Evidence Report/Technology Assessment

Number 221

Behavioral Programs for Diabetes Mellitus

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Number 221

Behavioral Programs for Diabetes Mellitus

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

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. 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.

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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Peer Reviewers

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

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Behavioral Programs for Diabetes Mellitus

Structured Abstract

Objectives. To conduct a systematic review focusing on the effectiveness of behavioral programs for type 1 diabetes (T1DM) and identifying factors contributing to program effectiveness for type 2 diabetes (T2DM).

Data sources. MEDLINE®, Cochrane Central Register of Controlled Trials, Embase®, CINAHL, PsycINFO® (January 1, 1993, to January 2015), and PubMed® (2015); ClinicalTrials.gov, World Health Organization International Clinical Trials Registry Platform, conference proceedings (2011–14); reference lists of relevant studies.

Methods. Two reviewers independently assessed studies for fit with predetermined selection criteria and assessed risk of bias. We included prospective controlled studies and randomized controlled trials (RCTs) for T1DM and RCTs for T2DM, evaluating behavioral programs compared with usual care, active controls (e.g., didactic education), or other behavioral programs. One reviewer extracted data, with verification by a second reviewer. For T1DM, we conducted pairwise meta-analysis to assess program effectiveness; subgroup analyses to examine patient variables (e.g., age, race/ethnicity, glycemic control); and metaregressions to assess potential moderators of effectiveness, such as program components (i.e., diabetes self-management education [DSME], DSME plus support, lifestyle), intensity, delivery format, and personnel. For T2DM, we conducted network meta-analysis (incorporating direct and indirect comparisons) to assess potential moderation of program effectiveness, and subgroup analyses to assess the impact of patient variables. Strength of evidence (SOE) for key outcomes in T1DM was assessed to determine our confidence in the results.

Results. The searches identified 47,149 citations, of which we included 34 studies for T1DM and 132 RCTs for T2DM. All trials had a medium or high overall risk of bias.
For T1DM, there was moderate SOE showing greater reductions in percent hemoglobin A_{1c} (HbA_{1c}) levels at 6-month postintervention followup for individuals receiving a behavioral program compared with usual care (0.31) or an active control (0.44); both were statistically significant, and the latter was considered clinically important based on our prespecified threshold of ≥0.4 unit change in percent HbA_{1c}. There was low SOE showing no difference in HbA_{1c} at end of intervention and at 12-month or longer followup. Generic health-related quality of life was no different at end of intervention in comparisons with usual care (moderate SOE). There was either low SOE or insufficient SOE for all other outcomes, including self-management and lifestyle behaviors, body composition, diabetes-specific quality of life, diabetes distress, and complications. From the subgroup analysis for percent HbA_{1c} by age in comparison with usual care, the effect for the adult subgroup appeared to be greater (0.28) than the effect for the youth subgroup (0.00) at end of intervention, although neither result reached statistical significance. In comparisons with active controls, the SOE of the findings for youths and adults was insufficient. Program intensity (duration, contact hours, frequency of contacts) appeared not to influence program effectiveness for T1DM; individual delivery (vs. group) may be beneficial.
For T2DM, relative to usual care, the effect sizes for all minimally intensive (≤10 contact hours) DSME programs were not considered clinically important based on our prespecified threshold of ≥0.4 unit change in percent HbA_{1c} for glycemic control. Programs having greater benefit for

HbA_{1c} reduction were more often delivered in person. For body mass index, lifestyle programs (usually combining structured diet and exercise) provided the most benefit. In subgroup analyses, results for reduced HbA_{1c} favored participants with suboptimal baseline glycemic control (≥7% HbA_{1c}), adults <65 years, and minority participants (sample ≥75% nonwhite and/or Hispanic); the findings by race/ethnicity were confounded by poorer baseline glycemic control among minorities.

Conclusion. Behavioral programs for T1DM offer some benefit for glycemic control when followup extends beyond end of intervention up to 6 months. There was no statistically significant difference at end of intervention or followup timepoints longer than 6 months, although our confidence in these findings is low and benefit cannot be ruled out. More evidence is required to determine the effects of behavioral programs for other outcomes, including lifestyle behaviors, body composition, diabetes-specific quality of life, diabetes distress, and complications. For T2DM, our analyses showed limited benefit in glycemic control from DSME programs offering ≤10 hours of contact with delivery personnel and suggested that in-person delivery of behavioral programs is more beneficial than communicating the information with incorporation of technology. Behavioral programs seem to benefit individuals having suboptimal or poor glycemic control more than those with good control. Tailoring programs to ethnic minorities appears to be beneficial.

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Executive Summary

Introduction

The high burden of diabetes necessitates careful attention to factors contributing to optimal diabetes care and self-management, including lifestyle behaviors and medication adherence. Over the past few decades, much of the care and education of people with diabetes in the United States has been transferred from hospitals to outpatient settings, and several guidelines and diabetes management programs have been developed to improve diabetes care in the community.[1] However, an evaluation of initiatives to implement guidelines and processes of care in community health centers did not find improved control of hemoglobin A_{1c} (HbA_{1c}) levels for patients with diabetes.[2]

Approaches for supporting patients with diabetes to change behaviors include interventions such as diabetes self-management education (DSME), with or without an additional support (clinical, behavioral, psychosocial, or educational) phase; lifestyle interventions; and medical nutrition therapy. Interventions vary widely in terms of content, duration, intensity, and delivery methods. The effectiveness of these interventions for patients with type 1 diabetes (T1DM) has not been evaluated in recent years and the few existing reviews have been inconclusive.[3-7] In contrast, there is a diverse evidence base supporting the effectiveness of these approaches for type 2 diabetes (T2DM). However, it is unknown what combination(s) of program components and delivery mechanisms are most effective for success for T2DM.

Epidemiology and Burden of Disease

In 2012, 29.1 million Americans had a form of diabetes (diagnosed and undiagnosed). This represents 9.3 percent of the entire population and 12.3 percent of the adult population 20 years or older.[8] Older adults are disproportionately affected with diabetes; 25.9 percent of people age 65 years or older have diabetes. African Americans, Hispanic Americans, American Indians and Alaska Natives, and some Asian Americans have a higher risk of T2DM than non-Hispanic whites.[8] Although most cases of diabetes are T2DM, T1DM is one of the most common chronic diseases in childhood and adolescence, and its prevalence in the United States (1 of 433 youths <20 years of age) has increased over the past couple of decades.[9] Non-Hispanic white youths are affected with T1DM more often than any other racial or ethnic group.[10]

Diabetes-related care accounts for 11 percent of all U.S. health care expenditures,[11] equating to $245 billion in total costs in 2012.[8] Average medical expenses are more than twice as high for a person with diabetes as they are for someone without diabetes.[12] When considering medical and productivity costs, some calculations provide even more extreme differentials, particularly in relation to T1DM: 2007 national costs per case were $2,864 for undiagnosed diabetes, $9,677 for diagnosed T2DM, and $14,856 for T1DM.[11] Complications from diabetes include cardiovascular disease, retinopathy, neuropathy, nephropathy, and cerebrovascular disease, as well as comorbidities such as depression and other mental health conditions.[13]

Diabetes Care and Self-Management

The mainstay of treatment for T1DM is lifelong insulin therapy. In order to achieve optimal glycemic control, people with T1DM (and especially those on multiple-dose insulin or insulin pump therapy) should self-monitor their blood sugar levels frequently during the day and adjust their insulin dose, diet, and/or physical activity accordingly.[14] The benefit of intensive control of

glycemia in reducing the incidence and progression of micro- and macrovascular complications was clearly demonstrated in the Diabetes Control and Complications Trial and its related longitudinal study.[15,16] Recently, these findings have extended to demonstrate reduced mortality.[17] Although these findings are promising, a meta-analysis of 12 trials (2,230 participants) of intensive versus conventional glucose control in T1DM confirmed the reduction in development but not progression of microvascular complications, and stressed that the benefits should be weighed against the risks of severe hypoglycemia.[18]

People with T2DM are often managed progressively, with an initial focus on diet (e.g., medical nutrition therapy) and physical activity, subsequent addition of one or more oral hypoglycemic medications, and in many cases also use of insulin (or sole use of insulin) to obtain optimal blood glucose control. The importance of tight glycemic control for reducing the risk of microvascular complications in T2DM was shown in the United Kingdom Prospective Diabetes Study.[19,20] As with T1DM, though, a meta-analysis pooling results from 28 trials (34,912 participants) of intensive control in T2DM found no significant differences for all-cause mortality or cardiovascular deaths, or for macrovascular complications, including nonfatal myocardial infarction.[21]

Factors other than blood glucose control are important to address. Reducing the risk for diabetes-related complications in T1DM and T2DM often requires lifestyle and/or pharmacological management of body weight, blood pressure, and cholesterol levels.[14,22-24] For instance, intensive lowering of blood pressure in people with diabetes has been shown to reduce major cardiovascular events by 11 percent.[25] Lifestyle interventions targeted at weight loss, diabetes nutrition, and physical activity recommendations have been shown to be associated with weight control and improved glycemic control.[26-29] Additionally, findings from two large cross-national studies—the Diabetes, Attitudes, Wishes, and Needs (DAWN) studies—have demonstrated the need to address other outcomes of importance for patients, such as diabetes-related distress and depression.[30]

A critical element of diabetes care is education and support to enable patients to adopt and adhere to several self-care or self-management and lifestyle behaviors. Because knowledge acquisition alone is insufficient for behavioral changes,[26,31] the focus of many national and international guidelines and recommendations for DSME has shifted from traditional didactic educational services to more patient-centered methodologies incorporating interaction and problem-solving.[32-35] In addition, the national standards for DSME developed by the American Association of Diabetes Educators and the American Diabetes Association have incorporated the provision of ongoing diabetes self-management support "to encourage behavior change, the maintenance of healthy diabetes-related behaviors, and to address psychological concerns."[32] In addition to DSME, a diverse range of interventions and programs have been developed that focus on supporting patients' efforts in changing lifestyle behaviors in order to better manage glycemia and prevent complications.[27]

Despite the availability of new medications and devices (e.g., insulin pumps, continuous glucose monitoring), several standards for care management and DSME programs, and implementation of lifestyle interventions, the National Health and Nutrition Examination Survey found that 45 percent of adults with diabetes in the United States do not achieve glycemic targets.[36]

Rationale for Evidence Review

Health providers working in outpatient and primary care settings in the community struggle with how to best support, educate, and work with patients with diabetes to improve their disease control. To date, it is not clear whether there is (or what constitutes) a set of best practices associated with behavioral programs that can be implemented in the community health setting. For the purpose of this review, community health settings include ambulatory care (i.e., outpatient) clinics, primary care clinics, family physician clinics, and federally qualified health centers (i.e., Community Health Centers and Rural Health Centers).

Self-management and lifestyle interventions have been shown to improve glycemic control for T2DM to a clinically significant extent, at least in the short term;[37-44] the evidence for these programs in T1DM is less conclusive and based on older literature. Many previous systematic reviews on topics relevant to this review for T2DM have included studies evaluating a broad scope of interventions, some of them falling short of meeting current recommendations and others incorporating some enhancement of medical management that may confound the effects of the behavioral program. Many reviews have also included studies evaluating interventions targeted at a single behavior/component (e.g., diet) rather than multiple behaviors, as seems necessary for optimal disease self-management. Moreover, few reviews assessed factors contributing to the success of the interventions,[37,39,43,45,46] and even fewer analyzed the data in a manner that assessed multiple factors simultaneously:[45] the moderating effects of program content and characteristics have therefore not been fully investigated.

Our focus for T1DM was to determine the effectiveness of behavioral programs and for T2DM was to identify factors contributing to the effectiveness of multicomponent programs. We investigated a range of outcomes and conducted a network meta-analysis (enabling simultaneous assessment of multiple variables and a wide variety of comparisons) to analyze potential moderators of effectiveness, such as delivery personnel, effective community linkages, and demographic characteristics. Because of our focus on moderation of effectiveness for T2DM, we did not examine harms, as we did for T1DM. This review provides information regarding the effectiveness and harms of behavioral programs (T1DM) and the combination of program components and delivery methods that is most effective for implementation of these programs in community health settings (T2DM).

Scope and Key Questions

For the purpose of this review we developed an operational definition of behavioral programs that encompasses DSME (without or with an additional clinical, psychosocial, or behavioral support phase—i.e., "DSME plus support"), as well as other programs incorporating interactive components that target multiple important behavioral changes (e.g., diet and physical activity). A commonality of all programs was that they incorporated one or more behavior change techniques,[47] with or without explicit use of a theory or model of behavior change. Our operational definition of a behavioral program is as follows:

> An organized, multicomponent diabetes-specific program with repeated interactions by one or more trained individuals, with a duration of ≥4 weeks, to improve disease control and/or patient health outcomes, and consisting of at least one of the following: (a) DSME; (b) a structured dietary intervention (related to any of the following: weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; or (c) a structured exercise or physical activity intervention

together with one or more additional components. Additional components for (b) and (c) may include interventions related to diet or physical activity; behavioral change (including but not limited to goal-setting, problem-solving, motivational interviewing, coping-skills training, cognitive behavioral therapy strategies); relaxation or stress reduction; blood glucose regulation; medication adherence; or self-monitoring for diabetic complications (foot, eye, and renal tests).

We addressed the following six Key Questions (KQs):

Key Question 1. For patients with T1DM, are behavioral programs implemented in a community health setting effective compared with usual or standard care, or active comparators in—

a. Improving behavioral, clinical, and health outcomes?
b. Improving diabetes-related health care utilization?
c. Achieving program acceptability as measured by participant attrition rates?

Key Question 2. For patients with T1DM, do behavioral programs implemented in the community health setting differ in effectiveness for behavioral, clinical, and health outcomes; their effect on diabetes-related health care utilization; or program acceptability for the following subgroups of patients?

a. Age—children and adolescents (≤18 years) and their families, young adults (19–30 years), adults (31–64 years), older adults (≥65 years)
b. Race or ethnicity
c. Socioeconomic status (e.g., family income, education level, literacy)
d. Time since diagnosis (≤1 year vs. >1 year)
e. Baseline level of glycemic control (HbA_{1c} <7% vs. ≥7%)

Key Question 3. For patients with T1DM, does the effectiveness of behavioral programs differ based on the following factors?

a. Program components
b. Intensity (i.e., program duration, frequency/periodicity of interactions)
c. Delivery personnel (e.g., dietitian, exercise specialist, physician, nurse practitioner, certified diabetes educator, lay health worker)
d. Method of communication (e.g., individual vs. group, face to face, interactive behavior change technology, social media)

e. Degree of tailoring based on needs assessment (e.g., educational/behavioral deficits, age or other demographics, readiness to change)
f. Level and nature of community engagement

Key Question 4. For patients with T1DM, what are the associated harms (i.e., activity-related injury) of behavioral programs implemented in a community health setting compared with usual care, standard care, or active comparators?

Key Question 5. Among behavioral programs targeted at adults with T2DM implemented in a community health setting, what factors contribute to (a) their effectiveness for behavioral, clinical, and health outcomes; (b) their effect on diabetes-related health care utilization; and (c) program acceptability as measured by participant attrition rates? Factors include the following:

a. Program components
b. Program intensity
c. Delivery personnel
d. Methods of delivery and communication
e. Degree of tailoring
f. Community engagement

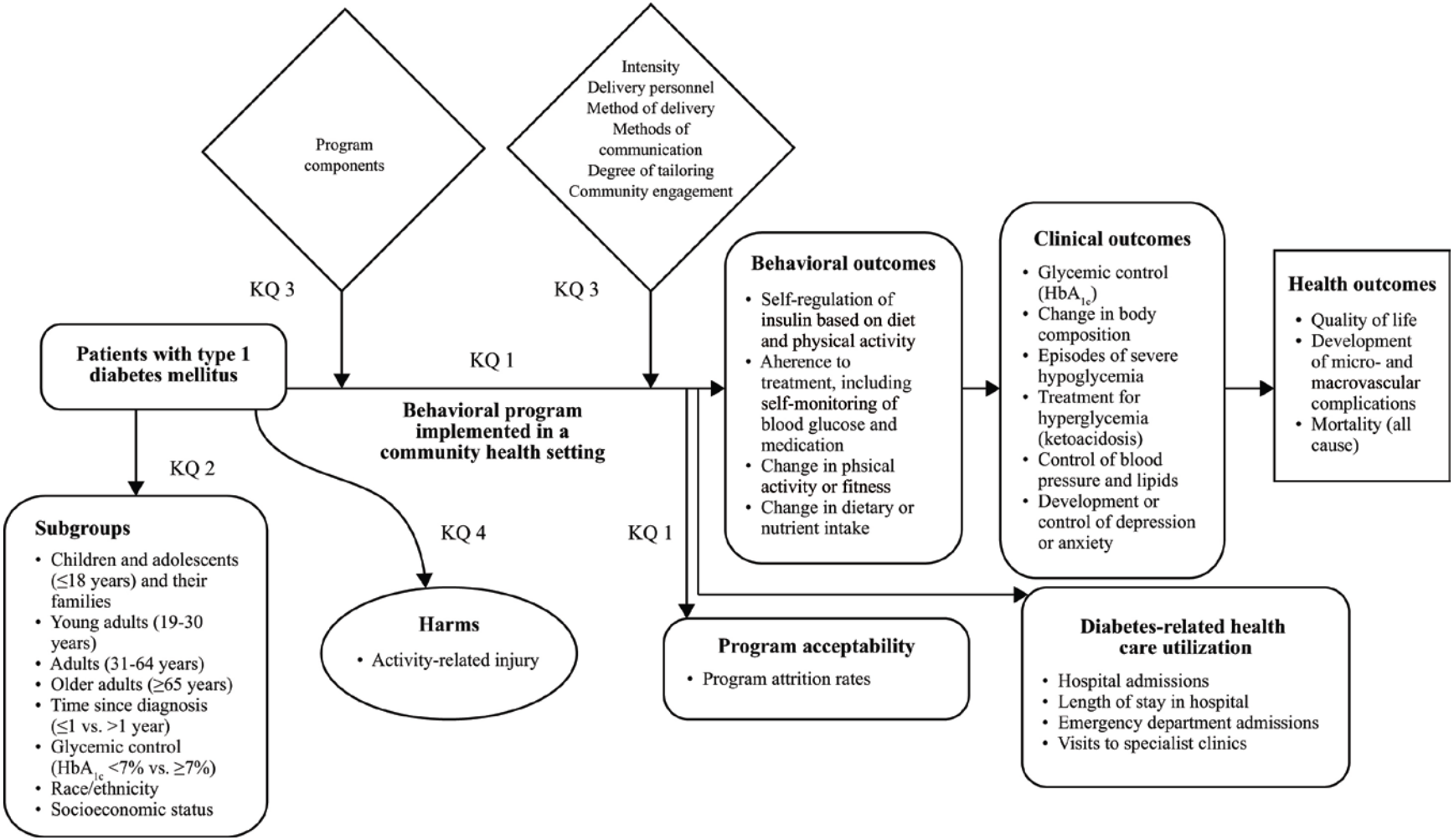
Key Question 6. Do the factors that contribute to program effectiveness for patients with T2DM vary across the following subpopulations?

a. Age—young adults (19–30 years), adults (31–64 years), older adults (≥65 years)
b. Race or ethnicity
c. Socioeconomic status (e.g., family income, education level, literacy)
d. Time since diagnosis (≤1 year vs. >1 year)
e. Baseline level of glycemic control (HbA_{1c} <7% vs. ≥7%)

Analytical Frameworks

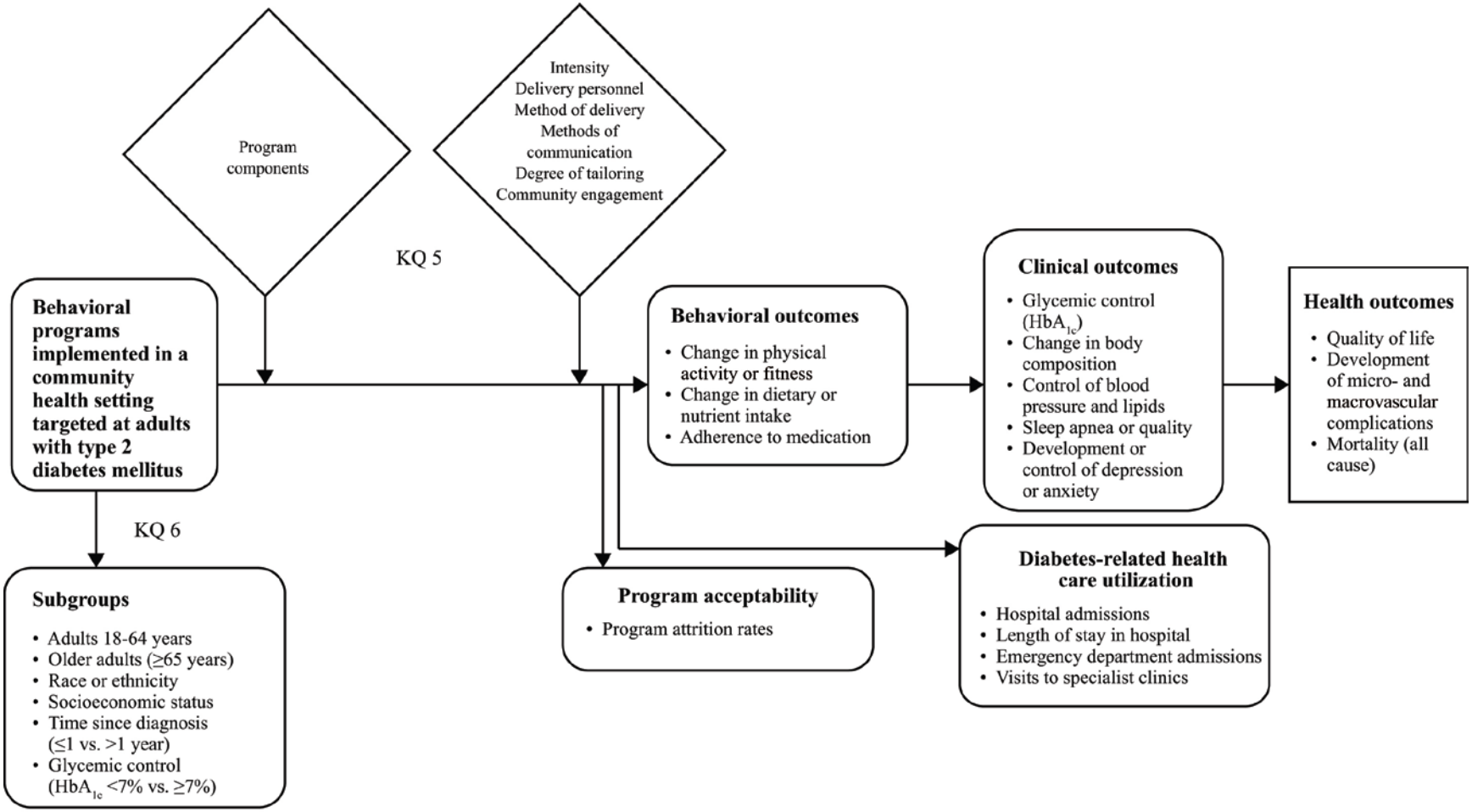
We developed two analytic frameworks to guide the systematic review process and specific KQs for T1DM and T2DM (Figure A and Figure B, respectively). The figures illustrate the populations of interest and the outcomes that we reviewed.

Figure A. Analytic framework for behavioral programs for type 1 diabetes mellitus



HbA_{1c} = hemoglobin A_{1c}; KQ = Key Question

Figure B. Analytic framework for behavioral programs for type 2 diabetes mellitus



HbA_{1c} = hemoglobin A_{1c}; KQ = Key Question

Methods

Literature Search Strategy

We used the same approach and search strategies for T1DM and T2DM. Our research librarian searched the following bibliographic databases from 1993 to May 2014: Ovid MEDLINE® and Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Cochrane Central Register of Controlled Trials via Cochrane Library, Embase® via Ovid, CINAHL Plus with Full Text via EBSCOhost, PsycINFO® via Ovid, and PubMed® via the National Center for Biotechnology Information Databases. We limited the search to prospective controlled studies published in English. On January 15, 2015, we performed a search update in all databases except Embase, from which none of the previously included studies was exclusively obtained. We reviewed the reference lists of relevant systematic reviews and of all included studies. We searched ClinicialTrials.gov and the World Health Organization International Clinical Trials Registry Platform. We searched the conference proceedings (2011–14) from the American Diabetes Association, American Association of Diabetes Educators, National Institute of Diabetes and Digestive and Kidney Diseases, Canadian Diabetes Association, European Association for the Study of Diabetes, International Diabetes Federation, Society of Behavioral Medicine, and International Society for Behavioral Nutrition and Physical Activity.

Eligibility Criteria

The research team developed eligibility criteria with respect to populations, interventions, comparators, outcomes, timing, and setting (PICOTS). For both T1DM and T2DM, we included studies conducted in the United States or other highly developed countries[48] and published in the English language on or after 1993. The publication date limit was chosen because of changes to usual care/medical management (the comparator in most cases in this review) resulting from the findings of landmark trials published from 1993 onward.[15,24,49] For T1DM, we included prospective comparative studies—i.e., randomized controlled trials (RCTs), nonrandomized controlled trials (non-RCTs), prospective cohort studies, and controlled before-after studies. For T2DM, we included RCTs.

For T1DM, we included studies of patients (any age) diagnosed with T1DM who had undergone basic diabetes education. For T2DM, we included studies of adults with T2DM who had undergone basic diabetes education.

For behavioral programs, we included studies of interventions that met the criteria included in our operational definition. The comparators were usual care (i.e., usual medical management provided to all participants), an active comparator (i.e., an intervention not meeting our definition of a behavioral program, such as basic education or a dietary or physical activity intervention), or another behavioral program. When two or more behavioral programs were compared, we considered this an evaluation of comparative effectiveness.

Study Selection

Two reviewers independently screened all titles and abstracts using broad inclusion criteria. We retrieved the full text of any publications marked for inclusion by either reviewer. Two reviewers independently assessed the full texts using a priori inclusion criteria and a standard form. We resolved disagreements by consensus or consulting a third member of the review team.

Risk of Bias

Two reviewers independently assessed the risk of bias of included studies. Discrepancies were resolved through discussion and consensus. We assessed the internal validity of RCTs and non-RCTs using the Cochrane Risk of Bias tool.[50] The tool examines seven domains of potential bias (sequence generation, concealment of allocation, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and "other" sources of data) and is used to categorize the overall risk of bias. Each domain was rated as having low, medium, or high risk of bias.

We assessed the risk of bias for prospective cohort studies and controlled before-after studies using the Newcastle-Ottawa Scale.[51] This tool uses a star system to assess methodological quality across three categories: selection of participants, comparability of study groups, and ascertainment of the outcome of interest. The star rating indicates the quality of a study, with a maximum assessment of nine.

Data Extraction

We used structured data extraction forms to gather pertinent information, including characteristics of study populations, settings, interventions, comparators, and outcomes; study designs; and methods. We extracted data directly into the Systematic Review Data Repository™ (http://srdr.ahrq.gov/).[52] One reviewer extracted data, and a second reviewer checked the data for accuracy and completeness. We resolved disagreements through consensus or by consulting a third member of the review team.

Data Synthesis

We analyzed data separately for T1DM and T2DM, with different approaches for each KQ. For each condition we summarized the characteristics of included studies qualitatively and presented important features of the study populations, interventions, and comparators in summary tables. All outcome data were extracted and reported in figures of meta-analyses (if pooled) or in outcomes tables. We extracted and analyzed data from different postintervention followup timepoints: end of intervention to ≤1 month postintervention, >1 month to ≤6 months, >6 months to ≤12 months, >12 months to ≤24 months, and >24 months.

We focused on the following key outcomes: HbA_{1c}, quality of life, development of micro- and macrovascular complications, all-cause mortality, adherence to diabetes self-management behaviors, change in body composition, change in physical activity or fitness, and change in dietary or nutrient intake. To enable interpretation of the results in terms of clinical significance and the precision of the effect sizes during assessment of the strength of the body of evidence for our key outcomes, discussed later, we defined a threshold for clinical importance when there was literature to provide guidance. For HbA_{1c}, we used a difference of 0.4 percent (e.g., 7.6% vs. 8.0%).[53] For quality-of-life measures and other patient-reported outcomes represented by continuous data, we used a difference of one-half standard deviation (SD)—i.e., 0.50 standardized mean difference (SMD)—based on the mean SD from the pooled studies, which has been shown to represent a universal conservative estimate of a meaningful difference.[54,55] For adherence to self-management behaviors, we did not apply a threshold for clinical importance because of poor reporting of the scoring and unknown meaning of a threshold for an optimal number of self-monitoring tests (the most common reporting for this outcome).

