=0.05). 70-80 subjects per group was deemed sufficient to achieve a satisfactory power.	157	12 months

COPD = chronic obstructive pulmonary disease; NR = not reported; RCT = randomized control trial; SD = standard deviation; UK = United Kingdom

Table C-57. COPD and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age (years)	% Female	Disease Severity	Rural Population
Arbillaga-Etxarri et al. (2018)[52]	Patients with a diagnosis of COPD according to the American Thoracic Society/European Respiratory Society recommendations (post-bronchodilator forced expiratory volume in 1 s (FEV1) to forced vital capacity (FVC) ratio <0.70) who were seen in any of the participating 33 primary care and five hospital health centers from five Catalan seaside municipalities were included. Authors excluded patients with severe or life-threatening comorbidities, or those clinically unstable.	69 (SD: 8)	13	GOLD 2017 assessment: 34% A, 48% B, 5% C, 13% D; airflow limitation: 10% mild, 53% moderate, 31% severe, 6% very severe; dyspnea mMRC grade (0 to 4): 1 (SD: 1); post-bronchodilator FEV1 % predicted: 57 (SD: 17)	No

Study	Key Inclusion Criteria	Mean Age (years)	% Female	Disease Severity	Rural Population
Boer et al. (2019)[166]	Patients were eligible for participation if they (1) were aged at least 40 years, (2) had a spirometry-confirmed diagnosis of COPD (postbronchodilator forced expiratory volume in 1 second (FEV1)/forced vital capacity <0.7), and (3) had experienced 2 or more symptom-based exacerbations in the previous 12 months, defined as a change for greater than or equal to 2 consecutive days in either greater than or equal to 2 major symptoms (dyspnea, sputum purulence, and sputum amount) or any 1 major symptom plus greater than or equal to 1 minor symptoms (colds, wheeze, sore throat, and cough). Exclusion criteria were (1) severe comorbid conditions that prohibited safe participation, (2) insufficient knowledge of the Dutch language, and (3) persisting difficulties in using the mHealth system after a 2-week practice period and additional assistance.	67.6	38	Diagnosed with COPD >5 years ago: PGHD: 29/43 (68%) and UC: 28/44 (64%)	NR
Demeyer et al. (2017)[161]	Patients with a physician-based diagnosis of COPD,4 age >40 with a smoking history of at least 10 pack-years, who were not actively participating in a pulmonary rehabilitation program at the moment of inclusion (or did not plan to start), were enrolled at six centers across Europe (Leuven (Belgium), Athens (Greece), London and Edinburgh (the UK), Zurich (Switzerland) and Groningen (The Netherlands)); these centers were chosen in order to recruit patients with a range of severity of COPD. Patients were excluded if they had any comorbidity limiting a normal activity pattern, had another respiratory disease as primary diagnosis or were unable to understand or operate a smartphone device. Stable patients as well as patients having an acute exacerbation in the last month were included in this trial. Patients using walking aids or those on long-term oxygen treatment were as well included in the trial.	66.5	36.2	BMI (kg/m2) UC: 25.9 (SD: 4.8), PGHD: 26.7 (SD: 5.3) FEV1 (% predicted) UC: 57 (SD: 21), PGHD: 55 (SD: 20) GOLD (n and [%]) Quadrant A UC: 66 (38%), PGHD: 52 (30%) Quadrant B UC: 17 (10%), PGHD: 16 (9%) Quadrant C UC: 37 (22%), PGHD: 43 (25%) Quadrant D UC: 52 (30%), PGHD: 60 (35%)	NR

Study	Key Inclusion Criteria	Mean Age (years)	% Female	Disease Severity	Rural Population
Jehn et al. (2013)[169]	Diagnosed with COPD Stage IIIV on the basis of a clinical history such as smoking status, physical examination and meet the post-bronchodilator spirometric criteria according to the GOLD guidelines (FEV1 <80% predicted & FEV1/FVC ratio <0.7). Patients also had to have at least one exacerbation during the previous year, be ≥40 years of age and clinically stable for the four weeks prior to inclusion. Patients were excluded from the study if they suffered from 1) asthma, 2) required long-term oxygen therapy, 3) had severe heart, liver or kidney disease, 4) any end stage malignant disease with life expectancy of less than six months, 5) were listed for a lung transplant, 6) had severe depression, 7) were residents in a nursing home, 8) had any physical disabilities limiting them from performing a six minute walk test (6MWT) and/or 9) were mentally disabled.	65.7 (SD: 10.3)	26	Moderate to very severe disease: GOLD II (N=25), GOLD III (N=25) and GOLD IV (N=12)	NR
Jodar-Sanchez et al. (2013)[164,165]	The inclusion criteria were: (1) being an adult patient with a diagnosis of COPD and chronic respiratory failure (CRF) with LTOT indication according to international guidelines; (2) at least one hospitalization for respiratory illness in the previous year; (3) being clinically stable during the previous three months. The exclusion criteria were: patients who did not follow LTOT at enrolment, had no home telephone line or did not give their informed consent.	72.6	5	FEV1, % pred (SD) UC: 37 (13), PGHD: 38 (10) Total Lung Capacity, % pred (SD) UC: 142 (15), PGHD: 138 (15)	NR
Kawagoshi et al. (2015)[162]	Patients who were diagnosed with stable COPD from mild to very severe stage (GOLD) were enrolled in the present study. The patients were all retired. The inclusion criteria for this study were: (1) the patient was in stable condition with no infection or exacerbation of COPD for at least the prior 3 months; (2) the patient was able to walk unassisted and operate the device to measure their PA; (3) the patient had no severe and/or unstable cardiac disease, orthopedic disease, or mental disorder that could impair physical activities in daily life.	74.6	11	GOLD stage was 2.2 (SD: 0.9) for UC: 2.5 (SD: 1.2) for PGHD and FEV1 predicted was 60.6 (SD: 20.8) for UC: 58.0 (SD: 23.2) for PGHD	NR

Study	Key Inclusion Criteria	Mean Age (years)	% Female	Disease Severity	Rural Population
Mendes de Oliveira et al. 2010[167]	The following were the inclusion criteria: COPD based on the GOLD classification; clinical stability in the eight weeks prior to the study (no reports of worsening of dyspnea, increased phlegm production or phlegm purulence). The exclusion criteria were: hospitalization; COPD instability; presence of neuromuscular disease, associated respiratory disease, orthopedic or neurological disease that affected gait; recent impairment due to comorbidities, such as myocardial infarction, heart failure, stroke or neoplasm; prior pneumonectomy or other thoracic surgery. The presence of stable comorbidities was not considered an exclusion criterion as most patients with COPD are elderly and commonly affected by multiple comorbidities.	69.2 SD 8.7 years	23.5	Mean post-bronchodilator FEV1 in % of predicted value was 46.5±22.0%, with the majority of patients in more advanced stages (GOLD III and IV respectively 34.1% and 28.2%). At the beginning of the study, 40 patients (47.0% of the sample) were on long-term home oxygen therapy.	NR
Nolan et al. (2017)[168]	Eligible participants were at least 35 years of age, had a physician's diagnosis of COPD consistent with the GOLD criteria, had a Medical Research Council dyspnea scale score greater than or equal to 2, and consented to undergo supervised pulmonary rehabilitation (PR). Exclusion criteria included contraindications to exercise (e.g., significant cardiovascular comorbidities) or participants choosing a community PR site without access to specialist exercise equipment.	68	28	Chronic Respiratory Questionnaire (CRQ) dyspnea PGHD: 14.1 (SD: 6.3), PR: 12.7 (SD: 4.9) Age, dyspnea, airflow obstruction (ADO) index PGHD: 4.7 (SD: 1.6), PR: 4.6 (SD: 1.6) Spo2 on room air % PGHD: 95% (SD: 3), PR: 96% (3) FEV1, % predicted PGHD: 50.6 (SD: 20.7), PR: 50.3 (SD: 21.8)	NR
Tabak et al. (2014)[163]	Patients with a clinical diagnosis of COPD were recruited by a chest physician or nurse practitioner. Inclusion criteria were: no infection or exacerbation in the four weeks prior to measurement; current or former smoker; able to read and speak Dutch; and internet access at home. Exclusion criteria were: impaired hand function causing inability to use the application; disorders or progressive disease seriously influencing daily activities (e.g., amputation); other diseases influencing bronchial symptoms and/or lung function (e.g., sarcoidosis); need for regular oxygen therapy (>16 hours per day or pO2 <7.2 kPa); a history of asthma, and less than six weeks ago started training with a physiotherapist.	66.6	37	FEV1% predicted: PGHD: 48.7 (SD: 16.7), UC: 56.4 (SD: 10.6)	NR

Study	Key Inclusion Criteria	Mean Age (years)	% Female	Disease Severity	Rural Population
Vorrink et al. (2016)[50,58]	Patients diagnosed with COPD, GOLD stage 2 or 3 (forced expiratory volume in 1 s (FEV1) <80%, FEV1/forced vital capacity (FVC) <70% after bronchodilatation), aged ≥40 years, who had completed a PR program of 3 months within the past 6 months and lived independently were recruited. Patients were not included in the trial if they were suffering from a comorbidity that greatly influences PA, using an assistive device for PA (e.g., walker or mobility scooter), intermittently ceased the PR program and/or experienced an exacerbation resulting in a hospital admission in the 6 months prior to the commencement of the study.	62.5	50.3	BMI overweight PGHD: 31/84 (38%), UC: 22/73 (30%); Obese PGHD: 25/84 (31%), UC: 22/73 (30%) CRQ-SAS (score 1 to 7) dyspnea: PGHD: 4.8 (SD: 1.3), UC: 4.8 (1.3) FEV1 % predicted PGHD: 59 (SD: 20), UC: 53 (SD: 15)	NR

