

# Effective Health Care Program

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Future Research Needs Paper  
Number 43

## **Strategies To Prevent Weight Gain in Adults: Future Research Needs**



**Agency for Healthcare Research and Quality**  
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# ***Future Research Needs Paper***

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**Number 43**

## **Strategies To Prevent Weight Gain in Adults: Future Research Needs**

**Identification of Future Research Needs From Comparative Effectiveness Review  
No. 97**

**Prepared for:**

Agency for Healthcare Research and Quality  
U.S. Department of Health and Human Services  
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**Addendum August 2013**

**Addendum**  
August 5, 2013

The report *Strategies To Prevent Weight Gain in Adults: Future Research Needs* was posed for public comment from June 27, 2013, to July 26, 2013, on the Effective Health Care Program Web site. We received three sets of comments.

In response to the comments received, the authors add the following discussion point:

- Adults with physical disability may need to be considered as an additional subgroup at high risk for obesity and targeted for weight gain prevention interventions. If this group is selected, then investigators should consider including additional outcome measures such as health-related quality of life and physical function.

All other comments were related to gaps outside the scope of the original systematic review including endocrine and hormonal causes of weight gain, and the association of geographic positioning data and weight gain. These comments were considered, and no other changes were made in this report.

This report is based on research conducted by the Johns Hopkins University Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10061-I). The findings and conclusions in this document are those of the author(s), 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.

The information in this report is intended to help health care researchers and funders of research make well-informed decisions in designing and funding research and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of scientific judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical research and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances.

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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 health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

An important part of evidence reports is to not only synthesize the evidence, but also to identify the gaps in evidence that limited the ability to answer the systematic review questions. AHRQ supports EPCs to work with various stakeholders to identify and prioritize the future research that is needed by decisionmakers. This information is provided for researchers and funders of research in these Future Research Needs papers. These papers are made available for public comment and use and may be revised.

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. The evidence reports undergo public comment prior to their release as a final report.

We welcome comments on this Future Research Needs document. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

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# Strategies To Prevent Weight Gain in Adults: Future Research Needs

## Structured Abstract

**Objective.** To identify and prioritize questions for future research in adult weight gain prevention.

**Methods.** We identified potential research needs based on gaps identified from a recent systematic review, and then engaged seven stakeholders to participate in a Delphi process to prioritize PICOTS (populations, interventions, comparisons, outcomes, timing, settings) elements. We then used these results to create research questions, which our stakeholders prioritized.

**Results.** Based on consensus, seven questions were of highest priority: (1) To prevent weight gain in all adults, what is the comparative effectiveness of adding physical activity versus not adding physical activity to a work-based self-management and diet intervention? (2) To prevent weight gain in all adults, what is the comparative effectiveness of adding physical activity versus not adding physical activity to a home-based self-management and diet intervention? (3) To prevent weight gain in all adults, what is the comparative effectiveness of a work-based self-management and physical activity intervention versus a self-management and diet intervention? (4) To prevent weight gain in all adults, what is the comparative effectiveness of a home-based self-management and physical activity intervention versus a self-management and diet intervention? (5) To prevent weight gain in overweight (body mass index [BMI]  $\geq 27\text{kg/m}^2$ ) adults, what is the comparative effectiveness of adding physical activity versus not adding physical activity to a home-based self-management and diet intervention? (6) To prevent weight gain in overweight (BMI  $\geq 27\text{kg/m}^2$ ) adults, what is the comparative effectiveness of a home-based self-management and physical activity intervention versus a self-management and diet intervention? (7) To prevent weight gain in young adults (age 18–35), what is the comparative effectiveness of adding physical activity versus not adding physical activity to a home-based self-management and diet intervention?

**Conclusion.** Stakeholders prioritized strategies to prevent weight gain for all/overweight/young adults in work/home settings, as they may lead to significant benefits from avoiding obesity. Rigorous studies that evaluate high-quality interventions addressing these topics are needed.

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# Executive Summary

## Background

The most recent estimates classify more than 35 percent of U.S. adults as obese. Obesity has been linked to increased risk of diseases such as hypertension, diabetes mellitus, kidney disease, and cancer; decreased life expectancy; and increased costs. Healthy People 2020 identified preventing weight gain and the development of obesity as a priority area, specifically to increase the prevalence of a healthy weight among adults from 31 percent to 34 percent and reduce the prevalence of obesity among adults to less than 30 percent. Despite this goal, we know of no treatment guidelines for the prevention of weight gain or maintenance of weight.

In 2012, the Johns Hopkins University Evidence-based Practice Center completed a comparative effectiveness review (CER) funded by the Agency for Healthcare Research and Quality on the comparative effectiveness of strategies to prevent weight gain in adults. Prior systematic reviews on weight gain prevention were limited by the inclusion of studies that included a weight loss component or measured only short-term outcomes (less than 12 months). Understanding what strategies are the most effective to prevent weight gain in adults may help establish treatment guidelines in order to achieve the Healthy People 2020 goal to increase the prevalence of a healthy weight among adults to 34 percent. The report, “Strategies To Prevent Weight Gain Among Adults,” released in 2013 ([www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm)), focused on the six Key Questions listed in Table A.

**Table A. Key Questions of the comparative effectiveness review**

| Number | Question   |
|--------|--|
| KQ1.   | What is the comparative effectiveness of self-management strategies for the prevention of weight gain among adults?  |
| KQ2.   | What is the comparative effectiveness of dietary strategies for the prevention of weight gain among adults?  |
| KQ3.   | What is the comparative effectiveness of physical activity strategies for the prevention of weight gain among adults?  |
| KQ4.   | What is the comparative effectiveness of medications for the prevention of weight gain among adults?   |
| KQ5.   | What is the comparative effectiveness of a combination of self-management, dietary, physical activity, and medication strategies for the prevention of weight gain among adults? |
| KQ6.   | What is the comparative effectiveness of environment level strategies for the prevention of weight gain among adults?  |

**Abbreviation:** KQ = Key Question

In the CER, the authors graded almost all of the evidence as low or insufficient in strength to address the Key Questions. As a result, all research questions were identified as gaps in the literature, limiting the report authors' ability to answer the Key Questions and make conclusions. The authors also identified broader methodological issues that limited the quality of available studies and resulted in the downgrading of the evidence.

## **Methods**

We identified potential research needs by abstracting research gaps from the CER and gaps identified by the authors of the report during in-person discussions. We also searched the National Institutes of Health's [clinicaltrials.gov](http://clinicaltrials.gov) Web site to identify any ongoing clinical trials that may address the Key Questions proposed in the CER. Since all research questions were identified as gaps in the literature, we used a Delphi process with our stakeholders to prioritize evidence gaps using PICOTS elements (population, intervention, comparison, outcome, timing, setting) that need future research.

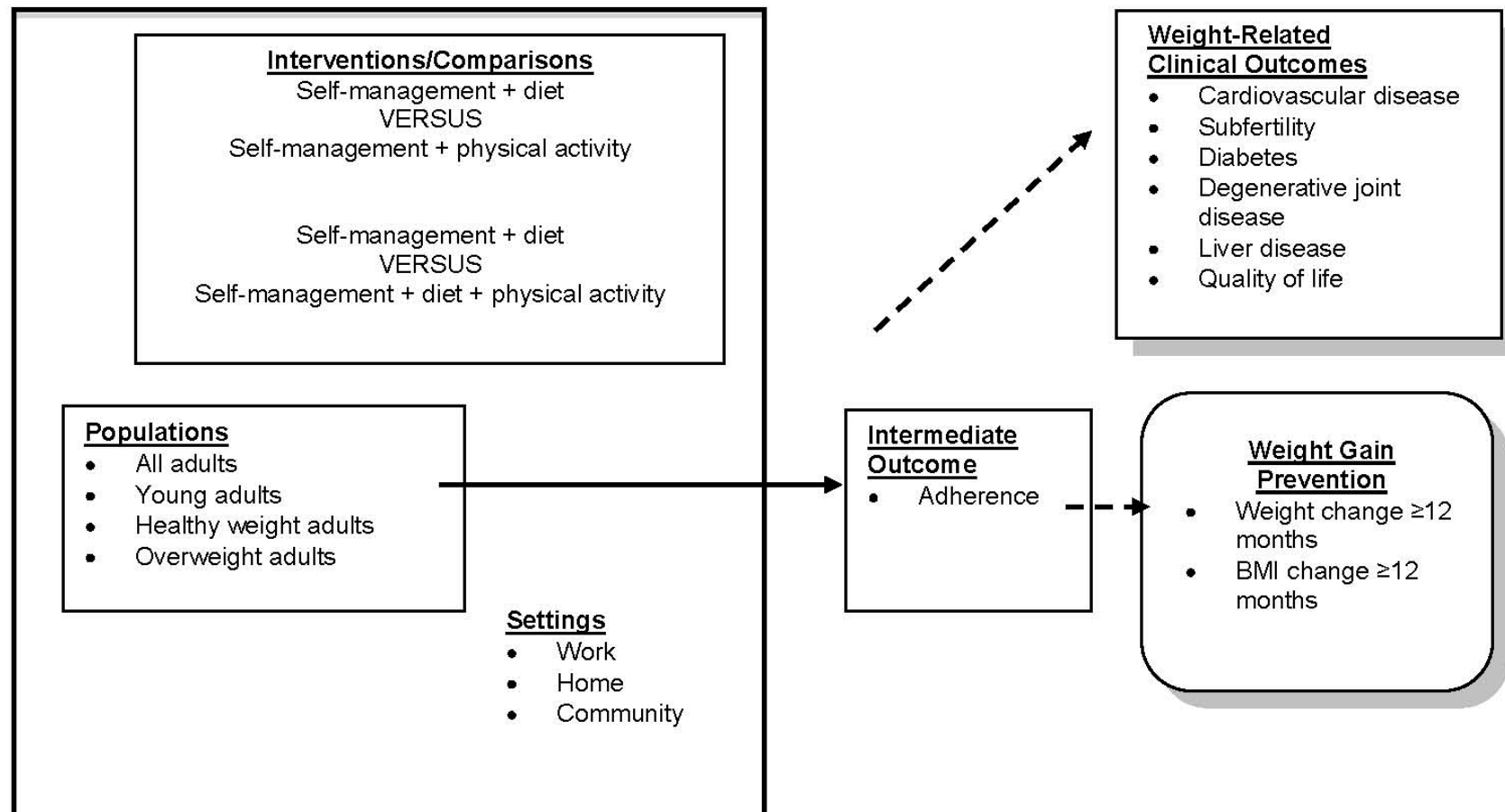
We recruited a diversity of stakeholders to represent various groups with potential interest in weight gain prevention, such as patients, physicians, researchers, insurers, employers, and funding agencies. Stakeholders were recruited via email and completed all rounds of the Delphi process using Web-based surveys. Stakeholders were directed to read the Executive Summary of the 2012 draft of the CER and use this document to inform their answers.