With input from our Technical Expert Panel, we categorized various components and implementation methods, as outlined in Table A. Many behavioral programs comprised DSME with or without the addition of a support component (i.e., DSME + support); we separated these into two categories to recognize that the support phase was often of a lower intensity (e.g., less frequent contacts) and focused on different content, such as psychosocial support, as compared with the DSME phase. Programs not considered DSME were considered "lifestyle" programs.

Table A. Categorization of program components and implementation factors

Program Factors	Categories and Description Variables
Program components[a]	1. DSME 2. DSME + support: DSME plus an added phase to extend program duration and support; often clinically focused but may be psychosocial, educational, or behavioral 3. Lifestyle programs: Behavioral programs focused on diet and/or physical activity rather than on diabetes-specific self-management behaviors; may also include other components as long as program does not meet the criteria for DSME with emphasis on education/training
Duration of program	No categories; duration was used as a continuous variable for the regression analyses for KQs 3 and 6
Intensity[a] (contact hours; where contact hours could not be calculated, we used number of contacts as a proxy)	1. ≤10 hours[b] 2. 11 to 26 hours (e.g., weekly for up to 6 months) 3. ≥27 hours (allowing for monthly followup for 1 year)
Frequency of contacts	No categories; this was a composite variable combining duration and intensity (hours/month); the continuous variable was used for the regression analyses for T1DM
Method of communication[c]	1. In person only 2. Mixture of in person and technology 3. All technology with minimal interaction with providers
Method of delivery[d]	1. Individual 2. Mixed individual and group 3. Group
Delivery personnel[e]	1. Delivered entirely by non–health professional (e.g., lay/community health worker, undergraduate student) after training and under some supervision 2. One health professional for large majority (>75%) of delivery 3. Provision by multidisciplinary team of health professionals
Degree of tailoring[f]	1. None/minimal—no tailoring or only small portion is tailored (e.g., personalized diet prescription in otherwise highly structured lifestyle program or delivery based on flexible hours but same content for all) 2. Moderate/maximum—most of program has content and/or delivery tailoring (e.g., topics are based on needs assessment, and delivery timing/duration/location is based on participant's schedule/needs/location preferences)
Level and nature of community engagement	1. Present—e.g., peer delivery of program or peer support groups for support stage, use of community resources (infrastructure) for delivery or maintenance stages 2. Absent—e.g., nothing reported or, at most, providing written information about community resources
Presence of support person[g]	1. Family or parent involved in >1 session 2. No family or parent involvement in sessions

DSME = diabetes self-management education; KQ = Key Question; T1DM = type 1 diabetes mellitus

[a]In analyses for KQ 5 and 6 only.

[b]Based on the current number of hours billable for patients eligible for public health care administered by the Centers for Medicare & Medicaid Services in the United States (described by Technical Expert Panel as a practical limitation on implementing programs having higher intensity).

[c]2 and 3 were combined for analysis.

[d]1 and 2 were combined for analysis.

[e]2 and 3 were combined for KQs 5 and 6.

[f]Used in summary tables and the analysis for T1DM.

[g]For T1DM only.

Synthesis for T1DM (KQs 1–4)

For each comparison of interest, we conducted a pairwise meta-analysis when two or more eligible trials were sufficiently similar on the basis of study design and clinical homogeneity. We present both pooled and subgroup analysis based on age when there was more than one trial in each age category at any timepoint. We used the Hartung-Knapp-Sidik-Jonkman random-effects model[56,57] for all meta-analyses and used Stata 11.2 and Excel 2010 software. We calculated pooled mean differences (MDs), SMDs, and risk ratios (RRs) with corresponding 95% confidence intervals (CIs), as appropriate, and weighted by sample size and variance. We analyzed outcomes at different postintervention timepoints.

For KQ 2, we searched for subgroup analyses reported by individual trials that focused on whether a particular behavioral program was more or less effective for the outcome reported by the most studies (i.e., HbA_{1c}) based on variables of interest. (See Figure A.) We also compared subgroups of studies—for example, when the mean age of participants fell within one of the age categories.

To assess whether the effectiveness of behavioral programs differed based on various program factors (KQ 3), we performed univariate metaregressions for comparisons between behavioral programs and usual care for HbA_{1c} from each study's longest followup timepoint. Each behavioral program was coded using the categorization scheme in Table A, and these variables were used in the analysis. For KQ 4, harms (i.e., activity-related injury), we planned to descriptively summarize all outcomes presented in studies.

Synthesis for T2DM (KQs 5 and 6)

Before synthesizing findings to answer KQs 5 and 6, we performed pairwise meta-analyses for all outcomes identified in the PICOTS using the same analytical approach described for KQ 1. To answer KQs 5 and 6, we performed network meta-analyses for key outcomes reported by the most studies (HbA_{1c} and BMI). A network meta-analysis allows for simultaneous evaluation of a suite of comparisons, and considers both direct and indirect evidence while preserving the within-study randomization. A network of different comparisons is constructed (with "nodes" representing groupings of sufficiently similar interventions and comparators). To assess the effectiveness of programs based on different combinations of moderator variables, we grouped the behavioral programs into nodes after coding them in terms of the program components and implementation factors described in Table A. We also formed three categories for the comparator groups: usual care, active "non-DSME education" control (i.e., basic education not meeting our criteria for DSME), and active "other" control (e.g., stand-alone dietary or physical activity interventions). The analysis was conducted using a Bayesian network model. Results are presented as estimates of the treatment effects (MDs) relative to usual care with 95-percent credibility intervals, as well as the rank probabilities for each behavioral program strategy (e.g., probability that a particular combination of components and delivery methods for a behavioral program is the "best program").

KQ 6 focused on whether variability between population groups affected the role of potential factors contributing to effectiveness of behavioral programs for the key outcome with the most data (i.e., HbA_{1c}). We first conducted subgroup analyses of the pairwise meta-analysis results for HbA_{1c} for behavioral programs compared with usual care and active controls at longest followup; subgroup analyses based on between-study baseline glycemic control (HbA_{1c}), age, and ethnicity were performed. For baseline glycemic control and age, we then performed subgroup analysis of the network meta-analysis used for KQ 5 using only studies in which

participants had suboptimal baseline glycemic control (>7% HbA_{1c}), or were under 65 years of age. For subgroups based on race/ethnicity (≥75% vs. <75% percent nonwhite and/or Hispanic), the number of trials in either subgroup was not sufficient to perform a meaningful network meta-analysis (i.e., the number of studies in each node would be very low, thus limiting the validity of this method), so we conducted a set of univariate metaregressions using the variables in Table A and methods outlined for KQ 2. All of our results for this KQ relied on between-study rather than within-study comparisons, such that the effect of randomization is removed and the results are considered observational and possibly biased through confounding by other study-level characteristics.

Strength of the Body of Evidence

We followed the "Methods Guide for Effectiveness and Comparative Effectiveness Reviews" (Methods Guide)[58] to evaluate the strength of evidence (SOE) for KQ 1 for all health outcomes (i.e., quality of life, development of micro- and macrovascular complications, all-cause mortality) and selected behavioral and clinical outcomes (i.e., glycemic control, adherence to diabetes self-management behaviors, change in body composition, change in physical activity or fitness, and change in dietary or nutrient intake). For KQ 2, we assessed SOE for HbA_{1c}, which was the outcome reported by the most studies and thus the focus of this KQ. SOE assessments were based on evidence from trials. The body of evidence was graded by one reviewer and reviewed by a second reviewer. Disagreements were resolved through discussion or by consulting with a third reviewer, as needed.

For each outcome, we assessed five major domains of most relevance to reviews of RCTs (anticipated to be the large majority of included studies): risk of bias (rated as low, medium, or high), consistency (rated as consistent, inconsistent, or unknown), directness (rated as direct or indirect), precision (rated as precise or imprecise), and reporting bias (rated as suspected or not suspected). A precise estimate is one that allows for a clinically useful conclusion. The overall SOE was graded as high, moderate, low, or insufficient. High, moderate, and low SOE reflect the confidence we have in the effect estimate and the likelihood that the estimate will change with further research. Insufficient SOE implies that we are unable to estimate an effect, that we had no or very little evidence, or that the 95% CI included clinically important effects both for and against behavioral programs.

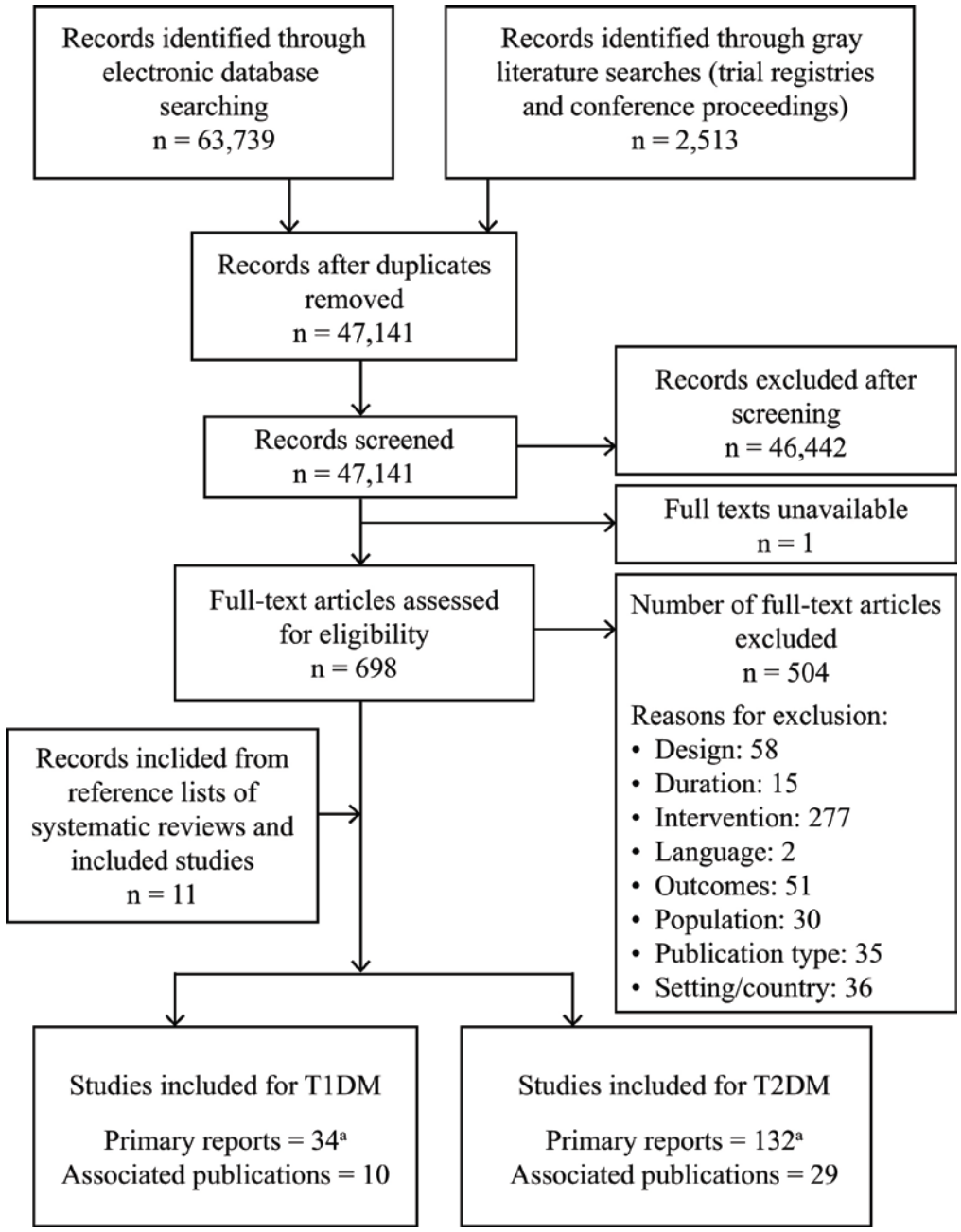
Applicability

We assessed applicability of the body of evidence following guidance from the Methods Guide.[58] We used the PICOTS framework to explore factors that may affect applicability.

Results

Our database and gray literature searches identified 47,141 citations, and 11 additional records were identified from reference lists of systematic reviews and included studies. For T1DM, we included 34 studies described in 44 publications. For T2DM, we included 132 studies described in 161 publications. Figure C describes the flow of literature through the screening process.

Figure C. Flow diagram of study –



T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus
[a]One study was included for both T1DM and T2DM.

T1DM: Description and Risk of Bias of Studies

Twenty-five studies were conducted in children and adolescents; nine were conducted in adults. Most trials were two-arm trials comparing DSME with usual care. For most studies (70%), the mean HbA_{1c} was 8.5 percent or higher. For studies targeting children and adolescents, the mean age across most studies ranged from 12 to 15 years; because of this, we refer to the included studies as being conducted in "youths." For studies targeting adults, the mean age ranged from 30 to 49 years. No studies specifically targeted older adults (≥65 years). The mean

duration of diabetes ranged from 2.7 to 7.3 years among studies that targeted youths and from 2.5 to 23 years for those targeting adults.

The total duration of the behavioral programs for youths ranged from 1.2 to 25 months (median = 5.6 months). The number of contact hours ranged from 1 to 48 hours (median = 9.5 hours). Five trials delivered the programs to youths only; 16 delivered the programs to both youths and their parents or family members. There was a mixture of delivery to individuals and to groups, and programs were delivered by a variety of personnel, with seven trials not using health care professionals.

In studies on adults, the total duration of the behavioral programs ranged from 1.5 to 12 months (median = 6 months), and the number of contact hours ranged from 9 to 52 hours (median = 16 hours). There was a mixture of individual and group formats. All trials were provided by health care professionals; one used a peer who served as coleader.

All trials were assessed as having either moderate or high overall risk of bias. For objective outcomes (i.e., HbA_{1c}), 58 percent of trials had a medium risk of bias and 42 percent had a high risk. The assessment of high risk was largely driven by incomplete outcome data (i.e., loss to followup). For trials reporting subjective outcomes of interest to this review (e.g., health-related quality of life [HRQL], patient-reported self-management behaviors), all but one trial had a high risk of bias (95%), primarily because of lack of blinding of participants, study personnel, and outcome assessors.

T1DM: Results for KQs 1–4

A summary of the key findings and SOE assessments for behavioral programs compared with usual care and active controls are presented in Tables B and C, respectively.

When comparing behavioral programs with usual care, there was moderate SOE showing reduction in HbA_{1c} at 6-month postintervention followup, with percent HbA_{1c} reduced by 0.31. This result failed to reach our threshold of clinical significance of a change by 0.4 percent HbA_{1c}. For all other timepoints, there was no significant difference in HbA_{1c}; the SOE was low because of risk of bias and imprecise effect estimates. For followup timepoints of 12 months or longer, the 95% CIs included our threshold for clinical importance such that we cannot rule out benefit for behavioral programs based on the available evidence. For individuals who were enrolled in behavioral programs compared with those receiving an active control, there was moderate SOE showing a statistically significant and clinically important reduction in percent HbA_{1c} of 0.44 at 6-month postintervention followup. There was no difference in HbA_{1c} at other timepoints; however, the SOE was low and we cannot rule out a benefit for behavioral programs.

There was low SOE showing no difference in adherence to diabetes self-management behaviors (i.e., frequency of blood glucose checks or overall self-management) at end of intervention and 6-month followup for comparisons with usual care; for comparisons with active controls, there was insufficient SOE for this outcome at any followup timepoint. For participants receiving behavioral programs compared with usual care, there was no difference in generic HRQL at the end of intervention (moderate SOE). Few trials reported on generic HRQL at longer followup timepoints. In comparisons with usual care, there was insufficient SOE to assess whether there was any effect on diabetes-specific HRQL at any timepoint, and low SOE of no difference for diabetes distress at end of intervention and 6-month followup. The 95% CIs for diabetes distress included our threshold for clinical importance such that we cannot rule out a favorable effect for behavioral programs. There were no data on HRQL for comparisons of behavioral programs with active controls. Few trials reported on symptoms of depression or on

episodes of severe hypo- or hyperglycemia. No trials reported on micro- and macrovascular complications or on all-cause mortality.

Few trials reported on the number of diabetes-related hospital admissions or emergency department admissions. Behavioral programs appear to be acceptable to patients with T1DM; our meta-analysis found a 21-percent higher risk of attrition for individuals receiving usual care compared with those receiving the behavioral program.

Table B. Type 1 diabetes: summary of key findings and strength of evidence for behavioral programs compared with usual care

Outcome	Outcome Timing	# Trials (# Subjects); Tool if Applicable	Mean Difference or Standardized Mean Difference	Strength of Evidence
HbA_{1c}	EOI	16 (1,155)	MD, -0.11; 95% CI, -0.33 to 0.11[a]	Low for no significant difference
HbA_{1c}	6m followup	12 (1,463)	MD, -0.31; 95% CI, -0.47 to -0.15	Moderate for benefit[b]
HbA_{1c}	12m followup	7 (1,333)	MD, -0.22; 95% CI, -0.49 to 0.05	Low for no significant difference
HbA_{1c}	≥12m followup	4 (1,138)	MD, -0.40; 95% CI, -0.92 to 0.12 (>12m to <24m) MD, -0.08; 95% CI, -1.96 to 1.8 (≥24m)	Low for no significant difference
Adherence to diabetes self-management	EOI	4 (282); SMBG 1 (74); SDSCA 1 (54); DSMP 1 (74); DSCI	MD, 0.15; 95% CI, -0.54 to 0.84 MD, 1.4 days; 95% CI, 0.35 to 2.43 MD, 5.00; 95% CI, 0.60 to 9.40 MD, 0.22; 95% CI, -0.60 to 1.04	Low for no significant difference
Adherence to diabetes self-management	6m followup	5 (252); SMBG 1 (244); SDSCA 2 (471); DSMP	MD, 0.40; 95% CI, -0.36 to 1.16 MD, -0.06; 95% CI, -0.60 to 0.48 No difference (different measures)	Low for no significant difference
Adherence to diabetes self-management	12m followup	1 (54); DSMP 1 (180); skipping 1 or more doses in past month	MD, 4.00; 95% CI, -1.69 to 9.69 OR, 0.82; 95% CI, 0.48 to 0.1.38	Insufficient
Adherence to diabetes self-management	>12m followup	1 (390); SMBG 1 (190); skipping 1 or more doses in past month	MD, -0.36; 95% CI, -0.69 to -0.03 (≥24m) OR, 1.30; 95% CI, 0.78 to 2.17 (24m)	Insufficient
Change in body composition (BMI [$kg.m^{-2}$])	EOI	1 (60)	MD, 0.08; 95% CI, -0.35 to 0.51	Insufficient
Change in body composition (BMI [$kg.m^{-2}$])	6m followup	1 (227)	MD, -0.21; 95% CI, -0.62 to 0.20	Insufficient
Change in body composition (kg)	EOI	1 (61)	MD, -0.50; 95% CI, -5.69 to 4.69	Insufficient
Change in physical activity (fitness, VO_2 max)	EOI	1 (43)	MD, 0.59; 95% CI, 0.22 to 0.96	Insufficient
Change in physical activity (intensity/duration)	EOI	2 (91)	SMD, 0.16; 95% CI, -0.25 to 0.57	Insufficient

Table B. Type 1 diabetes: summary of key findings and strength of evidence for behavioral programs compared with usual care (continued)

Outcome	Outcome Timing	# Trials (# Subjects); Tool if Applicable	Mean Difference or Standardized Mean Difference	Strength of Evidence
Change in physical activity (intensity/duration)	6m followup	2 (272)	SMD, -0.26; 95% CI, -1.00 to 0.49	Insufficient
Change in dietary or nutrient intake (energy [kcal/day])	EOI	1 (61)	MD, -247.10; 95% CI, -281.7 to -212.5	Insufficient
Change in dietary or nutrient intake (% saturated fat)	EOI	1 (61)	MD, -1.80; 95% CI, -3.53 to -0.07	Insufficient
Generic HRQL	EOI	7 (474)	SMD, 0.10; 95% CI, -0.18 to 0.38	Moderate for no difference
Generic HRQL	6m followup	1 (53)	SMD, -0.29; 95% CI, -0.83 to 0.26	Insufficient
Generic HRQL	12m followup	2 (405)	SMD, 0.02; 95% CI, -0.11 to 0.15	Insufficient
Generic HRQL	≥12m followup	1 (291)	SMD, -0.04; 95% CI, -0.27 to 0.19	Insufficient
Diabetes-specific quality of life	EOI	3 (212)	SMD, 0.08; 95% CI, -1.44 to 1.60	Insufficient
Diabetes distress	EOI	4 (209)	SMD, -0.31; 95% CI, -0.83 to 0.21	Low for no significant difference
Diabetes distress	6m followup	4 (236)	SMD, -0.28; 95% CI, -0.94 to 0.38	Low for no significant difference

BMI = body mass index; CI = confidence interval; DSCI = Diabetes Self-Care Inventory (scale not reported; higher scores better); DSMP = Diabetes Self-Management Profile (scale not reported; higher scores better); EOI = end of intervention to ≤1month postintervention followup (interventions 1.5–25 months); HbA_{1c} = hemoglobin A_{1c}; HRQL = health-related quality of life; m = month; MD = mean difference; OR = odds ratio; SDSCA = Summary of Diabetes Self-Care Activities (days per week adhering to self-management behaviors); SMBG = self-monitoring of blood glucose (frequency; tests per day); SMD = standardized mean difference; VO_2max = maximal oxygen uptake

[a]Negative values for MDs or SMDs are favorable for HbA_{1c}, change in body composition, change in dietary intake, and diabetes distress.

[b]This point estimate did not meet the threshold for clinical significance, although the 95% CI included a clinically important difference.

Table C. Type 1 diabetes: summary of key findings and strength of evidence for behavioral programs compared with an active control

Outcome	Outcome Timing	# Trials (# Subjects); Tool if Applicable	Mean Difference	Strength of Evidence
HbA_{1c}	EOI	4 (566)	MD, -0.32; 95% CI, -0.78 to 0.14[a]	Low for no significant difference
HbA_{1c}	6m followup	4 (504)	MD, -0.43; 95% CI, -0.62 to -0.24	Moderate for benefit
HbA_{1c}	12m followup	3 (342)	MD, -0.34; 95% CI, -0.71 to 0.03	Low for no significant difference
Adherence to diabetes self-management	EOI	1 (54); DSMP 1 (149); DBRS	MD, 2.40; 95% CI, -2.46 to 7.26 No data reported; those in behavioral program did more poorly	Insufficient
Adherence to diabetes self-management	6m followup	1 (149); SMBG 1 (149); DBRS	MD, -0.20; 95% CI, -0.76 to 0.36 No data reported; those in behavioral program did more poorly	Insufficient
Adherence to diabetes self-management	12m followup	1 (54); DSMP 1 (149); DBRS	MD, 2.00; 95% CI, -3.78 to 7.78 No data reported; those in behavioral program did more poorly	Insufficient

CI = confidence interval; DBRS = Diabetes Behavior Rating Scale (scale not reported; higher scores better); DSMP = Diabetes Self-Management Profile (scale not reported; higher scores better); EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; m = month; MD = mean difference; SMBG = self-monitoring of blood glucose (frequency; tests per day)
[a]Negative values for MDs are favorable for HbA_{1c}.

For KQ 2, we examined the differential effect of patient characteristics on the effectiveness of behavioral programs for T1DM. In comparisons with usual care, results for the subgroups of studies in adults and in youths were consistent with the results when looking at all studies combined for KQ 1. At 6 months, behavioral programs reduced HbA_{1c} in studies of youths by a statistically significant 0.28 percent and in studies of adults by a non–statistically significant 0.38 percent. At end of intervention, the point estimates indicated greater benefit in the adult subgroup (0.28) than in the youth subgroup (0.00), although neither of these values reached statistical significance. None of the point estimates exceeded the clinically important difference of 0.4 percent HbA_{1c}, which was established a priori. In the comparisons with active controls based on age of study participants, the small number of studies in most subgroups provided insufficient SOE.

One trial reported results separately for youths with baseline $HbA_{1c} \geq 8$ percent and found favorable results for this subgroup; no other subgroup analysis was conducted because the majority of trials enrolled participants with poor control (HbA_{1c} >8.5%). No trials reported on HbA_{1c} by race or ethnicity, socioeconomic status, or time since diagnosis.

For KQ 3, our univariate metaregressions did not find any statistically significant differences for moderation by any program factor. Examining the coefficients (e.g., change in HbA_{1c} from switching from one category to another or adding an increment in a continuous variable such as program hours) and their 95% CIs suggested that program intensity (duration, contact hours, frequency of contacts) did not influence effectiveness, and that individual (vs. group) delivery was beneficial. No studies reported on the associated harms (i.e., activity-related injury) of behavioral programs (KQ 4).

T2DM: Description and Risk of Bias of Studies

The majority of RCTs were two-arm trials, with many comparing DSME with usual care (55 trials) or an active control (7 trials); 16 three- or four-arm trials were included, as were several trials comparing two different behavioral programs (21 trials). Trials were conducted in 16 countries, but the majority (63%) were undertaken in the United States. Several trials evaluated more than one behavioral program; there were 166 intervention arms in total. The mean age of the participants ranged from 45 to 72 years (median = 58). Baseline HbA_{1c} ranged from 6.3 to 12.3 percent (median = 8%). Median duration of diabetes was 8.1 years (range, 1–18 years). The proportion of nonwhite and/or Hispanic participants was between 0 and 100 percent; the majority (≥75%) of participants in 32 trials reported nonwhite and/or Hispanic race/ethnicity.

Overall, median program duration was 6 months (range, 1–96) and median number of contact hours was 12 (range, 1–208). Sixty-four programs were delivered to individuals only, 56 were delivered to groups only, and 44 had some mixture of individual and group delivery. A small majority of programs were delivered by one health care professional, with or without the assistance of a non–health care professional; other programs were delivered by a multidisciplinary team or solely by non–health care professionals. Technology was the primary method of communication for 17 programs studied in 16 trials and was used in combination with in-person communication in 25 programs; based on our inclusion criteria, all programs were delivered with some form of communication with delivery personnel.

All trials were assessed as having a medium or high overall risk of bias. For objective outcomes (e.g., HbA_{1c}, weight, blood pressure), 42 percent of trials had a medium risk of bias and 58 percent had a high risk. The assessment of high risk was largely driven by incomplete outcome data (i.e., loss to followup). Of trials (n = 92) reporting on subjective outcomes of interest for this review (e.g., HRQL, depression), 13 percent had a medium risk of bias; the remainder (87%) had a high risk of bias. This was primarily because of lack of blinding of participants, study personnel, and outcome assessors. See the Supplementary File: Full Text Screening Form, Risk of Bias Tools, and Results of Meta-Analyses for T2DM Across Outcomes (available at http://srdr.ahrq.gov) for a description of decision rules for these assessments.

T2DM: Overall Effectiveness of Behavioral Programs and Results for KQs 5 and 6

Effectiveness of Behavioral Programs Across Outcomes

There is evidence showing a beneficial effect of behavioral programs compared with both usual care and active interventions at end of intervention for glycemic control; however, for followup timepoints of 6 and 12 months, only the results at 6 months for comparisons with active controls were statistically significant. None of the results were considered to be clinically important based on our prespecified threshold of a 0.4 change in percent HbA_{1c}. There was substantial statistical heterogeneity in these pairwise meta-analyses, supporting our subsequent analysis for KQs 5 and 6 to determine which program factors and population characteristics mediate (and optimize) the effects.

Compared with usual care but not active controls, behavioral programs showed some benefits in terms of reducing BMI (0.2–0.9 kg/m^2) up to 12-month followup. There were reductions in weight (1.3–1.7 kg) and waist circumference (3.2 cm) at end of intervention, and (vs. usual care) in daily energy intake (65–150 kcal per day at 6 months). Few studies reported on outcomes

related to changes in physical activity and medication adherence, and findings were consistently of no difference.