BMI = body mass index; COPD = chronic obstructive pulmonary disease; CRQ-SAS = chronic respiratory disease questionnaire self-administered standardized; GOLD = Global Initiative for Chronic Lung Disease; kPa = kilopascal; LTOT = long-term oxygen therapy; mMRC = modified Medical Research Council; NR = not reported; PA = physical activity; PR = pulmonary rehabilitation; PGHD = patient-generated health data; pO2 = partial pressure of oxygen; PR = pulmonary rehabilitation; SD = standard deviation; Spo2 = blood oxygen saturation; UC = usual care

Table C-58. COPD and PGHD: treatment details

Study	Treatment 1	Treatment 2
Arbillaga-Etxarri et al. (2018)[52]	UC: Usual standardized pharmacological and/or non-pharmacological treatment for COPD, including PR, at the discretion of their physician and without any intervention by the research team. Patients in the UC group were provided with general health counselling and the European Lung Foundation (ELF) information brochure "Living an active life with COPD", which recommends ≥30 min moderate physical activity ≥5 days per week.	Urban Training: Usual standardized pharmacological and/or non-pharmacological treatment for COPD, including PR, at the discretion of their physician and without any intervention by the research team. The Urban Training intervention consisted of the following six components: 1) At baseline, a respiratory physiotherapist adequately trained in behavioral strategies used motivational interviewing techniques, integrated with a stage-matched approach, for a maximum of 1 hour. The interview was centered on empathy, reflective listening and affirmation, and addressed patients' resistance (personal difficulties, barriers and limitations) to eliciting behavioral change. Information on the remaining components of the intervention was provided during this interview. During the follow-up period, the physiotherapist administered up to four phone calls lasting 5 to 10 minutes to maintain motivation, depending on patients' self-efficacy and stage of change. 2) Participants received a dossier containing various maps of Urban Training walking trails, previously validated, according to their mobility options and preferences. Trails of different intensities (low, moderate or high, combining urban elements of varying intensity (stairs, ramps and types of surfacing)) were available in several walkable public spaces (boulevards, beaches and parks) of the five municipalities. The physiotherapist provided a complete explanation of trails characteristics and instructed patients to train following the FITT (frequency, intensity, time and type) principle. Each patient was advised to start with a trail of intensity appropriate to his/her baseline dyspnea and 6-min walking distance (6MWD), and instructed how to increase progressively the volume (number of walks per day on the same trail) and/or the intensity of the trails during the following 12 months according to their symptoms and motivation. In all cases, the instructions were to walk at least one trail per day ≥5 days per week, at a pace reaching a dyspnea Borg scale score of 4–6. 3) Patients were provided with both a pedometer and a personalized calendar to monitor their physical activity and maintain motivation. 4) Patients received the same ELF information brochure as the usual-care group and the link to the project website (www.entrenament-urba.cat/). They were requested to provide a personal cell phone number where they would receive phone text messages every 2 weeks with educational or motivational messages. 5) Once per month during the follow-up period, patients could join a walking group for walking a trail accompanied by an experienced physical activity trainer. 6) Patients were given a phone number to contact the physiotherapists for any questions during follow-up. The Urban Training intervention was proposed as a supplement to the physical activities of daily life and in no case as a substitute activity.

Study	Treatment 1	Treatment 2
Boer et al. (2019)[166]	UC: Before randomization, all participants received a 20-min educational session based on the Dutch version of the Living Well with COPD self-management program provided by the nurse in groups of 4 to 10 participants to establish a homogeneous baseline in exacerbation self-management knowledge.	PGHD (forehead thermometer only consumer PGHD): Before randomization, all participants received a 20-min educational session based on the Dutch version of the Living Well with COPD self-management program provided by the nurse in groups of 4 to 10 participants to establish a homogeneous baseline in exacerbation self-management knowledge. Participants in the PGHD group were instructed to visit the nurse within 2 weeks after allocation for instructions on the use of the mHealth tool. The tool consisted of a mobile phone (provided by the research team), a pulse oximeter (CMS50D, Contec Medical Systems,), a spirometer (PiKo-1 monitor, nSpire), and a forehead thermometer (FTN, Medisana AG). Patients answered 12 yes-or-no questions concerning changes in symptoms, physical limitations, and emotions using the touch screen on the mobile phone complemented by measurements with the pulse oximeter, spirometer, and forehead thermometer. All questions had to be answered to proceed. On the basis of a built-in Bayesian network decision model, the mHealth tool then provided one or more of the following advices: (1) increase your bronchodilator use (including a personalized medication instruction), (2) use your breathing techniques, (3) use your coughing techniques, (4) be thoughtful of how you distribute your energy during the day, (4) contact your health care professional today, (5) measure again tomorrow. Completing the questions and measurements took approximately 5 min. The mHealth tool has been developed in close collaboration with COPD patients and health care professional and has shown high sensitivity and specificity. Before the trial started, participants in the PGHD group were instructed to use the system daily for 2 weeks to get familiarized with the app, mobile phone, spirometer, pulse oximeter, and forehead thermometer. Data were sent to a secured Web-based interface and were monitored by the research team to make sure participants practiced sufficiently. After this 2-week run-in period, the nurses evaluated patients' use of the system, including the physiological measurements. Reference values for each patient's FEV1 and peripheral oxygen saturation were set. Then, the 12-month follow-up period started. Patients were instructed to use the tool every time they experienced or had any doubts about any change in symptoms or disease burden. At the 3-month follow-up, patients in both the PGHD and UC groups were invited by their nurse to evaluate their self-management of COPD exacerbations. In the intervention group, only the nurses received the patients' entries in the mHealth tool from the research team to enable tailoring of feedback on self-management behavior. In the control group, the nurses evaluated the use of the paper action plan. Patients in both the groups did not receive any feedback on self-management behavior before or after this nurse contact. All patients in both the PGHD and UC groups continued to have complete access to their health care professionals during the follow-up.

Study	Treatment 1	Treatment 2
Demeyer et al. (2017)[161]	UC: Patients in both groups received a standard leaflet explaining the importance of PA in COPD as well as information about PA recommendations. This leaflet was discussed with all patients in a 5 to 10 min one-to-one discussion with the investigator during visit 2. The usual medical treatment was not altered throughout the study.	PGHD (Fitbug Air): Patients in the PGHD group received UC plus the tele-coaching intervention. This intervention included several components: (1) a one-to-one interview with the investigator during V2 discussing motivation, barriers, favorite activities and strategies to become more active; (2) a step counter (Fitbug Air) providing direct feedback on the step count, on a 2 × 3 cm display; (3) smartphone with Fitbug application and a project-tailored coaching application. This application was specifically designed for use by patients with COPD in the present project. It provided automated coaching by displaying an activity goal (number of steps) and feedback on a daily basis. The feedback included a graphical representation of that day's performance and an educational tip. Patients' targets were automatically revised every Sunday, based on performance in the preceding week. Investigators could alter or 'lock' the goals if needed, based on interaction with the patient; (4) a booklet containing home exercises; (5) weekly group text message with activity proposals sent by the investigator, taking into account the local weather forecast; and (6) telephone contacts triggered in the case of non-compliance with wearing the step counter, failure to transmit data or failure to progress. UC consisted of a standard leaflet explaining the importance of PA in COPD as well as information about PA recommendations. This leaflet was discussed with all patients in a 5 to 10 minute one-to-one discussion with the investigator during visit 2. The usual medical treatment was not altered throughout the study.
Jehn et al. (2013)[169]	UC: UC was based on current guidelines for the treatment and management of COPD and included an initial baseline examination and regular follow-up visits at 3, 6, and 9 months.	PGHD (Aipermotion accelerometer): Included 1) daily in home assessment of clinical status by means of the COPD Assessment Test (CAT), 2) daily lung function testing (spirometry), and 3) a weekly six-minute walk test measured by accelerometry (PGHD). Patient data were transmitted via a mobile network directly to the study center in Berlin. Patients completed all measurements in the morning within a two-hour time window of their choice following inhalation of their usual bronchodilators. Patients were thoroughly trained how to use all technical equipment during their baseline visit. A study nurse was available to provide technical support and he/she also contacted patients if data was not sent during the agreed time window. Incoming data was reviewed by the study physician on a daily basis. PGHD arm patients also received UC. Exercise capacity was assessed by a 6 minute walk test (6MWT). The study nurse trained the patients to conduct the 6MWTs on their own in their outdoors environment using a flat walking path that would allow them to walk continuously for six minutes without interruption. The AiperMotion 300 device is a three dimensional accelerometer customized especially for recording data during the 6MWT with a "start 6MWT" button and automatic end of data recording after 6 minutes. The accelerometer is matchbox sized and worn on hip level attached to the belt via a pocket pouch. Data output includes the number of total steps taken, distance and walking speed in six minutes. Measurement accuracy of the device has been previously validated in patients with chronic heart failure under laboratory conditions as well as in a field based setting during which the validity of 6MWT steps was established to be a suitable measure of functional exercise capacity.