We created a list of crucial questions for future research using the PICOTS elements identified as high-priority research gaps, which our stakeholders prioritized again through a Delphi process. Based on the identified high-priority research needs, we created a matrix of potential research questions. Stakeholders were directed to evaluate research questions based on their potential to positively impact health and public health.

## **Results**

Using the PICOTS framework, stakeholders prioritized all adults, young adults, healthy-weight adults, and overweight adults according to their prevalence in the U.S. population and the potential health benefits of preventing the development of obesity in these groups (Figure A).

**Figure A. Framework for future research on strategies for the prevention of adult weight gain to address high-priority evidence gaps**



**Note:** BMI = body mass index

Stakeholders identified combination interventions as the priority for future research. They stated that multiple factors contribute to weight gain. Therefore, they felt that interventions would need to address multiple factors, which would likely require multiple components. Stakeholders selected interventions that combined either self-management, diet, and exercise or self-management, diet, exercise, and environmental alterations as the two highest priority combinations of interventions. However, in selecting comparisons of interventions that would be of greatest priority, stakeholders downgraded interventions that included environmental approaches (not included in Figure A). The two highest priority comparisons of interest were self-management and diet versus either self-management and exercise or self-management, diet, and exercise. Stakeholders prioritized three settings for the interventions to take place: work, home, and community. These settings were selected because adults spend the majority of their time in these three locations, and that is where they interact with other people who are likely to have some influence on their habits and behaviors.

Stakeholders identified the primary outcome of interest for all interventions as weight gain prevention. Because no standard definition of weight maintenance exists, all stakeholders agreed that the field of weight gain prevention would benefit from the establishment of a standard definition. This definition would ensure that future studies of weight gain prevention have an adequate duration of followup to confirm weight maintenance and also improve comparability of results across studies. In addition, stakeholders identified two priority secondary outcomes that should be assessed in future interventions (Figure A). First, they felt that adherence was a critical intermediate outcome in evaluating the efficacy of the intervention and identifying subgroups that may be most responsive to a particular intervention. Second, the stakeholders identified weight-related clinical conditions, including cardiovascular disease and diabetes, as important secondary outcomes. Their justification was that interventions that not only prevent weight gain but also prevent or reduce the incidence of weight-related diseases would have a significant public health impact.

In their response to the matrix of questions, stakeholders identified seven research questions and one methodologic question as high priorities for future research (Table B). Stakeholders stated that creating a standard definition of weight maintenance was critical to helping researchers confirm true weight maintenance over time, as well as to increase comparability of results across studies.

**Table B. Questions prioritized for future research**

| <b>Research Questions</b>   |
|---|
| To prevent weight gain in <b>all adults</b> , what is the comparative effectiveness of adding <b>physical activity</b> versus not adding physical activity to a <b>work-based self-management and diet</b> intervention?                |
| To prevent weight gain in <b>all adults</b> , what is the comparative effectiveness of adding <b>physical activity</b> versus not adding physical activity to a <b>home-based self-management and diet</b> intervention?                |
| To prevent weight gain in <b>all adults</b> , what is the effectiveness of a <b>work-based self-management and physical activity</b> intervention versus a <b>self-management and diet</b> intervention?                                |
| To prevent weight gain in <b>all adults</b> , what is the effectiveness of a <b>home-based self-management and physical activity</b> intervention compared with a <b>self-management and diet</b> intervention?                         |
| To prevent weight gain in <b>overweight adults</b> , what is the comparative effectiveness of adding <b>physical activity</b> versus not adding physical activity to a <b>home-based self-management and diet</b> intervention?         |
| To prevent weight gain in <b>overweight adults</b> , what is the effectiveness of a <b>home-based self-management and physical activity</b> intervention compared with a <b>self-management and diet</b> intervention?                  |
| To prevent weight gain in <b>young adults</b> , what is the comparative effectiveness of adding <b>physical activity</b> versus not adding physical activity to a <b>home-based self-management and diet</b> intervention?              |
| <b>Methodologic Question</b>  |
| What is a clinically meaningful definition of weight maintenance among adults, expressed as both weight (kg) and body mass index ( $\text{kg}/\text{m}^2$ ), that can be used as the standard across studies of weight gain prevention? |

## Discussion

Using the draft of the 2013 CER “Strategies To Prevent Weight Gain Among Adults,” we identified and prioritized future research needs. We identified seven research questions that a multidisciplinary group of stakeholders considered to have great potential health impact. We also identified one methodologic question considered to be of critical importance to the advancement of the weight gain prevention field. This report will help researchers to develop studies evaluating the questions identified, as well as enable funding agencies to dedicate their resources to areas most likely to make a health impact.

The populations denoted in our research questions are likely to achieve significant health benefits with the avoidance of obesity. We would also encourage researchers to consider recruiting subgroups at high risk of obesity such as adults with cardiovascular disease or diabetes and low-income adults. We recommend that researchers consider designing head-to-head comparison interventions that combine self-management and diet intervention with a self-management and exercise intervention or compare a self-management and diet intervention with a self-management, diet, and exercise intervention. These combination interventions might use a multidimensional approach that consists of a specific diet or exercise plan, counseling, and the use of tailored self-management strategies. Given the findings from this report, these comparisons of interventions should occur either in the work or home setting. In addition to measuring the interventions’ effect on weight or body mass index, future studies should measure and evaluate adherence, as well as the impact of the intervention on the prevention or reduction of weight-related clinical outcomes.

This project was limited by the large number of evidence gaps, which made it unfeasible to present all research questions developed from these gaps to our stakeholders. Therefore, we used a method that relied heavily on input from the CER authors and the stakeholders to identify priority gaps and key research questions. We feel that the questions developed, if answered, can impact much of the population and are appropriate first steps in increasing the breadth and quality of the evidence base in the field of adult weight gain prevention.

## Conclusions

Using the draft CER “Strategies To Prevent Weight Gain Among Adults,” we identified and prioritized future research needs. We identified seven research questions that a multidisciplinary group of stakeholders considered to be of potential health impact. These questions focus on high-priority populations, interventions, comparisons, and settings identified by our stakeholders. We also identified a methodologic research question regarding the creation of a standard definition of weight maintenance that all of our stakeholders agreed would benefit the overall field of weight gain prevention. This report may inform and support researchers to develop studies to evaluate the research questions identified, as well as enable funding agencies to dedicate their resources to areas most likely to make a health impact.

# Background

## Context

The most recent estimates classify more than 35 percent of U.S. adults as obese.<sup>1</sup> Obesity has been linked to increased risk of diseases such as hypertension, diabetes mellitus, kidney disease, and cancer;<sup>2</sup> decreased life expectancy;<sup>3</sup> and increased costs.<sup>4</sup> Healthy People 2020 identified preventing weight gain and the development of obesity as a priority area, specifically to increase the prevalence of a healthy weight among adults from 31 percent to 34 percent and reduce the prevalence of obesity among adults to less than 30 percent.<sup>5</sup> Despite this goal, we know of no treatment guidelines for the prevention of weight gain or maintenance of weight.

Prior systematic reviews have focused on weight loss or weight maintenance after weight loss,<sup>6,7</sup> and the few systematic reviews on weight gain prevention included studies that targeted weight loss or reported outcomes at less than 12 months, which we would not consider true weight maintenance.<sup>8,9</sup> Therefore, a synthesis of the literature on long-term weight gain prevention was needed. The Johns Hopkins University Evidence-based Practice Center carried out a comparative effectiveness review (CER), funded by the Agency for Healthcare Research and Quality (AHRQ), on the comparative effectiveness of strategies to prevent weight gain among adults.<sup>10</sup> The draft review, completed in 2012, was used for the study of future research needs; the CER was posted in 2013. The report focused on six Key Questions, listed in Table 1.

**Table 1. Key Questions of the comparative effectiveness review**

| Number | Question   |
|--------|--|
| KQ1    | What is the comparative effectiveness of self-management strategies for the prevention of weight gain among adults?  |
| KQ2    | What is the comparative effectiveness of dietary strategies for the prevention of weight gain among adults?  |
| KQ3    | What is the comparative effectiveness of physical activity strategies for the prevention of weight gain among adults?  |
| KQ4    | What is the comparative effectiveness of medications for the prevention of weight gain among adults?   |
| KQ5    | What is the comparative effectiveness of a combination of self-management, dietary, physical activity, and medication strategies for the prevention of weight gain among adults? |
| KQ6    | What is the comparative effectiveness of environment level strategies for the prevention of weight gain among adults?  |

**Abbreviation:** KQ = Key Question

The report authors identified 58 publications describing 51 studies. No tested interventions or described approaches in observational studies achieved a high strength of evidence to prevent weight gain in adults. From this body of literature, the authors made the following conclusions: (1) work-based interventions that combine self management, diet, physical activity, and/or environmental strategies prevent weight gain as compared to control, and (2) home-based aerobic and resistance exercise prevent weight gain among women with cancer, as these interventions were rated as having moderate strength of evidence. These studies compared their interventions with control or usual care. The report authors graded almost all evidence as low or insufficient in strength to address the Key Questions.

Overall, the report had limited ability to answer the Key Questions or draw conclusions, given the lack of high-quality evidence in this field. Much of the existing evidence was downgraded to low strength of evidence due to study designs and methods that were considered to be either at high risk for bias for reasons such as lack of blinding of outcome assessors or imprecise due to a lack of reporting of variance measures. Additionally, weight gain prevention

was not the stated goal for many studies included in the review. Other comparisons were graded as insufficient, as no studies were identified that addressed those specific questions, such as examining any intervention among adults with low socioeconomic status.