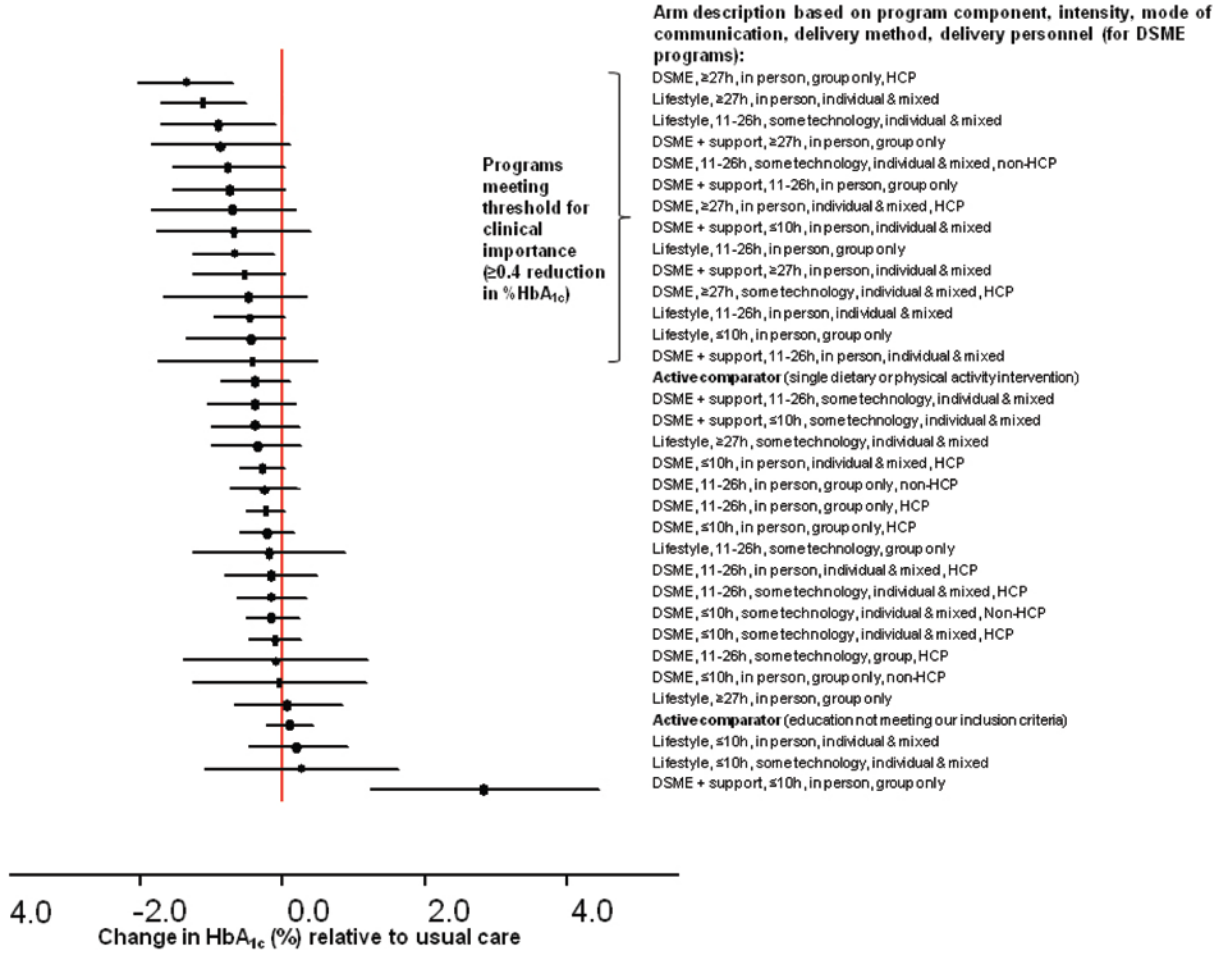
HRQOL was reported by fewer studies than anticipated, and the results mostly showed no difference. Results for diabetes distress favored behavioral programs compared with usual care at end of intervention (MD, -1.8; not clinically important based on prespecified threshold of 0.5 SD from the pooled studies), but not at longer followup. Diabetic retinopathy was reduced by 14 percent and very high–risk chronic kidney disease was reduced by 31 percent in participants receiving an intensive lifestyle program lasting 8 years or longer compared with didactic education and support in the largest trial, conducted by the LookAHEAD research group. All-cause mortality was 14 percent lower for those receiving behavioral programs than active control groups (RR, 0.86).

KQ 5. Potential Mediators of Effectiveness for T2DM

When interpreting the results for potential modifiers of effectiveness (components, intensity, delivery personnel, method of communication, degree of tailoring, and level of community engagement), we relied primarily on the relative ranking of the nodes that represented grouped factors and looked for trends in the findings based on program variables that appeared to determine whether the effects would offer clinical benefit. Some nodes had very few studies, small sample sizes, and/or wide credibility intervals. Thus we did not make any firm conclusions for a single node or for differences in 561 potential comparisons, but rather from looking across nodes with similar features.

In a network meta-analysis with usual care serving as the main reference, programs demonstrating relative effect sizes for HbA_{1c} above our threshold for clinical importance (i.e., 0.4%) represented all three major program component categories of DSME, DSME plus support, and lifestyle. The effect sizes of minimally intensive DSME programs (≤10 contact hours) were all less than our threshold for clinical importance but were all higher than the effect sizes of active controls of educational interventions not meeting our criteria for a behavioral program (e.g., didactic education programs). Programs having higher effect sizes were more often delivered in person rather than including technology; the effective programs incorporating technology were all of moderate or high intensity (>10 contact hours). Figure D summarizes the results of the network meta-analysis for HbA_{1c}.

Figure D. Plot of network meta-analysis results for HbA_{1c}



DSME = diabetes self-management education; HbA_{1c} = hemoglobin A_{1c}; HCP = health care practitioner
This plot depicts the results from our network meta-analysis for the outcome of HbA_{1c} (negative values favorable) when comparing groups ("nodes") of interventions, with each group differing by at least 1 level in the categories of program component, intensity, mode of communication, delivery method, and (for DSME programs only) delivery personnel. (See Table A for categorization schema.) The factors of program duration, program tailoring, and community engagement were not used for the analysis because of overlap in meaning with other factors (e.g., community engagement often attained through use of non–health care providers) and ability to categorize based on reporting (e.g., tailoring). The dots and lines represent the mean difference (MDs) and 95% credibility intervals for the represented programs relative to usual care; the figure indicates which MDs meet or exceed our predetermined threshold for clinical importance (change of ≥0.4% HbA_{1c}).

For the network meta-analysis of BMI, we created nodes using four variables (i.e., program component, program intensity, method of communication, and method of delivery). Lifestyle programs resulted in the highest effect sizes for BMI. Program intensity appeared to be less important than method of delivery; providing some in-person delivery appears to be beneficial.

KQ 6. Subgroups for Factors Mediating Effectiveness in T2DM

In terms of overall effectiveness at longest followup for HbA_{1c}, participants with suboptimal glycemic control (≥7% HbA_{1c}) appear to benefit more than those with good control (<7%) from behavioral programs when compared with usual care and active controls. The effect sizes were not clinically important for either group. Few differences were evident when a network meta-analysis was used to evaluate potential mediation by program factors in a subgroup of studies having participants with suboptimal baseline glycemic control.

At longest followup, older adults (≥65 years) did not benefit in terms of reduction in HbA_{1c} from behavioral programs compared with usual care or active controls. In adults <65 years, the effect size for behavioral programs compared with active controls at longest followup (up to 12 months) was clinically important. When using the studies of only participants <65 in the network analysis, the active "other" control group (e.g., dietary or physical activity intervention) showed clinically important benefit for glycemic control (MD, -0.55).

Programs offered to predominantly minority participants (≥75% nonwhite and/or Hispanic) appear to provide more benefit than those offered to populations with a lower proportion (<75%) of minority participants. The effect size for minority participants reached clinical importance. None of the program implementation factors (e.g., intensity, delivery personnel) reached statistical significance for influencing the effectiveness of behavioral programs compared with usual care on HbA_{1c}. Lifestyle programs appeared to be favorable over DSME or DSME plus support for the group of studies (n = 24) with predominantly white non-Hispanic individuals (p = 0.07); the difference in reduction in HbA_{1c} between these two categories approached our threshold for clinical importance. Our results for ethnicity need to be interpreted with caution because of the apparent worse baseline glycemic control in studies of minority versus white non-Hispanic participants (8.8% vs. 7.6% HbA_{1c}); because behavioral programs seem to preferentially benefit those with higher baseline HbA_{1c}, this factor may account for much of the increase in benefit.

Discussion

Type 1 Diabetes Mellitus

Overall, behavioral programs appear to have benefit in T1DM for reducing HbA_{1c} when followup extends beyond the immediate postintervention period up to 6 months. The delay in benefit may in part reflect the time required for this marker of glycemic control, indicating control over the past 2 to 3 months, to demonstrate change. Notable, though, is the large diversity in program duration, whereby end of intervention was anywhere between 1.5 and 25 months from the beginning of the program. Another contributor to the delay in benefit may be that a period of time is needed to integrate newly learned self-management behaviors into one's life; however, the largely insufficient level of evidence for the behavioral outcomes does not allow us to determine this with any certainty. These beneficial findings for HbA_{1c} at 6 months appear to be tempered by those of no difference at longer followup timepoints (≥12 months), although we are unable to confidently rule out benefit at long-term followup because of low SOE. Our findings may underestimate the effect of these programs should they be implemented in routine practice. The usual care group in several studies received some form of attention from the investigators (e.g., periodic telephone calls to maintain contact and encourage study participation), which may have resulted in improved glycemic control for the comparator group and reduced the relative effects observed for the behavioral program. Participants, or their providers, in the usual care or active control groups (not being blinded to group assignment in most studies) may have become more motivated to practice better self-management (including blood glucose regulation using insulin titrations), which could also attenuate differences between groups. Differences in the "usual care" provided may have also played a role, although this effect may be minimal considering recent evidence that variations in standard care in studies of behavioral interventions for youths with T1DM did not significantly impact study results.[58]

The positive findings for behavioral programs compared with active controls are notable. By offering an intervention to both study arms, these studies may also have introduced less potential bias from lack of allocation concealment and blinding. Our finding of a statistically significant and clinically important reduction (by 0.44%) in HbA_{1c} at 6-month followup for these comparisons is promising.

Self-management of T1DM during adolescence is complex, often characterized by personal challenges and uncertainty, transitions to adult care, less frequent health care visits, and diminished parental involvement; consequently, glycemic control deteriorates over the course of childhood and adolescence for many youths with T1DM.[59-62] For these reasons, many of the studies included in this review aimed to prevent deterioration of glycemic control rather than to improve it. The statistically significant reductions in HbA_{1c} at 6-month followup (vs. usual care) and the clinically important reductions in HbA_{1c} at 6- and 12-month followup (0.60% and 0.52%, respectively) in comparisons with active controls in youths lend substantial support for these programs. Likewise, incorporating more demanding self-management behaviors may negatively impact social and emotional functioning, such that our findings of no difference in generic HRQL at end of intervention may be viewed positively.

For T1DM, there was the suggestion that effectiveness was not moderated by program intensity (i.e., duration, contact hours, or frequency of contacts) and that individual versus group delivery may be beneficial. Because of insufficient data, we were unable to examine the difference between educational and lifestyle programs, or the benefit from addition of a support component to DSME programs.

Type 2 Diabetes Mellitus

Moderate- and high-intensity (≥11 hours contact time) programs appear to be necessary to provide individuals with clinically important effects on glycemic control. This outcome may also benefit from in-person delivery rather than incorporating technology. For BMI, providing some individual delivery, rather than solely relying on group formats, appears to be beneficial.

Lifestyle programs, focusing more on weight reduction and increases in physical activity than diabetes self-care, may provide similar or more benefit than DSME programs for improving glycemic control for individuals with T2DM. Our review also confirms previous suggestions that programs that have an interactive nature and employ behavioral change techniques are beneficial when compared with didactic educational interventions. While some of our findings may not result in clinically important changes at an individual level, the burgeoning growth of this disease means that even small gains in glycemic control from behavioral programs may serve as a substantial benefit for public health.

Our network meta-analysis results suggest that both individual and group delivery of programs is beneficial. Delivery format may be highly dependent on the population served and program content. Studies having clinically important effect sizes that offered programs in groups tended to be those offered to minorities, in which support from peers was incorporated as a key program feature.

We were unable to draw any conclusions about the choice of delivery personnel from the network meta-analysis. Drawing from the pairwise meta-analysis of five RCTs (647 subjects) comparing two or more interventions, there may be no difference between program delivery conducted by health care professionals or by lay providers (e.g., peers with diabetes, community health workers). One reason that programs delivered by health care professionals were not

superior may be that physicians, nurses, and dietitians receive little or no training in behavioral techniques as part of their formal education.

Our findings suggest that people with suboptimal, or poor, baseline glycemic control (≥7% HbA_{1c}), younger age (<65 years), and racial/ethnic minority status may benefit the most from behavioral programs. Because there were apparent differences in baseline glycemic control between subgroups of race/ethnicity (i.e., 8.8% HbA_{1c} in the ≥75% minority group vs. 7.6% HbA_{1c} in the <75% minority group), it is hard to distinguish if ethnicity or glycemic control is more likely to have the greater influence in moderating program effectiveness. There are likely several other factors to also consider. Many investigators enrolling a large proportion of ethnic minorities in the trials included in this review also adapted programs in ways to make them more culturally and linguistically acceptable, often including peers in the delivery or social support groups, which appeared to enhance their effectiveness. Our reliance on study-level data to create subgroups (i.e., the entire study was delivered to minorities) may have limited our ability to capture differences in effects from programs delivered to a wider population base, which may reflect routine practice in many community health settings.

Applicability

Type 1 Diabetes Mellitus

The results of this report may be most applicable to individuals with suboptimal and poor glycemic control. Nevertheless, clinicians may view the results as highly relevant to their patient population, of whom many—particularly in their pubertal years—are struggling to achieve optimal control. The results should be generally applicable to older children and adolescents (youth studies), and middle-aged adults.

It is unclear whether the results are applicable to youths or adults with recently diagnosed T1DM. We did not find evidence to confirm or refute whether behavioral programs are more or less efficacious for other subgroups, including males or females, or racial or ethnic minorities.

All of the studies targeting adults were conducted in the United Kingdom, Europe, or New Zealand. It is unclear whether the results from these studies are applicable to community health settings in the United States. For youths, most studies (73%) were conducted in the United States; the remaining studies were conducted in Europe and Australia. Despite potential differences in settings and health systems, results were similar across the studies. The studies were conducted primarily in outpatient diabetes clinics affiliated with a secondary or tertiary care hospital. Our findings are generally applicable to these settings in the United States.

Type 2 Diabetes Mellitus

Our results appear to be applicable to the majority of people enrolling in behavioral programs. There were few studies of older (≥65 years) adults or for those with good glycemic control. Our exclusion criteria related to duration of diabetes (mean <1 year)—implemented in order to capture programs providing training in ongoing self-management and lifestyle behaviors—limit the relevance of this review for newly diagnosed patients. The results appear to be applicable to both men and women, and for people on a variety of diabetes treatment regimens (19.2% were on insulin). Overall, there was fairly good representation of individuals reporting a minority racial/ethnic background.

The results seem to be applicable to community health settings in the United States. The majority (63%) of trials were conducted in the United States, and based on our inclusion criteria

related to the Human Development Index,[48] all studies were performed in countries of similar development status. Although reported inconsistently, health systems differences (i.e., usual care) may vary widely between study populations and could potentially influence the results from behavioral programs. The effect from this difference should be minimal for this review, since we limited our results to changes from baseline between groups randomly assigned and judged to receive similar medical care.

Limitations of the Comparative Effectiveness Review Process

This review followed rigorous methodological standards, which were detailed a priori. Nevertheless, several limitations are inherent within systematic reviews in general.

First, there is a possibility of selective reporting bias (e.g., reporting only positive outcomes) and publication bias, whereby unexpectedly strong results from large trials are selectively reported. In terms of selective outcome reporting, we were able to locate several trial registries and protocols to compare planned and published outcome reporting; most studies included in this review were judged as having low bias in this respect. Our prespecified tests for publication bias provided no significant indication of bias. Selected studies were confined to the English language because we felt that these reports would be most applicable to the end-users of this review, who create recommendations or implement programs for people with diabetes within the United States. Moreover, effect sizes in language-restricted reviews have shown to not differ significantly (overestimating effect sizes by 2%) from those not having restrictions.[63] Study selection bias was limited by having two independent reviewers perform screening and selection; we feel confident that study exclusion was based on explicit and appropriate reasoning, which was clearly understood by reviewers.

The interventions evaluated in the included trials were highly diverse in their content, delivery, and setting; accordingly, some of our statistical analyses indicated substantial heterogeneity. Our analyses for KQs 3, 5, and 6 were designed to determine some of the factors leading to variability in success for behavioral programs. Variability may still exist in terms of several factors. An example is length of followup; our analyses for these KQs were based on longest followup to maximize study inclusion and capture outcome durability. Another example, applicable to T2DM, is within-program intensity; DSME plus support and lifestyle programs often had lower intensity maintenance phases of varying durations.

The effects of programs delivered solely through technology (i.e., no interaction with personnel) were not assessed. Cost analysis of implementing differing behavioral programs was not addressed in this review.

Limitations of the Evidence Base

The evidence base was inadequate to fully answer the KQs, particularly with respect to the limited number of outcomes evaluated in several studies. We were unable to fully evaluate all outcomes of interest for several KQs. For KQ 1, for T1DM, limited data were available to assess the SOE for many outcomes, including behavioral outcomes related to changes in dietary intake or physical activity, and clinical and health outcomes apart from HbA_{1c}. No studies contributed data for our assessment of harms (KQ 4). Our assessment of factors contributing to effectiveness of behavioral programs for T1DM (KQ 3) was limited to the outcome of HbA_{1c} and to univariate metaregressions.

For KQs 5 and 6, related to T2DM, our network meta-analysis allowed for multiple comparisons (i.e., all comparison groups and followup timepoints), but there were still too few

studies reporting on outcomes besides HbA_{1c} and BMI. The metaregressions used for the subgroup analysis on ethnicity in KQ 6 are limited by comparator (only usual care), and the number of studies did not allow us to capture multiple variables in a single analysis. Moreover, our reliance on study-level data for the subgroup analyses makes these results exploratory. Several outcomes of importance to patients and policymakers, such as quality of life, development of complications, and health care use, were reported by too few studies to confidently support conclusions of effect or to analyze in terms of mediation by implementation factors.

Many trials had methodological limitations introducing some risk of bias. Blinding of participants and personnel is arguably difficult for trials of behavioral programs, especially when the comparator is usual care. According to our decision rules for assessing risk of bias, a low risk of bias for participant and personnel blinding was granted if the comparator was an active control or another program, the authors stated some means to blind the study hypothesis from participants, and personnel followed a structured training and protocol. Participant blinding in this manner was rarely reported. Similarly, blinding of outcome assessors, highly feasible in any situation, was rarely reported or sufficient. These two domains resulted in medium or high risk of bias being assigned for the subjective outcomes of most trials. For both subjective and objective outcomes, medium or high risk of bias was assigned in many cases from lack of intention-to-treat analysis (e.g., reporting only on results for completers) and/or from high participant attrition. Some studies had small sample sizes, and a few failed to achieve baseline comparability in their samples.

Research Gaps

Table D highlights some potential research needs based on our KQs.

Table D. Potential research needs by Key Question

KQ	Potential Research Needs
1 Effectiveness for T1DM	There were limited data to determine the effectiveness of behavioral programs for T1DM at durations of followup beyond 6 months. Future studies should strive to assess outcomes at longer term followup, to better determine the effects of these programs for periods of time that may better influence long-term outcomes of complications and quality of life.
1 Effectiveness for T1DM	There was insufficient evidence to demonstrate whether lifestyle programs (i.e., combining structured physical activity and dietary interventions) are effective for T1DM. Many individuals with T1DM under good glycemic control may have other risk factors (e.g., overweight, hyperlipidemia, hypertension) for which these programs may be warranted. Trials of lifestyle programs enrolling people with both types of diabetes should undertake subgroup analysis.
1 & 3 Effectiveness & moderating factors for T1DM	The effectiveness of adding a clinical, behavioral, psychosocial, or educational support phase to programs for T1DM is unknown. These may be useful for prolonging the effects of behavioral programs and to address some of the psychosocial aspects of the disease (particularly in adolescents) to a greater extent.
3 Moderating factors for T1DM	Only one study in T1DM compared behavioral programs delivered in person with those delivered via some form of technology allowing for interaction between the provider and patient. Transitioning individuals with diabetes between pediatric and adult care facilities and providers can be challenging, hampered by the scheduling structure of traditional clinics at a time in life when contact information and location of home, work, and education are often changing frequently. As a result, further research on providing behavioral programs via technology or creative scheduling is warranted for adolescents and young adults with diabetes.

Table D. Potential research needs by Key Question (continued)

KQ	Potential Research Needs
3 Moderating factors for T1DM	Several studies for T2DM included a small subsample of people with T1DM. Trials of lifestyle programs that incorporate exercise need to perform subgroup analysis by type of diabetes, particularly when evaluating the outcome of glycemic control. Adjustment of insulin for exercise in individuals with T1DM can be challenging and could result in differential effects of lifestyle programs on glycemic control, depending on the medical management of the participants.
3 & 5 Moderating factors for T1DM & T2DM	There was large diversity in the reporting and use of behavior change techniques employed within the programs. An evaluation of the effects of different strategies may shed additional light on the factors (within components) determining effectiveness for behavioral programs.
5 Moderating factors for T2DM	The identification of the combination of providers (e.g., physician, nurse, dietitian, pharmacist, social worker, psychologist, and trained lay individual) that is best for implementation of behavioral programs for T2DM deserves further evaluation.
5 Moderating factors for T2DM	Clinical psychologists are often employed to deliver program components that incorporate advanced behavioral approaches, such as motivational interviewing; this approach may not be feasible for all settings or within all program budgets. More research is required to determine the effectiveness of similar programs when delivered by other personnel trained to use these behavioral techniques.
5 Moderating factors for T2DM	Few trials directly compared interactive programs delivered in person with those delivered via technology. Because a technology-based approach may lessen resource burden, help to reach patients living in rural areas, and/or be desirable for younger adults more familiar with technology, its effectiveness needs further evaluation.
6 Effectiveness for different subgroups in T2DM	Trials including populations of diverse ethnic backgrounds should perform subgroup analysis based on age, race/ethnicity, and baseline glycemic control to further explore outcomes for these groups from programs that are not designed specifically for them, as might be common in most community health settings.
All	Few trials evaluated outcomes important to patients and decisionmakers (e.g., quality of life, micro- and macrovascular complications, health care use) in a manner that allowed pooling of results across studies. Use of widely accepted generic quality-of-life measures would be beneficial.
All	Study attrition rates affected the overall risk of bias substantially. More research on methods for maintaining study participation is required.
All	The risk of bias from participant and personnel blinding was high in most trials. Although many trials compared behavioral programs with active controls (limiting risk of bias because of blinding) comparisons with usual care would benefit from some mechanism to blind participants from the study hypothesis. Blinding of outcome assessors should always be attempted for subjective outcomes.
All	There is a need for consensus on what constitutes clinically important differences in outcomes for behavioral programs, such that they can be interpreted in meaningful ways for clinicians and patients.

KQ = Key Question; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus

Conclusions

Behavioral programs for T1DM offer some benefit for glycemic control when followup extends beyond end of intervention up to 6 months. There was no significant difference at end of intervention or followup longer than 6 months, although our confidence in these findings is low and we cannot rule out benefit. There was no difference in generic HRQL at end of intervention, or in diabetes distress or self-management behaviors at up to 6-month followup, although the SOE was low for these findings with the exception of generic HRQL at end of intervention (moderate SOE). Behavioral programs appear to be acceptable to patients with T1DM, given a 21-percent lower rate of attrition among those in behavioral programs than among those

receiving usual care. Data were insufficient to draw any conclusions for other outcomes, including diabetes-specific HRQL, change in body composition or lifestyle behaviors, micro- and macrovascular complications, and mortality. Encouraging patients with T1DM to participate in behavioral programs to improve outcomes apart from HbA_{1c} is not supported by the current evidence.

For T2DM, our analyses showed limited benefit in glycemic control from DSME programs offering ≤10 hours of contact with delivery personnel and suggested that in-person delivery of behavioral programs is more beneficial than incorporation of technology. We found that programs focused on lifestyle or on DSME can have similar benefit in terms of glycemic control, and that lifestyle programs appear to be better for reducing BMI. Whether the behavioral program is delivered by a health care professional or a trained lay person, or via individual or group format, appears to be less important based on the available evidence. Behavioral programs seem to benefit individuals having suboptimal or poor glycemic control more than those with optimal control. Tailoring programs to ethnic minorities—such as offering culturally appropriate materials and incorporating group interaction with peers—appears to be beneficial. While efforts should be made to provide culturally sensitive programs, community health settings that serve populations that are diverse in language and ethnicity may not have the opportunity to provide this flexible programming to meet each group's needs.

Efforts at integrating behavioral programs into care settings that incorporate the latest management guidelines should be prioritized. Program evaluation is an important component to build into the implementation of any behavioral program for diabetes, to ensure that it is the correct fit to be effective for the population that it is meant to serve. At this time, there remains a need for clinicians to evaluate each patient's success after participating in these programs, in case additional means are necessary to control their disease more adequately to prevent devastating complications.

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Introduction

Background

The high burden of diabetes necessitates careful attention to factors contributing to optimal diabetes care and self-management including lifestyle behaviors and medication adherence. Over the past few decades, much of the care and education of people with diabetes in the United States has transferred from hospitals to outpatient settings, and several guidelines and diabetes management programs have been developed to improve diabetes care in the community.[1] However, an evaluation of initiatives to implement guidelines and processes of care in community health centers did not find improved control of hemoglobin A_{1c} (HbA_{1c}) levels for patients with diabetes.[2]

Approaches for supporting patients with diabetes to change behaviors include interventions such as diabetes self-management education (DSME) with or without an additional support (clinical, behavioral, psychosocial, or educational) phase, lifestyle interventions, and medical nutrition therapy. Interventions vary widely in terms of content, duration, intensity, and delivery methods. The effectiveness of these interventions for patients with type 1 diabetes (T1DM) has not been evaluated in recent years and the few existing reviews have been inconclusive.[3-7] In contrast, there is a diverse evidence base supporting moderate effectiveness of these approaches for type 2 diabetes (T2DM). However, it is unknown what combination(s) of program components and delivery mechanisms are most effective for the success for T2DM. Health providers struggle with how to best support, educate, and work with patients to improve their disease control. To date, it is not clear whether there is (or what constitutes) a set of best practices associated with behavioral programs that could be implemented in community health settings.

Pathophysiology

The American Diabetes Association defines diabetes mellitus as "… a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both."[8] T1DM and T2DM are the major classes of diabetes although several others exist. T1DM accounts for 5–10 percent of cases of diabetes and usually results when the body's immune system destroys the beta cells of the pancreas, the only cells that make insulin.[8] The incidence of T1DM peaks in adolescents although it can occur at any age.

T2DM accounts for 90–95 percent of cases of diabetes. It usually begins with insulin resistance in which it takes more than the usual amount of insulin to achieve a given degree of glucose regulation. T2DM occurs if, over time, the pancreas is progressively less able to secrete enough insulin to normalize blood glucose.[8,9] T2DM is associated with obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity, and nonwhite race or ethnicity.