Study	Treatment 1	Treatment 2
Jodar-Sanchez et al. (2013)[164,165]	UC: UC received conventional medical care.	PGHD (BP monitor): Patients measured their vital signs from Monday to Friday according to a set schedule. Vital signs were acquired 20 min after taking prescribed inhaled therapy, seated and rested, and while on oxygen therapy. At the beginning of the study, nursing personnel installed the equipment in the patient's home and conducted a training session, showing each patient how to use the equipment and take measurements. Vital signs were recorded using the following equipment: a spirometer, a pulse oximeter, a heart rate (Spirotel, Medical International Research Inc.) and a blood pressure monitor (model UA-767 BT, A&D Company). Each day, after taking these measurements, the data were sent via a hub (Tele-Modem, Aerotel Medical Systems) connected to the patient's home telephone line. Once measurements had been recorded by each connected instrument, the user pressed a button to activate data transmission. Study monitoring lasted 4 months. Patients began participation in the study in a stable situation and the first measurements were taken at home under the supervision of the nursing staff. These measurements were used as reference values (baseline parameters) for each patient and alerts – to detect possible exacerbations – were activated by excursions outside the range of these reference values. The information was then received by the clinical call center (CCC), manned by The clinical response is the result of communication between the CCC staff, the case manager and a specialist in respiratory medicine. When a red alert is triggered, and before contacting the case manager, the CCC staff contact the patient to confirm the patient's symptoms, and gain more information about the severity of the exacerbation. If the clinical alert is confirmed, the CCC staff escalate the information to the case manager for an early response to a possible exacerbation. After receiving a red alert, the case manager analyses the vital sign measurements together with the clinical questionnaire responses, accessing the platform via mobile telephony (a smart phone) and initiating the clinical response. The severity of the exacerbation dictates the subsequent actions: (1) Mild to moderate: in this case the case manager may choose to monitor vital signs for the following 24 hours, recommend treatment prescribed by the patient's doctor or refer to the primary care doctor. (2) Severe: referral to specialized care on the same day the alert is triggered. (3) Very severe: referral to an A&E department. If the patient is admitted to hospital, the case manager will inform the CCC staff when the patient is discharged and the patient's monitoring process will resume.

Study	Treatment 1	Treatment 2
Kawagoshi et al. (2015)[162]	UC: PR only PR program is a multidisciplinary home-based program. Breathing retraining consisted of pursed-lip breathing, diaphragmatic breathing, and slow-deep breathing, in both the supine and sitting positions. Exercise training included upper and lower limb exercises including COPD sitting calisthenics, respiratory muscle stretching calisthenics, level walking for at least 15 minutes, and inspiratory muscle exercises using an inspiratory muscle trainer, the Threshold (HealthScan Products, Cedar Grove, NJ) set at a training intensity of 30% to 40% of the maximal inspiratory (PImax) muscle forces. The patients also underwent a monthly 45-minute education program including lectures about equipment use, nutrition, stress management, relaxation techniques, home exercises and the benefits of PR. Patients were instructed to practice this program daily at home and were supervised by a respiratory therapist every 2 weeks in our hospital, and then we reset the intensity of exercise as their conditions allowed. The achievements of this home program have been reported. Indeed, the participants in the present study were able to perform our daily program at home for 239 (SD: 25) days of a year (65.4%, SD: 6.8%). A nurse periodically visited each patient at home and provided information on the role of the PR program. The overall training intensity was set at a dyspnea rating scale of 3, which corresponds to approximately 50% of the maximum oxygen consumption.	PGHD (Kens Lifecorder pedometer): PGHD group (PR and feedback from pedometer use): The subjects in the PGHD group completed the monitoring using a pedometer (Kens Lifecorder EX, Nagoya, Japan) and received monthly feedback about their pedometer use by PR staff for 1 year in addition to the other aspects of the program described above for the UC group. They attached the pedometer (which is small and lightweight) to their belt at the waist for a period of 12 h (from waking time until going to bed) each day for 1 year. The pedometer contains a uniaxial accelerometer to measure the wearer's energy expenditure and the number of steps every 4 seconds throughout each day. A proprietary algorithm determines daily step counts with an intramodel reliability of 0.998 and accuracy within 3% of the actual number of steps taken. The memory of this instrument has a 36-day date storage capacity. When a patient went to the hospital for a consultation every 2 to 4 weeks, the investigators retrieved the data and replaced the battery. The patients received feedback monthly with their average daily PA of the previous month from the PR staff. The patients received this feedback 11 times in the year. The Nakanojo study reported that 8000 steps per a day was correlated with lower limb function, and thus the COPD patients in that study were given the goal of taking 8000 steps per a day. The PR staff also gave verbal reinforcement to the patients to increase their PA when they received their PA feedback.

Study	Treatment 1	Treatment 2
Mendes de Oliveira et al. 2010[167]	No PR: No pulmonary rehabilitation.	PGHD (at home PR plus heart monitor): Pulmonary rehabilitation consisted of aerobic and strengthening of upper and lower limbs 3 times a week for 12 weeks. At home PR program with heart rate monitoring (Polar S810, Polar®, Finland) provided by the clinic to all patients was used to monitor heart rate during aerobic exercise. A log was designed and the patients were instructed to fill it out at the end of each training session. During the 12-week period, the individuals received telephone calls from the same professional at the clinic in order to follow up on the load increase, detect problems, clarify questions and reinforce the importance of the rehabilitation. Plus all patients took part in an educational program in the auditorium at the clinic, where they received information on the development and progression of COPD, its treatment (both pharmacological and non-pharmacological), the correct use of oxygen for oxygen dependent patients and the importance of an exercise-based rehabilitation program.
Nolan et al. (2017)[168]	UC: Outpatient pulmonary rehabilitation for 8 weeks, 2 supervised sessions per week.	PGHD (Yamax Digi-walker CW700 pedometer: PR plus a pedometer (Yamax Digi-walker CW700; Yamax, Bridgnorth, UK), an individualized daily pedometer step-count target (with weekly review for 8 weeks), and a step-count diary provided during the PR program and the following 6 months. During PR, the daily pedometer step-count target was an increase of 5% on the preceding week's average daily pedometer step count, with the first week's target derived from the baseline pre-PR assessment (e.g., 250 additional steps from a mean daily step count of 5,000). At this weekly step-count review, each patient was counseled on the importance of achieving the pedometer step count and given advice on how to increase physical activity levels, focusing on barriers and opportunities arising during daily life. On completion of the PR program, participants in the intervention group received a final step-count target based on a 20% increase in daily step count from the baseline pre-PR assessment and a step-count diary.

Study	Treatment 1	Treatment 2
Tabak et al. (2014)[163]	UC: UC consisted of medication and physiotherapy. Physiotherapy consisted of weekly (group) training sessions at the local physiotherapy practices. In case of an exacerbation, the participants had to contact their medical doctor.	PGHD (accelerometer only PGHD): The application consisted of two modules: 1) activity coach for ambulant activity registration and feedback and 2) web portal with a symptom diary for self-treatment of exacerbations and an overview of the measured activity levels. The activity coach consisted of a three-dimensional-accelerometer (MTx-W sensor, Xsens Technologies, Enschede, the Netherlands, which is our PGHD) and a smartphone (HTC P3600/3700). The sensor had a wireless connection with the smartphone by Bluetooth. Both the activity sensor and smartphone were worn on the subject's belt. The smartphone showed the measured activity cumulatively in a graph, together with the cumulative activity the users should aim for. The reference activity is the line between the mean baseline of the participant and a social norm line (based on the data of 56 healthy controls). Participants were asked to try to be active in such a way during the day that the displayed reference line is closely approached. In addition, the users automatically received feedback text messages, for awareness and extra motivation. These messages were based on the difference between the measured activity and the reference line and always consist of 1) a short summary of activity behavior and 2) advice on how to improve or maintain the activity behavior. The participant's measured activity levels were also displayed on the web portal. Every day, participants were asked to fill in the diary on the web portal, which is the digital version of the diary used by Effing et al. A decision-support system automatically forms an advice to start medication in case of an exacerbation. Before using this diary, participants had to attend two 90-minute self-management sessions given by a nurse practitioner, to learn how to complete the daily diary, how to recognize symptoms of an impending exacerbation, and how to deal with the exacerbation. The intervention group received UC and the tele-rehabilitation intervention. Participants in the intervention group used the activity coach for four weeks from waking till 22:00 h, for a minimum of four days per week. The first week was a baseline measurement to establish the reference line, followed by three weeks in which the participant received feedback to change activity behavior. Participants were asked to continue the routine of their daily life during baseline measurement.

Study	Treatment 1	Treatment 2
Vorrink et al. (2016)[50,58]	UC: All participants continued to receive UC according to the guidelines of the Dutch College of General Practitioners.	PGHD (HTC Desire accelerometer): The intervention consisted of two components: 1) a smartphone application and 2) a website for the physiotherapists. The application showed physical activity in real time in quantitative and qualitative form, measured by the accelerometer embedded in the smartphone (HTC Desire A8181; HTC, Taoyuan, Taiwan). Subjects were persuaded to achieve their personalized PA goal by automated persuasive messages and an emoticon. The physiotherapists could monitor their patients via the (secure) website, which showed a detailed view of individual patients. The physiotherapist was able to adjust each patient's PA goal and send group or individual text messages. No automated adjustments of the PA goal were performed. Physiotherapists received individual face-to-face (and written) instruction on the functionalities of the website. Patients received a smartphone, a phone/ internet contract and an individual face-to-face (and written) instruction on the use of the smartphone and the application. They were instructed to wear the smartphone in a pouch on their belt and use it as their usual phone. They were to transfer the SIM card from their personal mobile phone into the study smartphone. For the first week of the study, PA goals were not set, and subjects were instructed to perform their day-to-day activities as usual. Afterwards, initial personal PA goals were calculated using data from this baseline week as follows. 1) Average steps per day +20% as daily step goal; 2) daily, the number of steps during the 30 most intensive minutes were counted and averaged into a value for a week. This latter value +20% was set as the minimum required number of steps in 1 minute to account for an intensive minute of PA; and 3) 30 intensive minutes performed per day, according to the Dutch healthy exercise norm. After this initial PA goal setting, physiotherapists were given responsibility for PA goal adjustment. They could reduce or increase the amount and intensity of the PA goal via the website, based on the individual ability of their patient over time. All participants continued to receive UC according to the guidelines of the Dutch College of General Practitioners.