## **Evidence Gaps**

The CER suggests that future research separately examine interventions to prevent weight gain among healthy-weight, overweight, and obese individuals. The report also places a priority on designing interventions for adults with severe mental illness taking antipsychotics and for diabetics taking certain oral medications or insulin, given their high risk of weight gain, attributed in part to side effects from these medications.

The CER also notes several methodological and reporting limitations that should be considered during the design of future studies. The authors state that studies designed to measure weight over time are more likely to collect high-quality weight measurements and have adequate power to study weight gain prevention; therefore, observational cohorts should make measuring weight a stated goal in their protocols. In addition, intervention trials should be of sufficient duration (longer than 12 months) to assess the efficacy of weight gain prevention intervention. The authors conclude that longer followup will help to identify true effectiveness (weight gain of only 0.5 kg per year, which was the definition of weight maintenance used in the report).

## **Objective**

In this report, we aimed to establish key areas for future adult weight gain prevention research by developing a prioritized list of research needs with considerations for potential research designs for researchers and funders to use for developing research proposals or solicitations.



## Methods

We identified potential research needs based on research gaps identified while writing the report and prioritized with input from stakeholders. The protocol for developing the evidence gaps into a prioritized list of research needs and feasible researchable questions involved the following steps: (1) identification of evidence gaps, (2) engagement of stakeholders, (3) prioritization of PICOTS (population, intervention, comparison, outcome, timing, setting) research gaps through the Delphi process, (4) creation and prioritization of research questions through the Delphi process, and (5) identification of ongoing studies through external literature search.

### Identification of Evidence Gaps

To identify evidence gaps, our research team abstracted evidence gaps from the draft CER “Strategies To Prevent Weight Gain Among Adults.”<sup>10</sup> The report authors identified evidence gaps based on the strength of evidence, applicability, and limitations of the review. We also identified additional evidence gaps and limitations of the review during in-person discussions with the original report authors. We created an intervention matrix of comparisons for each Key Question.

We considered all findings with low or insufficient strength of evidence as evidence gaps. Given that the report authors graded almost all evidence as low or insufficient to address the Key Questions (Table 2), all research questions were identified as gaps in the literature. This extensive deficiency made the use of the typical analytic framework for identifying future research needs difficult.<sup>11</sup> A prior report also noted this challenge in a similar situation,<sup>12</sup> and we modeled our approach based on its methods. We opted to have our stakeholders prioritize different PICOTS gaps (populations, interventions or comparisons of interventions to each other, outcomes, timing of interventions, settings) for future research needs. We then used this prioritization to create a list of questions for future research.

**Table 2. Summary of the strength of evidence from comparative effectiveness review**

| Population  | BMI   | Weight Change  | Waist Circumference                                       | Adherence                 |
|---|---|--|---|---------------------------|
| General population  | Low with physical activity favored                                      | Low with dietary change favored  | Low with dietary and lifestyle changes favored            | Low<br>Adherence was poor |
| Obese   | Insufficient  | Low<br>No difference between walking or bicycling to work                    | Low<br>No difference between walking or bicycling to work | Low<br>Adherence was poor |
| Work based  | Low with combination of individual and environmental strategies favored | Moderate with combination of individual and environmental strategies favored | Low with no difference                                    | Low<br>Adherence was poor |
| College based   | Low with combination strategy favored                                   | Low with combination strategy favored  | Low with no difference                                    | Low<br>Adherence was poor |
| With or at risk for cardiovascular disease or diabetes mellitus | Low with physical activity favored                                      | Low with no difference   | Low with no difference                                    | Insufficient              |

**Table 2. Summary of the strength of evidence from comparative effectiveness review (continued)**

| <b>Population</b> | <b>BMI</b>                                    | <b>Weight Change</b>                           | <b>Waist Circumference</b> | <b>Adherence</b>   |
|-------------------|---|--|----------------------------|--|
| Cancer            | Low with decreased television viewing favored | <u>Moderate</u> with physical activity favored | Insufficient               | Low<br>Adherence was good in dietary trials and poor in physical activity and combination trials |
| Mental illness    | Low with no difference                        | Low with no difference                         | Insufficient               | Insufficient   |

## Criteria for Prioritization

We used the Delphi method to prioritize and develop consensus about future research needs.<sup>13</sup> After reading the Executive Summary of the draft CER, each stakeholder was asked to select the highest and lowest priority populations, interventions/strategies, comparisons, outcomes, and settings. Stakeholders were asked to respond based on their reading of the executive summary and the potential health impact of each element. We defined consensus as a majority of respondents identifying an element as being among the highest priority.

### Delphi Round 1: Prioritization of Populations, Interventions, Outcomes, and Settings

**Populations.** Stakeholders identified four populations that they felt were the highest priority from a list of all populations in the CER and populations not represented in the report such as age, sex, race/ethnicity, or socioeconomic status. The list of possible populations included: all adults, adults with cardiovascular disease/diabetes, adults with severe mental illness, adults with cancer, young adults (age 18–35), middle-aged adults (age 36–64), older adults (age >64), women, men, low income, racial/ethnic minorities, normal weight, overweight, obese, or other.

**Interventions/strategies.** Stakeholders selected two interventions/strategies that they felt were the highest priority from a list of all possible interventions proposed in the Key Questions of the CER: self-management, diet, physical activity, medication, environmental/policy, a combination of these interventions, or other. The stakeholders also chose the lowest priority intervention/strategy from this same list.

**Outcomes.** Given the widespread usage of weight and body mass index to study weight gain prevention, we opted to ask stakeholders to prioritize the top two secondary outcomes in this field of research. We created a list of secondary outcomes based on elements of the analytic framework from the CER and other outcomes noted by the report authors to be commonly assessed throughout the literature. These secondary outcomes included waist circumference, body fat percentage, skinfold thickness, adherence, adverse effects, weight-related clinical conditions, mortality, or other. Stakeholders selected the one lowest priority secondary outcome from this same list.

**Settings.** Stakeholders identified the two highest priority settings for future research from a list of settings identified from the CER. The list included college, clinic, work, community, home, or other. Stakeholders also selected the lowest priority setting from this same list.

## **Delphi Round 2: Prioritization of Populations, Interventions, and Comparisons**

**Populations.** In round 1, several population subgroups received few or no votes from the stakeholders; however, the report authors had identified these populations as potential important subgroups for future research given their high risk of obesity. These subgroups included adults with cardiovascular disease/diabetes, adults with severe mental illness, adults with cancer, racial/ethnic minorities, and obese adults. Therefore, we asked the stakeholders to rank these subgroups for future research in adult weight gain prevention from highest to lowest on a scale of 1–5.

**Interventions/strategies.** In round 1, stakeholders overwhelmingly identified combination interventions as the highest priority and medications as the lowest priority. To clarify which combination of interventions they would recommend, we asked them to select the two highest priority combination strategies from a list. We created this list based on the possible combinations of self-management plus diet, physical activity, and/or environment. We defined self-management as goal setting, self-monitoring, problem solving, relapse prevention, and stimulus control. We included self-management in all combinations, as our study team felt these targeted behaviors to be an essential part of any behavior change intervention. The stakeholders also selected the lowest priority combination strategy from this same list.

**Comparisons.** In the CER, few head-to-head comparative studies were described, since virtually all studies compared intervention to control. Based on comments from the report authors and stakeholders in round 1, we asked stakeholders to select the five highest priority comparisons of combination interventions. We selected comparisons identified by more than 50 percent of stakeholders as high-priority comparisons.

## **Delphi Round 3: Prioritization of Components of Interventions and Research Questions**

**Interventions/strategies.** In round 2, the majority of stakeholders identified the comparison of (1) self-management + diet versus self-management + physical activity and (2) self-management + diet versus self-management + diet + physical activity. Concerning these priority combination interventions, the report authors commented on the heterogeneity of elements included within diet and physical activity interventions. Therefore, we asked stakeholders to select the two highest priority combinations of elements of diet and physical activity interventions. Stakeholders could choose to include a diet/exercise plan and/or intervention and/or targeted behavior. For dietary interventions, dietary plans included changes in dietary composition, caloric restriction, both, or none and targeted behaviors included meal planning, calorie tracking, both, or none. For exercise interventions, exercise plans included all combinations of aerobic exercise, resistance training, and/or stretching and targeted behaviors included exercise tracking, pedometer, both, or none. Stakeholders could select from group counseling, individual counseling, telephone/Web-based counseling, education session, or printed materials for the intervention aspect for both diet and exercise. We created a list of elements based on components identified in the CER.

Concurrent with ranking components of dietary and exercise interventions, Delphi round 3 also asked stakeholders to prioritize the top five questions for future research based on results from Delphi rounds 1 and 2. (See research question development section below.)

## Delphi Round 4: Ranking of Prioritized Research Questions

Delphi round 4 asked stakeholders to rate the value of the prioritized research questions based on potential value and impact of results. (See research question development section below.)

## Engagement of Stakeholders, Researchers, and Funders

The stakeholders' role was to participate in the prioritization of PICOTS elements and subsequent questions for future research.

## Identification and Recruitment of Stakeholders

We wanted to identify and recruit stakeholders that represented a variety of interests. Our team first generated a list of stakeholder groups that would potentially have an interest in the prevention of weight gain in adults, which included patients, physicians, exercise and nutrition researchers, funding agencies, and health insurers. We then identified possible stakeholders within each of these groups who could represent their interests. All possible stakeholders were contacted via email. We invited previous stakeholders and reviewers for the CER, of whom two prior Key Informants agreed to participate. We also invited new participants. Table 3 lists our stakeholders. All participating stakeholders provided curriculum vitae and disclosure statements to ensure that all potential conflicts of interest were disclosed. The list of stakeholders and their disclosure statements were approved by AHRQ.

**Table 3. Composition of stakeholders group**

| Area of Expertise             | Number of Stakeholders* |
|-------------------------------|-------------------------|
| Patients                      | 2                       |
| Physicians                    | 2                       |
| Researchers                   | 2                       |
| Nutrition providers/educators | 2                       |
| Exercise                      | 1                       |
| College students              | 1                       |
| Funding agencies              | 1                       |
| Health insurers               | 1                       |
| Employers                     | 1                       |
| <b>Total</b>                  | <b>7</b>                |

\*Several stakeholders represented multiple interests; a total of 7 stakeholders participated.