Epidemiology and Burden of Disease

In 2012, 29.1 million Americans had diabetes (all types diagnosed and undiagnosed). This represents 9.3 percent of the entire population and 12.3 percent of the adult population (20 years or older).[9] Older adults are disproportionately affected with diabetes; 25.9 percent of people over the age of 65 years have diabetes. African Americans, Hispanic Americans, American Indians and Alaska Natives, and some Asian Americans have a higher risk of T2DM compared to non-

Hispanic whites.[9] Although most cases of diabetes are T2DM, T1DM is one of the most common chronic diseases in youth, and its prevalence in the United States (1 of 433 youth aged <20) has increased over the past couple decades.[10] Non-Hispanic white youth are affected with T1DM more often than all other racial or ethnic groups.[11]

In addition to disparities in disease prevalence, several subpopulations are considered vulnerable to poor health care access and outcomes for a variety of individual and social reasons. Race or ethnicity and socioeconomic considerations including literacy, educational levels, and household income have been shown to be associated with sub-optimal care[2,12] and poorer diabetes outcomes for both T1DM and T2DM. [13-15]

Diabetes-related care accounts for 11 percent of all U.S. health care expenditure[16] equating to $245 billion in total costs in 2012.[9] Average medical expenses are more than twice as high for a person with diabetes as they are for someone without diabetes.[17] When considering medical and productivity costs, some calculations provide even more extreme differentials particularly in relation to T1DM, with national costs in 2007 per case of $2,864 for undiagnosed diabetes, $9,677 for diagnosed T2DM, and $14,856 for T1DM.[16]

Complications from diabetes include cardiovascular disease, retinopathy, neuropathy, nephropathy, and cerebrovascular disease, as well as comorbidities such as depression and other mental health conditions.[18] In adults, the most frequent first-listed diagnoses among hospital discharges in 2010 were diseases of the circulatory system (24 percent) and diabetes (12 percent). Between 5 and 11 percent of emergency department visits are for diabetes-related complications.[16] For children and adolescents in 2009, 74 percent of hospital discharges and 42 percent of emergency visits had diabetes listed as the first diagnosis. About 64 percent of these discharges and 46 percent of the emergency visits were for diabetic ketoacidosis.[9]

Diabetes Care and Self-Management

The mainstay of treatment for T1DM is lifelong insulin therapy. In order to achieve optimal glycemic control, people with T1DM (and especially those on multiple-dose insulin or insulin pump therapy) should self-monitor their blood sugar levels frequently during the day and adjust their insulin dose, diet and/or physical activity accordingly.[19] The benefit of intensive control of blood glucose in reducing the incidence and progression of micro- and macrovascular complications was clearly demonstrated in the Diabetes Control and Complications Trial (DCCT) and a related longitudinal study.[20,21] Recently, these findings have extended to demonstrate reduced mortality.[22] Although these findings are promising, a meta-analysis of 12 trials (2,230 participants) of intensive versus conventional glucose control in T1DM only confirmed the reduction in development (but not progression) of microvascular complications, and stressed that the benefits should be weighed against the risks of severe hypoglycemia.[23]

People with T2DM are often managed progressively with an initial focus on diet (e.g., medical nutrition therapy) and physical activity, and subsequent addition of one or more oral hypoglycemic medications and in many cases also (or sole use of) insulin to obtain optimal blood glucose control. The importance of tight glycemic control for reducing the risk of microvascular complications in T2DM was first shown in the United Kingdom Prospective Diabetes Study.[24,25] As with T1DM though, a meta-analysis pooling results from 28 trials (34,912 participants) of intensive control in T2DM found no significant differences for all-cause mortality or cardiovascular deaths, or for macrovascular complications including non-fatal myocardial infarction.[26]

Factors other than blood glucose control are important to address. Reducing the risk for diabetes-related complications in T1DM and T2DM often requires lifestyle and/or pharmacological management of body weight, blood pressure, and cholesterol levels.[19,27-29] For instance, intensive lowering of blood pressure has shown to reduce major cardiovascular events by 11%.[30] Lifestyle interventions targeted at weight loss, diabetes nutrition, and physical activity recommendations have been shown to be associated with weight control and improved glycemic control.[31-34] Additionally, findings from two large cross-national (Diabetes, Attitudes, Wishes, and Needs [DAWN]) studies have demonstrated the importance to address other outcomes of importance for patients such as diabetes-related distress and depression.[35,36]

A critical element of diabetes care is education and support to enable patients to adopt and adhere to several self-care or self-management and lifestyle behaviors.[37,38] DSME is designed to "reduce the burden of diabetes on individuals, families, communities and healthcare systems, and, by supporting good health, prevent or delay the onset of diabetes-related long-term complications."[39] Because knowledge acquisition alone is insufficient for behavioral changes,[40,41] the focus of many national and international guidelines and recommendations for DSME has shifted from traditional didactic educational services to more patient-centered methodologies incorporating interaction and problem-solving.[39,42-44] In addition, the national standards for DSME developed by the American Association of Diabetes Educators and the American Diabetes Association have incorporated the provision of ongoing diabetes self-management support "…to encourage behavior change, the maintenance of healthy diabetes-related behaviors, and to address psychological concerns."[42] In addition to DSME, a diverse range of interventions and programs have been developed that focus more on supporting patients' efforts in changing lifestyle behaviors in order to better manage glycemia and prevent complications.[32]

Despite the availability of new medications and devices (e.g., insulin pumps, continuous glucose monitoring), several standards for care management and DSME programs, and implementation of lifestyle interventions, the National Health and Nutrition Examination Survey found that 45 percent of adults with diabetes in the United States do not achieve glycemic targets.[45] Further, the Centers for Disease Control and Prevention's Behavioral Risk Surveillance System found that 36 percent of adults diagnosed with diabetes reported no physical activity in the past 30 days.[17] Other reported risk factors for diabetes-related complications included smoking (20 percent), self-reported overweight or obesity (86 percent), hypertension (58 percent), and high cholesterol (58 percent).[8]

Rationale for Evidence Review

Health care providers working in outpatient and primary care settings in the community struggle with how to best support, educate, and work with patients with diabetes to improve their disease control. To date, it is not clear whether there is (or what constitutes) a set of best practices associated with behavioral programs that can be implemented in the community health setting. For the purpose of this review, community health settings include ambulatory care (i.e., outpatient) clinics, primary care clinics, family physician clinics, and federally qualified health centers (i.e., Community Health Centers, and Rural Health Centers).

Self-management and lifestyle interventions have been shown to improve glycemic control for T2DM to a clinically significant extent at least in the short term.[46-53] The evidence for these programs in T1DM is less conclusive. Many previous systematic reviews on topics relevant to this review for T2DM have included studies evaluating a broad scope of interventions, some of

which fall short of meeting current recommendations (e.g., didactic educational interventions focused on relaying information without some form of interactive or collaborative training), and others which incorporate some enhancement of medical management (e.g., treatment algorithms) which may confound the effects of the behavioral program. Many reviews have also included studies evaluating interventions targeted at a single behavior/component (e.g., diet) rather than multiple behaviors as seems necessary for optimal disease self-management. Moreover, few assessed factors contributing to the success of the interventions,[46,48,51,54,55] and even fewer analyzed the data in a manner to assess multiple factors simultaneously[54]—the moderating effects of program content and characteristics have therefore not been fully investigated.

Our focus for T1DM was to determine the effectiveness of behavioral programs, and for T2DM was to identify factors contributing to the effectiveness of multicomponent programs. We investigated a range of outcomes and conducted network meta-analysis (enabling simultaneous assessment of multiple variables and a wide variety of comparisons) to analyze potential moderation of effectiveness, by factors such as delivery personnel, effective community linkages, and demographic characteristics. Because of our focus on moderation of effectiveness for T2DM, we did not examine harms as we did for T1DM. This review provides information regarding the effectiveness and harms of behavioral programs (T1DM), and what combination of program components and delivery methods are most effective for implementation of these programs in community health settings (T2DM).

Scope of Review and Key Questions

A member of the public nominated this topic; the nominator wanted to know whether there is a set of best practices associated with behavioral interventions for diabetes that could be replicated in community health centers in the United States. The nominator commented that while diabetes behavioral programs that promote self-management have demonstrated various benefits, the efforts of community health centers to improve their patients' diabetes control have achieved poor results.

To address these issues, we conducted a systematic review and meta-analysis of the effectiveness of behavioral programs for diabetes. For the purpose of this review we developed an operational definition of behavioral programs that encompasses DSME (without or with an additional clinical, psychosocial, or behavioral support phase, i.e., "DSME plus support") as well as other programs incorporating interactive components that target multiple behaviors (e.g., diet and physical activity) (see Appendix A). A commonality with all programs was that they incorporated one or more behavior change techniques,[56] with or without an explicit use of a theory or model of behavior change. This definition focuses on *programs*, defined as "…a plan of action for an event or sequence of actions over a period that may be short or prolonged…. A health program is generally long term and often multi-faceted, whereas a health project is usually short-term and narrowly focused."[57] Our operational definition of a behavioral program is as follows.

> An organized, multicomponent diabetes-specific program with repeated interactions by one or more trained individuals, with a duration of ≥4 weeks, to improve disease control and/or patient health outcomes, and consisting of at least one of the following: (a) DSME; (b) a structured dietary intervention (related to any of the following: weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; or (c) a structured exercise or physical activity intervention together with one or more additional components. Additional components for (b) and (c)

may include interventions related to diet or physical activity; behavioral change (including but not limited to goal-setting, problem-solving, motivational interviewing, coping-skills training, cognitive behavioral therapy strategies); relaxation or stress reduction; blood glucose regulation; medication adherence; or self-monitoring for diabetic complications (foot, eye, and renal tests).

We include contact with those delivering the program, rather than relying solely on "interactive behavior change technology" (e.g., patient-centered websites, automated telephone calls, and touch screen kiosks). While these tools show great promise for helping health systems meet the growing demand for diabetes management and support, they have been shown to be most effective when they support human contact.[58]

We address the following six Key Questions (KQs):

Key Question 1. For patients with T1DM, are behavioral programs implemented in a community health setting effective compared with usual or standard care, or active comparators in—

a. Improving behavioral, clinical, and health outcomes?
b. Improving diabetes-related health care utilization?
c. Achieving program acceptability as measured by participant attrition rates?

Key Question 2. For patients with T1DM, do behavioral programs implemented in the community health setting differ in effectiveness for behavioral, clinical, and health outcomes; their effect on diabetes-related health care utilization; or program acceptability for the following subgroups of patients?

a. Age—children and adolescents (≤18 years) and their families, young adults (19–30 years), adults (31–64 years), older adults (≥65 years)
b. Race or ethnicity
c. Socioeconomic status (e.g., family income, education level, literacy)
d. Time since diagnosis (≤1 year vs. >1 year)
e. Baseline level of glycemic control (HbA_{1c} <7% vs. ≥7%)

Key Question 3. For patients with T1DM, does the effectiveness of behavioral programs differ based on the following factors?

a. Program components
b. Intensity (i.e., program duration, frequency/periodicity of interactions)
c. Delivery personnel (e.g., dietitian, exercise specialist, physician, nurse practitioner, certified diabetes educator, lay health worker)

d. Method of communication (e.g., individual vs. group, face to face, interactive behavior change technology, social media)
e. Degree of tailoring based on needs assessment (e.g., educational/behavioral deficits, age or other demographics, readiness to change)
f. Level and nature of community engagement

Key Question 4. For patients with T1DM, what are the associated harms (i.e., activity-related injury) of behavioral programs implemented in a community health setting compared with usual care, standard care, or active comparators?

Key Question 5. Among behavioral programs targeted at adults with T2DM implemented in a community health setting, what factors contribute to (a) their effectiveness for behavioral, clinical, and health outcomes; (b) their effect on diabetes-related health care utilization; and (c) program acceptability as measured by participant attrition rates? Factors include the following:

a. Program components
b. Program intensity
c. Delivery personnel
d. Methods of delivery and communication
e. Degree of tailoring
f. Community engagement

Key Question 6. Do the factors that contribute to program effectiveness for patients with T2DM vary across the following subpopulations?

a. Age—young adults (19–30 years), adults (31–64 years), older adults (≥65 years)
b. Race or ethnicity
c. Socioeconomic status (e.g., family income, education level, literacy)
d. Time since diagnosis (≤1 year vs. >1 year)
e. Baseline level of glycemic control (HbA_{1c} <7% vs. ≥7%)

Analytic Frameworks

We developed two analytic frameworks to guide the systematic review process. The figures illustrate the populations of interest and the outcomes that we reviewed. Figure 1 for T1DM notes four KQs. KQ 1, KQ 2, and KQ 4 address the potential benefits and harms of behavioral

programs. The overarching boxes (components, program features) address KQ 3 related to how program components and features contribute to the effectiveness of behavioral programs.

Figure 2 for T2DM notes KQ 5 and KQ 6 that address how program components and features contribute to the effectiveness of behavioral programs.

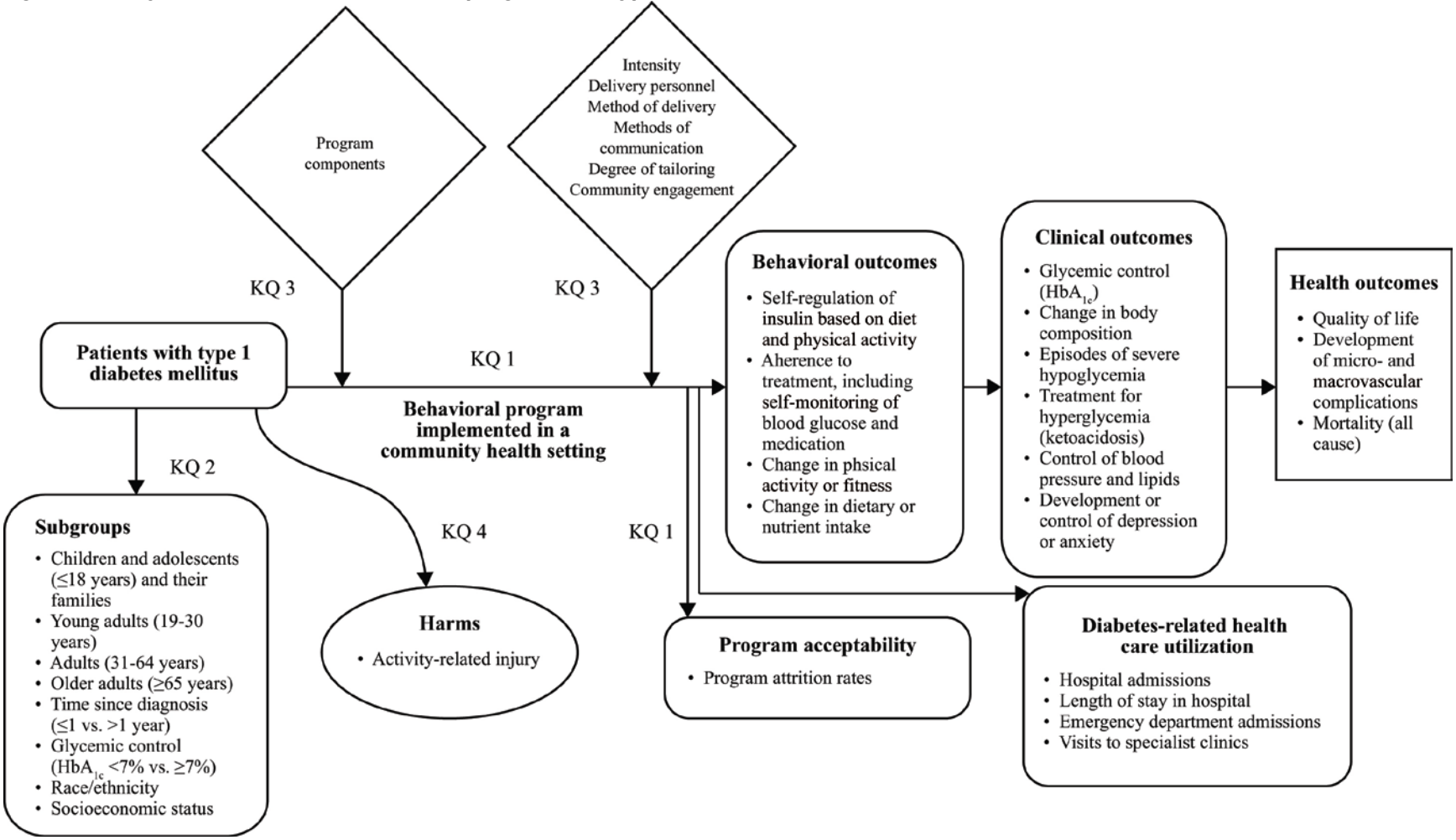
Organization of This Report

The remainder of the report describes our methods in detail and presents the results of our synthesis of the evidence with key points and detailed syntheses. For KQ 1 we also present our assessment of the strength of evidence. The results section is organized by type of diabetes—T1DM (KQs 1-4) and T2DM (KQs 5-6). The discussion section offers our conclusions, summarizes our findings, and provides other information relevant to the interpretation of this work for clinical practice and future research. References and a list of abbreviations and acronyms follow the discussion section.

The report includes a number of appendices to provide further detail on our methods, the studies assessed, and the results not presented in the text. There is also reference to a supplementary file which may be accessed for additional information on the methods for study selection and risk of bias assessment, and for the syntheses of outcomes for T2DM which were not directly applicable to our KQs. The appendixes and supplementary file are as follows:

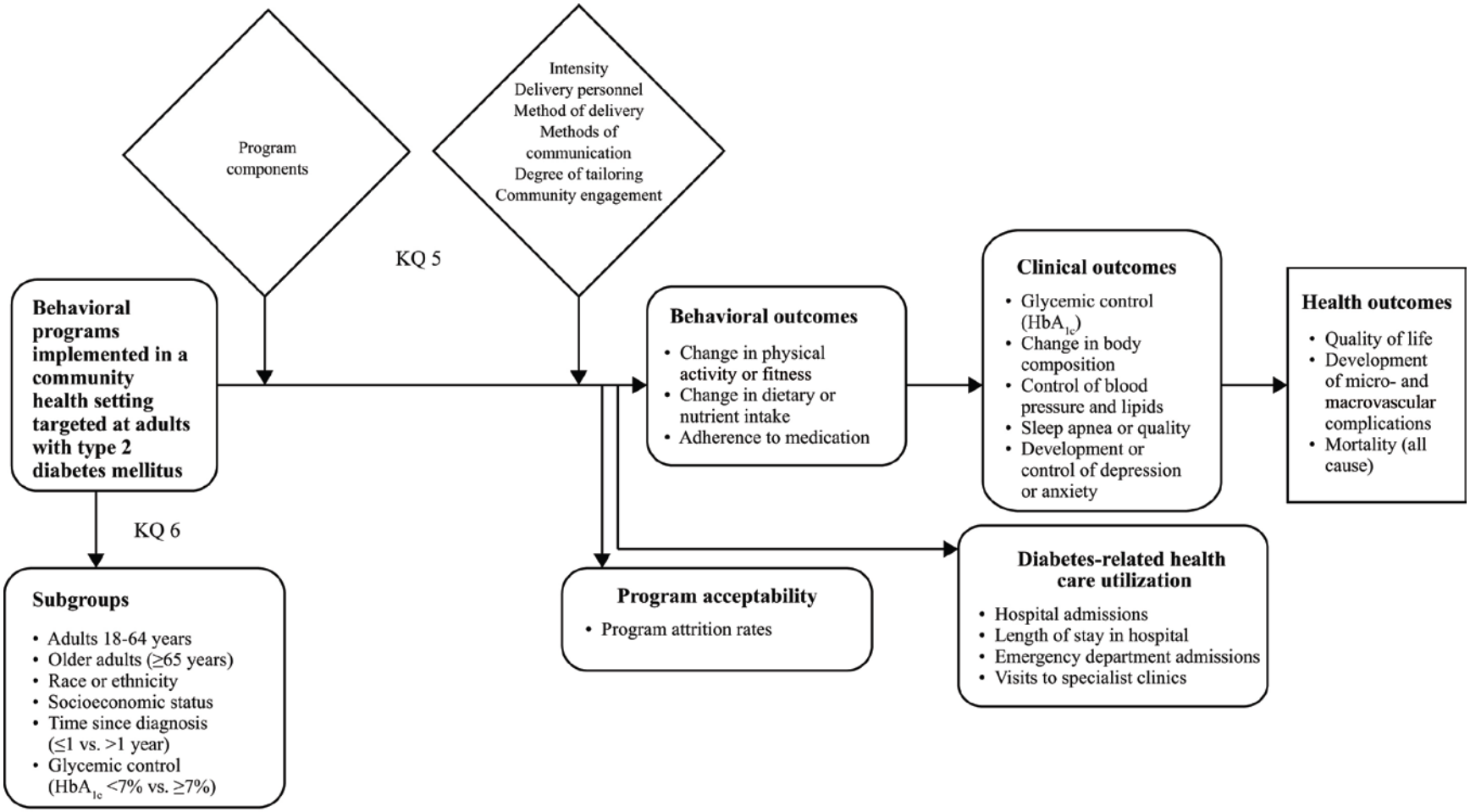
- Appendix A: Operational Definitions
- Appendix B: Literature Search Strategies
- Appendix C: Very High Human Development Index Countries
- Appendix D: Studies Excluded After Full-Text Review
- Appendix E: Risk of Bias
- Appendix F: Description of Studies and Interventions
- Appendix G: Type 1 Diabetes Mellitus: Summary of Results From Observational Studies
- Appendix H: Strength of Evidence Tables for Type 1 Diabetes Mellitus
- Appendix I: Effectiveness Across Outcomes for Type 2 Diabetes Mellitus
- Appendix J: Network Meta-analysis Results for Glycemic Control and Age Subgroup Analyses
- Supplementary File: Full Text Screening Form, Risk of Bias Tools, and Results of Meta-Analyses for T2DM Across Outcomes (available at http://srdr.ahrq.gov)

Figure 1. Analytic framework for behavioral programs for type 1 diabetes mellitus



HbA_{1c} = hemoglobin A_{1c}; KQ = Key Question

Figure 2. Analytic framework for behavioral programs for type 2 diabetes mellitus



HbA_{1c} = hemoglobin A_{1c}; KQ = Key Question

Methods

The methods for this review of behavioral programs for diabetes mellitus are based on the methods specified in the Agency for Healthcare Research and Quality (AHRQ) "Methods Guide for Effectiveness and Comparative Effectiveness Reviews" (Methods Guide).[59] The main sections in this chapter reflect the elements of the protocol established for the review.[60] The methods and analyses were determined a priori, except where otherwise specified.

Topic Refinement and Review Protocol

The Centers for Disease Control and Prevention (CDC) are partners with AHRQ in this review. During the topic development and refinement processes, we developed draft versions of the analytic frameworks, Key Questions (KQs), and inclusion/exclusion criteria in the form of PICOTS (populations, interventions, comparators, outcomes, timing, settings). The processes were guided by the information provided by the topic nominator, a scan of the literature, and discussions with methods and contents experts, and Key Informants (KIs); we worked with CDC and nine KIs during topic refinement. Subsequently, the analytic frameworks, KQs and PICOTs were posted for public comment on AHRQ's Effective Health Care Web site from January 8 through January 27, 2014. After consultation with AHRQ and responding to the public comments, we engaged representatives from CDC and a Technical Expert Panel (TEP)—including two of the KIs—to develop the systematic review protocol. Conference calls and discussions through email were undertaken to review the analytic framework, KQs, PICOTS, and operational definition of a behavioral program (Appendix A), and to gain input on categorizing the interventions based on the various program components and delivery methods. The final protocol was posted on AHRQ's Effective Healthcare Web site on June 12, 2014.[60] The protocol was registered with the PROSPERO database (No. CRD42014010515) on July 11, 2014.

Literature Search Strategy

We used the same approach and search strategies for type one diabetes mellitus (T1DM) and type two diabetes mellitus (T2DM). Our research librarian searched the following databases from 1993 to May 2014: Ovid MEDLINE and Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Cochrane Central Register of Controlled Trials via Cochrane Library, EMBASE® via Ovid, CINAHL Plus with Full Text via EBSCOhost, PsycINFO® via Ovid, and PubMed® (2014 only) via the National Center for Biotechnology Information Databases. On January 15, 2015, we performed a search update in all databases except EMBASE, from which none of the previously included studies was exclusively obtained.

We limited the search to prospective controlled studies published in English. Search strategies included a combination of subject headings and keywords for diabetes, behavioral interventions, and diabetes education. We applied a validated search filter for randomized controlled trials (RCTs) and a search filter to identify prospective comparative studies.[61] The search strategy was developed in MEDLINE, peer reviewed by a second librarian, and adapted to accommodate the controlled vocabularies and search languages of the other databases. Appendix B presents the full search strategy for each database.

We reviewed the reference lists of relevant systematic reviews and of all included studies. We searched for trials in ClinicialTrials.gov and the World Health Organization International Clinical Trials Registry Platform. We hand searched the conference proceedings from the

American Diabetes Association, American Association of Diabetes Educators, National Institute of Diabetes and Digestive and Kidney Diseases, Canadian Diabetes Association, European Association for the Study of Diabetes, International Diabetes Federation, Society of Behavioral Medicine, and International Society for Behavioral Nutrition and Physical Activity from 2011 to 2014 (when available). When a trial protocol or abstract met our screening criteria, we searched online for associated publications and contacted the authors to enquire whether a report was available to undergo full-text screening.

We used EndNote® database (Thomson Reuters, New York, NY) to manage the results of our literature searches.

Inclusion and Exclusion Criteria

The eligibility criteria are outlined in the PICOTS for T1DM and T2DM for the KQs (Tables 1 and 2). For both T1DM and T2DM, we included studies conducted in the United States or other high-income countries (Appendix C) and published in the English language.[62] We included studies conducted in high-income countries because we believed that the results would be more relevant to community health settings in the United States. We included English-language publications because we believed it was unlikely that we would miss important data reported in non-English articles. The earliest publication date for studies was 1993. This date was chosen because of changes to usual care/medical management (the comparator in most cases in this review) resulting from the findings of landmark trials published from this date onwards.[20,29,63]

For T1DM, we included prospective comparative studies (i.e., RCTs, nonrandomized controlled trials [non-RCTs], prospective cohort studies, controlled before-after studies).[64] For T2DM we included RCTs. RCTs are the gold standard for determining the effectiveness of interventions particularly when there are multiple potential confounding patient and intervention factors that may bias the results.[65] Our preliminary searches during topic refinement identified over 400 potentially relevant RCTs involving patients with T2DM and we believed that there would be sufficient trials and variability with respect to program factors to address the relevant KQs. We did not have a minimum sample size for inclusion, or a threshold for extent of incomplete followup or participant attrition.

We included a broad range of comparators to behavioral programs and categorized them as follows. Usual (standard) care control arms consisted of usual medical management (often multidisciplinary and including some form of education) provided to all study participants regardless of study participation; this could be provided by the study investigators or other health care professionals. Because medical care is so diverse between settings, some study arms (i.e., receiving educational pamphlets or an individual session with a dietitian) were classified as usual care even when described by the authors as active control. Interventions that were offered for the purposes of the study and provided content addressing behavior changes, but did not meet our operational definition of a behavioral program, were considered active controls. Examples of active controls include a dietary intervention or a basic education program of short duration or not including behavioral approaches. We categorized some control arms as attention control, when the group received similar contact time as the intervention arm but no intervention hypothesized to promote behavioral change. These arms were grouped with usual care arms for analysis and sensitivity analysis was conducted (i.e., removal of these arms) when the heterogeneity in the meta-analysis was substantial (see Data Synthesis). All trial arms that met our definition of a behavioral program were considered "interventions"; when two intervention

arms were compared "head-to-head" we considered this to evaluate their comparative effectiveness.

To help distinguish between the effects of behavioral programs (targeting patient behaviors) and other interventions, we excluded studies where the intervention was a disease/care management program (e.g., consisting of one or more interventions actively adjusting diabetes-related medications, monitoring patient medical data, or coordinating care provision)[66] or other quality improvement programs that incorporate strategies targeting health systems or providers.[67] This criterion was further refined after the protocol was published. Specifically, usual medical management (usual care) of all study participants needed to be stated by the authors or judged by the reviewers to be similar; for example, studies were excluded if the intervention arm(s) received stricter targets for glycemic control or more intensive medication regimes than the control arm. Additionally, studies investigating behavioral programs as one component of innovative medical care models (e.g. group appointments, pharmaceutical care) were only included if the effect of the behavioral program could be isolated. Other exclusion criteria included: (1) studies focusing exclusively on newly diagnosed patients, who do not represent our target population; (2) reports of studies where the outcomes were not of interest to this review (e.g., short-term effects on glucose sensitivity, C-reactive protein), or when the only difference between the study groups was a factor outside of the review's scope (e.g., two intervention arms differing only by diet composition rather than delivery method, personnel etc.); (3) studies evaluating behavioral programs targeted at hospital inpatients; (4) studies evaluating community-based programs that were not implemented in affiliation with a community health setting (e.g., school-based programs); (5) studies published exclusively in abstract form (e.g., conference abstracts). Where relevant abstracts were identified we searched for a complete report including contacting authors, as needed.