COPD = chronic obstructive pulmonary disease; FEV1 = forced expiratory volume in 1 second; GOLD = Global Initiative for Chronic Lung Disease; mHealth = mobile health; PA = physical activity; PR = pulmonary rehabilitation; PGHD = patient-generated health data; PR = pulmonary rehabilitation; UC = usual care

Table C-59. COPD and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes prespecified and reported?	6 Were participants analyzed based on originally-assigned groups across timepoints?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Arbillaga-Etxarri et al. (2018)[52]	+	+	+	−	+	+	−	+	+	Moderate
Boer et al. (2019)[166]	+	?	−	−	+	+	+	−	?	High
Demeyer et al. (2017)[161]	+	+	+	−	+	+	+	−	+	Moderate
Jehn et al. (2013)[169]	?	?	−	−	+	+	?	?	+	High
Jodar-Sanchez et al. (2013)[164,165]	?	?	−	−	+	+	+	?	+	High
Kawagoshi et al. (2015)[162]	?	?	−	+	+	+	−	?	+	High
Mendes de Oliveira et al. 2010[167]	+	?	−	−	+	+	−	+	+	High
Nolan et al. (2017)[168]	+	+	+	+	+	+	−	+	+	Low
Tabak et al. (2014)[163]	+	+	−	−	+	+	−	−	+	High
Vorrink et al. (2016)[50,58]	+	?	−	+	+	+	−	+	+	Moderate

 solid green circle with a plus sign indicates low risk of bias;  solid yellow circle with a question mark indicates unclear risk of bias;  solid red circle with a minus sign indicates high risk of bias

Table C-60. COPD and PGHD: risk of bias for economic evaluations

Study	1 Competing alternatives described?	2 Economic study design appropriate o?	3 Important and relevant costs for alternatives identified?	4 Costs measured appropriately?	5 Costs valued appropriately?	6 Important and relevant outcomes for alternatives identified?	7 Outcomes measured appropriately?	8 Outcomes valued appropriately?	9 Incremental analysis of costs and outcomes of alternatives performed?	10 Future costs and outcomes discounted appropriately?	11 Sensitivity analysis?	Overall Risk of Bias
Jodar-Sanchez et al. (2013)[164,165]	+	+	−	−	+	−	+	+	+	+	−	High

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-61. COPD and PGHD: results

Study	Outcome Category	Outcome	Results	Statistical Significance
Arbillaga-Etxarri et al. (2018)[52]	Guiding Question 2	Adherence Physiotherapists noted patients' spontaneous report of unwillingness to follow the instructions (e.g., walking ≥5 days per week ≥30 min·day-1 in the UC or walking the Urban Training trails in the Urban Training group) at the baseline visit, as well as spontaneous reports of non-adherence (i.e., not having followed the instructions) at the 12-month visit. At the 12 month follow-up visit, patients also answered a questionnaire about satisfaction with the study components and any potential adverse events experienced during or after walks in the previous 12 months.	3/148 (2%) were non-adherent in the UC group vs. 44/132 (33%) in the Urban Training group, p not calculated. Of the 132 Urban Training patients participating in the follow-up visit, 70%, 87% and 90% used the trails maps, calendars and pedometers, respectively; 31% participated at least once in the walking groups; 41% contacted the researchers via phone during follow-up; and 2% visited the study website. At the 12-month visit, 65% of patients delivered the calendars, and the mean ± SD fulfilled months was 9±4 months. Satisfaction with the study and study staff was very high (mean satisfaction ≥9 in a score ranging from 0 to 10) both in the UC and Urban Training groups. Satisfaction with the study components in the Urban Training group was high or very high: 9.1±1.6 for trail maps, 9.1±1.7 for calendars, 9.0±1.8 for pedometers, 7.5±2.8 for walking groups, 9.4±1.0 for phone text messages, 9.5±1.4 for study phone-line and 8.7±2.3 for study website.	Not calculated

Study	Outcome Category	Outcome	Results	Statistical Significance
Boer et al. (2019)[166]	Guiding Question 2	Adherence	From the Web-based interface, 38/43 (88%) patients in the mHealth group used the app 727 times in total during follow-up. No data on usage was available for 5 patients. The range in frequency of usage was 1 to 250 times with a median of 7 (IQR: 3 to 14). Results of the evaluation questionnaire showed that more patients reported to have used their mHealth tool often (scores 6 and 7 on the 7-point rating scale) compared with patients in the control group who reported to have used their paper action plan (44.4% vs. 17.2%, respectively).	NR
Boer et al. (2019)[166]	Guiding Question 2	Device evaluation All participants were asked to evaluate the supportive function of either the mHealth tool or the paper action plan by using a paper survey including closed-ended questions regarding the use, difficulty in use, and intended future use of the mHealth tool or the paper action plan. Besides, 3 questions were asked related to clarity, suitability, and follow-up of the advice given by the mHealth tool or the paper action plan. All questions included answers on a 7-point rating scale from strongly disagree (score 1) to strongly agree (score 7). The survey also included 1 question about frequency of usage at times of symptom worsening, with answers on a 7-point rating scale varying from 1=never to 7=always. In addition, participants of the intervention group were asked to complete the System Usability Scale (SUS). The SUS contains 10 questions on system usability, which are calculated into 1 total score between 0 and 100. SUS scores less than 68 are considered as low, greater than or equal to 68 and less than or equal to 80.3 as good, and greater than 80.3 as excellent.	A total of 58 (67%) participants returned an evaluation form, of which 28 were in the intervention group. The mHealth tool was rated as a more useful support tool than the paper action plan (p=0.02). No differences were found between the mHealth tool and the action plan in the self-reported frequency of use; in difficulty and future use of the tool; or in clarity, suitability, and follow-up of the advice. 26 participants in the PGHD group completed all 10 SUS questions with a mean score of 78.5 (SD: 14.4).	PGHD more useful than UC (paper action plan) but no for frequency of use, clarity, suitability, or follow-up of advice.

Study	Outcome Category	Outcome	Results	Statistical Significance
Demeyer et al. (2017)[161]	Guiding Question 2	Adherence Chart review	Patients in the PGHD group (n=140) wore the Fitbug step counter for a median of 91 (IQR: 84 to 98) % of the days they were included in the coaching program, representing 6.3 (5.8 to 6.8) days/week. Patients in the PGHD group who completed the trial were contacted for a median of 6 (IQR: 4 to 9) times (range 0 to 25 times), with a total time consumption for the investigator of 50 (30 to 95) minutes per patient (range 0 to 375 minutes). 75% of contacts were initiated by the application ('flags') and 25% were patient driven.	NA
Jodar-Sanchez et al. (2013)[164,165]	Guiding Question 2	Adherence	Patients in the PGHD group took high rates of daily measurements of vital signs: BP on 75% of days (average 90 days; SD: 0.22), HR on 79% of days (average 96 days; SD: 0.19), blood oxygen saturation on 71% of days (average 86 days; SD: 0.22) and spirometry on 52% of days (average 63 days; SD: 0.26). During the study, a total of 14 technical home visits and 408 telephone calls were made by the CCC: an average of 0.58 visits (SD: 0.88) and 17 telephone calls (SD: 7.75) per patient. The reasons for the telephone calls by the CCC were as follows: 38% for non-adherence (measurements had not been taken), 34% for non-receipt of data (technical or training problems), 19% clinical alerts (red alerts), 7% for technical reinforcement and 2% for other reasons.	NA
Kawagoshi et al. (2015)[162]	Guiding Question 2	Adherence NR	Patients wore their pedometers for 293 (SD: 49) days of a year (80.4, SD: 13.3%).	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Tabak et al. (2014)[163]	Guiding Question 2	Adherence Use of the system was expressed as number of visits to the web portal and the time the activity sensor was worn. Only those days were included in which ≥50% of the day was measured, for all day parts. Compliance was calculated by dividing the number of days the activity sensor was worn by the minimal number of days that was prescribed (i.e., ≥four days/week). Compliance for the triage diary was calculated by dividing the number of diary fill-outs by the number of days that was prescribed (every day).	The activity coach was worn more than prescribed: for 17.5±2.2 days on average, which is 109% of prescribed. Only two patients used the system for less than the prescribed 16 days (13 and 14 days). Therefore, 86% of the patients complied with the activity coach. The average duration per day was almost 10 hours (588±101 minutes). The diary was filled in 242 times, 17.3±7.8 times on average per patient, which is 58% of prescribed. Only one patient complied with the intervention and filled in the diary every day. Two patients had a very low compliance regarding the diary: one patient did not use the web portal at all and one other patient only for four days. Activity sensor – total use 245 days, mean per patient 17.5±2.2 days, percent prescribed 109.4±14.0%, web portal mean 23.0±10.3 sessions per patient, diary filled out mean 17.3±7.8 times per patient and percent prescribed 57.6±0.26%.	NA
Vorrink et al. (2016)[50,58]	Guiding Question 2	Adherence % of days the intervention was used, and as % of days the PA goal was obtained.	The intervention was used on 89±18.5% of the study days. The personal PA goal was obtained on 34±16% of these days. Physiotherapists sent 362 personal and 10 group messages to their patients. The patients returned 162 messages to the physiotherapists.	NA