## Orientation of Stakeholders

All stakeholders received a copy of the executive summary from the draft 2012 CER on strategies to prevent adult weight gain<sup>10</sup> and a Web link to the complete draft report. We requested that stakeholders read the Executive Summary in order to meaningfully contribute to the Delphi process identifying future research needs. We informed stakeholders that we anticipated four rounds of surveys, which would be administered using a Web-based survey tool (Survey Monkey [www.surveymonkey.com](http://www.surveymonkey.com)). The surveys included both multiple-choice and drop-down menus, as well as comment boxes where stakeholders could add free-text responses to ensure that their input was heard and provide clarification and reasoning for their selections.

## Research Question Development

Based upon results from the first rounds of the Delphi process, we created a matrix of possible research questions based on PICOTS elements that stakeholders identified as highest priority through consensus. We continued to use the Delphi process with our same stakeholders to prioritize questions for future research. In Delphi round 3, we presented each stakeholder with the list of research questions created from our matrix. The stakeholders selected the top five research questions based on their potential health impact. Based on the rankings from round 3, we presented the final seven priority research questions to the stakeholders in round 4. We asked each stakeholder to assign a score from 1 to 5 to each question, where 5 indicates that the question is very likely to provide valuable and impactful results and 1 that it is less likely to provide valuable and impactful results. We opted not to integrate the prioritized components of dietary and exercise interventions into our research questions.

## Research Design Considerations

With the report authors, we reviewed the research questions that were prioritized by our stakeholders. We asked the report authors to weigh in on the potential research designs that would be most appropriate to answer these research questions, including their rationale and the factors that influenced their decision for choosing such designs over others.

With our stakeholders, we assessed methodologic gaps, which we defined as limitations in study design and reporting elements found within the literature base. We identified these methodologic gaps based upon study design limitations cited in the CER and through in-person discussions with the report authors. During round 1 of the Delphi process, stakeholders were given a list of methodologic issues and indicated which issues were important to incorporate into the design of future research. We created the list of study design and reporting elements from limitations abstracted from the CER and from in-person discussion with the report authors. Stakeholders were asked to base their responses upon the Executive Summary and to take into account factors such as feasibility, time, costs, and validity of incorporating these study design and reporting elements into future research. In addition, we had stakeholders consider whether a standard definition of weight maintenance in adults would benefit the field. Based upon their responses to this question, we created a methodologic question for future research.

## Identification of Ongoing Studies

We identified ongoing clinical trials that may address the Key Questions in the Comparative Effectiveness Review by searching the National Institutes of Health's registry, [clinicaltrials.gov](http://clinicaltrials.gov) ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)), for trials registered from January 1, 2008, through October 1, 2012. A single reviewer examined each title for entry. A single reviewer then examined the full information from [clinicaltrials.gov](http://clinicaltrials.gov) on these potential trials to determine whether they met the same inclusion/exclusion criteria used in the CER. If any ongoing studies met our inclusion criteria, then a single reviewer abstracted the trial identification number, date of registry, expected date of completion, study name, status, method compared, and any published results, and identified the Key Question that the study is likely to address.

# Results

We had six stakeholders participate in the first round, six stakeholders participate in the second round, six stakeholders participate in the third round, and five stakeholders participate in the fourth round.

## Research Needs

We describe below how our stakeholders prioritized future research needs within the PICOTS framework by each element. We have created a conceptual framework for studies to address future research needs in the field of adult weight gain prevention (Figure 1).

**Populations.** In round 1, our stakeholders reached majority consensus that the following four populations were of highest priority: all adults, young adults, normal-weight adults, and overweight adults (Table 4). Stakeholders gave the most votes to the young adult population. They commented that they made this decision given the potential for the continuation of healthy habits established in youth throughout the life course. Stakeholders commented that they selected all adults because they wanted to include the broadest possible audience for weight gain prevention in order to have the greatest impact on the obesity epidemic. Normal-weight and overweight adults were selected given that weight gain prevention would prevent the development of obesity and its associated comorbid conditions. In addition to identifying these broad populations, stakeholders also prioritized several subgroups at high risk for obesity by assigning them scores in Delphi round 2. We considered subgroups that received the lowest average rankings as highest priority. Stakeholders ranked racial/ethnic minorities (1.8) and adults with cardiovascular disease or diabetes (1.8) as these high-priority subgroups for future research. Obese adults (2.7), adults with cancer (3.8), and adults with severe mental illness (4.8) received the highest average scores, which indicated that stakeholders felt they were of lower priority.

**Table 4. Stakeholder priority ratings for population gaps for future research in strategies to prevent weight gain in adults**

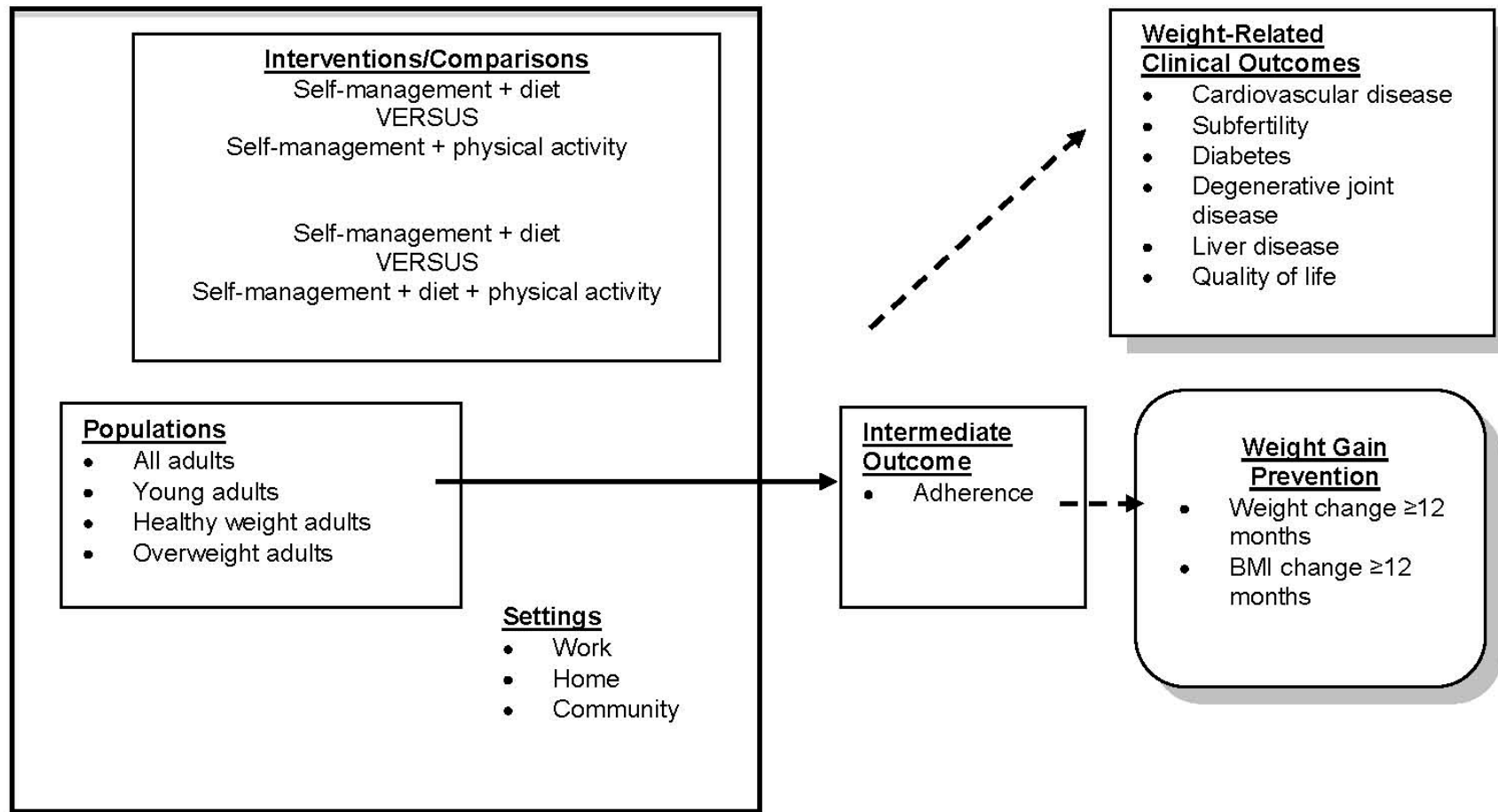
| Population Groups                  | Round 1 Votes<br>for High-Priority<br>Populations<br>(N=6) | Round 2<br>Scores<br>(N=6) |
|------------------------------------|--|----------------------------|
| Young adults (18–35)               | 5*   | ‡                          |
| All adults                         | 4*   | ‡                          |
| Overweight                         | 3*   | ‡                          |
| Normal weight                      | 3*   | ‡                          |
| Middle aged (36-64)                | 2  | ‡                          |
| Low income                         | 2  | ‡                          |
| Other                              | 2  | ‡                          |
| Older (65+)                        | 1  | ‡                          |
| Racial/ethnic minorities           | 1  | 1.8*                       |
| Obese                              | 1  | 2.7                        |
| Cardiovascular disease or diabetes | 0  | 1.8*                       |
| Severe mental illness              | 0  | 4.8                        |
| Cancer                             | 0  | 3.8                        |
| Women                              | 0  | ‡                          |
| Men                                | 0  | ‡                          |

**Notes:** \* Indicates prioritized research need from round 1.

‡ Indicates option not included for prioritization in round 2.

N = number of stakeholders who participated.

**Figure 1. Framework for future research on strategies for the prevention of adult weight gain to address high-priority evidence gaps**



**Note:** BMI = body mass index

**Interventions/strategies.** In round 1, our stakeholders reached majority consensus that a combination of interventions is the highest priority for future research (Table 5). They felt that no single strategy alone was likely to be effective, and therefore, only a combination of approaches should be employed in the future. The majority of stakeholders identified medications as the lowest priority strategies for weight gain prevention research (Table 6). Stakeholders commented that they ranked medications lower due to concerns about the long-term viability of such an approach and the potential for side effects.