Table 1. Inclusion criteria for type 1 diabetes (Key Questions 1–4)

Parameter	Criteria
Population	• Patients with T1DM (any age) who have undergone basic diabetes education
Interventions	• Multicomponent behavioral program that includes at least one of: - Diabetes self-management education; OR - Structured dietary intervention (related to any of weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; OR - Structured exercise/physical activity intervention together with one or more additional components. - Additional components may include interventions related to: diet or physical activity, behavioral change (including but not limited to: goal setting, problem solving, motivational interviewing, coping skills training, cognitive behavioral therapy strategies), relaxation or stress reduction, blood glucose awareness, medication adherence, or self-monitoring for diabetic complications (foot, eye, and renal tests). • Repeated provision by one or more trained individuals • Duration of intervention: minimum 4 weeks
Comparators	• Usual or standard care (i.e., medical management provided to all study participants), an active control (i.e., intervention in addition to usual care but not meeting our operational definition of behavioral program), or another behavioral program • Delivery methods (personnel, intensity, communication methods etc.) as reported for studies
Outcomes	• Behavioral outcomes - Self-regulation of insulin based on diet, physical activity, and glucose monitoring results - Change in physical activity (e.g., volume of activity per week) or fitness (e.g. cardiorespiratory fitness, strength) - Change in dietary or nutrient intake (i.e., energy intake, saturated fat consumption) - Adherence to treatment, including self-monitoring and medication • Clinical outcomes - Glycemic control (HbA_{1c}) - Change in body composition (i.e., weight, BMI, waist circumference, % body fat) - Episodes of severe hypoglycemia[68] - Treatment for hyperglycemia (ketoacidosis) - Control of blood pressure and lipids - Development or control of depression or anxiety • Health outcomes - Quality of life (e.g., validated tools for health-related quality of life, life satisfaction, psychosocial adaptation to illness, patient satisfaction) - Development of micro- and macrovascular complications (i.e., retinopathy, nephropathy, neuropathy, cardiovascular outcomes) - Mortality (all-cause) • Diabetes-related health care utilization - Hospital admissions - Length of stay in hospital - Emergency department admissions - Visits to specialist clinics • Program acceptability as measured by participant attrition rates • Harms from program as reported for studies - Activity-related injury
Timing	• Any length of postintervention followup
Study design	• Prospective comparative studies using a best evidence approach based on hierarchy of evidence: randomized controlled trials, nonrandomized controlled trials, prospective cohort studies, controlled before-after studies
Settings	• Community health setting (i.e. ambulatory care clinics, outpatient clinics, primary care clinics, family physician clinics, Community Health Centers, Rural Health Centers) • United States or other high-income countries with a very high Human Development Index[62]
Language	• English

BMI = body mass index; HbA_{1c} = hemoglobin A_{1c}; T1DM = type 1 diabetes

Table 2. Inclusion criteria for type 2 diabetes (Key Questions 5 and 6)

Parameter	Criteria
Population	• Adults (≥18 years) with T2DM who have undergone primary diabetes education
Interventions	• Multicomponent behavioral programs that include at least one of: - Diabetes self-management education; OR - Structured dietary intervention (related to any of weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; OR - Structured exercise/physical activity intervention together with one or more additional components. - Additional components may include interventions related to: diet or physical activity, behavioral change (including but not limited to: goal setting, problem solving, motivational interviewing, coping skills training, cognitive behavioral therapy strategies), relaxation or stress reduction, blood glucose awareness, medication adherence, or self-monitoring for diabetic complications (foot, eye, and renal tests). • Repeated provision by one or more trained individuals • Duration of intervention: minimum 4 weeks
Comparators	• Usual or standard care (i.e., medical management provided to all study participants), an active control (i.e. intervention in addition to usual care but not meeting our operational definition of behavioral program), or another behavioral program • Delivery methods (personnel, intensity, communication methods etc.) as reported for studies
Outcomes	• Behavioral outcomes - Change in physical activity (e.g., volume of activity per week) or fitness (e.g., cardiorespiratory fitness, strength) - Change in dietary or nutrient intake (i.e., energy intake, saturated fat consumption) - Adherence to medication • Clinical outcomes - Glycemic control (HbA_{1c}) - Change in body composition (i.e., weight, BMI, waist circumference, % body fat) - Control of blood pressure and lipids - Sleep apnea or sleep quality - Development or control of depression or anxiety • Health outcomes - Quality of life (e.g., validated tools for health-related quality of life, life satisfaction, psychosocial adaptation to illness, patient satisfaction) - Development of micro- and macrovascular complications (i.e., retinopathy, nephropathy, neuropathy, cardiovascular outcomes) - Mortality (all-cause) • Diabetes-related health care utilization - Hospital admissions - Length of stay in hospital - Emergency department admissions - Visits to specialist clinics • Program acceptability as measured by participant attrition rates
Timing	• Any length of postintervention followup
Study design	• Randomized controlled trials
Settings	• Community health setting (i.e., ambulatory care clinics, outpatient clinics, primary care clinics, family physician clinics, Community Health Centers, Rural Health Centers) • United States or other high-income country with a very high Human Development Index[62]
Language	• English

BMI = body mass index; HbA_{1c} = hemoglobin A_{1c}; T2DM = type 2 diabetes

Study Selection

Two members of the research team independently screened all titles and abstracts (when available) using broad inclusion/exclusion criteria (Tables 1 and 2). We retrieved the full text of any publications marked for inclusion by either reviewer. Two reviewers independently assessed the full texts using a standard form that outlined the inclusion and exclusion criteria (see Figure

S1 in the Supplementary File). The reviewers resolved any disagreements through consensus or by consulting a third member of the review team.

We used an internally developed online tool to manage the title and abstract screening and full text review. The results from the full text review were then exported to an EndNote® database. We recorded the principal reason for excluding full text publications that did not satisfy the eligibility criteria.

Data Extraction

We extracted data directly into the Systematic Review Data Repository (SRDR™). One reviewer extracted data, and a second reviewer checked the data for accuracy and completeness. We resolved disagreements through consensus or by consulting a third member of the review team. We extracted the following data: author identification, year of publication, source of funding, study design, population (i.e., inclusion and exclusion criteria, number of participants enrolled, study withdrawals, duration of followup), baseline characteristics (e.g., age, duration of diabetes, HbA_{1c}, race/ethnicity, weight, body mass index), details of the interventions and comparators, and outcomes. When more than one publication reported the results of a single study, we considered the earliest published report of the main outcome data to be the primary publication. We extracted data from the primary publication first and then any additional data reported in the associated publications; this report cites all study results to the primary publication. We only extracted outcome data at or after the end-of-intervention timepoint; interim results prior to the end of any intervention contact were not included. We recorded intention-to-treat results, if possible. Other decision rules were developed for extraction of outcome data: 1) when both subjective and objective assessment was performed for change in dietary or nutrient intake, or physical activity (e.g., exercise duration/intensity via self-report and accelerometer) we only extracted the objective data; and 2) for clinical or health outcomes relying on questionnaires (e.g., depression, anxiety, quality of life) we only extracted data when composite or component scores were provided.

For studies where it was unclear whether patients had T1DM or T2DM, we developed decision rules based on mean age of study population, duration of diabetes, and the description of medical management. In studies where both types of patients were included and results were not reported separately, if more that 75 percent were one type of diabetes we included the study with that disease group.

Risk of Bias Assessment of Individual Studies

Two reviewers independently assessed the risk of bias (ROB) of the included studies. Discrepancies were resolved through discussion and consensus.

We assessed the internal validity of RCTs and non-RCTs using the Cochrane Risk of Bias tool.[69] The tool examines seven domains of potential bias (sequence generation, concealment of allocation, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and "other" sources of data), and a categorization of the overall ROB.

Each domain was rated as having "low," "unclear (medium)," or "high" ROB. We assessed blinding and incomplete outcome data separately for subjective outcomes (e.g., quality of life) and objective outcomes (e.g., HbA_{1c}); we only rated the ROB for those outcomes of interest to this review and on which we report. We reported additional sources of bias, including baseline imbalances and design-specific ROB, in the "other" sources of bias domain.

We created decision rules for consideration of blinding of participants, personnel, and outcome assessors (see Figure S2 in the Supplementary File). Examples which met the criteria for low ROB for these domains include: 1) for participants, when the comparator was an attention control, active control, or another behavioral program, and the authors reported some mechanism for blinding the participants from the study hypothesis; 2) for personnel, if they followed a standard protocol and received structured training in program delivery; and 3) for outcome assessment, double blinding of participant and outcome assessor was deemed not necessary for subjective outcomes if the participants were blinded (as above) and independently completed questionnaires.

The overall ROB assessment was based on the responses to individual domains. If one or more individual domains had a high ROB, we rated the overall score as high ROB. We rated the overall ROB as low only if all components were assessed as having a low risk. In all other situations, the overall ROB was rated as medium.

We assessed the ROB for prospective cohort studies and controlled before-after studies using the Newcastle-Ottawa Scale (Figure S3 in Supplementary File).[70] This tool uses a star system to assess methodological quality across three categories: selection of participants, comparability of study groups, and ascertainment of the outcome of interest. The star rating indicates the quality of a study with a maximum assessment of nine. If a study scored eight or nine, we rated the overall ROB as low. We rated the overall risk as medium if the score was between five and seven. For scores below five, the overall ROB was rated as high.

Data Synthesis

We analyzed data separately for T1DM and T2DM with different approaches for each KQ as outlined below. For each condition we summarized the characteristics of included studies qualitatively and presented important features of the study populations, interventions, and comparators in summary tables. Outcome data are reported in figures of meta-analyses (if pooled) and/or outcomes tables. We calculated mean differences (MD) or standardized mean differences (SMD) for continuous variables, and risk ratios (RR) for dichotomous data. The findings represent differences between the intervention and comparator arm. When possible we used (or computed) change from baseline data; otherwise final values were used. If standard deviations were not given, they were computed from p-values, 95% confidence intervals (95% CIs), z-stats, or t-stats. If computation was not possible they were estimated from upper bound p-values, ranges, inter-quartile ranges, or (as a last resort) by imputation using the largest reported SD from the other studies in the same meta-analysis. When computing standard deviations for change from baseline values, we assumed a correlation of 0.5, unless other information was present in the study that allowed us to compute it more precisely. Results are reported with accompanying 95% CIs.

The focus of our analysis (and for determining which outcomes to grade for strength for evidence for KQs 1 and 2 [see relevant section in this chapter]) rested on outcomes we considered most clinically relevant or important to patients; we refer to these as “key outcomes”. Included in this category were all health outcomes (i.e., quality of life, development of micro- and macrovascular complications, all-cause mortality) and selected behavioral and clinical outcomes (i.e., glycemic control, adherence to diabetes self-management behaviors, change in body composition, change in physical activity or fitness, and change in dietary or nutrient intake). Where guidance from the literature was available, we defined a minimum clinically significant difference (i.e., the smallest difference between groups that can be considered

clinically significant); we refer to this in the results and discussion chapters by commenting on whether results were clinically important. For HbA_{1c}, we used a difference of 0.4 units in percent HbA_{1c} (e.g., 7.6% vs. 8.0% HbA_{1c}), which is based on the value used by the U.S. Food and Drug Administration.[68] For quality of life measures and other patient-reported outcomes represented by continuous data, we used a difference of one-half standard deviation (i.e., 0.50 SMD) based on the mean SD from the pooled studies, which has been shown to represent a universal, conservative estimate of a meaningful difference.[71,72] For adherence to self-management behaviors, we did not apply a threshold for clinical importance because of poor reporting of the scoring and unknown meaning of a threshold for an optimal number of self-monitoring tests (the most common reporting for this outcome).

With input from the TEP, we categorized various components and delivery mechanisms (e.g., program intensity, method of communication, presence of community engagement) as outlined in Table 3. We separated DSME and DSME plus support into two categories to recognize that the support phase was often (1) of a lower intensity (i.e., less frequent contacts), and (2) focused on different content such as psychosocial support, as compared with the DSME phase. The cut-points used for creating the intensity categories were based on practical considerations. The 10-hour "minimal intensity" limit was based on the current number of hours billable for patients eligible for public healthcare administered by the Centers for Medicare and Medicaid Services in the United States; this was described by our TEP as an important practical limitation on implementing programs having higher intensity. The value of 27 hours was based on what would be considered the lower range of highly intense (e.g., at least weekly 1-hour sessions for 6 months). The categories were used in the summary tables to describe the behavioral program(s) for each study, and for coding the variables used for the regression and network meta-analyses for KQs 3, 5, and 6 (described later in this section). For the network meta-analyses performed for KQs 5 and 6, the categories were used to define groups (nodes) of interventions that were "sufficiently similar" in terms of the factors of interest. Table 3 also indicates that actual values were used for program duration, intensity, and frequency of contacts where suitable (i.e., regression analyses for KQs 3 and 6). When calculating contact hours, we assumed telephone calls (when described in number and serving as more than a reminder/basic followup) would be 10 minutes each if their duration was not reported; this was based on reviewing studies from our preliminary searches that indicated most followup calls were reported as approximately 15 minutes (variable compliance) and that the duration of calls used for providing more substantial content were often not reported. Care was taken to avoid counting time/contacts required solely for research purposes (e.g., outcome assessment). Initially, the program components category included more items (i.e., diet plus additional component, physical activity plus additional component; see Appendix A for operational definitions) but because of very few studies evaluating these categories we collapsed all programs that were not DSME, or DSME plus support, into a "lifestyle" category largely containing programs focusing on diet and physical activity.

Table 3. Categorization of program components and delivery factors

Program Factors	Categories and Description Variables
Program Components[a]	1. DSME 2. DSME + Support: DSME plus a phase to extend program duration and provide support (often clinically focused but may be psychosocial, educational or behavioral) 3. Lifestyle programs: Behavioral programs focused on diet and/or physical activity rather than on diabetes-specific self-management behaviors; may also include other components as long as does not meet the criteria for DSME with emphasis on education/training
Duration of program	No categories; duration (m) was used as a continuous variable for the regression analyses for KQs 3 and 6
Intensity of program-continuous	No categories; intensity (h) was used as a continuous variable for the regression analyses for KQs 3 and 6
Intensity-categorical[a] (contact hours; where contact hours could not be calculated, we used number of contacts as a proxy)	1. ≤10h 2. 11 to 26h (e.g., weekly for up to 6m) 3. ≥27h (allowing for monthly followup for 1yr)
Frequency of contacts	No categories; this was a composite variable combining duration and intensity (h/m); the continuous variable was used for the regression analyses
Method of communication[b]	1. In person only 2. Mixture of in person and technology 3. All technology with minimal interaction with providers
Method of delivery[c]	1. Individual 2. Mixed individual and group 3. Group
Delivery personnel[d]	1. Delivered entirely by non-health professional (e.g., lay/community health worker, undergraduate students) after training and under some supervision 2. One health professional for large majority (>75%) of delivery 3. Provision by multidisciplinary team of health professionals
Degree of tailoring[e]	1. None/Minimal – none or only small portion is tailored (e.g., personalized diet prescription in otherwise highly structured lifestyle program or delivery based on flexible hours but same content for all) 2. Moderate/maximum – most of program has content and/or delivery tailoring (e.g., topics are based on needs assessment and delivery timing/duration/location is based participant's schedule/needs/location preferences)
Level and nature of community engagement	1. Present, e.g., peer delivering program or peer support groups for support stage, use of community resources (infrastructure) for delivery or maintenance stages 2. Absent, e.g., unreported or provision of information about community resources
Presence of support person[f]	1. Family or parent involved in >1 session 2. No family or parent involvement in sessions

DSME = diabetes self-management education; h = hour; m = month; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus; yr = year

[a]For network meta-analysis only.

[b]2 and 3 were combined for analysis.

[c]1 and 2 were combined for analysis.

[d]2 and 3 were combined for analysis for KQ 5 and 6.

[e]Used in summary tables only.

[f]For studies of youth/adolescents only.

Synthesis for T1DM (KQs 1–4)

KQ 1: Behavioral Programs for T1DM and Behavioral, Clinical, and Health Outcomes; Diabetes-Related Health Care Utilization; and Program Acceptability

For each comparison of interest, we conducted a pairwise meta-analysis when two or more eligible trials were sufficiently similar on the basis of study design, clinical homogeneity of patient populations, interventions, comparators, outcomes, and timepoints. Because we assumed that behavioral programs for T1DM would be sufficiently different when developed for and studied in children and adolescents ("youth") compared with adults, we present both pooled and subgroup analysis based on age when there was more than one trial in each age category at the relevant timepoint. We used the Hartung-Knapp-Sidik-Jonkman random effects model for all meta-analyses using Stata 11.2 and Excel 2010 software.[73-75] We calculated pooled MD, SMD, or RR with corresponding 95% CIs, as appropriate and each weighted by sample size and variance. We analyzed outcomes at different postintervention timepoints using strata: end of active intervention-≤1month, 1-≤6 months, >6-12 months, >12-24 months, and >24 months. If a study included more than one followup timepoint in each strata, we used data from the longer followup. We did not include the results of observational studies in any of the pooled analyses.

Sensitivity analyses (including leave-one-out analyses, assuming a fixed effects model, re-analyses after excluding a group of studies) were undertaken where appropriate (e.g., in the presence of studies with outlying effect sizes, for studies rated as high risk of bias in some domains such as incomplete [<70 percent] outcome data, to examine the effects from combining usual care and attention control groups). Heterogeneity was considered substantial when the I^2 statistic (the proportion of variation in study estimates attributable to heterogeneity) was greater than 50 percent.[76] We explored between-study heterogeneity using subgroup and meta-regression analyses where there were at least 10 studies.[77] Planned subgroups are listed in KQs 2 and 6. Publication bias was assessed both visually and quantitatively using Egger's test for the outcome with the greatest amount of data.[78]

KQ 2: Subgroups for Effectiveness in T1DM

For this KQ, we assessed the effects on subgroups for HbA_{1c}, which was the outcome reported by the most studies. We searched for subgroup analyses reported by individual trials (i.e., within-study subgroups) that focused on whether a particular behavioral program was more or less effective based on age (children and adolescents [≤18 years], young adults [19-30 years], adults [31-64 years], older adults ≥65 years]), race or ethnicity, socioeconomic status, time since diagnosis (≤1 year vs. >1 year), and baseline level of glycemic control (HbA_{1c} <7 vs. ≥7 percent). We also considered the studies themselves as units for possible subgroup analysis—that is we performed between-study comparisons—for example when the mean age of participants fell within one of the age categories, or the majority (≥75 percent) of the participants were stated as racial/ethnic minorities (i.e., nonwhite but including Hispanic groups).

KQ 3: Potential Moderation of Effectiveness for T1DM—Components, Intensity, Delivery Personnel, Method of Communication, Degree of Tailoring, and Level of Community Engagement

To assess whether the effectiveness of behavioral programs differed based on various potential moderating factors, we performed univariate meta-regressions for comparisons between behavioral programs and usual care. We performed the analyses for HbA_{1c}, which was the only outcome reported by at least 10 studies, and used data from each study's longest followup timepoint. There were insufficient studies to perform multivariable analysis. The following covariates were considered: program duration, program intensity (contact time), frequency of contacts (contacts per month), delivery mode, delivery personnel, presence of supports (e.g., family members), and community engagement. Each behavioral program was coded using the categorization scheme in Table 3.

KQ 4: Harms for T1DM

For harms (i.e., activity-related injury) we planned to descriptively summarize all outcomes presented in studies. We did not plan to conduct any quantitative analysis for this outcome.

Synthesis for T2DM (KQs 5 and 6)

Before synthesizing findings to answer KQs 5 and 6, we performed pairwise meta-analyses for all outcomes identified in the PICOTS. This served to summarize the findings on outcomes not reported by enough studies to contribute to the analyses for KQ 5 or 6, and to provide information when interpreting the results of the subsequent analyses. We used the same analytical approach described for KQ 1.

KQ 5: Potential Moderation of Effectiveness for T2DM—Components, Intensity, Delivery Personnel, Method of Communication, and Level of Community Engagement

Rather than providing a simple pairwise comparison of similar comparisons (e.g., a group of interventions versus usual care) through standard meta-analysis, a network meta-analysis allows for simultaneous evaluation of a suite of comparisons while still preserving the within-study randomization. A network of different comparisons is constructed (with "nodes" representing groupings of sufficiently similar interventions and comparators) to consider both direct evidence from comparisons of similar interventions/nodes and indirect evidence from comparisons where one intervention is in common, but not all (e.g., intervention A vs. usual care, and intervention A vs. intervention B infer knowledge about intervention B vs. usual care). Because numerous nodes can be created, this approach can be useful when a diverse range of interventions and comparators are being considered—the nuances of the various interventions can be captured.

The grouping of behavioral programs into nodes was based on the categories in Table 3. We also formed three categories for the comparator groups: usual care, active "non-DSME" control (i.e., basic education not meeting our criteria for DSME; see Appendix A), and active "other" control (e.g., stand-alone dietary or physical activity intervention). For the intervention arms (behavioral programs), we identified all plausible nodes differing by only one variable (e.g., a level within the intensity category) to assess the variation in effectiveness based on the potential moderating factors of interest for this review. We then coded all interventions and comparators into the various nodes; not all plausible nodes ended up containing data. The analysis was

conducted for HbA_{1c} and body mass index; because of the relatively low amount of outcome data for other key outcomes, only one or two variables could be considered and this was deemed to offer insufficient meaning.

The analysis was conducted using a Bayesian network model to compare all interventions simultaneously and to use all available information on treatment effects in a single analysis.[79,80] These methods ensure that correlation in multi-armed trials is preserved. Mean differences were modeled using noninformative prior distributions. A normal prior distribution with mean 0 and large variance (10,000) was used for each of the trial means, whereas their between study variance had a uniform prior with range 0 to 2. These priors were checked for influence with sensitivity analyses. Markov Chain Monte Carlo simulations using WinBugs software were carried out to obtain simultaneous estimates of all interventions compared with placebo, as well as estimates of which interventions were the best. A burn-in sample of 20,000 iterations was followed by 300,000 iterations used to compute estimates. A sensitivity analysis that thinned the amount of used data to every tenth iteration was also conducted to check for proper chain convergence. The model formulation and WinBugs codes can be obtained at request of the authors. Analysis was checked for consistency by contrasting direct and indirect estimates in each triangular and quadratic loop using the methods described by Vernoiki.[81] Results are presented as estimates of the treatment effects (MD) relative to usual care, 95 percent credibility intervals, as well as the rank probabilities for each behavioral program strategy (i.e., probability that a particular combination of components and delivery methods for a behavioral program is the "best program").

KQ 6: Subgroups for Factors Moderating Effectiveness in T2DM

This KQ focused on whether variability between population groups affected the role of potential factors contributing to effectiveness of behavioral programs for the key outcome reported by the most studies (i.e., HbA_{1c}). Similar to KQ 2, we searched for subgroup analyses reported by individual trials that focused on whether a particular behavioral program was more or less effective in reducing HbA_{1c} based on age (young adults [19-30 years], adults [31-64 years], older adults ≥65 years]), race or ethnicity, socioeconomic status, time since diagnosis (≤1 year vs. >1 year), and baseline level of glycemic control (HbA_{1c} <7 vs. ≥7 percent). This approach did not yield any appropriate data. We then considered the studies themselves as units for possible subgroup analysis.

As a starting point, we conducted subgroup analyses of the pairwise meta-analysis results for HbA_{1c} for behavioral programs compared with usual care and active controls at longest followup. When enough comparisons existed within an identified subgroup to maintain the structure of the network used for analysis of HbA_{1c} for KQ 5, we then performed subgroup analysis of this network. This was possible for studies with baseline HbA_{1c} ≥7 percent and with a mean participant age <65 years; the subgroups with baseline HbA_{1c} <7 percent and age ≥65 years were too small for their own network analysis. For subgroups based on race/ethnicity (≥75 vs. <75 percent minorities), the number of trials in either subgroup was insufficient, so we conducted a set of univariate meta-regressions within each subgroup using the variables in Table 3 and methods outlined for KQ 2. The number of studies did not allow for multivariable meta-regressions using the number of variables of interest.

Strength of the Body of Evidence

We followed the Methods Guide[59] to evaluate the strength of evidence (SOE) for KQ 1 for all health outcomes (i.e., quality of life, development of micro- and macrovascular complications, all-cause mortality) and selected behavioral and clinical outcomes (i.e., glycemic control, adherence to diabetes self-management behaviors, change in body composition, change in physical activity or fitness, and change in dietary or nutrient intake). For KQ 2, we assessed SOE for HbA_{1c} which was the outcome reported by the most studies and thus the focus of this KQ. SOE assessments were based on evidence from trials. The body of evidence was graded by one reviewer, and reviewed by a second reviewer. Disagreements were resolved through discussion or by consulting with a third reviewer, as needed.

We examined the five core domains most relevant to reviews of RCTs (anticipated to be the large majority of included studies): risk of bias, consistency, directness, precision, and reporting bias. We defined the risk of bias (low, medium, or high) on the basis of study design and methodological quality. We rated consistency (consistent, inconsistent, unknown [if there is only one study]) by assessing the direction and magnitude of the effects of the included studies. We assessed directness of the evidence (direct or indirect) on the basis of the use of surrogate outcomes or the need for indirect comparisons. We assessed precision (precise or imprecise) on the basis of the degree of certainty surrounding the effect estimate and based on sample size; for outcomes where clinically important thresholds were prespecified (i.e., HbA_{1c}, HRQL, behavioral outcomes with continuous data), we downgraded the SOE twice for imprecision when the 95% CI crossed thresholds both for and against behavioral programs. A precise estimate is one that allows for a clinically useful conclusion. Reporting bias (suspected or unsuspected) was evaluated with respect to publication bias, selective outcome reporting bias, and selective analysis reporting bias. For selective reporting and analysis biases, we evaluated the results across studies qualitatively on the basis of completeness of reporting for individual studies and reporting patterns across studies. We rated the body of evidence using four SOE grades which indicate our level of confidence that the evidence reflects the true effect for the major comparisons of interest:

- **High**. Very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies; the findings are stable, i.e., another study would not change the conclusions.
- **Moderate.** We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies; the findings are likely to be stable, but some doubt remains.
- **Low.** We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both); additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
- **Insufficient.** We have no (or very little) evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome (i.e., the 95% CI of the effect estimate includes values representing clinically important magnitudes favoring both behavioral programs and the comparator).

We did not assess SOE for the KQs 3-6. KQ 4 assesses harms, which was a minor focus of this review. KQs 5 and 6 explore factors that may be associated with the effectiveness of behavioral programs; there is no precedent for SOE assessments for these types of questions.

Applicability

We followed the Methods Guide to evaluate the applicability of the evidence to the delivery setting of interest (i.e., community health settings).[59] We considered important population characteristics, behavioral program characteristics, and delivery settings that may limit applicability of the findings. Factors that may limit the applicability include narrow eligibility criteria, components or delivery elements of behavioral programs that may not be feasible in some settings, and health system differences.

Peer Review and Public Commentary

Experts in behavioral medicine, diabetes education, clinical epidemiology, nutrition, physical education, psychology, and statistics fields, and individuals representing stakeholder and user communities were invited to provide external peer review of this report; AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ website for 4 weeks to elicit public comment. We addressed all reviewer comments, revising the text as appropriate, and documented everything in a disposition of comments report that will be made available 3 months after the Agency posts the final report on the AHRQ Effective Healthcare website.