Study	Outcome Category	Outcome	Results	Statistical Significance
Arbillaga-Etxarri et al. (2018)[52]	Health	Adverse events At the 12 month follow-up visit, patients answered a questionnaire about satisfaction with the study components and any potential adverse events experienced during or after walks in the previous 12 months.	Data are n (%) UC: 142 Urban Training 128 total. Any adverse event UC: 103 (73%), Urban Training: 99 (77%), p=0.363; Lower-extremity joint pain UC: 38 (27%), Urban Training: 41 (32%), p=0.342; Lower-extremity muscle pain UC: 36 (25%), Urban Training: 48 (38%), p=0.031; General malaise/fatigue UC: 61 (43%), Urban Training: 57 (45%), p=0.795; Dizziness UC: 12 (8%), Urban Training: 9 (7%), p=0.821; Fainting UC: 1 (1%), Urban Training: 0 (0), p not calculated; Dyspnea UC: 48 (34%), Urban Training: 46 (36%), p=0.713; Chest discomfort UC: 9 (6%), Urban Training: 17 (13%), p=0.064; Palpitations UC: 22 (16%), Urban Training: 23 (18%), p=0.586; Fall, twist or accident UC: 10 (7%), Urban Training: 13 (10%), p=0.360; Cold, flu or pneumonia UC: 24 (17%), Urban Training: 21 (16%), p=0.913; Heatstroke or dehydration UC: 1 (1%), Urban Training: 2 (2%), p=0.605	Yes (Urban training group had more lower extremity muscle pain) but no significant difference for all other AEs.
Arbillaga-Etxarri et al. (2018)[52]	Health	Exacerbations, severe leading to hospital or ER admission NR	UC baseline: 14, 12-month follow-up: 17 and Urban Training baseline: 8, 12-month follow-up: 17, logistic regression adjusted by group and corresponding outcome values at baseline: 0.3 (95% CI: -0.4 to 1.0)	No
Arbillaga-Etxarri et al. (2018)[52]	Health	QOL CAT	UC baseline: 12 (SD: 8), 12-month follow-up: 11 (SD: 7) and Urban Training baseline: 12 (SD: 7), 12-month follow-up: 11 (SD: 7), linear regression adjusted by group and corresponding outcome values at baseline: 0.1 (95% CI: -1.1 to 1.2)	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Arbillaga-Etxarri et al. (2018)[52]	Health	QOL CCQ total score	UC baseline: 1 (SD: 1), 12-month follow-up: 1 (SD: 1) and Urban Training baseline: 1 (SD: 1), 12-month follow-up: 1 (SD: 1), linear regression adjusted by group and corresponding outcome values at baseline: -0.1 (95% CI: -0.3 to 0.1)	No
Boer et al. (2019)[166]	Health	Exacerbations Exacerbation-free weeks defined as a week in which there had not been episodes of 2 or more consecutive days with worsening of 2 major symptoms (i.e., dyspnea, sputum purulence, and sputum amount) or 1 major and 1 or more minor symptoms (i.e., colds, wheeze, sore throat, and cough). Symptom changes were assessed using the Telephonic Exacerbation Assessment System (TEXAS, Radboudumc), an automated telephone call system that contacted participants weekly on the day and time of their preference. TEXAS consisted of closed questions regarding changes in respiratory symptoms, use of health care resources, and use of respiratory medication in the week before the call, and its validity has been demonstrated previously. Owing to the discontinuation of the contract with the provider of TEXAS, the last 19 participants in the trial received a weekly online questionnaire containing the same questions as TEXAS. These participants used both measuring tools during 2 weeks before stopping with TEXAS, which enabled investigators to compare data entries from TEXAS with the online survey tool. No differences in the data entries were found. Data retrieved from weekly patient reports except for treated with medication which was from patient medical files.	Exacerbation-free weeks PGHD: 30.6 (SD: 13.3), UC: 28.0 (SD: 14.8), Rate ratio: 1.21 (95% CI: 0.77 to 1.90), p=0.40 Symptom-based exacerbations PGHD: 4.5 (SD: 2.3), UC: 4.3 (SD: 2.1), Rate ratio: 1.07 (95% CI: 0.65 to 1.75), p=0.80 Exacerbations treated with antibiotics and/or prednisolone PGHD: 1.1 (SD: 1.5), UC: 1.0 (SD: 1.3), Rate ratio: 1.01 (95% CI: 0.53 to 1.93), p=0.97	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Boer et al. (2019)[166]	Health	COPD hospitalizations Patient medical files	PGHD: 6 hospitalizations, UC: 5 hospitalizations Exacerbation-related hospital admissions PGHD: 0.15 (SD: 0.43), UC: 0.14 (SD: 0.41), Rate ratio: 1.25 (95% CI: 0.35 to 4.44), p=0 .74	No
Boer et al. (2019)[166]	Health	QoL Health status, measured with (1) NCSI, which is a battery of instruments measuring 8 subdomains of health status—subjective symptoms, dyspnea emotions, fatigue, behavioral impairment, subjective impairment, general QoL, HRQoL, and satisfaction with relationships; (2) CCQ, which measures 3 subdomains, that is, symptoms, functional status, and mental status, resulting in a total score; and (3) EQ-5d, which measures HRQoL, with a total score based on weighted scores on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression as well as a vertical VAS varying between 0 and 100. At the start and at 12 months, data were gathered on exacerbation history, self-efficacy, and health status. CCQ and EQ-5d were also completed at 3, 6, and 9 months of follow-up.	NCSI QOL PGHD baseline: 12.90 (SD: 8.32), 12-month: 13.01 (SD: 8.27), UC baseline: 19.08 (SD: 11.93), 12-month: 17.11 (SD: 12.14), between group differences on change scores: 2.53 (95% CI: -1.28 to -6.33), p=0.19; NCSI HRQOL PGHD baseline: 4.19 (SD: 1.74), 12-month: 4.00 (SD: 1.61), UC baseline: 4.68 (SD: 1.78), 12-month: 4.76 (SD: 1.93), between group difference in change scores: -0.16 (95% CI: -0.89 to -0.57), p=0.66; CCQ total PGHD baseline: 2.06 (SD: 1.02), 12-month: 1.84 (SD: 0.77), UC baseline: 2.31 (SD: 1.09), 12-month: 2.16 (SD: 1.05), between group difference in change scores: -0.06 (95% CI: -0.38 to -0.26), p=0.70; EQ-5d PGHD baseline: 0.81 (SD: 0.15), 12-month: 0.79 (SD: 0.16), UC baseline: 0.74 (SD: 0.20), 12-month: 0.77 (SD: 0.21), between group difference in change scores: -0.05 (95% CI: -0.13 to -0.03), p=0.22; and EQ VAS PGHD baseline: 65.53 (SD: 17.37), 12-month: 70.94 (SD: 12.92), UC baseline: 64.20 (SD: 15.35), 12-month: 62.63 (SD: 19.14), between group difference in change scores: 6.28 (95% CI: -0.56 to -13.11), p=0.07	No
Demeyer et al. (2017)[161]	Health	Exacerbation Exacerbation history in the last 12 months.	In total, 48 patients (30%) in the control and 43 patients (27%) in the PGHD experienced at least one exacerbation (p=0.54) during the trial, 5 of which led to hospitalization.	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Demeyer et al. (2017)[161]	Health	Adverse events Adverse events were collected during the course of the trial as well as by direct questioning during the final visit.	Eleven musculoskeletal events were described in the PGHD compared with two in UC (p=0.01), none causing study discontinuation. Of those in the PGHD group only one event required treatment (knee inflammation). One patient experiencing back pain was advised to lower his PA in the acute situation. Another patient with back pain was observed for 1 day in hospital, without any treatment being initiated. Three events were judged as possibly related to the intervention by the investigators (two patients with back pain, one patient with a rib fracture), one event (back pain) was judged as unlikely related. Other adverse events, all not related to the study protocol, were cardiovascular problems (n=2), diagnosis of a toe melanoma (n=1), urinary problems (n=2), and gastrointestinal problems (n=3).	Yes
Demeyer et al. (2017)[161]	Health	QoL The following clinical outcomes were collected at visit 2 3: health status measured using CAT and CCQ. The CCQ is a 10-item, self-administered questionnaire that can be completed in less than 2 minutes. Items are divided into three domains: symptom, functional state and mental state; patients are required to respond to each item on a seven-point Likert scale where 0=asymptomatic/no limitation and 6=extremely symptomatic/ total limitation. The final score is the mean of all ten items, and scores for the three domains can be calculated separately if required. Two versions are available: a 7-day version, which asks patients to recall their COPD status over the past week, and a 24-hour version, which is usually used as a diary. CCQ has been validated and has shown strong discriminative properties, test-retest reliability and responsiveness.	CAT baseline median (IQR): UC: 13 (8 to 18) and PGHD: 13 (7 to 20), 3-month UC: 13 (9 to 20) and PGHD: 14 (9 to 19), p=0.39; CCQ symptoms: UC: 1.75 (1.5 to 2.75), PGHD: 1.75 (1.25 to 2.50), 3-month UC: 2 (1.25 to 2.75) and PGHD: 1.75 (1.25 to 2.50), p=0.35; CCQ functional state: UC: 1.50 (0.75 to 2.50), PGHD: 1.50 (1.00 to 2.75), 3-month UC: 1.75 (0.75 to 2.75) and PGHD: 1.50 (1.00 to 2.75), p=0.026; CCQ mental: UC: 1.00 (0 to 2.00), PGHD: 1.00 (0 to 2.50), 3-month UC: 1 (0 to 2.00) and PGHD: 1.00 (0 to 2.50), p=0.18	No except for functional state domain of the CCQ which favored PGHD group.