**Table 5. Stakeholder rating for the highest and lowest priority strategy gaps for future research in strategies to prevent weight gain in adults**

| Strategies                   | Round 1<br>Votes for High- Priority Strategy<br>(N=6) | Round 1<br>Votes for Low- Priority Strategy<br>(N=6) |
|------------------------------|---|--|
| Combination of interventions | 4*  | 1  |
| Other                        | 2   | N/A  |
| Policy                       | 2   | 1  |
| Self-management              | 2   | 0  |
| Diet                         | 1   | 0  |
| Physical activity            | 1   | 0  |
| Medications                  | 0   | 4  |

**Notes:** \* Indicates prioritized research need.  
N = number of stakeholders who participated.

Stakeholders reached majority consensus that combination interventions should combine the following elements: (1) self-management + diet + physical activity, or (2) self-management + diet + physical activity + environment (Table 6). No consensus majority was reached about the lowest priority combination of interventions (Table 6).

**Table 6. Stakeholder rating for the highest and lowest priority combination strategy gaps for future research in strategies to prevent weight gain in adults**

| Combination   | Round 2 Votes<br>for High-Priority<br>Combination<br>Strategy<br>(N=6) | Round 2 Votes<br>for Low-Priority<br>Combination<br>Strategy<br>(N=6) |
|---|--|---|
| Self-management AND diet AND physical activity                          | 4*   | 0   |
| Self-management AND diet AND physical activity AND environmental change | 3  | 1   |
| Self-management AND environmental change                                | 2  | 1   |
| Self-management AND diet  | 1  | 2   |
| Self-management AND diet AND environmental change                       | 1  | 0   |
| Self-management AND physical activity AND environmental change          | 1  | 1   |
| Self-management AND physical activity                                   | 0  | 1   |

**Notes:** \* Indicates prioritized research need.  
N = number of stakeholders who participated.

In Delphi round 3, stakeholders also identified what components should comprise diet and physical activity interventions. Stakeholders felt that diet interventions should combine counseling with specific dietary recommendations regarding calorie intake or dietary composition and a diet-related self-management strategy such as meal planning or calorie tracking (Table 7). Stakeholders did not reach consensus on the type of counseling, dietary recommendation, or self-management strategy of greatest priority. Similarly, stakeholders felt that physical activity interventions should combine counseling with an exercise plan that combines aerobic exercise, resistance training, and stretching and an exercise-related self-



management strategy such as exercise tracking (Table 8). Stakeholders did not reach consensus on the type of counseling, exercise plan, or self-management strategy of greatest priority. All stakeholders felt that printed materials were unlikely to change behavior, and therefore, should not be a prioritized strategy in future research.

**Table 7. Highest priority components of dietary interventions**

| Dietary Plan        | Round 3<br>Votes<br>(N=6) | Modality of Intervention<br>Delivery | Round 3<br>Votes<br>(N=6) | Targeted Behavior | Round 3<br>Votes<br>(N=6) |
|---------------------|---------------------------|--------------------------------------|---------------------------|-------------------|---------------------------|
| Dietary composition | 4                         | Group                                | 5                         | Meal planning     | 5                         |
| Calorie restriction | 3                         | Individual                           | 4                         | Calorie tracking  | 2                         |
| Both                | 5                         | Telephone/Web                        | 3                         | Both              | 5                         |
| None                | 0                         | Education session                    | 0                         | None              | 0                         |
|                     |                           | Printed materials                    | 0                         |                   |                           |

**Abbreviation:** N = number of stakeholders who participated.

**Table 8. Highest priority components of physical activity interventions**

| Exercise Plan                     | Round 3<br>Votes<br>(N=6) | Modality of Intervention<br>Delivery | Round 3<br>Votes<br>(N=6) | Targeted Behavior | Round 3<br>Votes<br>(N=6) |
|-----------------------------------|---------------------------|--------------------------------------|---------------------------|-------------------|---------------------------|
| Aerobic exercise                  | 3                         | Group                                | 4                         | Pedometer         | 2                         |
| Resistance training               | 0                         | Individual                           | 6                         | Exercise tracking | 8                         |
| Stretching                        | 0                         | Telephone/Web                        | 2                         | Both              | 2                         |
| Aerobic + resistance              | 3                         | Education session                    | 0                         | None              | 0                         |
| Aerobic + stretching              | 2                         | Printed materials                    | 0                         |                   |                           |
| Resistance + stretching           | 0                         |                                      |                           |                   |                           |
| Aerobic + resistance + stretching | 4                         |                                      |                           |                   |                           |

**Abbreviation:** N = number of stakeholders who participated.

**Comparisons.** Our stakeholders reached majority consensus that several head-to-head comparisons of interventions would be a high priority for future research. These high priority comparisons include: (1) self-management + diet VERSUS self-management + physical activity, or (2) self-management + diet VERSUS self-management + diet + physical activity (Table 9).

**Table 9. Stakeholder rating for the highest priority comparison strategy gaps for future research in strategies to prevent weight gain in adults**

| Arm 1  | Arm 2   | Round 2 Votes (N=6) |
|--|---|---------------------|
| Self-management AND diet AND physical activity                 | Self-management AND diet  | 4*                  |
|  | Self-management AND diet AND environmental change                       | 3                   |
|  | Self-management AND physical activity                                   | 2                   |
|  | Self-management AND diet AND physical activity AND environmental change | 2                   |
|  | Self-management AND environmental change                                | 2                   |
|  | Self-management AND physical activity AND environmental change          | 1                   |
| Self-management AND diet                                       | Self-management AND physical activity                                   | 5*                  |
|  | Self-management AND diet AND environmental change                       | 3                   |
|  | Self-management AND environmental change                                | 2                   |
|  | Self-management AND diet AND physical activity AND environmental change | 1                   |
| Self-management AND physical activity                          | Self-management AND physical activity AND environmental change          | 3                   |
|  | Self-management AND environmental change                                | 1                   |
| Self-management AND physical activity AND environmental change | Self-management AND diet AND physical activity AND environmental change | 1                   |

**Notes:** \*Indicates prioritized research need.

N = number of stakeholders who participated.

**Outcomes.** We felt that weight and body mass index were logical and well-established outcomes for the weight gain prevention field. Our stakeholders instead evaluated secondary outcomes. Our stakeholders reached majority consensus that two secondary outcomes should be assessed in future trials: weight-related clinical outcomes and adherence to the intervention (Table 10). Weight-related clinical outcomes may include conditions such as hypertension, diabetes mellitus, and dyslipidemia. Stakeholders felt that assessing adherence would help determine the efficacy and effectiveness of the intervention, and that understanding whether preventing weight gain improves clinical outcomes would justify investment in implementing such programs on a large scale. The majority of stakeholders identified skinfold thickness as the lowest priority secondary outcome (Table 10). Skinfold thickness was rated lower due to lack of association with health outcomes and the existence of other metrics that are easier to measure or provide better estimates of adiposity.

**Table 10. Stakeholder rating for the highest and lowest priority secondary outcome gaps for future research in strategies to prevent weight gain in adults**

| Secondary Outcomes               | Round 1 Votes for High-Priority Secondary Outcomes (N=6) | Round 1 Votes for Low-Priority Secondary Outcomes (N=6) |
|----------------------------------|--|---|
| Weight-related clinical outcomes | 4*   | 0   |
| Adherence                        | 3*   | 0   |
| Mortality                        | 2  | 2   |
| Waist circumference              | 1  | 0   |
| Body fat %                       | 1  | 0   |
| Other                            | 1  | 0   |
| Skinfold thickness               | 0  | 4   |
| Adverse effects                  | 0  | 0   |

**Notes:** \* Indicates prioritized research need.

N = number of stakeholders who participated.

**Settings.** In round 1, our stakeholders reached majority consensus regarding three high-priority settings, which included the workplace, the community, and the home (Table 11). Stakeholders were motivated to select these settings, because they felt that work, home, and community-based interventions would likely have the greatest impact on preventing weight gain and obesity. They noted that adults spend the majority of their time in one of these settings, and that other people in these settings are likely to have a strong influence on their behavior. The majority of stakeholders identified clinic-based weight gain prevention programs as the lowest priority for future research (Table 11). They rated clinic-based interventions low due to concerns of whether physicians and health care providers have time and adequate training to perform such tasks.

**Table 11. Stakeholder ratings for the highest and lowest priority setting gaps for future research in strategies to prevent weight gain in adults**

| Settings  | Round 1<br>Votes for High-Priority Settings<br>(N=6) | Round 1<br>Votes for Low-Priority Settings<br>(N=6) |
|-----------|--|---|
| Home      | 4*   | 1   |
| Work      | 4*   | 0   |
| Community | 4*   | 0   |
| Clinic    | 0  | 4   |
| College   | 0  | 1   |
| Other     | 0  | N/A   |

**Notes:** \* Indicates prioritized research need.  
N = number of stakeholders who participated.

## Research Questions

Based upon the results of the research needs, we created a matrix of possible research questions (N=16). In Delphi round 3, our stakeholders reached majority consensus regarding seven research questions as the highest priorities for future research from the matrix of possible questions. These seven questions are listed in Table 12. In round 4, stakeholders assigned a score of 1 to 5 to each question, where 5 means that the question is very likely to provide valuable and impactful results and 1 that it is less likely to provide valuable and impactful results. The mean score for each question is presented in Table 12.

**Table 12. Stakeholder rating for the value in addressing each research question to prevent weight gain in adults on a 1-5 scale, in which 1 is the lowest value and 5 is the highest value**

| Research Questions Prioritized in Round 3   | Round 4 Mean Impact Scores (N=5) |
|---|----------------------------------|
| To prevent weight gain in ALL adults, what is the comparative effectiveness of adding PHYSICAL ACTIVITY versus NOT adding physical activity to a WORK-based self-management and diet intervention?        | 4.0                              |
| To prevent weight gain in ALL adults, what is the comparative effectiveness of adding PHYSICAL ACTIVITY versus NOT adding physical activity to a HOME-based self-management and diet intervention?        | 3.8                              |
| To prevent weight gain in ALL adults, what is the effectiveness of a WORK-based self-management and PHYSICAL ACTIVITY intervention versus a self-management and DIET intervention?                        | 3.8                              |
| To prevent weight gain in ALL adults, what is the effectiveness of a HOME-based self-management and PHYSICAL ACTIVITY intervention compared with a self-management and DIET intervention?                 | 3.8                              |
| To prevent weight gain in OVERWEIGHT adults, what is the comparative effectiveness of adding PHYSICAL ACTIVITY versus NOT adding physical activity to a HOME-based self-management and diet intervention? | 3.4                              |
| To prevent weight gain in OVERWEIGHT adults, what is the effectiveness of a HOME-based self-management and PHYSICAL ACTIVITY intervention compared with a self-management and DIET intervention?          | 3.4                              |
| To prevent weight gain in YOUNG adults, what is the comparative effectiveness of adding PHYSICAL ACTIVITY versus NOT adding physical activity to a HOME-based self-management and diet intervention?      | 3.4                              |

**Abbreviation:** N = number of stakeholders who participated.

All stakeholders agreed that the field of weight gain prevention research would benefit from a standardized definition of weight maintenance (Table 13). The stakeholders felt that the definition should include standards for maintenance of both weight and BMI. One stakeholder commented that this standard should be clinically meaningful.