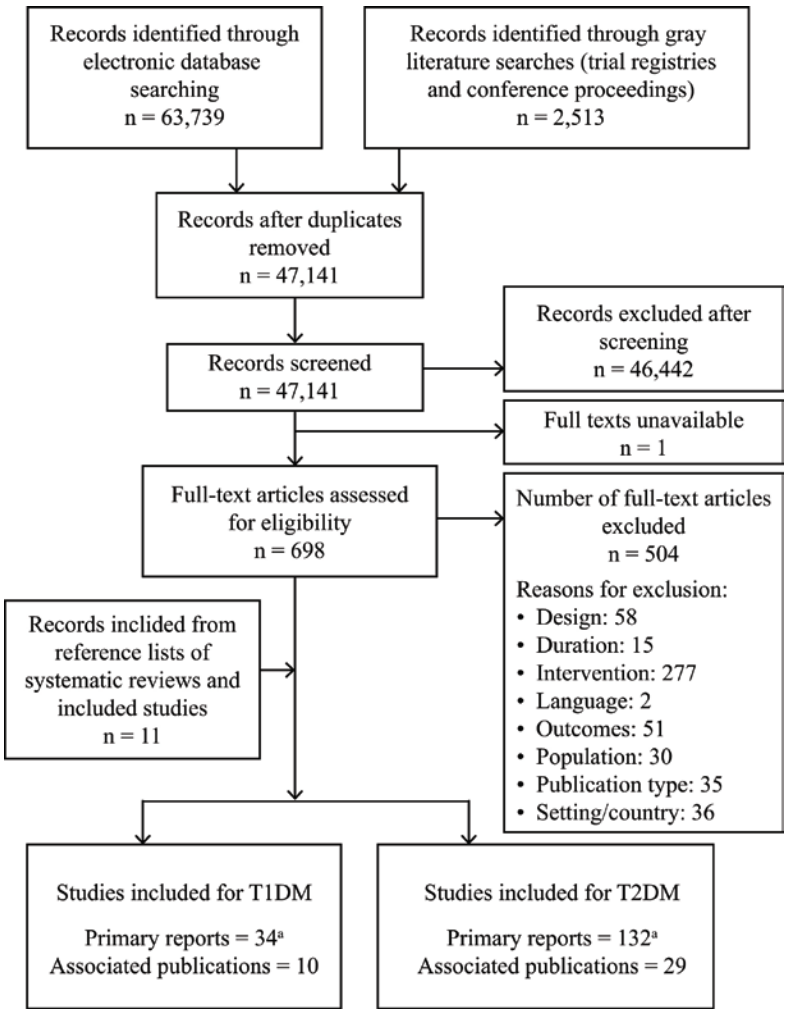
Results

This chapter begins with a summary of our literature search. We then present the findings separately for type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM). Within each section we present a general description of the included studies followed by our findings by Key Question (KQ). Specific details for the organization of the sections for T1DM and T2DM are included below.

Literature Search and Screening

Our database and gray literature searches identified 47,141 citations, and 11 additional records were identified from reference lists of systematic reviews and included studies. For T1DM, we included 34 studies described in 44 publications. For T2DM, we included 132 studies described in 161 publications. Figure 3 describes the flow of literature through the screening process. Appendix D provides a complete list of articles excluded at the full-text screening stage, with reasons for exclusion.

Figure 3. Flow diagram of study retrieval and selection



T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus
[a]One study was included for both T1DM and T2DM.

Type 1 Diabetes Mellitus

This section begins with the results of our literature search, a general description of all included studies, separate summaries of studies that focused on youth followed by those that focused on adults, and a summary of the risk of bias (ROB) assessment. We then present results by KQ. We begin with results of behavioral programs compared with usual care, followed by studies comparing behavioral programs with an active control, and then by those comparing two or more behavioral programs (i.e., comparative effectiveness). The results are grouped first by outcome (e.g., HbA_{1c}) and then by follow-up timepoint. For each outcome results are presented by age groups (youth and adults), where appropriate. We present results as mean differences (MD), standardized mean differences (SMD), or risk ratios (RR), with 95 percent confidence intervals (95% CI) in figures with meta-analyses or in summary tables. Where statistical heterogeneity was considered substantial (>50 percent) we report the I^2 Statistic (I^2%).

For each KQ, we give the key points and then present a detailed synthesis of the evidence. Appendix E (Table E2) includes the ROB assessments for each trial. Summary tables describing studies are found in Appendix F (Tables F1 and F2); they are organized alphabetically by author. For observational studies, we present a narrative summary of the results for HbA_{1c}. Other outcomes from the observational studies are documented in Appendix G. For KQs 1 and 2, we summarize the strength of evidence (SOE) assessments, which are provided in detail in Appendix H.

Literature Search and Screening

For T1DM, we included 34 studies described in 44 publications (Figure 3). Primary reports were identified for 30 randomized controlled trials (RCT),[82-111] 1 non-RCT,[112] and 3 controlled before-after studies.[113-115] Ten additional publications contributed information related to the study methodology, outcomes, or descriptions of the interventions.[116-125] One of the studies included both T1DM (49 percent) and T2DM (51 percent) patients; results were reported for each patient group and the study is included in both T1DM and T2DM of this review.[107]

Characteristics of Included Studies

The majority of studies (30 trials, 2 observational studies) examined diabetes self-management education (DSME); two studies (1 RCT,[105] 1 observational study[114]) focused on lifestyle programs (see Appendix A for operational definitions). For DSME, most trials (n=23) were two-arm trials comparing DSME to usual care. Three two-arm RCTs compared DSME to an active control.[87,91,92] The active controls included telephone support[87] and basic education.[91,92] Three RCTs were three-arm trials with one having two active control arms[107] and the other two each had a usual care and an active control arm.[83,108] For one, the authors combined the usual care and active control arms.[83] For the others, we analyzed the usual care and active control arms separately,[108] or combined the two active control arms.[107,108] One RCT evaluated the comparative effectiveness of the same DSME program delivered in person compared with delivery by internet-based videoconferencing (Skype™).[90] Two observational studies compared DSME with usual care.[113,115]

Both studies focusing on lifestyle programs compared them with usual care. One was a two-arm RCT[105] and the other was an observational study.[114]

Youth

Clinical Trials

Twenty-three RCTs[83-90,92,93,96-104,106,108,110,111] and six associated publications[117-119,121,122,125] examined the effectiveness of behavioral programs among youth; only one study examined children, hence our use of the term youth to categorize these studies. Most RCTs were two-arm trials and focused on DSME compared with usual care. One RCT compared a DSME program delivered in person compared with delivery using Skype[90] and another compared delivery of DSME in person compared with a telephone support active control.[87] Two three-arm trials compared a DSME program with usual care and an active control (basic education program),[83,108] although the authors of one combined the two control groups for their analyses.[83] Sixteen trials were conducted in the United States;[83,84,86-88,90,92,96-100,103,104,108,110] six were conducted in Europe,[85,89,93,101,102,106] and one was conducted in Australia.[111]

The mean age of the youth participants ranged from 9.7–15.4 years (median=13.4). One study did not report age.[97] The percentage of males ranged from 0–63 percent (median=47). The proportion of nonwhite participants was between 2–82 percent (median=23.5); nine trials did not present information on race or ethnicity.[90,93,98-101,106,110,111] For most trials, the mean HbA_{1c} was >7 percent and ranged from 7.4–15.7 percent (median=9.6 percent). One trial did not report absolute baseline HbA_{1c}.[103]

All trials in youth recruited patients/families from outpatient clinical settings providing usual care throughout the study period. Clinical settings mostly consisted of diabetes/endocrinology clinics located at university-affiliated hospitals, and care was commonly described to include quarterly clinic visits with a multidisciplinary team of providers offering education and additional consults as needed. One study's usual care included eight visits over a one-year period.[93] Some studies reported additional components including: regular adherence assessments,[83,98] in-clinic goal setting and a daily phone hour with education provided between visits,[87,88] access to an emergency hotline,[89] and basic care coordination with clinic reminders and assistance with scheduling appointments.[96,104] Three trials reported that usual care included more advanced education,[87,88,108] and one multicenter trial's exclusion criteria for study centers included the availability of a group education program.[85]

A basic description of the behavioral programs delivered to youth is provided in Appendix F (Table F1). Although all studies included in the review evaluated programs which, as reported, met our operational definition of a behavioral program, there was considerable diversity in terms of the program content and delivery. Some programs were designed to coincide with office/clinic visits; however, there was variability in the degree of integration with medical care and in program intensity. Some programs were fully integrated into the clinic visit and were delivered by the clinic's health care personnel.[93,101,102] Other programs were delivered by non-clinic staff (e.g., trained research assistant, internists) either prior to or after the patient was seen by the health care team.[83,92,96,98,104] One study combined in-clinic goal setting with automated weekly delivery of tailored education and support messages.[89] Two office-based programs had relatively high intensity with more than 10 contacts.[93,96] The majority of office-based programs were delivered to the family, with a focus on family teamwork, conflict, and coping.[83,92,96,98,101,102,104] Programs that did not coincide with clinic/office visits largely consisted of weekly or monthly sessions incorporating various behavioral approaches such as problem-solving, coping, and empowerment training.[84,86,97,99,100,103,106,110,111] Some also offered a more therapeutic approach together with some degree of self-management training (i.e., behavioral family systems

therapy,[90,99,108] motivational enhancement therapy combined with solution-focused therapy,[85] and multisystemic therapy[87,88]). Many programs were targeted at adolescents,[83,84,87-90,92,93,97,99,102,103,106,108,110,111] while others were tailored to children,[100] or offered to mixed age groups.[85,96,98,101,104] Below, we present a summary of the program delivery factors.

The total duration of the behavioral programs ranged from 1.2–25 months (median=5.6). The number of contact hours ranged from 1–48 hours (median=9.5). Four trials did not report enough information to calculate the number of contact hours.[84,89,98,103]

Five trials delivered the programs to youth only;[84,86,89,103,106] 16 delivered the programs to both youth and their parents or family members.[83,85,87,88,90,92,93,96-102,104,108] Four trials delivered the program in person to groups of youth only,[84,86,106,111] and two trials delivered the program to youth using a mix of in-person sessions supplemented by telephone calls[103] or text messaging.[89] Eight trials delivered the program in person to individual pairs of youth and family members.[83,87,88,90,93,98,108,110] Six trials delivered the program in person to groups of youth and family members.[85,97,100-102,106] Three trials delivered the program to individual pairs of youth and family members using a mix of in-person sessions supplemented by telephone calls.[92,96,104] Two trials delivered the program to individuals using telehealth[99] and Skype.[90]

For eight trials, the program was delivered by a single health care professional (e.g., nurse, psychologist, registered dietitian).[84,86-88,90,106,110,111] Six trials engaged two or more health professionals,[85,89,93,101,102,108] seven trials used non-health professionals (e.g., research assistants, health-related students or trainees),[83,92,96,98,99,103,104] and one trial used a combination of a health professional and a trainee.[97] One trial did not report this information.[100]

All of the behavioral programs had some degree of tailoring in terms of their content (e.g., individualized goal setting, topics based on age group) and/or delivery (e.g., coinciding with office visits, number of visits determined based on needs assessment). Several had a moderate–to–high level of tailoring in both content and delivery.[87,88,90,92,93,96,97,99,103,104,108,110] Four interventions included some degree of community engagement, including involvement of peers and/or school personnel.[85,87,88,90]

Observational Studies

Two controlled before-after studies explored the effectiveness of behavioral programs delivered to youth and their parents or families. One study compared a DSME intervention with usual care;[115] the other compared a lifestyle intervention with usual care.[114]

The study by Viner et al.[115] was conducted in the United Kingdom. The target population was youth with poor glycemic control (HbA_{1c} >8.5 percent). The mean ages were 13.0 and 13.1 years for the intervention and control groups, respectively; mean HbA_{1c} was 10.2 and 10.0 percent for the intervention and control groups. The 1.5-month program was delivered in person to groups of youth (6 meetings) and, separately, to groups of parents (1 meeting). The program was based on motivational and solution-focused techniques, with elements of cognitive behavioral therapy. The content of the program was tailored to youth with adherence issues and also targeted changes at self-identified behaviors. No information was reported for community engagement.

The study by Thomas-Dobersen et al.[114] examined a lifestyle program that targeted overweight adolescents; body mass index ranged from 22–36 kg/m^2. The study was conducted in the United States. The mean ages were 13.9 and 15.2 years and mean HbA_{1c} was 12.2 and 13.1 percent for the intervention and control groups, respectively. The 3-month program was delivered by a multidisciplinary team in person to groups of adolescents and, in separate group

sessions, to their parents. Program content was tailored to adolescents with diabetes although there was minimal tailoring in the delivery of the structured group sessions. No information was reported for community engagement.

Adults

Clinical Trials

Seven RCTs[82,91,94,95,105,107,109] with four associated publications,[116,120,123,124] and one non-RCT[112] examined the effectiveness of behavioral programs among adults. Two RCTs included participants with T2DM. One RCT presented results for HbA_{1c} separately for T1DM and T2DM and is included in both sections of this report.[107] The other study did not report results separately for T1DM or T2DM; however, the majority (>75 percent) of participants had T1DM so we have included it in this section of the report.[95] Six trials focused on DSME compared with usual care,[82,94,95,105,109,112] two examined DSME compared with one[91] or two[107] active controls, and one compared a lifestyle intervention with usual care.[105] Six of the trials were conducted in European countries,[82,91,94,95,109,112] one was conducted in the United States,[107] and one was conducted in New Zealand.[105]

The mean age of participants ranged from 30–49 years. The percentage of males ranged from 35–62 percent. The proportion of nonwhite participants was between 4.5–25 percent in two trials;[94,107] the other trials did not present information on race or ethnicity. For all trials, the mean HbA_{1c} was >7 percent and ranged from 7.7–9.6 percent. The mean BMI ranged from 24.8–27.6 kg/m^2; three trials did not report BMI.[95,109,112]

Similar to the trials in youth, usual care was usually provided by out-patient diabetes clinics/centers from which the participants were recruited. Usual care was not described by Karlsen et al.[95] who took a different approach by recruiting survey respondents, and may have been diverse in the trial of Perry et al.[105] which supplemented clinic recruitment with that from radio and newspaper advertisements. Visit frequency was described less often, but for half of the studies was biannually to quarterly.[94,105,107,112] The usual care in one trial included provision of and training in a continuous glucose monitoring system.[82]

A basic description of the behavioral programs delivered to adults is provided in Appendix F (Table F2). Several of the programs incorporated elements of cognitive behavioral therapy,[82,94,95,107] with one combining cognitive behavioral therapy with motivational enhancement therapy.[94] In one study authors described their program as taking an empowerment approach,[91] another incorporated guided self-determination group training,[109] and one offered self-management training using an ongoing self-help group style.[112] The program presented by Amsberg et al.[82] included a 9-month maintenance period during which telephone support calls were provided; this study also incorporated training using a continuous glucose monitoring system. Below, we present a summary of implementation factors.

The total duration of the behavioral programs ranged from 1.5–12 months (median=6 months). The number of contact hours ranged from 9–52 hours (median=16). One trial included an intense phase (2 months) followed by a 9-month support period.[82] Five trials delivered the program in person to groups of participants,[91,95,107,109,112] two delivered the program in person to individuals,[94,105] and one trial used a mix of individual and small group sessions that were delivered in person and by telephone.[82] For three of the trials, the program was delivered by a single health care professional (i.e., nurse, registered dietitian, physician).[91,94,112] Four trials engaged two or more health professionals,[82,105,107,109] and one trial used a health care professional

and a peer (with diabetes and trained in program delivery) who served as coleader. All reports described the programs to have a moderate-to-high degree of tailoring of content to the participants' individual needs; fewer had mechanisms (e.g., telephone followup, collaborative delivery by professional and participants) to tailor the delivery of the program.[82,95,109,112] One trial incorporated community engagement through the use of a peer coleader;[95] the remaining trials either involved no community engagement or did not report this information.

Observational Studies

One controlled before-after study explored the effectiveness of a DSME program among adults (≤65 years) who were receiving intensive insulin therapy.[113] The study was conducted in Italy. Baseline HbA_{1c} was ≥7.5 percent in 59 and 63 percent of the intervention and control groups, respectively. The 4-month intervention was an education program including empowerment group teaching and situation simulation, and comprised eight 2-hour group sessions led by a physician or dietitian. There was some tailoring of the content towards patients receiving intensive therapy; no information was reported for community engagement.

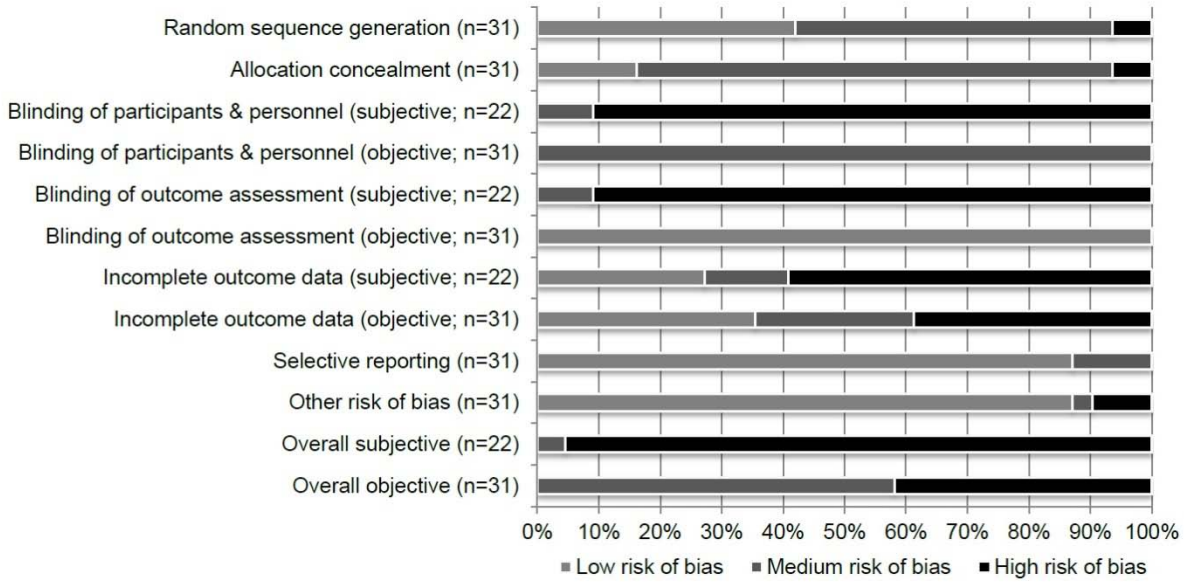
Risk of Bias of Individual Studies

A summary of the ROB assessments for the 31 trials is presented in Figure 4; the consensus assessments in all domains for each study are presented in Appendix E. All trials were assessed as having a medium (unclear) or high overall ROB. For objective outcomes (e.g., $HbA_{1c,}$ weight), 58 percent of trials had a medium ROB and 42 percent had a high risk. The assessment of high risk was largely driven by incomplete outcome data (i.e., loss to followup). For trials (n=22) reporting subjective outcomes of interest to this review (e.g., health-related quality of life [HRQL], patient-reported self-management behaviors), all but one trial had a high risk of bias (95 percent). This was primarily due to lack of blinding of participants, study personnel, and outcome assessors.

The risk of bias for the three observational studies was assessed using the Newcastle Ottawa Scale. The study by Viner et al.[115] was assessed as having medium ROB (seven stars out of a possible nine); the study by Forlani et al.[113] was assessed as medium ROB (five stars); and the study by Thomas-Dobersen et al.[114] was assessed as low ROB (eight stars). For all studies there was concern about the control of potential confounding variables including baseline HbA_{1c} and socioeconomic status. For Forlani et al. and Viner et al. there were concerns about the representativeness of the exposed cohort.

Five studies (15 percent) received funding from industry; 26 (76 percent) received funding from non-industry sources (e.g., government or foundations). Funding was not reported by three (9 percent) studies.

Figure 4. Risk of bias summary for trials of behavioral programs for type 1 diabetes



KQ 1. Behavioral Programs for T1DM and Behavioral, Clinical, and Health Outcomes; Diabetes-Related Health Care Utilization; and Program Acceptability

Key Points: HbA_{1c}

- There was no significant difference (low SOE) in changes in HbA_{1c} at the end of intervention between behavioral programs and usual care.
- Behavioral programs compared with usual care reduced HbA_{1c} (moderate SOE) at 6-month postintervention followup; the change was statistically significant but not clinically important.
- There was no significant difference in reduction of HbA_{1c} between behavioral programs and usual care at followup timepoints longer than 6 months. The SOE for these findings was low because of risk of bias and imprecise effect estimates; further, because the 95% CIs included our threshold for clinical importance (favoring behavioral programs) we cannot rule out benefit for behavioral programs.
- Behavioral programs compared with an active control reduced HbA_{1c} to a statistically significant and clinically important (moderate SOE) degree at 6-month followup.
- Compared with active controls, the estimates of effect for behavioral programs showed no significant difference in HbA_{1c} at end of intervention and at 12-month followup. The SOE was low for both; risk of bias as well as imprecise effect estimates and inclusion of a clinically important benefit reduces confidence in their accuracy.

Key Points: Other Clinical and Behavioral Outcomes

- Participants receiving behavioral programs compared with usual care did not differ in terms of adherence to diabetes self-management at the end of intervention or 6-month

followup (low SOE for both); there was insufficient SOE for longer followup and for all comparisons with active controls.
- Few trials reported on change in body composition, physical activity or fitness, or change in dietary or nutrient intake.
- Few trials reported on symptoms of depression, or on episodes of severe hypo- or hyperglycemia.
- The SOE was insufficient to determine whether behavioral programs increased or decreased changes in body composition, physical activity or fitness, or dietary or nutrient intake.

Key Points: Health Outcomes

- For participants receiving behavioral programs compared with usual care, there was no difference in generic HRQL at the end of intervention (moderate SOE). Few trials reported on generic HRQL at longer followup timepoints.
- In comparisons with usual care, there was insufficient SOE to assess whether there was any effect on diabetes-specific HRQL at any timepoint, and low SOE of no difference for diabetes distress at end of intervention and 6-month followup. The 95% CIs for diabetes distress included our threshold for clinical importance such that we cannot rule out a favorable effect for behavioral programs.
- There were no data on HRQL for comparisons of behavioral programs with active controls.
- No trials reported on micro- and macrovascular complications or on all-cause mortality.

Key Points: Diabetes-Related Health Care Utilization

- Few trials reported number of diabetes-related hospital admissions, emergency department admissions, or other measures of health care utilization.

Key Points: Program Acceptability

- There was a 21 percent increased risk of attrition for individuals receiving usual care compared with those receiving a behavioral program.

Detailed Synthesis

HbA_{1c}: Behavioral Programs Compared With Usual Care

Figures 5-7 present our meta-analyses and forest plots of trials reporting HbA_{1c} stratified by age (youth and adults). A negative MD represents a greater reduction in percent HbA_{1c} for the behavioral program compared with usual care. We present separate forest plots for different timepoints—end of intervention, 6-month postintervention followup, and 12-month postintervention followup. We provide a narrative summary of the four RCTs that reported outcomes for longer followup timepoints.

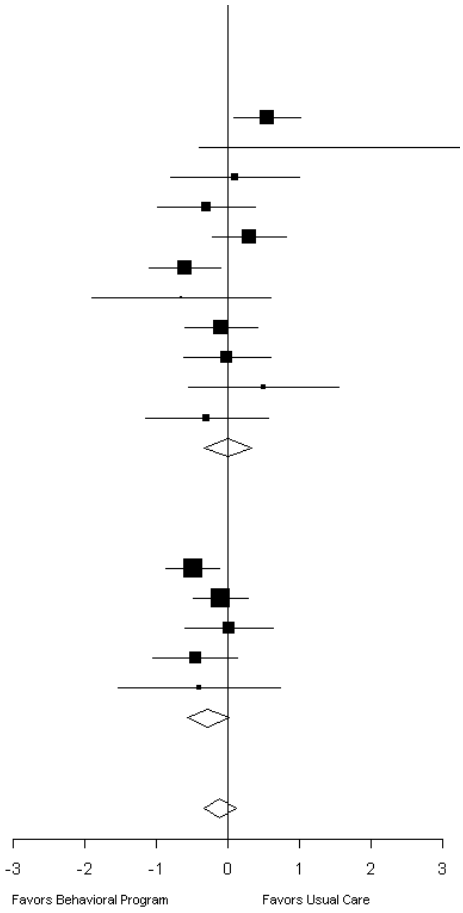
At the end of intervention for youth and adults combined, our meta-analysis (16 trials, 1,155 subjects) found no difference in percent HbA_{1c} between individuals receiving a behavioral program and those receiving usual care (MD, -0.11; 95% CI, -0.33 to 0.11).[82-84,89,93-96,98,99,101,105,106,108,110,112] There was no difference between groups for youth (11 trials, 653 subjects)[83,84,89,93,96,98,99,101,106,108,110] or for adults (5 trials, 502 subjects)[82,94,95,105,112]—MD = 0.00 (95% CI, -0.33 to 0.33) and MD = -0.28 (95% CI, -0.57 to 0.01), respectively.

At the end of 6-month postintervention followup for youth and adults combined, our meta-analysis (12 trials, 1,463 subjects) showed that HbA_{1c} improved for persons who received a behavioral program compared with those receiving usual care (MD, -0.31 percent; 95% CI, -0.47 to -0.15).[84,86,88,93,94,100,102-104,108,109,111] The reduction in HbA_{1c} was not clinically important. For youth (10 trials, 1,213 subjects),[84,86,88,93,100,102-104,108,111] the difference between groups was statistically significant, but it was not clinically important (MD, -0.28 percent; 95% CI, -0.51 to -0.05). For adults (2 trials, 250 subjects), there was no difference between groups.[94,109]

At the end of 12-month postintervention followup for youth, our meta-analysis (7 trials, 1,333 youth) found no difference in HbA_{1c} between individuals receiving a behavioral program and those receiving usual care (MD, -0.22 percent; 95% CI, -0.49 to 0.05).[83,85,102-104,108,111]

Figure 5. Behavioral programs for type 1 diabetes compared with usual care: HbA_{1c} at the end of intervention

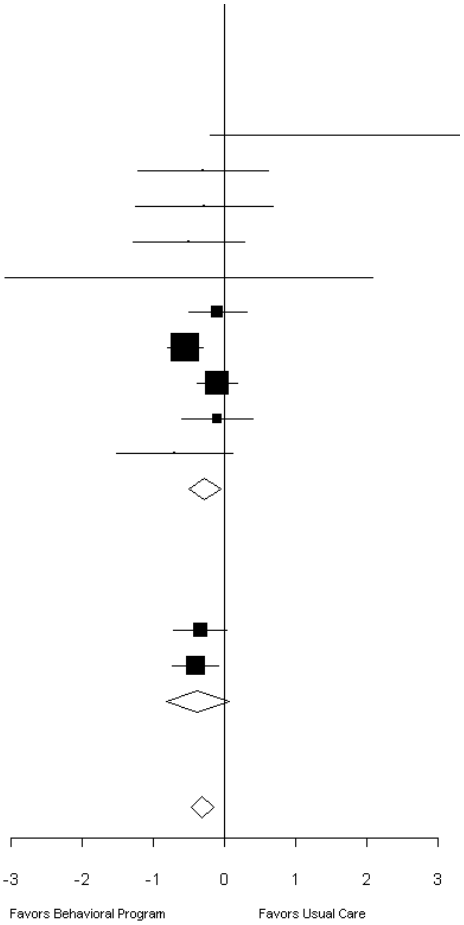
	Behavioral Program			Usual Care			Mean Difference
	Mean	SD	n	Mean	SD	n	[95% CI]
Youth Studies							
Anderson 1999	0.60	1.08	28	0.05	0.97	57	0.55 [0.08, 1.02]
Boardway 1993	2.52	2.54	8	-0.10	3.77	9	2.62 [-0.40, 5.64]
Franklin 2008	0.30	1.96	33	0.20	1.60	27	0.10 [-0.80, 1.00]
Husted 2014	0.00	1.53	26	0.30	0.96	31	-0.30 [-0.98, 0.38]
Katz 2014	0.20	1.35	50	-0.10	1.30	51	0.30 [-0.22, 0.82]
Laffel 2003	-0.20	1.21	50	0.40	1.32	50	-0.60 [-1.10, -0.10]
Lehmkuhl 2010	-0.74	1.50	11	-0.09	1.50	11	-0.65 [-1.90, 0.60]
Mayer-Davis 2014	-0.10	1.20	29	0.00	0.70	29	-0.10 [-0.61, 0.41]
Murphy 2007	-0.08	1.00	33	-0.07	1.50	34	-0.01 [-0.62, 0.60]
Viklund 2007	0.80	1.50	18	0.30	1.50	14	0.50 [-0.55, 1.55]
Wysocki 2007	-0.80	1.55	28	-0.50	1.67	26	-0.30 [-1.16, 0.56]
Subtotal			**314**			**339**	**-0.00 [-0.33, 0.33]**
Heterogeneity: $I^2 = 46\%$							
Adult Studies							
Amsberg 2009	7.72	0.83	36	8.21	0.83	38	-0.49 [-0.87, -0.11]
Ismail 2008	-0.45	1.28	84	-0.35	1.32	89	-0.10 [-0.49, 0.29]
Karlsen 2004	0.11	1.10	31	0.09	1.38	32	0.02 [-0.60, 0.64]
Mannuci 2005	-0.70	1.64	46	-0.24	1.73	85	-0.46 [-1.06, 0.14]
Perry 1997	-0.30	2.39	31	0.10	2.17	30	-0.40 [-1.54, 0.74]
Subtotal			**228**			**274**	**-0.28 [-0.57, 0.01]**
Heterogeneity: $I^2 = 0\%$							
Total			**542**			**613**	**-0.11 [-0.33, 0.11]**
Heterogeneity: $I^2 = 40\%$							