Study	Outcome Category	Outcome	Results	Statistical Significance
Jehn et al. (2013)[169]	Health	Exacerbations Acute exacerbation of COPD (AECOPD) was defined according to significant worsening of respiratory symptoms requiring change in medication (oral corticosteroids and/or antibiotics) and the presence of at least one of the following items: 1) increased dyspnea, 2) increase in the amount of sputum production and 3) change in sputum purulence. Primary diagnosis of AECOPD was done by the treating physician in the ER and later confirmed by the study physician. All exacerbations in this study analysis were defined as a minimum of ≥ 24 hour hospital stay–duration time.	Summer period (June 1st–August 31st) Significantly fewer PGHD patients suffered exacerbation of COPD during the summer period compared to UC patients (3 for TG vs. 14 for CG; p=0.006). Tempmax on days of exacerbation reached an average of 32.6 ±2.0°C and atmospheric ozone levels of 130.3±20.1 mg/m3.	Yes
Jehn et al. (2013)[169]	Health	Hospital admissions due to exacerbation AECOPD was defined according to significant worsening of respiratory symptoms requiring change in medication (oral corticosteroids and/or antibiotics) and the presence of at least one of the following items: 1) increased dyspnea, 2) increase in the amount of sputum production and 3) change in sputum purulence [20]. Primary diagnosis of AECOPD was done by the treating physician in the emergency room and later confirmed by the study physician. All exacerbations in this study analysis were defined as a minimum of ≥24 hour hospital stay–duration time.	Over 9-month follow-up, PGHD patients showed a significantly lower number of exacerbation related hospital admissions over the 9 month follow-up time compared to UC (7 for PGHD vs. 22 for UC, p=0.012).	Yes
Jehn et al. (2013)[169]	Health	LOS in hospital NR	Over 9-month follow-up, patients in the PGHD group spent significantly less cumulative time in hospital due to COPD complications compared to the UC (34 days versus 97 days).	Yes

Study	Outcome Category	Outcome	Results	Statistical Significance
Jehn et al. (2013)[169]	Health	QOL CAT: A decrease on the CAT is an improvement.	At 9-month follow-up: PGHD group score decreased by 2.9 (SD: 4.5) and the UC group score increased by 4.4 (SD: 5.7).	No test of significance done for between groups. Both groups changed significantly from baseline to the 9-month follow-up visit.
Jodar-Sanchez et al. (2013)[164,165]	Health	Death	Two patients, one from each group, died during the study. This represents 5% of control patients and 4% of telehealth patients.	NR
Jodar-Sanchez et al. (2013)[164,165]	Health	QoL SGRQ15 and EuroQol-5D questionnaires were administered at the beginning and end of the trial period. On SGRQ a lower score indicates an improvement in QoL while on the EuroQol-5D it indicates a worsening.	SGRQ difference Symptom score (SD): UC: -3.7 (19.6), PGHD: -12.8 (32.6), p=0.31; Total score (SD): UC: -4.5 (19.7), PGHD: -10.9 (21.9), p=0.53; EuroQol-5D difference (SD): UC: 0.0034 (0.24), PGHD: 0.0359 (0.28), p=0.68 There were no significant improvements in the HRQoL of patients. However, patients were asked at the end of the study if their health had improved over the previous months. Of the control patients, 35% stated that their QoL had improved, for 12% it had stayed the same, and for 53% it had worsened. In contrast, 46% of the telehealth patients said their QoL had improved, 36% that it had stayed the same, and 18% that it had worsened (p=0.05).	No for SGRQ and EuroQoL-5D but when asked by study staff using a non-standard-ized instrument, yes.
Jodar-Sanchez et al. (2013)[164,165]	Health	ER visits – COPD related	Percentage of patients visiting the A&E department at least once was UC: 33% and PGHD: 17%; number of visits per patient (SD): UC: 0.43 (0.68), PGHD: 0.29 (0.75), p=0.25.	No for number of visits per patient, yes for difference in % of patients visiting ER at least once in favor of PGHD.

Study	Outcome Category	Outcome	Results	Statistical Significance
Jodar-Sanchez et al. (2013)[164,165]	Health	Hospitalizations – COPD related	Percentage of patients who were hospitalized at least once was UC: 14, PGHD: 21; average number of hospitalizations per patient (SD): UC: 0.14 (0.36) PGHD: 0.38 (0.82), p=0.47; average LOS, days (SD): UC: 1.4 (4.0), PGHD: 4.4 (12.2), p=0.50.	No for average number of hospitalizations per patient and LOS but NR for % of patients hospitalized at least once.
Kawagoshi et al. (2015)[162]	Health	Death NR	One patient in each group died.	NR
Kawagoshi et al. (2015)[162]	Health	Hospitalizations NR	One patient in each group required hospitalization due to a COPD exacerbation.	NR
Kawagoshi et al. (2015)[162]	Health	QoL CRQ total score and dyspnea and fatigue subscores	CRQ total scores. Both groups improved over time but study authors did not perform a between group test of statistical significance. The results were: PGHD baseline: 98 (SD: 20), 1-year follow-up: 108 (SD: 19) and UC: 99 (SD: 19) and 1-year follow-up: 110 (SD: 19). The authors reported on the subscales dyspnea (only PGHD group improved over time) and fatigue (neither group improved significantly over time). Again, no between group test of statistical significance was performed.	NR
Kawagoshi et al. (2015)[162]	Surrogate	6-minute walk distance (6MWD)	Kawagoshi found both groups significantly improved on this outcome. The results were as follows: PGHD baseline: 369 (SD: 119), 1-year follow-up: 445 (SD: 138) and UC baseline: 404 (SD: 148) and 1-year follow-up: 467 (SD: 151). No between group comparison was performed.	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Nolan et al. (2017)[168]	Health	QoL CRQ total score (range 20 to 140, with higher scores representing better health)	Change from baseline to immediately following PR: PGHD group: 11.0 (95% CI: 3.0 to 20.0) and for UC group: 20.0 (95% CI: 8.0 to 27.0), p=0.008; Change from baseline to 6-month following PR: PGHD group: 3.0 (95% CI: -8.0 to 16.0) and for UC: 10.0 (95% CI: -2.0 to 19.0), p=0.07	Yes for short-term change only, favoring the control group. Authors adjusted for baseline CRQ values, and the group effect for differences in the total scores remained significant. However, between-group differences in CRQ did not persist at 6 months.
Nolan et al. (2017)[168]	Health	QoL CRQ dyspnea scored as follows: 5 to 35, higher scores better health status	The authors found nonstatistically significant differences between the two study arms: change from baseline to immediately following PR, PGHD: 3.7 (95% CI: 2.1 to 5.2) versus usual care: 5.6 (95% CI: 4.2 to 7.0), p=0.07 and change from baseline to 6 months following PR: PGHD: 1.8 (95% CI: -0.1 to 3.6) versus usual care: 3.7 (95% CI: 2.1 to 5.3), p=0.10.	No
Nolan et al. (2017)[168]	Health	AEs Gathered throughout study, no further explanation.	One participant experienced an allergic reaction to the nickel baseplate of the accelerometer during baseline assessments and as a result was not randomized.	NR
Nolan et al. (2017)[168]	Health	Hospitalizations	In total, there were 56 hospital admissions (PGHD group, n=23; control group, n=33, p=0.50). Thirty of these admissions were for COPD (PGHD group, n=14; control group, n=16, p=0.29).	No
Nolan et al. (2017)[168]	Health	Death	Four deaths (two in each group) were recorded during the study period.	NR