**Table 13. Methodological question for future research**

|   |
|---|
| What is a clinically meaningful definition of weight maintenance among adults, expressed as both weight (kg) and body mass index (kg/m <sup>2</sup> ), that can be used as the standard across studies of weight gain prevention? |
|---|

## Study Design Considerations

After the report's authors reviewed the research questions prioritized by our stakeholders, they suggested that randomized controlled trials (RCTs) may be the most appropriate study design to answer these questions. They felt that the advantage of the RCT is the lack of confounding and selection bias; however, they stipulated that a well-conducted RCT should assess outcomes by individuals blinded to treatment assignment, assess adherence to the intervention, and maintain adequate followup of enrolled patients. The report authors recognized that such RCTs would be costly.

Stakeholders also identified improvements in study design, methods, and reporting that they would recommend be employed by future studies. In Table 14, we present the study design, methods, and reporting elements that at least 50 percent of our stakeholders agreed should be used in future studies.

**Table 14. Stakeholder rating for the highest priority methodological needs for future research in strategies to prevent weight gain in adults**

| Methods  | Round 1 Votes<br>(N=6) |
|--|------------------------|
| Describe randomization process                   | 6                      |
| Recruit adequate sample size to power            | 6                      |
| Adjust for confounding in observational studies  | 5                      |
| Report non-statistically significant results     | 5                      |
| Report measures of variance                      | 4                      |
| Mask outcome assessors to study group assignment | 3                      |
| Minimize or account for losses to followup       | 3                      |
| Other  | 0                      |

**Abbreviation:** N = number of stakeholders who participated.

## Identification of Ongoing Studies

We identified 3,027 titles in clinicaltrials.gov, of which 727 were identified as potentially eligible during title review. During full review, we identified 51 studies currently recruiting or ongoing that may address at least one of the Key Questions from the original report. We also identified 35 recently completed studies that may address at least one of the Key Questions; however, results were not yet available from these studies. These 86 ongoing or recently completed studies are listed in Appendix Table 2.

## Discussion

Using the 2012 version of the CER “Strategies To Prevent Weight Gain Among Adults,”<sup>10</sup> we identified and prioritized future research needs. We identified seven research questions considered to be of potential health impact by a multidisciplinary group of stakeholders. We believe that this report will help researchers to develop studies evaluating the Key Questions identified, as well as enable funding agencies to dedicate their resources to areas most likely to make a health impact.

The populations within our research questions purposely target broad audiences (all adults, young adults, and overweight adults) who are likely to achieve significant health benefit from preventing the development of obesity. Our stakeholders preferred a broad population, given the lack of evidence in this field. However, our stakeholders did consider adults with cardiovascular disease or diabetes and low-income adults to be high-priority subgroups, given their high risk of obesity.<sup>14,15</sup> We would encourage researchers to specifically recruit representatives from these subgroups in future research studies with an a priori plan for subgroup analyses.

Our stakeholders selected head-to-head comparisons of specific combinations of interventions as priority comparisons in our research questions. We feel that the lack of these head-to-head comparisons is a significant evidence gap, as most studies identified in the CER compared intervention to usual care/control. These head-to-head comparisons would likely provide critical insight into the creation of guidelines to prevent weight gain, as these types of comparisons represent real clinical conundrums that patients and health care providers face daily. The first pairing compares a self-management and diet intervention to a self-management and exercise intervention to answer the question of whether diet or exercise is superior to prevent weight gain. The second pairing compares a self-management and diet intervention to a self-management, diet, and exercise intervention to answer whether the addition of exercise to diet is superior to diet alone in preventing weight gain. We recommend that future diet and/or exercise interventions have a multidimensional approach in order to successfully result in behavior change. These approaches should combine a specific diet or exercise plan with either individual or group counseling and the use of tailored self-management strategies. Printed educational materials were not selected as a priority intervention strategy, and prior evidence has shown that such methods are unlikely to result in behavior change.<sup>16</sup>

Our research questions also target only work or home settings, as adults spend the majority of their time there. Family, friends, and colleagues in these places are also likely to influence behavior through mechanisms such as social influence, norms, and modeling.<sup>17</sup> We would discourage future studies from relying on clinic-based interventions, as health care providers typically have limited time and training to perform the multicomponent interventions described above.

With respect to outcomes, we identified weight or body mass index as the prevailing measures of choice. However, no standard definition of weight maintenance exists. In the CER, the authors defined weight maintenance as 0.5 kg over 12 months, which was based upon the predicted average weight gain of an adult.<sup>18</sup> We recommend that future research in this field should first address this major methodologic gap by creating a standard definition of weight maintenance. Our stakeholders felt that this definition should include standards for change in both weight and body mass index over a prespecified time period, given the common use of both these measures. In addition, we feel that the definition should be clinically relevant and be associated with the prevention or reduction of weight-related comorbidities such as hypertension

and diabetes mellitus as well as mortality. The establishment of this definition would help future researchers ensure that their trials are designed to actually evaluate weight gain prevention and would facilitate the comparability of weight gain prevention across studies.

In addition to the primary outcome of weight gain prevention, certain secondary outcomes need to be evaluated in future studies that address our priority research questions. First, all interventional studies should assess adherence to the intervention. Adherence is essential in understanding whether and in whom certain interventions work best. This knowledge is critical in translating an approach to a different population or scaling up a successful program. Second, studies should also evaluate the effect of the intervention or approach on weight-related clinical outcomes. In the CER, the authors included cardiovascular disease, diabetes mellitus, infertility, degenerative joint disease, and liver disease as outcomes of interest. Our stakeholders also agreed that these weight-related clinical outcomes would be of interest in future studies. Interventions that prevent weight gain, as well as prevent or reduce these conditions linked with high morbidity and costs to both the health care system and society, will have significant public health impact.

There are some limitations of this project. The large number of evidence gaps made it unfeasible to create and present all research questions from these gaps to our stakeholders, which would be a more standard approach to identifying future research needs. We modified the approach piloted in a prior future research needs report<sup>12</sup> for this purpose. This method relied heavily on input from the authors of the CER and the stakeholders, who all have their own priorities and biases that influence their perceptions of the topic and reflections on the CER process. We feel that the questions developed would influence a broad audience and are appropriate first steps in increasing the breadth and quality of the evidence base in the field of adult weight gain prevention.

There are several strengths to this report. Our research team included several members of the original report's research team, which provided ready access to their insight on the process of the CER and challenges experienced by that original team. We also recruited stakeholders to represent a variety of interests. The prevention of adult weight gain is not only important to patients, health care providers, and researchers, but is also of particular interest to health insurers and employers, given that obesity has been associated with increased morbidity,<sup>2,19</sup> health care costs,<sup>4</sup> and decreased workplace productivity.<sup>20</sup> We also had high levels of participation from our stakeholders at each step. We feel that our diverse array of engaged stakeholders helps to ensure that the priority questions we developed will be of significant public health impact. Finally, we encouraged stakeholders to provide comments in addition to performing rankings. This qualitative component gave important insight on the thought process behind many of the stakeholders' choices and added an additional element of richness to the data we collected.

## **Conclusion**

Using the CER “Strategies To Prevent Weight Gain Among Adults,” we identified and prioritized future research needs. We identified seven research questions considered to be of potential health impact by a multidisciplinary group of stakeholders. These questions focus on high-priority populations, interventions, comparisons, and settings identified by our stakeholders. We also identified a methodologic research question regarding the creation of a standard definition of weight maintenance that all of our stakeholders agreed would benefit the overall field of weight gain prevention. This report may inform and support researchers to develop studies to evaluate the priority questions identified, as well as enable funding agencies to dedicate their resources to areas most likely to make a health impact.



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## Appendix A. Ongoing/Recently Completed Studies Related to Adult Weight Maintenance Search Strategies

**Appendix Table 1. Search strategies for ongoing studies**

| <b>Resource<br/>URL</b>  | <b>Search Parameters</b>                           | <b>Search Terms/Strategy</b>                          |
|--|--|---|
| ClinicalTrials.gov<br><a href="http://clinicaltrials.gov/">http://clinicaltrials.gov/</a>  | Advanced search, Conditions field used             | Prevent adult weight gain OR adult weight maintenance |
| EU Clinical Trials Register<br><a href="https://www.clinicaltrialsregister.eu/">https://www.clinicaltrialsregister.eu/</a>   | Not applicable                                     | Prevent adult weight gain OR adult weight maintenance |
| NIH Reporter<br><a href="http://projectreporter.nih.gov/reporter.cfm">http://projectreporter.nih.gov/reporter.cfm</a>  | Projects field searched                            | Prevent adult weight gain OR adult weight maintenance |
| Canadian Institute for Health Research<br><a href="http://www.cihr-irsc.gc.ca/">http://www.cihr-irsc.gc.ca/</a>  | Funding Decisions Data field searched              | Prevent adult weight gain OR adult weight maintenance |
| World Health Organization International Clinical Trials Registry Platform Search Portal<br><a href="http://apps.who.int/trialsearch/">http://apps.who.int/trialsearch/</a> | Searched Condition field, Recruitment status = ALL | Prevent adult weight gain OR adult weight maintenance |