CI = confidence interval; HbA_{1c} = hemoglobin A_{1c}; n = number of participants; SD = standard deviation

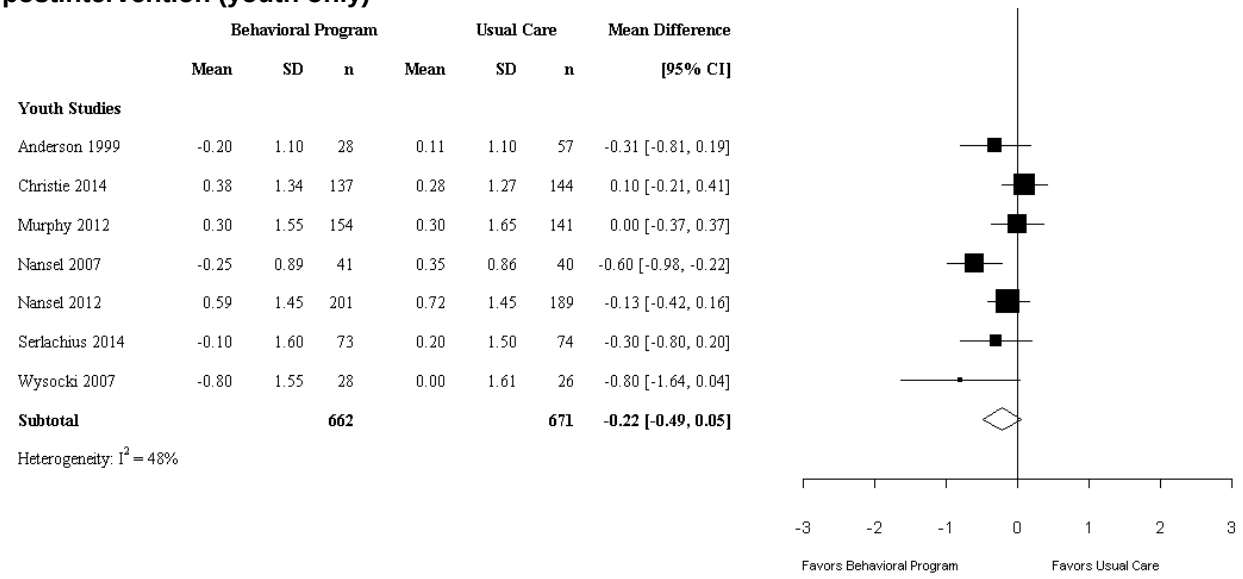
Figure 6. Behavioral programs for type 1 diabetes compared with usual care: HbA_{1c} at 6-month postintervention

	Behavioral Program			Usual Care			Mean Difference
	Mean	SD	n	Mean	SD	n	[95% CI]
Youth Studies							
Boardway 1993	2.42	2.41	8	-0.06	3.21	9	2.48 [-0.20, 5.16]
Cook 2002	-0.60	1.35	26	-0.30	2.01	27	-0.30 [-1.22, 0.62]
Ellis 2007	-0.45	2.46	49	-0.17	2.52	52	-0.28 [-1.25, 0.69]
Husted 2014	0.10	1.44	23	-0.40	1.45	30	-0.50 [-1.28, 0.28]
McNabb 1994	-0.90	2.54	10	-0.40	3.62	12	-0.50 [-3.08, 2.08]
Murphy 2012	-0.10	1.61	154	0.00	1.97	141	-0.10 [-0.51, 0.31]
Nansel 2007	-0.30	0.65	41	0.25	0.48	40	-0.55 [-0.80, -0.30]
Nansel 2012	0.40	1.45	201	0.50	1.45	189	-0.10 [-0.39, 0.19]
Serlachius 2014	-0.20	1.60	73	-0.10	1.50	74	-0.10 [-0.60, 0.40]
Wysocki 2007	-0.70	1.51	28	0.00	1.55	26	-0.70 [-1.52, 0.12]
Subtotal			**613**			**600**	**-0.28 [-0.51, -0.05]**
Heterogeneity: $I^2 = 28\%$							
Adult Studies							
Ismail 2008	-0.50	1.32	95	-0.16	1.38	105	-0.34 [-0.72, 0.04]
Zoffmann 2006	0.00	0.58	30	0.41	0.58	20	-0.41 [-0.74, -0.08]
Subtotal			**125**			**125**	**-0.38 [-0.82, 0.06]**
Heterogeneity: $I^2 = 0\%$							
Total			**738**			**725**	**-0.31 [-0.47, -0.15]**
Heterogeneity: $I^2 = 15\%$							



CI = confidence interval; HbA_{1c} = hemoglobin A_{1c}; n = number of participants; SD = standard deviation

Figure 7. Behavioral programs for type 1 diabetes compared with usual care: HbA_{1c} at 12-month postintervention (youth only)



CI = confidence interval; HbA_{1c} = hemoglobin A_{1c}; n = number of participants; SD = standard deviation

Four studies provided data at longer followup timepoints (data not shown). Three RCTs (2 youth,[103,104] 1 adult;[94] 671 subjects) reported data at more than 1 year, but less than 2 years; there was no difference in HbA_{1c} between groups (MD, -0.40; 95% CI, -0.92 to 0.12). Two trials (1 youth,[85] 1 adult;[94] 467 subjects) reported outcomes at 24 months and found no difference in HbA_{1c} (MD, -0.08; 95% CI, -1.96 to 1.8).

One trial in adolescents did not report sufficient data to be included in our meta-analysis; the authors found no statistically significant difference between groups at 6-month followup.[97]

Three observational studies (2 youth,[114,115] 1 adult;[113] 148 subjects) provided data on HbA_{1c} at 12-month followup. One youth study (41 subjects) reported a statistically significant and clinically important improvement in HbA_{1c} for the group receiving the behavioral program (MD, -1.2; 95% CI, -2.24 to -0.16).[115] The other youth study (17 subjects) found no difference between groups (MD, 0.67; 95% CI, -1.47 to 2.81).[114] The study that was conducted in adults (90 subjects) reported a statistically significant and clinically important improvement in HbA_{1c} for the group receiving the behavioral program (MD, -0.70; 95% CI, -1.31 to -0.09).[113] These results should be interpreted with caution because of concerns with bias and confounding in observational studies; the only study assessed as having low risk of bias found no difference.[114]

HbA_{1c}: Behavioral Programs Compared With Active Control

Figures 8-10 present our meta-analyses of trials reporting HbA_{1c} for youth and adults in comparisons with active controls. We present the results by followup timepoint (end of intervention, 6-month followup, 12-month followup) and age group. One trial in adults was a three-arm trial comparing a behavioral program to two different active controls (didactic education to either groups or individuals); these arms were combined for the meta-analysis.[107]

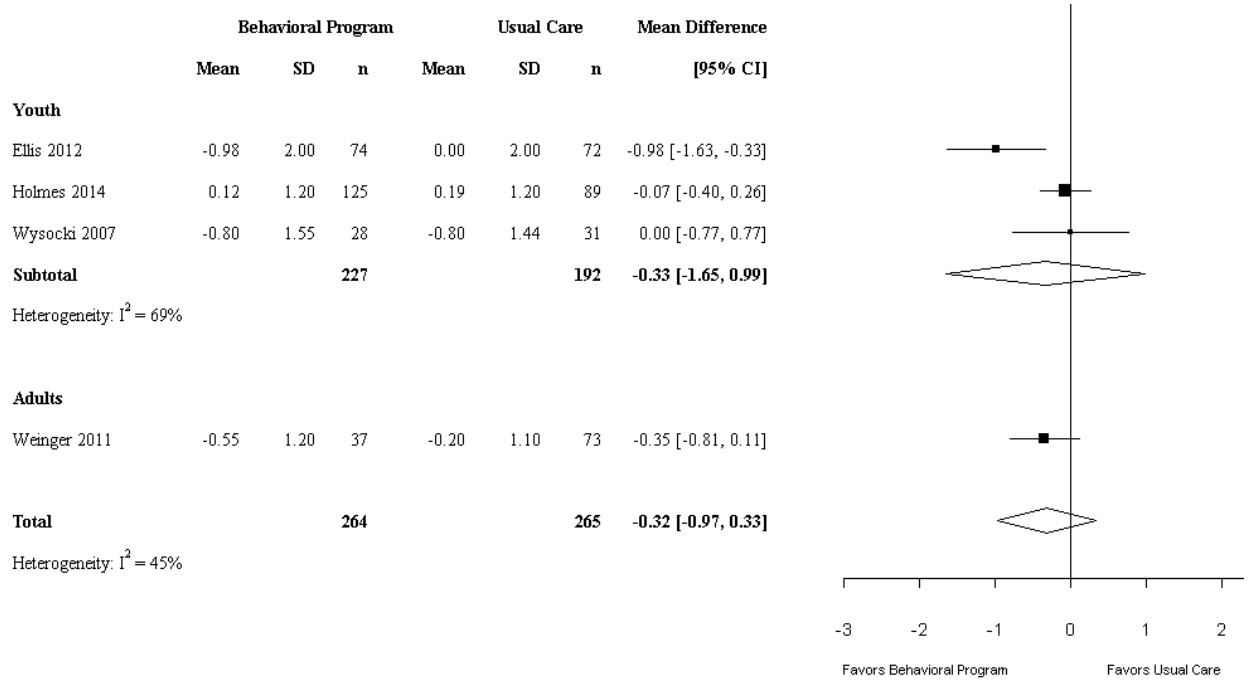
At the end of intervention, our meta-analysis for youth and adults (4 trials, 419 youth[87,92,108] and 110 adults[107]) found no difference between behavioral programs and active controls for HbA_{1c} (MD, -0.32; 95% CI, -0.97 to 0.33). When examining the results by age subgroups,

similar results were found for youth (MD, -0.33; 95% CI, -1.65 to 0.99; I^2=69%).[87,92,108] and adults (MD, -0.35; 95% CI, -0.81 to 0.11).[107]

At the end of 6 months postintervention, our meta-analysis for youth and adults combined (4 trials [259 adults,[91,107] 208 youth[92,108]]) showed that HbA_{1c} improved for those receiving a behavioral program compared with those receiving an active control (MD, -0.44; 95% CI, -0.69 to -0.19); this reduction in HbA_{1c} is clinically important. For youth, the difference was not statistically significant (MD, -0.60; 95% CI, -2.56 to 1.36);[92,108] for adults, the difference was not statistically significant and the effect size was not clinically important (MD, -0.38; 95% CI, -0.93 to -0.17).[91,107]

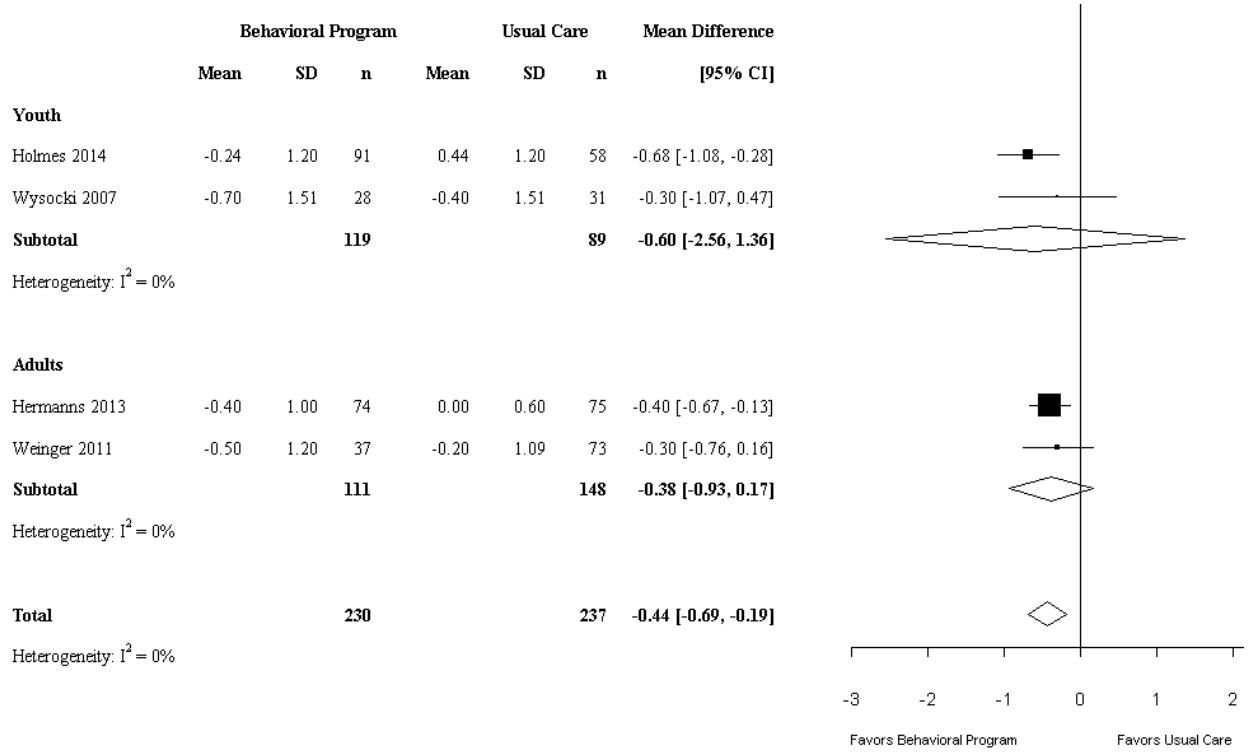
At the end of 12-month followup, our meta-analysis for youth and adults combined (3 trials [110 adults,[107] 195 youth[92,108]) found no difference in HbA_{1c} (MD, -0.44; 95% CI, -1.04 to 0.16). For youth, the difference was statistically significant and clinically important (MD, -0.52; 95% CI, -1.04 to 0.00); the behavioral program studied by Weinger et al.,[107] failed to demonstrate any difference (MD, -0.14; 95% CI, -0.61 to 0.33).

Figure 8. Behavioral programs for type 1 diabetes compared with active control: HbA_{1c} at end of intervention



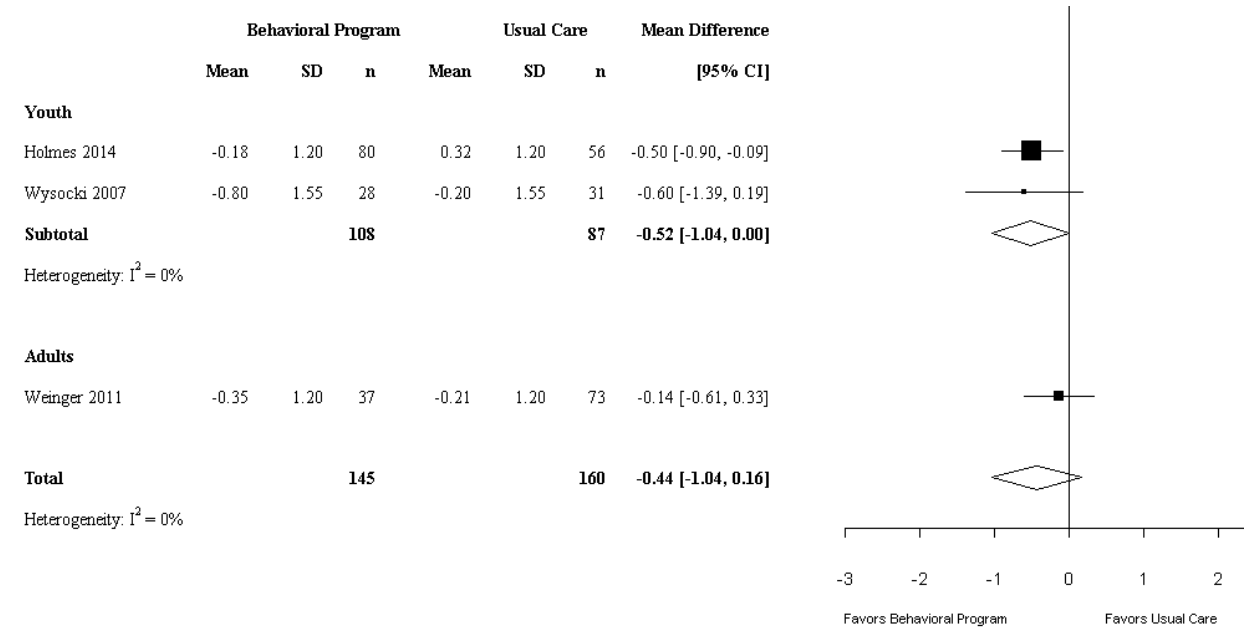
CI = confidence interval; HbA_{1c} = hemoglobin A_{1c}; n = number of participants; SD = standard deviation

Figure 9. Behavioral programs for type 1 diabetes compared with active control: HbA_{1c} at 6-month postintervention



CI = confidence interval; HbA_{1c} = hemoglobin A_{1c}; n = number of participants; SD = standard deviation

Figure 10. Behavioral programs for type 1 diabetes compared with active control: HbA_{1c} at 12-month postintervention



CI = confidence interval; HbA_{1c} = hemoglobin A_{1c}; n = number of participants; SD = standard deviation

HbA_{1c}: Comparative Effectiveness of Two Behavioral Programs

One RCT (72 youth) examined the same DSME program delivered in person compared with delivery by Skype.[90] There was no difference in HbA_{1c} between groups at the end of intervention (MD, -0.04; 95% CI, -0.87 to 0.79) or at 6-month followup (MD, -0.24; 95% CI, -1.10 to 0.62).

Adherence to Diabetes Self-Management: Behavioral Programs Compared With Usual Care

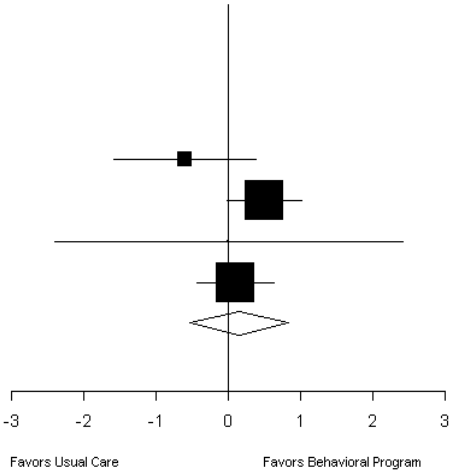
This section presents the results from trials that reported on adherence to diabetes self-management. This outcome was measured in a number of ways and we report them separately. The most common measure was self-monitoring of blood glucose (SMBG) and was most commonly reported as the frequency of blood glucose testing over 1 day.[84,86,88,96,104] Two studies reported the frequency of testing over the past week;[93,109] we converted this to the number of tests per day. We present separate forest plots for different timepoints (end of intervention, 6 month followup). We provide a narrative summary of the one RCT that reported outcomes for longer followup.

At the end of intervention (Figure 11), our meta-analysis (4 trials, 282 youth) found no difference in frequency of SMBG between youth receiving a behavioral program and those receiving usual care (MD, 0.15; 95% CI, -0.54 to 0.84).[84,88,93,96]

Figure 11. Behavioral programs for type 1 diabetes compared with usual care: self-monitoring of blood glucose (tests per day) at end of intervention

	Behavioral Program			Usual Care			Mean Difference
	Mean	SD	n	Mean	SD	n	[95% CI]
Youth Studies							
Boardway 1993	1.10	1.10	8	1.70	0.90	8	-0.60 [-1.58, 0.38]
Ellis 2007	2.62	1.30	57	2.12	1.44	51	0.50 [-0.02, 1.02]
Husted 2014	4.57	2.00	26	4.57	6.50	31	0.00 [-2.41, 2.41]
Katz 2014	3.90	1.30	50	3.80	1.40	51	0.10 [-0.43, 0.63]
Subtotal			**141**			**141**	**0.15 [-0.54, 0.84]**

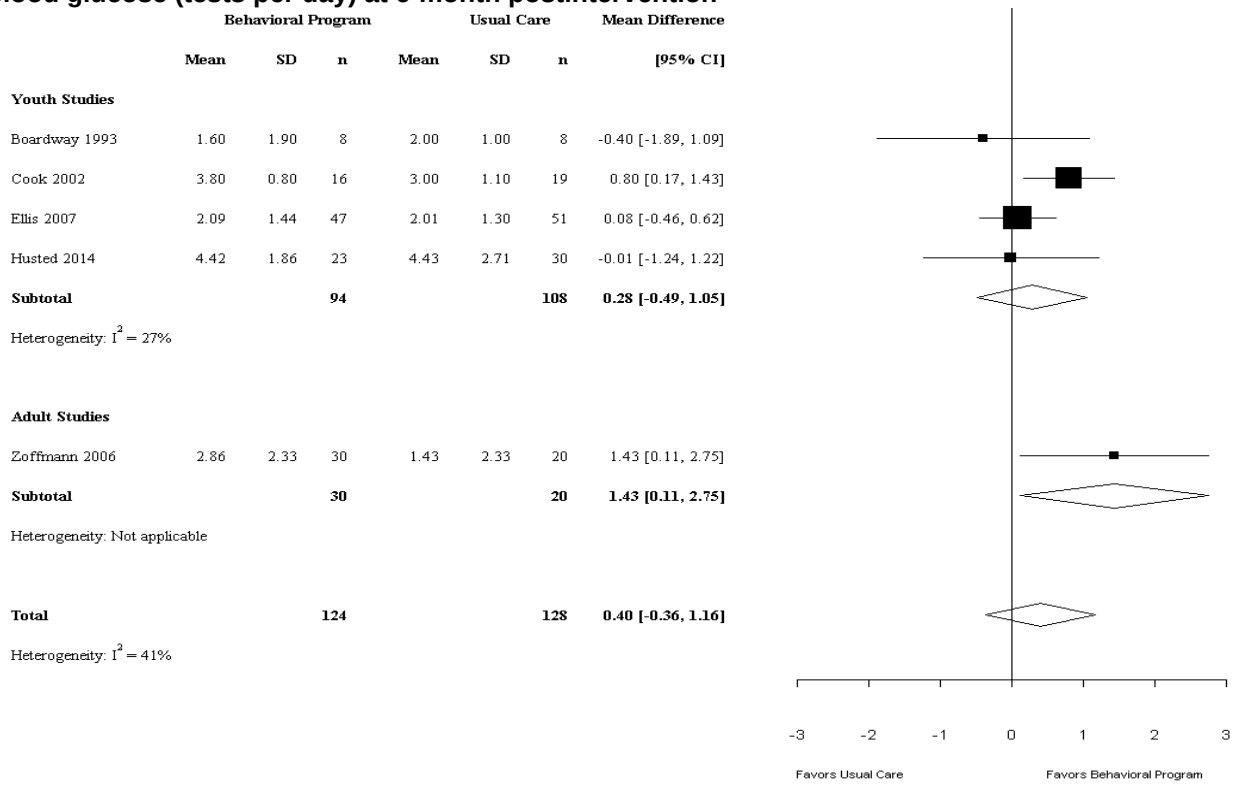
Heterogeneity: $I^2 = 25\%$



CI = confidence interval; n = number of participants; SD = standard deviation

At the end of 6-month postintervention for youth and adults combined (Figure 12), our meta-analysis (5 trials [4 youth,[84,86,88,93] 1 adult[109]], 252 subjects) found no difference in SMBG between individuals receiving a behavioral program and those receiving usual care (MD, 0.40; 95% CI, -0.36 to 1.16). Adults receiving the behavioral program in the trial of Zoffmann et al.[109] increased their frequency of SMBG (MD, 1.42; 95% CI, 0.11 to 2.75).

Figure 12. Behavioral programs for type 1 diabetes compared with usual care: self-monitoring of blood glucose (tests per day) at 6-month postintervention



CI = confidence interval; n = number of participants; SD = standard deviation

One trial (390 youth) reported SMBG at 24-months postintervention.[104] The results showed individuals receiving the behavioral program performed more poorly than those receiving usual care (MD, -0.36; 95% CI, -0.69 to -0.03).

Two trials in adults measured adherence of blood glucose testing using an item from the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire.[126] This self-report measure assesses the number of days in the previous week that SMBG was practiced. At the end of intervention one trial (74 adults) found that those in the behavioral program reported performing SMBG 1.4 days (95% CI, 0.35 to 2.43) more than those receiving usual care.[82] At 6-month postintervention, one trial (244 adults) found no difference between groups (MD, -0.06; 95% CI, -0.60 to 0.48).[94]

Four trials in youth used the Diabetes Self-Management Profile (DSMP)[127] to assess adherence to the diabetes regimen at different timepoints. At the end of intervention, Wysocki et al.[108] (54 youth) reported a clinically important improvement in the overall DSMP score for those who received the behavioral program compared with those receiving usual care (MD, 5.00; 95% CI, 0.60 to 9.40). This difference had disappeared by 12-month postintervention. Two studies assessed adherence at 6-month postintervention followup; we did not pool the results as the studies reported different summary measures. In 2012, Nansel et al.[104] (390 youth) found no difference between groups (MD, 1.31; 95% CI, -1.12 to 3.74). In an earlier study, Nansel et al.[103] (81 youth) reported the proportion of adherence to an optimal diabetes regimen using the modified DSMP. They found no difference between groups (MD, -0.03; 95% CI, -0.06 to -0.01). The fourth study reported that there was no difference between groups on the DSMP at end of intervention; however, the authors did not provide any data.[99]

Two trials reported on adherence to medication. One trial (190 youth) used a questionnaire item to assess the number of times youth skipped an insulin dose in the past month.[85] The authors reported that the odds of skipping one or more doses compared with no doses of insulin at 12-month followup was 0.82 (95% CI, 0.48 to 1.38) and at 24-month followup was 1.30 (95% CI, 0.78 to 2.17) for the group receiving the behavioral program. One trial in adults (74 adults) used the medication item of the Diabetes Self-Care Inventory[128] and found no difference at the end of intervention between those receiving the behavioral program and those receiving usual care (MD, 0.22; 95% CI, -0.60 to 1.04).[82]

Adherence to Diabetes Self-Management: Behavioral Programs Compared With Active Control

One trial (149 adults) found no difference in frequency of SMBG between groups at 6-months postintervention (MD, -0.20; 95% CI, -0.76 to 0.36).[91] The same trial measured adherence to several diabetes self-care activities using the SDSCA and found no difference between groups at 6-month postintervention (MD, 0.00; 95% CI, -0.35 to 0.35).[91]

One trial (54 youth) used the DSMP to assess adherence to the diabetes regimen.[108] At the end of intervention and 12-month followup, Wysocki et al.[108] found no difference between the group that received the behavioral program compared with those receiving an active control—MD = 2.40 (95% CI, -2.46 to 7.26) and MD = 2.00 (95% CI, -3.78 to 7.78), respectively).

One trial (149 youth)[92] used the Diabetes Behavior Rating Scale, which reflects the frequency of routine diabetes care behaviors over the previous week.[129] No data were provided; however, the authors reported that at end of intervention, and 6- and 12-month followup, those receiving the behavioral program performed more poorly that than those in the active control group.

Adherence to Diabetes Self-Management: Comparative Effectiveness of Two Behavioral Programs

One RCT (71 youth) studied the same DSME program delivered in person compared with delivery by Skype.[90] The authors used the DSMP to assess adherence and found no difference between the groups at the end of intervention or at 6-month followup (MD, 0.85; 95% CI, -4.56 to 6.26 and MD, 0.74; 95% CI, -4.97 to 6.45, respectively).

Other Clinical and Behavioral Outcomes

Table 4 summarizes the results for other clinical and behavioral outcomes. For most outcomes results were reported in single trials.