Study	Outcome Category	Outcome	Results	Statistical Significance
Tabak et al. (2014)[163]	Health	QoL CCQ: A change of 0.4 represents the minimal important difference for an individual patient. MRC Dyspnea Scale was used to grade the effect of dyspnea on daily activity.	CCQ score PGHD baseline: 2.0±0.8, change: -0.3±0.5, UC baseline: 1.8±1.0, change: 0.0±0.6, between group p=0.10 MRC score PGHD baseline: 2.0±0.9, change: -0.3±0.7, UC baseline: 2.3±1.4, change: -0.2±0, between group p=NS A minimal clinical important improvement in health status of ≥0.4 was found in five patients in the intervention group (n=13), and one patient significantly decreased health status. In the control group (n=15), three patients showed a clinical improvement and three patients showed a clinical significant worsening of the health status.	No for CCQ and MRC.
Vorrink et al. (2016)[50,58]	Health	QoL CRQ-SAS: found to be a reproducible, reliable and stable measure of health status. In addition, it has been found to be reliable and valid in the Dutch language. Scores range from 1 to 7 for each item. CRQ incorporates patient perceptions of both physical and emotional health. Four aspects of HRQL are evaluated: dyspnea, fatigue, emotional function, and mastery (related to psychological status). Each domain includes 4 to 7 items, with each item graded on 7-point Likert scale; item scores within a domain are summated to provide a total score for each domain. Higher scores indicate better HRQL. The 4 domains are scored separately and can illustrate changes in individual domains of HRQL.	Only fatigue showed a significant group by time interaction, however one group was not consistently favored over the other. For dyspnea, the results were as follows: PGHD baseline: 4.84 (SD: 0.15), change at 3 months: 0.17 (95% CI: -0.45 to 0.38), change at 6 months: 0.11 (95% CI: -0.14 to 0.35), change at 12 months: -0.17 (95% CI: -0.44 to 0.09) and UC baseline: 4.79 (SD: 0.15), change at 3 months: 0.01 (95% CI: -0.21 to 0.23), change at 6 months: -0.13 (95% CI: -0.33 to 0.08), and change at 12 months: -0.08 (95% CI: -0.30 to 0.14), showing no differences between the groups (p=0.859). The group by time interaction was also nonsignificant (p=0.179). For fatigue, the results were: PGHD baseline: 4.35 (SD: 0.1), change at 3 months: 0.05 (95% CI: -0.15 to 0.26), change at 6 months: -0.19 (95% CI: -0.39 to 0.01), change at 12 months: -0.14 (95% CI: -0.35 to 0.07) and UC baseline: 4.20 (SD: 0.13), change at 3 months: -0.06 (95% CI: -0.28 to 0.17), change at 6 months: 0.13 (95% CI: -0.12 to 0.37), change at 12 months: -0.12 (95% CI: -0.37 to 0.13).	No
Arbillaga-Etxarri et al. (2018)[52]	Surrogate	6-minute walk distance (m)	6MWD: PGHD baseline: 509 (SD: 83) and 12-month follow-up: 502 (SD: 97) and UC baseline: 503 (SD: 79) and 12-month follow-up: 496 (SD86)	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Demeyer et al. (2017)[161]	Surrogate	6-minute walk distance (m)	Change in 6MWD was significantly different (13.4, 95% CI (3.40 to 23.5) m, p<0.01), favoring the PGHD	Yes, favored PGHD.
Jehn et al. (2013)[169]	Surrogate	6-minute walk distance (m)	The PGHD group showed a significant improvement in 6MWT distance between baseline and 9-month follow-up (Mean Difference in 6MWT: +87.0 (SD: 65.7) meters, p=0.006) versus UC group, which showed no significant change (MD: +23.9 (SD: 70.3) meters, p=0.23). There was no between group difference.	No
Jehn et al. (2013)[169]	Surrogate	FEV1% Measured by handheld spirometer	At the 9 month follow-up: PGHD increased by 2.5 (SD: 5.2) while UC decreased by 0 .07 (SD: 9.2).	No
Mendes de Oliveira et al. 2010[167]	Surrogate	6-minute walk distance (m) Control group data based on a graph. According to study authors “an increase in the distance walked on the 6MWT of at least 54 meters over baseline values is clinically important in terms of the improvement in physical capacity."	There was a clinically significant improvement in the distance walked between the pre-post data for patients in the at home pulmonary rehabilitation group: 73.2 (SD: 50.2) meters, p<0.05. The control group demonstrated no change at the end of the study compared to baseline (p>0.05). Based only on graph data, the distance at baseline was 300 m and at 12 weeks it was 285 m for the control patients. Between group difference was p<0.05 favoring at home PR plus PGHD.	Yes, favored at home PR with PGHD over no treatment.
Nolan et al. (2017)[168]	Surrogate	Incremental Shuttle Walk Test (m)	The authors did not find a significant between group difference for either the end of treatment time point or the 6-month follow-up visit. The results were as follows: change from baseline to end of treatment (PGHD: 60 [95% CI: 20 to 90] and UC: 50 [95% CI: 10 to 90], p=0.83) and change from baseline to 6-month follow-up (PGHD: 30 [0 to 70] and UC: 10 [-30 to 70], p=0.25).	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Vorrink et al. (2016)[50,58]	Surrogate	Lung function FEV1 and FVC were measured using a Spiromed 2000 (Medikro, Finland). Spirometry was performed according to American Thoracic Society/European Respiratory Society guidelines, and the results were compared to normal values of QUANJER et al.	Vorrink reported on lung function but did not find a statistically significant between-group difference for this outcome. FEV1/FVC showed no between group difference (p=0.34) or group by time interaction (p=0.908), meaning that the decline over time was not significantly different between the groups. FEV1 was significantly higher in the intervention group at the end of follow-up (PGHD group decreased at an average of 56 mL over the 1-year followup period and 98 mL in the UC group [p=0.05]). However, the group by time interaction was non-significant (p=0.508), meaning that there was no effect of the intervention on FEV1.	No
Vorrink et al. (2016)[50,58]	Surrogate	6-minute walk distance	Vorrink did not find a statistically significant difference between groups for this outcome. There was no significant decrease in 6MWD over time (p=0.53), and no differences between the groups (p=0.485). The group by time interaction was also non-significant (p=0.585). The results were as follows: PGHD baseline: 456 (SD: 14), change at 3 months: 4.1 (95% CI: -2.8 to 11.1), change at 6 months: 4.8 (95% CI: -3.9 to 13.5), change at 12 months: 0.8 (95% CI: -8.8 to 10.3) and UC baseline: 461 (SD: 8), change at 3 months: 1.9 (95% CI: -4.1 to 7.9), change at 6 months: 3.3 (95% CI: -2.9 to 9.6), and 4 (-2.4 to 10.3).	No
Vorrink et al. (2016)[50,58]	Surrogate	BMI Height was measured only at baseline. Weight was measured at all visits.	BMI: PGHD baseline: 27.7 (SD: 0.58); change at 3 months: 0.08 (95% CI: -0.11 to 0.26), change at 6 months: 0.12 (95% CI: -0.14 to 0.37), change at 12 months: -0.05 (95% CI: -0.37 to 0.27) and UC baseline: 26.7 (SD: 0.60), change at 3 months: 0.06 (95% CI: -0.13 to 0.26), change at 6 months: 0.32 (95% CI: 0.07 to 0.57), change at 12 months: 0.09 (95% CI: -0.20 to 0.39)	No
Boer et al. (2019)[166]	Process	Resource use Chart review	Unscheduled healthcare consultations because of respiratory complaints: PGHD: 1.6 (SD: 1.7), UC: 1.6 (SD: 2.0), Rate ratio: 0.89 (95% CI: 0.50 to 1.60), p=0.70.	No

Study	Outcome Category	Outcome	Results	Statistical Significance
Boer et al. (2019)[166]	Process	Symptom-based exacerbation self-management Logistic regression including participant as cluster variable, controlling for age and gender.	Out of 377 total exacerbations, 187 in PGHD and 190 in UC: Contact health care professional n (%): PGHD: 61 (32.6%), UC: 68 (35.8%), Odds ratio: 0.94 (95% CI: 0.51 to 1.73), p=0.83; Start prednisolone and/or antibiotics: PGHD: 64 (34.2%), UC: 62 (32.6%), Odds ratio: 1.16 (95% CI: 0.55 to 2.44), p=0.69; Increase bronchodilator use: PGHD: 135 (72.2%), UC: 135 (71.1%), Odds ratio: 1.08 (95% CI: 0.56 to 2.06), p=0.82	No
Jehn et al. (2013)[169]	Process	Visits to lung specialist NR	Over 9-month follow-up: Overall the PGHD group had significantly fewer visits to the lung specialist (24 for PGHD vs. 42 visits for UC, p=0.042).	Yes
Jehn et al. (2013)[169]	Process	Visits to primary care doctor NR	Over 9-month follow-up: PGHD group had slightly fewer visits to the primary care physician (9 for TG vs. 11 visits for the CG, p=0.76).	No
Jodar-Sanchez et al. (2013)[164,165]	Process	Resource use - COPD related	Specialized care consultations: Percentage of patients who were referred to specialized care unit, UC: 4.8% vs. PGHD: 16.7%; number of visits per patient (SD): UC: 0.05 (0.22), PGHD: 0.25 (0.61), p=0.20.	No

Jodar-Sanchez et al. (2013)[164,165]	Cost-utility	Cost utility analysis The costs of the healthcare utilization, costs of the professionals' intervention and costs of the telehealth system were measured in euros at 2014 prices. Prices from previous years were updated by the Spanish consumer price index. The following variables were analyzed: 1. A&E department visits, specialized care consultations and hospital admissions were evaluated according to public prices. 2. The time employed by the CCC was estimated according to the type of alert generated in the triage application: 25 min for clinical alerts, 15 min for alerts generated by non-adherence to the system, non-receipt of data and technical reinforcement, and 10 min for alerts generated for other reasons. The cost per hour of the CCC, with nursing graduate, was calculated in line with the salary rates of the Andalusian Health Service. 3. The time employed by the case manager was estimated depending on the level of seriousness of the exacerbation: 20 min for mild to moderate exacerbations, 25 min for severe exacerbations and 30 min for very severe exacerbations. The cost per hour of the case manager, with nursing graduate, was calculated in line with the salary rates of the Andalusian Health Service. 4. The time employed by technical staff was estimated as 60 min for equipment installation and 30 min for technical incidents. This cost includes the journey to the patient's house and was calculated by the company supplying the service. 5. The cost of the software and equipment was provided by the service supplying company and was calculated using the equivalent annual cost, a method which takes into account both depreciation and the opportunity cost of the capital. The	The average healthcare cost was E2064 for the PGHD and E1103 for the UC, (a difference of E961, 95% CI: -809 to 2731). The average total cost was E2300 for the PGHD and E1103 for the UC (difference of E1197, 95% CI: -579 to 2973). The average increase in the utility score was 0.036 score for the PGHD and 0.003 score for the UC (difference of 0.032 score, 95% CI: -0.12 to 0.19). The UC obtained a higher average QALY than PGHD, determined by the differences in the basal utility scores. Cost-utility analysis based on 5000 bootstrap replications: The average total cost per patient was E2300 for the PGHD and E1103 for the UC, resulting in an incremental cost of E1197. The average QALY gain was 0.0059 for the PGHD and 0.0006 for the UC, resulting in an incremental QALY gain of 0.0053. Authors report an ICER of 223,726 E/QALY. The cost-effectiveness plane showed that 59% of the bootstrap simulations were located in the upper-right quadrant, and that 33% of the bootstrap simulations were located in the upper-left quadrant. The acceptability curve showed that for a willingness to pay of 30,000 E/QALY, the probability of the telehealth program being cost-effective was 15%. COST utility analysis based on 5000 bootstraps: All patients PGHD: 2300.08, UC: 1103.17, ICER: 1196.91 (-498.97 to 2892.80), without comorbidity PGHD: 855,13 UC: 1353.85, ICER: -498.72 (-2451.38 to 1453.94), with comorbidity PGHD: 2781.73, UC: 948.91 (-223.00 to 3888.66). Average QALY gain: All patients PGHD: 0.0059, UC: 0.0006, ICER: 0.0053 (-0.0193 to 0.0300), without comorbidity PGHD: 0.0288, UC: 0.0082, ICER: 0.0206 (-0.0259 to 0.0671), with comorbidity PGHD: -0.0017, UC: -0.0041, ICER: 0.0024 (-0.0251 to 0.0300). ICER (E/QALY): All patients 223,726.18; without comorbidity dominant; with comorbidity 754,591.69.	For all patients combined (regardless of co-morbidity status) with 30,000 E/QALY being the threshold for determining whether a health technology is cost-effective in Spain, the authors report that the telehealth program for patients with severe COPD treated with long-term oxygen therapy may not be cost-effective compared to UC. The acceptability curve showed that there is little uncertainty, since only 15% of the bootstrap simulations are below the threshold of 30,000 E/QALY.

		lifetime of the equipment and software was set at 5 years and the discount rate at 3%. To calculate the cost of the software we took into account that up to a maximum of 500 patients can be tele-monitored with this infrastructure/software and we used this to estimate the cost associated for each patient. EuroQol-5D: The scores were used to estimate a utility score, a single index on health-related quality of life between 1 and 0, where 1 is the best possible state of health and 0 is death. However, there were also negative utility scores because some states of health are considered to be worse than death. The effectiveness of the telehealth program was estimated as a QALYs gain. For each patient, QALYs were calculated by using the area under the curve analysis, with linear interpolation of utility scores between baseline and four months of follow-up. Deceased patients were assigned a EuroQol-5D utility score of zero at four months. For each patient, the QALY (not taking into account the differences in the basal utility scores) and QALY gain (taking into account the differences in the basal utility scores) corresponding to the four months of monitoring was calculated. Cost and QALY were estimated for each patient. Results of cost-utility analysis were expressed in terms of the ICER, calculated as the difference in the average costs between TG and CG divided by the difference in the average QALY gain between TG and CG. Discounting of costs and QALYs was not necessary because the time horizon of the study, four months, did not extend beyond 12 months. To analyze uncertainty and verify the robustness of the ICER, we conducted an analysis using a non-parametric bootstrap with 5000 replications.		