**Appendix Table 2. Index of ongoing/recently completed studies potentially applicable to Key Questions from Comparative Effectiveness Review “Strategies To Prevent Weight Gain Among Adults”**

| <b>Study Title</b>  | <b>URL</b>  | <b>Status</b>      |
|---|---|--------------------|
| Move and Moderate in Balance  | <a href="http://ClinicalTrials.gov/show/NCT00715130">http://ClinicalTrials.gov/show/NCT00715130</a> | Recently Completed |
| Diet and Physical Activity Interactions in Obesity  | <a href="http://ClinicalTrials.gov/show/NCT00067964">http://ClinicalTrials.gov/show/NCT00067964</a> | Recently Completed |
| Prevention of Weight Gain   | <a href="http://ClinicalTrials.gov/show/NCT00011102">http://ClinicalTrials.gov/show/NCT00011102</a> | Recently Completed |
| Walking For Wellness Program Evaluation   | <a href="http://ClinicalTrials.gov/show/NCT00156351">http://ClinicalTrials.gov/show/NCT00156351</a> | Recently Completed |
| Long-Term Exercise Maintenance Via Internet Support   | <a href="http://ClinicalTrials.gov/show/NCT00260117">http://ClinicalTrials.gov/show/NCT00260117</a> | Recently Completed |
| Strength Training for Obesity Prevention  | <a href="http://ClinicalTrials.gov/show/NCT00030160">http://ClinicalTrials.gov/show/NCT00030160</a> | Recently Completed |
| Effect of Exercise on Prevention of Weight Gain   | <a href="http://ClinicalTrials.gov/show/NCT00177502">http://ClinicalTrials.gov/show/NCT00177502</a> | Recently Completed |
| Veterans Enhanced Fitness Study   | <a href="http://ClinicalTrials.gov/show/NCT00594399">http://ClinicalTrials.gov/show/NCT00594399</a> | Recently Completed |
| Study of Impact of Behavioral Intervention-Exercise; Nutrition; Education- on Body Mass Index (BMI)                             | <a href="http://ClinicalTrials.gov/show/NCT00132132">http://ClinicalTrials.gov/show/NCT00132132</a> | Recently Completed |
| A Physical Activity and Diet Program to Prevent Accumulation of Abdominal Fat Mass in Recently Retired Men and Women            | <a href="http://ClinicalTrials.gov/show/NCT00122213">http://ClinicalTrials.gov/show/NCT00122213</a> | Recently Completed |
| LIFT: Lifestyle Interventions For Two   | <a href="http://ClinicalTrials.gov/show/NCT01616147">http://ClinicalTrials.gov/show/NCT01616147</a> | Ongoing            |
| Promoting Activity and Changes in Eating (PACE) to Reduce Obesity   | <a href="http://ClinicalTrials.gov/show/NCT00119782">http://ClinicalTrials.gov/show/NCT00119782</a> | Ongoing            |
| Make Better Choices   | <a href="http://ClinicalTrials.gov/show/NCT01249989">http://ClinicalTrials.gov/show/NCT01249989</a> | Ongoing            |
| Maintenance After Initiation of Nutrition Training  | <a href="http://ClinicalTrials.gov/show/NCT01357551">http://ClinicalTrials.gov/show/NCT01357551</a> | Ongoing            |
| An Intergenerational Community Based Participatory Research (CBPR) Intervention to Reduce Appalachian Health Disparities        | <a href="http://ClinicalTrials.gov/show/NCT01373307">http://ClinicalTrials.gov/show/NCT01373307</a> | Ongoing            |
| Study of Ongoing Approaches for Prevention  | <a href="http://ClinicalTrials.gov/show/NCT01183689">http://ClinicalTrials.gov/show/NCT01183689</a> | Ongoing            |
| Helping People to Exercise Regularly  | <a href="http://ClinicalTrials.gov/show/NCT01335880">http://ClinicalTrials.gov/show/NCT01335880</a> | Ongoing            |
| Whole Grain Polyphenol Bioavailability and Effects on Health  | <a href="http://ClinicalTrials.gov/show/NCT01293175">http://ClinicalTrials.gov/show/NCT01293175</a> | Ongoing            |
| Planned CORR: Planned Care for Obesity and Risk Reduction   | <a href="http://ClinicalTrials.gov/show/NCT01134029">http://ClinicalTrials.gov/show/NCT01134029</a> | Ongoing            |
| African American Church-based Cohort  | <a href="http://ClinicalTrials.gov/show/NCT00823394">http://ClinicalTrials.gov/show/NCT00823394</a> | Ongoing            |
| Tu Salud Si Cuenta Media Campaign   | <a href="http://ClinicalTrials.gov/show/NCT00788879">http://ClinicalTrials.gov/show/NCT00788879</a> | Ongoing            |
| Efficacy of Lifestyle Changes in Modifying Practical Markers of Wellness and Aging  | <a href="http://ClinicalTrials.gov/show/NCT00395837">http://ClinicalTrials.gov/show/NCT00395837</a> | Ongoing            |
| Calorie Restriction and Changes in Body Composition; Disease; Function; and Quality of Life in Older Adults                     | <a href="http://ClinicalTrials.gov/show/NCT00955903">http://ClinicalTrials.gov/show/NCT00955903</a> | Ongoing            |
| A Randomized Clinical Trial of Home-based Exercise Combined With a Slight Caloric Restriction on Obesity Prevention Among Women | <a href="http://ClinicalTrials.gov/show/NCT01206413">http://ClinicalTrials.gov/show/NCT01206413</a> | Recently Completed |
| The Women's Healthy Lifestyle Study   | <a href="http://ClinicalTrials.gov/show/NCT00583726">http://ClinicalTrials.gov/show/NCT00583726</a> | Recently Completed |
| Lifestyle Intervention for Pakistani Women in Oslo  | <a href="http://ClinicalTrials.gov/show/NCT00425269">http://ClinicalTrials.gov/show/NCT00425269</a> | Recently Completed |
| Healthy Mothers on the Move   | <a href="http://ClinicalTrials.gov/show/NCT01584063">http://ClinicalTrials.gov/show/NCT01584063</a> | Recently Completed |

**Appendix Table 2. Index of ongoing/recently completed studies potentially applicable to Key Questions from Comparative Effectiveness Review “Strategies To Prevent Weight Gain Among Adults” (continued)**

| <b>Study Title</b>   | <b>URL</b>  | <b>Status</b>      |
|--|---|--------------------|
| Childhood Obesity Prevention   | <a href="http://ClinicalTrials.gov/show/NCT00630617">http://ClinicalTrials.gov/show/NCT00630617</a> | Recently Completed |
| Nutrition Intervention and Play Group Exercise for Low-Income Latinas  | <a href="http://ClinicalTrials.gov/show/NCT00454948">http://ClinicalTrials.gov/show/NCT00454948</a> | Ongoing            |
| Community Based Obesity Prevention Among Black Women   | <a href="http://ClinicalTrials.gov/show/NCT00938535">http://ClinicalTrials.gov/show/NCT00938535</a> | Ongoing            |
| Fit Over 45 - a Health Promotion Project for Inactive Female Hospital Staff Age 45+ From the University Hospital of Zürich   | <a href="http://ClinicalTrials.gov/show/NCT01033110">http://ClinicalTrials.gov/show/NCT01033110</a> | Ongoing            |
| The Mediterranean Diet and Lactation Study: A Diet Study in Lactating Women  | <a href="http://ClinicalTrials.gov/show/NCT01459991">http://ClinicalTrials.gov/show/NCT01459991</a> | Ongoing            |
| eMOMS of Rochester: Electronically-Mediated Weight Interventions for Pregnant and Postpartum Women   | <a href="http://ClinicalTrials.gov/show/NCT01331564">http://ClinicalTrials.gov/show/NCT01331564</a> | Ongoing            |
| Healthy Homes/Healthy Families   | <a href="http://ClinicalTrials.gov/show/NCT01326897">http://ClinicalTrials.gov/show/NCT01326897</a> | Ongoing            |
| Family Program for Weight Gain Prevention  | <a href="http://ClinicalTrials.gov/show/NCT00989170">http://ClinicalTrials.gov/show/NCT00989170</a> | Ongoing            |
| Study of a Smart Growth Community's Effect on Prevention of Obesity in Middle-, Moderately Low- and Low-Income Families  | <a href="http://ClinicalTrials.gov/show/NCT00986011">http://ClinicalTrials.gov/show/NCT00986011</a> | Ongoing            |
| Health Promotion of People With Disabilities   | <a href="http://ClinicalTrials.gov/show/NCT00164489">http://ClinicalTrials.gov/show/NCT00164489</a> | Recently Completed |
| Weight Management and Coping Skills Training For Patients With Knee Osteoarthritis   | <a href="http://ClinicalTrials.gov/show/NCT00305890">http://ClinicalTrials.gov/show/NCT00305890</a> | Recently Completed |
| Longitudinal Study of Weight Change Following Lower Limb Amputation  | <a href="http://ClinicalTrials.gov/show/NCT00932399">http://ClinicalTrials.gov/show/NCT00932399</a> | Ongoing            |
| A Study on Induced Weight Gain During Atypical Antipsychotic Treatment and Its Management With Psychoeducational Programme   | <a href="http://ClinicalTrials.gov/show/NCT00191828">http://ClinicalTrials.gov/show/NCT00191828</a> | Recently Completed |
| The Effect of a Weight Management Program During Treatment With Olanzapine   | <a href="http://ClinicalTrials.gov/show/NCT00169702">http://ClinicalTrials.gov/show/NCT00169702</a> | Recently Completed |
| Effect of Dietary and Life Style Modification on Post Liver Transplant Obesity   | <a href="http://ClinicalTrials.gov/show/NCT00878592">http://ClinicalTrials.gov/show/NCT00878592</a> | Ongoing            |
| CCRC: Understanding the Effects of Omega-3 Fatty Acids Versus Lignans in Flaxseed on Metabolic and Inflammatory Markers Leading to Diabetes and Cardiovascular Disease | <a href="http://ClinicalTrials.gov/show/NCT00935922">http://ClinicalTrials.gov/show/NCT00935922</a> | Recently Completed |
| Reduced Cardiac Rehabilitation Program   | <a href="http://ClinicalTrials.gov/show/NCT01483235">http://ClinicalTrials.gov/show/NCT01483235</a> | Recently Completed |
| Shared Decision-Making: Effects on Cardiac Risk Factor Modification Behavior   | <a href="http://ClinicalTrials.gov/show/NCT00714935">http://ClinicalTrials.gov/show/NCT00714935</a> | Recently Completed |
| PBWST (Partial Body-Weight Supported Treadmill Training) and Muscle Power Training After Sub-Acute Stroke  | <a href="http://ClinicalTrials.gov/show/NCT00108030">http://ClinicalTrials.gov/show/NCT00108030</a> | Recently Completed |
| The Effects of Health Education in Cardiovascular Diseases Prevention and Treatment  | <a href="http://ClinicalTrials.gov/show/NCT01426282">http://ClinicalTrials.gov/show/NCT01426282</a> | Recently Completed |
| Cardiovascular Risk Reduction Program Aimed at African American Women (The HHER Lifestyle Program)   | <a href="http://ClinicalTrials.gov/show/NCT00860444">http://ClinicalTrials.gov/show/NCT00860444</a> | Recently Completed |
| A Randomized Controlled Trial of a Community-based Primary and Secondary Cardiovascular Prevention Program   | <a href="http://ClinicalTrials.gov/show/NCT00236210">http://ClinicalTrials.gov/show/NCT00236210</a> | Recently Completed |
| Walking Away: Structured Education Versus Written Information for Individuals With High Risk of Developing Type 2 Diabetes   | <a href="http://ClinicalTrials.gov/show/NCT00941954">http://ClinicalTrials.gov/show/NCT00941954</a> | Ongoing            |

**Appendix Table 2. Index of ongoing/recently completed studies potentially applicable to Key Questions from Comparative Effectiveness Review “Strategies To Prevent Weight Gain Among Adults” (continued)**

| <b>Study Title</b>   | <b>URL</b>  | <b>Status</b>      |
|--|---|--------------------|
| Japan Diabetes Optimal Integrated Treatment Study for 3 Major Risk Factors of Cardiovascular Diseases  | <a href="http://ClinicalTrials.gov/show/NCT00300976">http://ClinicalTrials.gov/show/NCT00300976</a> | Ongoing            |
| Use of Information Technology in the Prevention of Diabetes  | <a href="http://ClinicalTrials.gov/show/NCT00819455">http://ClinicalTrials.gov/show/NCT00819455</a> | Ongoing            |
| A Culturally Tailored Lifestyle Intervention to Prevent Diabetes in South Asians   | <a href="http://ClinicalTrials.gov/show/NCT01084928">http://ClinicalTrials.gov/show/NCT01084928</a> | Ongoing            |
| Impact of Lifestyle Intervention Programs on Glucose Metabolism and Biomarkers for Type 2 Diabetes: Ethnical Aspects   | <a href="http://ClinicalTrials.gov/show/NCT01420198">http://ClinicalTrials.gov/show/NCT01420198</a> | Ongoing            |
| Peer-led and Telehealth Comparative Effectiveness Research (CER) Adoption for Diabetes Prevention and Management   | <a href="http://ClinicalTrials.gov/show/NCT01307137">http://ClinicalTrials.gov/show/NCT01307137</a> | Ongoing            |
| Jordan Diabetes Microclinic Project  | <a href="http://ClinicalTrials.gov/show/NCT01596244">http://ClinicalTrials.gov/show/NCT01596244</a> | Ongoing            |
| The Diabetes TeleCare Study  | <a href="http://ClinicalTrials.gov/show/NCT00288132">http://ClinicalTrials.gov/show/NCT00288132</a> | Ongoing            |
| A Randomized Trial of an Intensive Education Intervention Using a Network of Involved Diabetic Patients (Peer Educators) to Improve Glycemic Control of Type 2 Diabetic Patients | <a href="http://ClinicalTrials.gov/show/NCT01485913">http://ClinicalTrials.gov/show/NCT01485913</a> | Ongoing            |
| Can a Modified Fat Diet With Low Glycaemic Load Improve Insulin Sensitivity and Inflammatory Mediators in Overweight People With Chronic Heart Failure?                          | <a href="http://ClinicalTrials.gov/show/NCT00163904">http://ClinicalTrials.gov/show/NCT00163904</a> | Ongoing            |
| Risk Reduction in Coronary Heart Disease - a Prospective Randomized Study  | <a href="http://ClinicalTrials.gov/show/NCT00679237">http://ClinicalTrials.gov/show/NCT00679237</a> | Ongoing            |
| Step Monitoring to Improve ARTERial Health   | <a href="http://ClinicalTrials.gov/show/NCT01475201">http://ClinicalTrials.gov/show/NCT01475201</a> | Ongoing            |
| Effect of Balanced Hypocaloric Diet Associated with Supplementation of Eggplant Meal in the Remission of Cardiovascular Risk Factors   | <a href="http://ClinicalTrials.gov/show/NCT01622309">http://ClinicalTrials.gov/show/NCT01622309</a> | Ongoing            |
| Study of Macronutrients and Heart Disease Risk   | <a href="http://ClinicalTrials.gov/show/NCT00609271">http://ClinicalTrials.gov/show/NCT00609271</a> | Ongoing            |
| Workplace-Sponsored Program to Reduce Obesity  | <a href="http://ClinicalTrials.gov/show/NCT00123513">http://ClinicalTrials.gov/show/NCT00123513</a> | Recently Completed |
| Worksite Program to Prevent Weight Gain Among Bus Drivers  | <a href="http://ClinicalTrials.gov/show/NCT00122993">http://ClinicalTrials.gov/show/NCT00122993</a> | Recently Completed |
| A Cafeteria Based Study of Weight Gain Prevention  | <a href="http://ClinicalTrials.gov/show/NCT00573482">http://ClinicalTrials.gov/show/NCT00573482</a> | Recently Completed |
| Preventing Obesity in the Worksite: A Multi-Message; Multi-Step Approach   | <a href="http://ClinicalTrials.gov/show/NCT01585480">http://ClinicalTrials.gov/show/NCT01585480</a> | Recently Completed |
| Work; Weight; and Wellness Program: The 3W Program   | <a href="http://ClinicalTrials.gov/show/NCT00123019">http://ClinicalTrials.gov/show/NCT00123019</a> | Recently Completed |
| Workplace Intervention: Activity Monitoring as a Tool for Corporate Wellness and Weight Loss   | <a href="http://ClinicalTrials.gov/show/NCT01461382">http://ClinicalTrials.gov/show/NCT01461382</a> | Recently Completed |
| Peer Education; Exercising and Eating Right - Obesity Prevention in Freshmen Women   | <a href="http://ClinicalTrials.gov/show/NCT01043614">http://ClinicalTrials.gov/show/NCT01043614</a> | Recently Completed |
| School Intervention With Daily Physical Activity and Healthy Food for Students With an Intellectual Disability   | <a href="http://ClinicalTrials.gov/show/NCT01291238">http://ClinicalTrials.gov/show/NCT01291238</a> | Recently Completed |
| Diabetes Prevention and Control in the Workplace: A Pilot Study  | <a href="http://ClinicalTrials.gov/show/NCT00739336">http://ClinicalTrials.gov/show/NCT00739336</a> | Ongoing            |
| Efficacy of 'Tailored Physical Activity' in Health Care Workers  | <a href="http://ClinicalTrials.gov/show/NCT01543984">http://ClinicalTrials.gov/show/NCT01543984</a> | Ongoing            |
| A Web-Based Cardiovascular Intervention for the Workplace  | <a href="http://ClinicalTrials.gov/show/NCT00763308">http://ClinicalTrials.gov/show/NCT00763308</a> | Ongoing            |
| Wellness Program for Elementary School Personnel   | <a href="http://ClinicalTrials.gov/show/NCT00123500">http://ClinicalTrials.gov/show/NCT00123500</a> | Ongoing            |

**Appendix Table 2. Index of ongoing/recently completed studies potentially applicable to Key Questions from Comparative Effectiveness Review “Strategies To Prevent Weight Gain Among Adults” (continued)**

| <b>Study Title</b>   | <b>URL</b>  | <b>Status</b>      |
|--|---|--------------------|
| School Worksite Weight Gain Prevention Intervention Study  | <a href="http://ClinicalTrials.gov/show/NCT01467284">http://ClinicalTrials.gov/show/NCT01467284</a> | Ongoing            |
| Choosing Healthy Options in College Environments and Settings  | <a href="http://ClinicalTrials.gov/show/NCT01134783">http://ClinicalTrials.gov/show/NCT01134783</a> | Ongoing            |
| Prevention of Obesity at Universities: A Randomized Trial  | <a href="http://ClinicalTrials.gov/show/NCT00456131">http://ClinicalTrials.gov/show/NCT00456131</a> | Ongoing            |
| DAMES: Daughters And MothErS Against Breast Cancer   | <a href="http://ClinicalTrials.gov/show/NCT00630591">http://ClinicalTrials.gov/show/NCT00630591</a> | Recently Completed |
| Weight Gain Prevention for Breast Cancer Survivors   | <a href="http://ClinicalTrials.gov/show/NCT00533338">http://ClinicalTrials.gov/show/NCT00533338</a> | Ongoing            |
| Exercise Program of Breast Cancer Patients Undergoing Chemotherapy With or Without Radiation                   | <a href="http://ClinicalTrials.gov/show/NCT01157767">http://ClinicalTrials.gov/show/NCT01157767</a> | Ongoing            |
| Effects of Physical Activity and Dietary Change in Minority Breast Cancer Survivors                            | <a href="http://ClinicalTrials.gov/show/NCT00811824">http://ClinicalTrials.gov/show/NCT00811824</a> | Ongoing            |
| Weight Control Programs in Women Who Have Undergone Surgery for Early Stage Breast Cancer                      | <a href="http://ClinicalTrials.gov/show/NCT00869466">http://ClinicalTrials.gov/show/NCT00869466</a> | Ongoing            |
| Individual Counseling and/or Computer-Based Counseling in Helping Healthy Women Adopt a Cancer Prevention Diet | <a href="http://ClinicalTrials.gov/show/NCT00217490">http://ClinicalTrials.gov/show/NCT00217490</a> | Ongoing            |
| Energy Balance Interventions for Colorectal Cancer Prevention  | <a href="http://ClinicalTrials.gov/show/NCT00653484">http://ClinicalTrials.gov/show/NCT00653484</a> | Ongoing            |
| Isoflavones in Preventing Further Development of Cancer in Patients With Stage I or Stage II Prostate Cancer   | <a href="http://ClinicalTrials.gov/show/NCT00027950">http://ClinicalTrials.gov/show/NCT00027950</a> | Ongoing            |