BMI = body mass index; BP = blood pressure; CCC = clinical call center; CCQ = Clinical Chronic Obstructive Pulmonary Disease Questionnaire; CI = confidence interval; COPD = chronic obstructive pulmonary disease; CRQ-SAS = chronic respiratory disease questionnaire self-administered standardized; ER = emergency room; GOLD = Global Initiative for Chronic Lung Disease; HR = heart rate; HRQoL = health-related quality of life; IQR = interquartile range; LTOT = long-term oxygen therapy; mMRC = modified Medical Research Council; NR = not reported; PA = physical activity; PR = pulmonary rehabilitation; PGHD = patient-generated health data; pO2 = partial pressure of oxygen; PR = pulmonary rehabilitation; QoL = quality of life; SD = standard deviation; Spo2 = blood oxygen saturation; UC = usual care; VAS = visual analog scale

Table C-62. Asthma and PGHD: trials identified in Clinicaltrials.gov

Title	Status	Conditions	Interventions	Locations
Using Technology-Assisted Stepped Care Intervention to Improve Adherence in Adolescents With Asthma https://ClinicalTrials.gov/show/NCT04365556	Recruiting	Adolescents with Asthma	Device: Inhaler Adherence Electronic Monitoring using a Bluetooth enabled sensor attached to the patient's inhaler. Comparator: usual care	Children's Hospital Medical Center, Cincinnati
Mitigating the Health Effects of Desert Dust Storms Using Exposure-Reduction Approaches https://ClinicalTrials.gov/show/NCT03503812	Recruiting	Asthma in Children, Adults with Atrial Fibrillation	Device: Intervention for outdoor exposure reduction, by reducing the time spend outdoors and by avoiding physical activity including bidirectional, patient-centered e-Platform, smart wristwatches equipped with Global Positioning System (GPS) and an accelerometer. Device: Same as above plus an indoor exposure reduction intervention (by minimizing home ventilation and filtering indoor air) using particle samples. Comparator: No intervention	Medical School, University of Cyprus, Nicosia, Aglantzia, Cyprus School of Medicine, University of Crete, Heraklion, Crete, Greece, Soroka University Medical Center, Be'er Sheva, Israel
Digital Prevention of Asthma https://ClinicalTrials.gov/show/NCT04132778	Recruiting	Asthma|, Care Management, Patient	Device: AsthmaTuner Comparator: Traditional self-management	Healthcare Region Tiohundra, Norrtälje, Sweden, Astrid Lindgren Children's Hospital, Stockholm, Sweden

Table C-63. Asthma and PGHD: general study information

Study	Design	Country	Years Enrollment	Statistical Power Methods	N at Baseline	Study Duration
Ljungberg et al. (2019)[170]	RCT	Sweden	05/2016 to 09/2018	The sample size was estimated assuming that AsthmaTuner would improve the average ACT/C-ACT score by 2 points compared with conventional treatment (mean SD: 3.3). Assuming a dropout rate up to 10%, our power calculation estimated that enrolment of 43 adults and 43 children would be clinically relevant and feasible to attain 80% power at a 5% significance level.	77	2 months

ACT = asthma control test; C-ACT = children asthma control test; SD = standard deviation

Table C-64. Asthma and PGHD: patient characteristics

Study	Key Inclusion Criteria	Mean Age	% Female	Disease Severity	Rural Population
Ljungberg et al. (2019)[170]	The study subjects were children aged ≥6 years and adults with at least a doctor's diagnosis of asthma, and ACT/C-ACT scores <20 points from May 2016 to September 2018. Exclusion criteria were presence of any comorbidity with significant impact on symptom control, participation in drug trials and patient/caregiver difficulties in reading Swedish. The study was conducted in Stockholm, Sweden, in the primary healthcare sector and specialized pediatric healthcare, at Liljeholmen Health Care Centre, Sophiahemmet Health Care Centre and Astrid Lindgren Children's Hospital.	22 (SD: 14.5)	60	ACT/C-ACT score: 15.6±3.1 FVC % pred: 88.9±12.4 FEV1 % pred: 86.4±14.2	NR

ACT = asthma control test; C-ACT = children asthma control test; FEV1 = forced expiratory volume in 1 second; FVC = forced vital capacity; NR = not reported; SD = standard deviation

Table C-65. Asthma and PGHD: treatment details

Study	Treatment 1	Treatment 2
Ljungberg et al. (2019)[170]	Usual care (UC): UC was defined as non-digital self-management using individual printed treatment plans, which contained treatment adjustments of prescribed medications according to symptoms of controlled, partly controlled or uncontrolled asthma, along with instructions according to national guidelines.	PGHD (SmartOne Spirometer): Whole intervention was AsthmaTuner (MediTuner, Stockholm, Sweden), a certified (CE-marked) cloud computing-based system with a healthcare interface and a downloadable patient app (Android or iOS). AsthmaTuner was conceptualized and developed in response to the perceived gap between guidelines/treatment recommendations and clinical practice. The primary aims were to facilitate distribution of treatment plans to patients and to improve self-management and education for patients, as the software helps patients decide the current state of their asthma. The intended use of AsthmaTuner is to automate asthma self-management by letting patients register symptoms and measure forced expiratory volume in 1 s (FEV1) with a Bluetooth spirometer (MIR SmartOne; Medical International Research, Rome, Italy). The patient then receives immediate feedback on the status of symptom control (controlled, partly controlled or uncontrolled) and a treatment recommendation, with an image of the correct inhaler or other type of medication and the dose. Symptom control is quantified based on lung function (percentage of personal best FEV1, using a cut-off of 80%) and symptoms during the last week, based on four questions identifying: 1) need for rescue medication more than twice due to asthma symptoms, 2) any daytime symptoms, 3) nocturnal symptoms/awakenings and 4) limitation in physical activities. AsthmaTuner offers patients and healthcare providers longitudinal data views of assessed symptom control, prescribed treatments and lung function measurements. The back-end data storage of the cloud-based system provides information about participant adherence with AsthmaTuner use.

FEV1 = forced expiratory volume in 1 s; PGHD = patient-generated health data

Table C-66. Asthma and PGHD: risk of bias

Study	1 Random sequence generation	2 Allocation concealment	3 Groups similar at baseline or were differences controlled for?	4 Isolated effect?	5 Were outcomes prespecified and reported?	6 Were participants analyzed based on originally-assigned groups across timepoints?	7 Was attrition low and adherence high?	8 Were outcome assessors and data analysts masked?	9 Were reliable measures of outcomes used consistently across all participants?	Overall Risk of Bias
Ljungberg et al. (2019)[170]	+	−	−	+	+	+	+	+	+	Moderate

+ solid green circle with a plus sign indicates low risk of bias; ? solid yellow circle with a question mark indicates unclear risk of bias; − solid red circle with a minus sign indicates high risk of bias

Table C-67. Asthma and PGHD: Results

Study	Outcome Category	Outcome	Results	Statistical Significance
Ljungberg et al. (2019)[170]	Health	Adverse events	Three patients (one each) terminated the study due to severe snake bite, pertussis, and another respiratory diagnosis.	NR
Ljungberg et al. (2019)[170]	Guiding Question 2	Adherence to device	PGHD (Smart One Spirometer) vs. UC, 62/77 patients used AsthmaTuner (including the SmartOne spirometer, the PGHD of interest) on average once weekly or more. That was 27/37 adults and 35/40 pediatric patients.	NA
Ljungberg et al. (2019)[170]	Health	Asthma control Assessed at baseline and at end-visit in each treatment period with a validated ACT in patients aged ≥12 years and C-ACT in children aged 6–11 years. A mean score less than or equal to 19 points indicated uncontrolled asthma in both tests.	PGHD (SmartOne Spirometer) vs. UC PGHD mean: 19.45 (95% CI: 18.70 to 20.21) vs. UC: 18.75 (95% CI: 17.97 to 19.53), difference between PGHD and UC: 0.70 (95% CI: 0.06 to 1.34, p=0.03) Adult patients only: PGHD: 19.14 (95% CI: 18.08 to 20.19) vs. UC: 18.78 (95% CI: 17.63 to 19.94), difference between PGHD and UC: 0.33 (95% CI: -0.68 to 1.35, p=0.51) Pediatric specialist care only: PGHD: 19.75 (95% CI: 18.65 to 20.85) vs. UC: 18.73 (95% CI: 17.61 to 19.84), difference between PGHD and UC: 0.97 (95% CI: 0.13 to 1.81, p=0.02)	Significantly better for PGHD group when adults and children combined and for children only group. No for the adults only.

ACT = asthma control test; C-ACT = children asthma control test; NA = not applicable; NR = not reported; PGHD = patient-generated health data; UC = usual care