Table 4. Other clinical and behavioral outcomes for type 1 diabetes

Outcome	Timepoint	# Trials (# Subjects, Control Group)	Study Effect[a]	Conclusion
Change in body composition (BMI [$kg.m^{-2}$])	EOI	1 (60 youth, UC)[89]	MD, 0.08; 95% CI, -0.35 to 0.51	No difference
Change in body composition (BMI [$kg.m^{-2}$])	6m followup	1 (227 adults, UC)[94]	MD, -0.21; 95% CI, -0.62 to 0.20	No difference
Change in body composition (kg)	EOI	1 (61 adults, UC)[105]	MD, -0.50; 95% CI, -5.69 to 4.69	No difference
Change in physical activity (intensity/duration)	EOI	2 (17 youth, 73 adults, UC)[82,84]	SMD, 0.16; 95% CI, -0.25 to 0.57	No difference
Change in physical activity (intensity/duration)	6m followup	2 (17 youth, 255 adults, UC)[84,94]	SMD, -0.26; 95% CI, -1.00 to 0.49	No difference
Change in physical activity (fitness [VO_2 max])	EOI	1 (43 adults, UC)[105]	MD, 0.59; 95% CI, 0.22 to 0.96	Improved with behavioral program
Change in dietary or nutrient intake (% saturated fat)	EOI	1 (61 adults, UC)[105]	MD, -1.80; 95% CI, -3.53 to -0.07	Improved with behavioral program
Change in dietary or nutrient intake (energy [kcal/day])	EOI	1 (61 adults, UC)[105]	MD, -247.10; 95% CI, -281.7 to -212.5	Improved with behavioral program
Severe hypoglycemia (# episodes needing 3rd party assistance)	EOI	1 (60 youth, UC)[89]	MD, -1.02; 95% CI, -2.16 to 0.11	No difference
Severe hypoglycemia (# episodes needing 3rd party assistance)	6m followup	1 (160 adults, AC)[91]	MD, -0.10; 95% CI, -0.48 to 0.28	No difference
Severe hypoglycemia (# episodes needing 3rd party assistance)	6m followup	1 (227 adults, UC)[94]	MD, -0.62; 95% CI, -1.61 to 0.37	No difference
Severe hypoglycemia (# episodes needing 3rd party assistance)	12m followup	1 (295 youth, UC)[102]	MD, -0.05; 95% CI, -0.22 to 0.12	No difference
Severe hypoglycemia (# episodes needing 3rd party assistance)	>12m followup	1 (343 youth, UC)[85]	RR, 0.55; 95% CI, 0.10 to 2.97	No difference
Diabetic ketoacidosis (requiring treatment)	EOI	1 (61 youth, UC)[89]	MD, -0.38; 95% CI, -1.43 to 0.67	No difference
Diabetic ketoacidosis (requiring hospital admission)	12m followup	1 (295 youth, UC)[102]	MD, 0.01; 95% CI, -0.09 to 0.11	No difference
Diabetic ketoacidosis (requiring hospital admission)	>12m followup	1 (343 youth, UC)[85]	RR, 0.96; 95% CI, 0.72 to 1.27	No difference
HDL cholesterol (mmol/l)	EOI	1 (61 adults, UC)[105]	MD, 0.10; 95% CI, -0.06 to 0.26	No difference
LDL cholesterol (mmol/l)	EOI	1 (61 adults, UC)[105]	MD, -0.20; 95% CI, -0.67 to 0.27	No difference
Systolic blood pressure (mmHg)	EOI	1 (61 adults, UC)[105]	MD, -2.00; 95% CI, -11.25 to 7.25	No difference

Table 4. Other clinical and behavioral outcomes for type 1 diabetes (continued)

Outcome	Timepoint	# Trials (# Subjects, Control Group)	Study Effect[a]	Conclusion
Triglycerides (mmol/l)	EOI	1 (61 adults, UC)[105]	MD, 0.00; 95% CI, -0.39 to 0.39	No difference
Depression (Swedish Hospital Anxiety and Depression scale)	EOI	1 (74 adults, UC)[82]	SMD, -0.51; 95%CI, -0.97 to -0.05	Improved with behavioral program
Depression (Patient Health Questionnaire-9)	6m followup	1 (235 adults, UC)[94]	SMD, 0.20; 95% CI, -0.05 to 0.46	No difference
Depression (Center for Epidemiologic Studies Depression Scale)	6m followup	1 (149 adults, AC)[91]	SMD, -0.30; 95% CI, -0.63 to 0.02	No difference

AC = active control; BMI = body mass index; CI = confidence interval; EOI = end of intervention; m = month; MD = mean difference; QOL = quality of life; SMD = standardized mean difference; UC = usual care

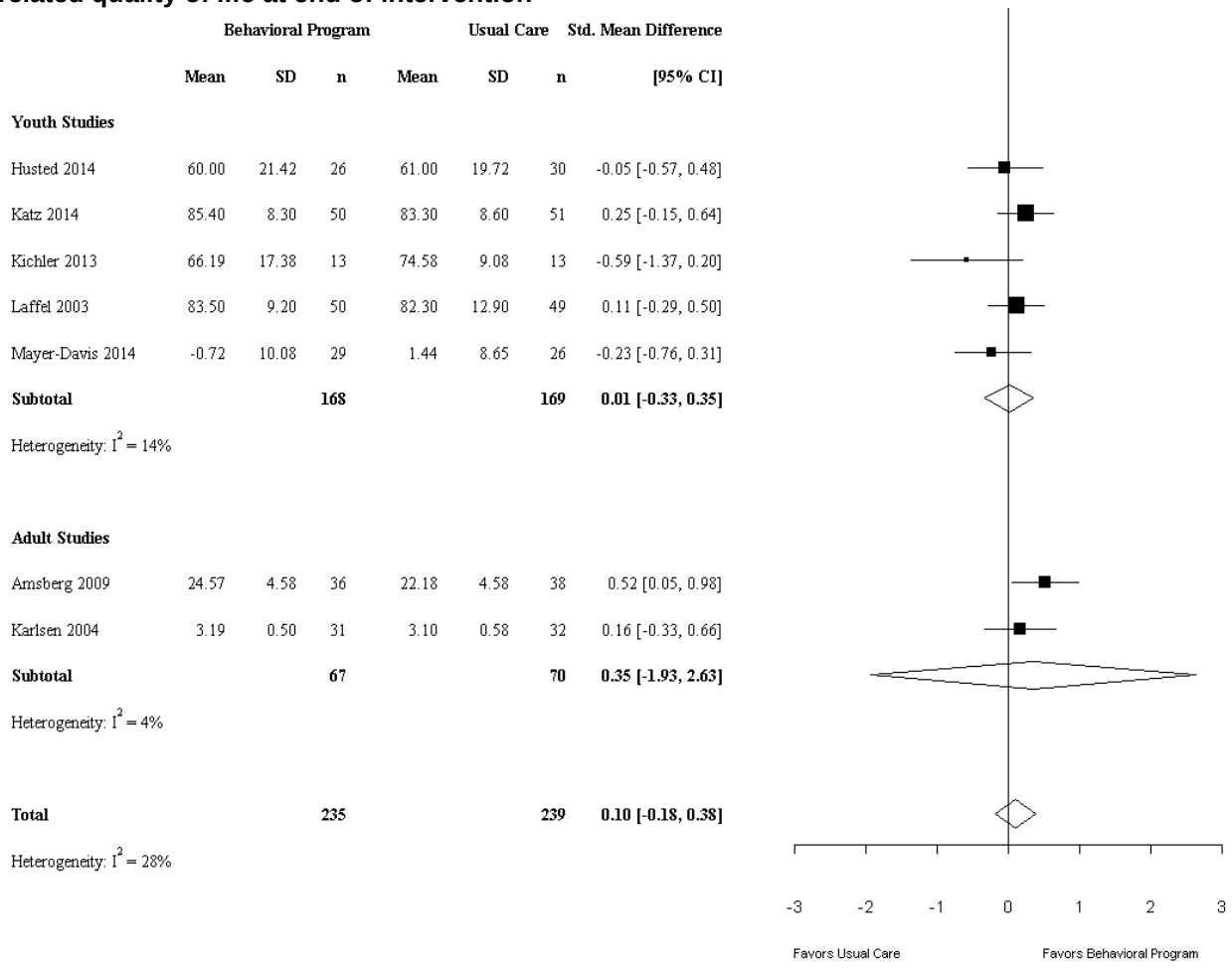
[a]Negative values of MDs or SMDs are favorable for change in body composition, change in dietary intake, severe hypoglycemia, diabetic ketoacidosis, LDL cholesterol, systolic blood pressure, triglycerides, and depression.

Health-Related Quality of Life: Behavioral Programs Compared With Usual Care

Studies reporting on HRQL assessed this using generic and diabetes-specific quality of life measures. Generic HRQL was measured by a number of tools (e.g., World Health Organization Well-Being Index,[130] Pediatric Quality of Life [PedsQL],[131] Wellbeing Questionnaire[132]), as was diabetes-specific HRQL (PedsQL diabetes module,[131] Pediatric Diabetes Quality of Life, Well-being Enquiry for Diabetes[133]). A group of studies reported on diabetes distress/stress (tools included Problem Areas in Diabetes[134] and Diabetes Stress Questionnaire[84]), for which we analyzed separately from diabetes-specific HRQL. For all analyses we present the results as SMD. Figure 13 presents our meta-analyses of trials, stratified by age (youth and adults), that reported generic HRQL at end of intervention. Longer-term followup results were reported for generic HRQL and are summarized in Table 5. The meta-analysis results in Figure 14 for diabetes-specific HRQL at end of intervention were not stratified by age. Figures 15 and 16 present the meta-analyses for diabetes distress at end of intervention (stratified by age) and 6-month followup, respectively.

At the end of intervention for youth and adults combined (Figure 13), our meta-analysis (7 trials [5 youth,[93,96-98,110] 2 adult[82,95]], 474 subjects) found no difference in generic HRQL between individuals receiving a behavioral program and those receiving usual care (SMD, 0.10; 95% CI, -0.18 to 0.38). The lack of difference remained for the subgroups of adults (2 trials, 137 subjects; MD, 0.35; 95% CI -1.93 to 2.63)[82,95] and youth (5 trials, 337 subjects; MD, 0.01; 95% CI -0.33 to 0.35).[93,96-98,110]

Figure 13. Behavioral programs for type 1 diabetes compared with usual care: generic health-related quality of life at end of intervention



CI = confidence interval; n = number of participants; SD = standard deviation

Three RCTs in youth reported on generic HRQL for longer followup timepoints (Table 5).[85,93,98] There was no difference in HRQL between groups at any of the timepoints.

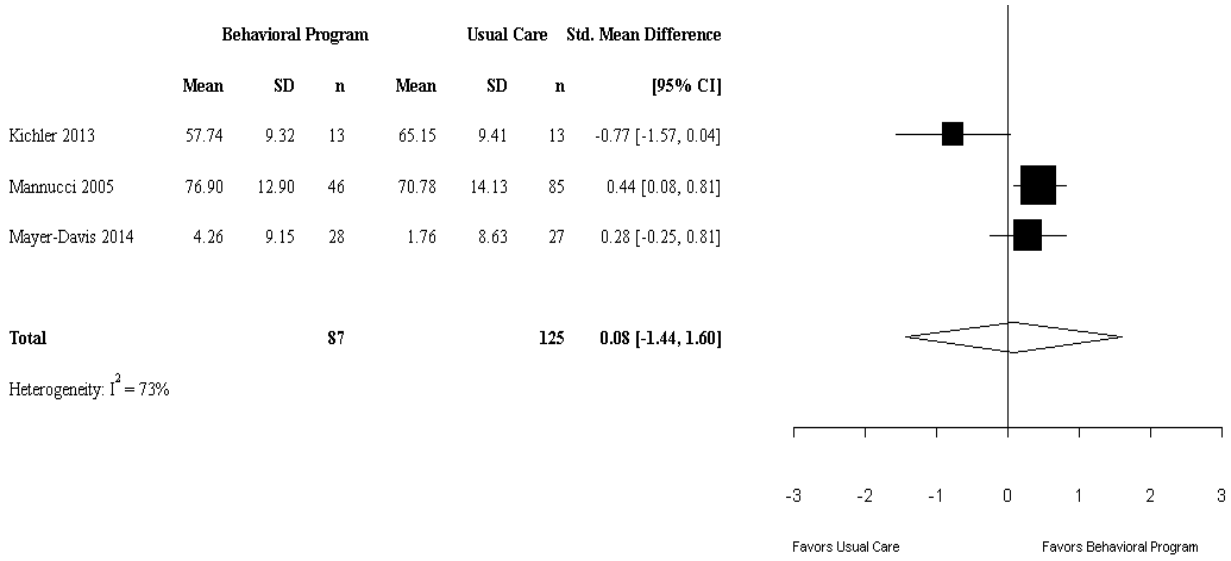
Table 5. Behavioral programs for type 1 diabetes compared with usual care: generic health-related quality of life at 6-, 12-, and 24-month postintervention

Timepoint	# Trials (#Subjects)	Study Effect	Conclusion
6m followup	1 RCT (53)[93]	SMD, -0.29; 95% CI, -0.83 to 0.26	No difference
12m followup	2 RCTs (405)[85,98]	SMD, 0.02; 95% CI, -0.11 to 0.15	No difference
24m followup	1 RCT (291)[85]	SMD, -0.04; 95% CI, -0.27 to 0.19	No difference

CI = confidence interval; m = month; RCT = randomized controlled trial; SMD = standardized mean difference

Diabetes-specific HRQL was reported by three trials at the end of intervention (Figure 14). Our meta-analysis of these trials (2 youth,[97,110] 1 adult,[112] 212 subjects) found no difference between behavioral programs and usual care (SMD, 0.08; 95% CI, -1.44 to 1.60; I^2=73%). One observational study in adults (90 subjects) found no difference between groups at 12-months postintervention (SMD, 0.03; 95% CI, -0.39 to 0.45).[113]

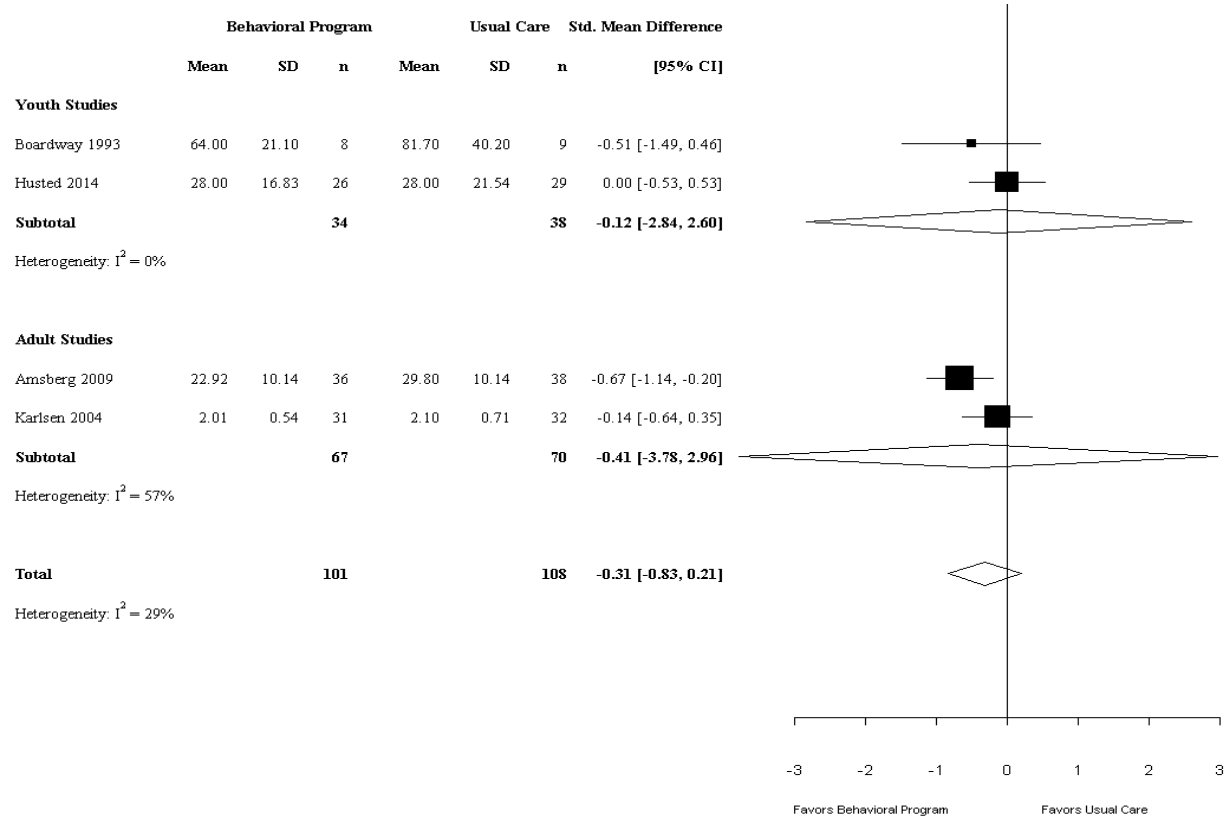
Figure 14. Behavioral programs for type 1 diabetes compared with usual care: diabetes-specific health-related quality of life at end of intervention



CI = confidence interval; n = number of participants; SD = standard deviation; Std = standardized

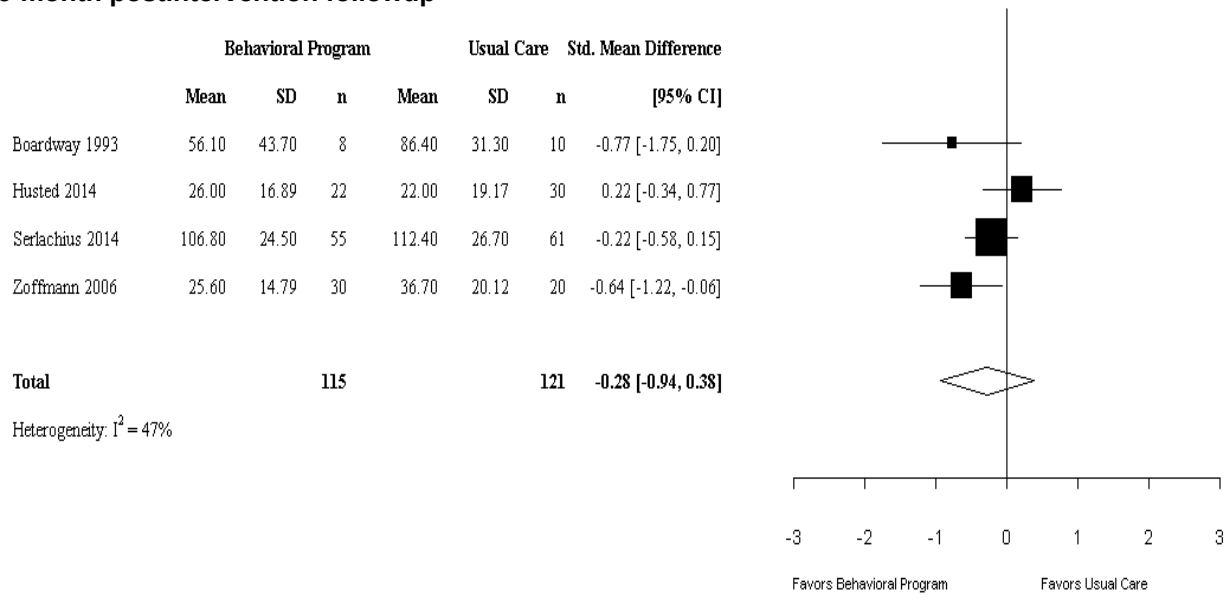
Distress/stress was reported for six trials; negative scores represent reduced distress. At end of intervention (Figure 15), our meta-analysis for youth and adults combined (4 trials [2 youth,[84,93] 2 adults[82,95]], 209 subjects) found no statistically significant difference in diabetes distress for behavioral programs compared with usual care (SMD, -0.31; 95% CI, -0.83 to 0.21). Stratified by age, there was no difference for the studies of youth (SMD, -0.21; 95% CI, -2.84 to 2.60) or adults (SMD, -0.41; 95% CI, -3.78 to 2.96; I^2= 57%). At 6-month followup for youth and adults combined (4 trials [3 youth,[84,93,111] 1 adult[109]], 236 subjects), changes to diabetes distress did not differ for behavioral programs compared with usual care (SMD, -0.28; 95% CI, -0.94 to 0.38) (Figure 16).

Figure 15. Behavioral programs for type 1 diabetes compared with usual care: diabetes distress/stress at end of intervention



CI = confidence interval; n = number of participants; SD = standard deviation; Std = standardized

Figure 16. Behavioral programs for type 1 diabetes compared with usual care: diabetes distress at 6-month postintervention followup



CI = confidence interval; n = number of participants; SD = standard deviation; Std = standardized

Health-Related Quality of Life: Behavioral Programs Compared With Active Control

One trial in youth failed to demonstrate a difference in diabetes-related quality of life between a behavioral program and an active control at 12-month followup (130 subjects; insufficient data reported to calculate SMD).[92]

Diabetes-Related Health Care Utilization: Behavioral Programs Compared With Usual Care

Diabetes-related health care utilization was reported infrequently and only for trials comparing behavioral programs to usual care. We summarize the results in Table 6. One RCT in youth found a reduced risk of diabetes-related hospital admissions at end of intervention and at 6-month followup for those receiving behavioral programs compared with usual care.[88] The same trial also reported fewer admissions to the emergency department at the end of intervention. Another RCT in youth[85] and one in adults[94] found no difference in hospital admission at any timepoint. One trial reported that there was no difference in the number of diabetes-related hospital and emergency department admissions at the 6-month followup; however, the authors did not provide any data.[97]

Table 6. Behavioral programs for type 1 diabetes compared with usual care: diabetes-related health care utilization at end of intervention, 6-, 12-, and 24-month postintervention followup

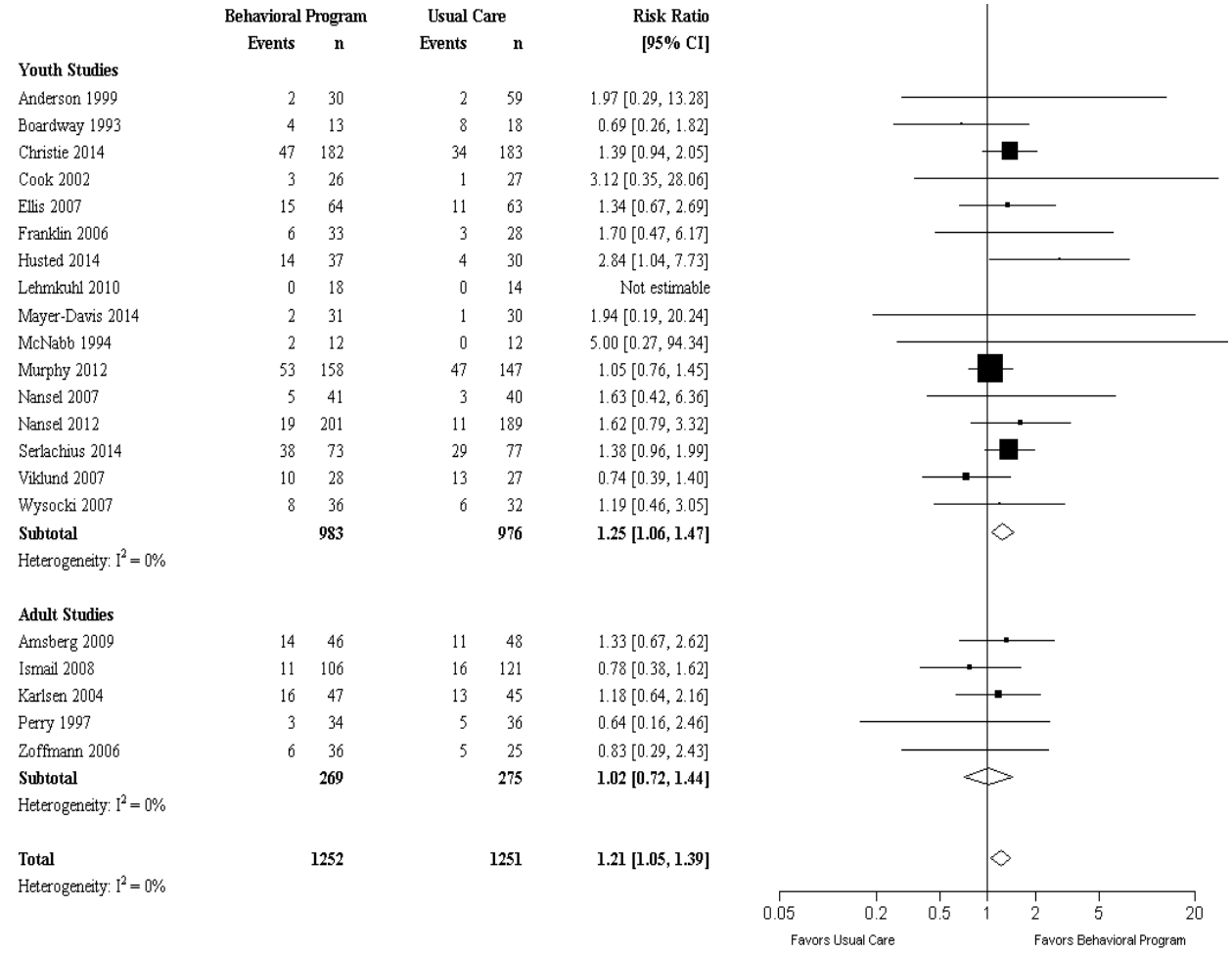
Outcome	Timepoint	# Trials (#Subjects)	Study Effect	Conclusion
Hospitalizations (# admissions)	EOI	1 (95 youth)[88]	RR, 0.28; 95% CI, 0.15 to 0.55	Lower risk of admissions for behavioral program
Hospitalizations (# admissions)	6m followup	1 (98 youth)[88]	RR, 0.41; 95% CI, 0.21 to 0.78	Lower risk of admissions for behavioral program
Hospitalizations (# admissions)	24m followup	1 (343 youth)[85]	RR, 0.78; 95% CI, 0.45 to 1.34	No difference
Hospitalizations (# admissions)	EOI	1 (159 adults)[94]	RR, 1.88; 95% CI, 0.49 to 7.25	No difference
Hospitalizations (# admissions)	6m followup	1 (198 adults)[94]	RR, 0.90; 95% CI, 0.35 to 2.32	No difference
Emergency Dept (# admissions)	EOI	1 (98 youth)[88]	MD, -0.21; 95% CI, -0.34 to -0.08	Fewer admissions for behavioral program

CI = confidence interval; EOI = end of intervention; m = month; MD = mean difference; RR = risk ratio

Program Acceptability: Behavioral Programs Compared With Usual Care

Figure 17 presents our meta-analysis stratified by age (youth and adults) of trials that reported participant attrition at their longest followup timepoint. Our meta-analysis (21 trials, 2,503 subjects) found a 21 percent increased risk of attrition for individuals receiving usual care compared with those receiving the behavioral program (RR, 1.21; 95% CI, 1.05 to 1.39).[82-86,88,89,93-95,99,100,102-106,108-111]

Figure 17. Behavioral programs for type 1 diabetes compared with usual care: participant attrition



CI = confidence interval; n = number of participants

Program Acceptability: Behavioral Programs Compared With Active Control

Three RCTs (218 youth[87,108] and 160 adults[91]) compared behavioral programs with active comparators. The pooled analysis (data not shown) found no difference between the groups for participant attrition (RR, 1.05; 95% CI, 0.46 to 2.4).

Program Acceptability: Comparative Effectiveness of Two Behavioral Programs

One RCT (72 youth) compared the same DSME program delivered in person compared with delivery by Skype.[90] There was no difference between the groups in participant attrition (RR, 0.55; 95% CI, 0.28 to 1.11).

Summary of Key Findings and Strength of Evidence for KQ 1

There was moderate SOE showing differences in HbA_{1c} at 6-month postintervention followup with greater reduction in HbA_{1c} for individuals who were enrolled in behavioral programs compared with those receiving usual care (Table 7). For other timepoints, there was low SOE for no significant difference in HbA_{1c}. At followup greater than 6 months, the

estimated effects were imprecise and because the 95% CIs included our threshold for clinical importance we cannot rule out benefit for behavioral programs. There was low SOE showing no difference in adherence to diabetes self-management at end of intervention and 6-month followup. There was moderate SOE of no difference at the end of intervention for generic HRQL, and low SOE of no difference for diabetes distress at end of intervention and at 6-month followup. The 95% CIs for diabetes distress included our threshold for clinical importance such that we cannot rule out a favorable effect for behavioral programs. There was insufficient SOE for diabetes-related HRQL, and for outcomes related to changes in body composition, physical fitness, and dietary intake.

Table 7. Type 1 diabetes: summary of key findings and strength of evidence for behavioral programs compared with usual care

Outcome	Outcome Timing	# Trials (# Subjects); Tool if Applicable	Mean Difference or Standardized Mean Difference[a]	Strength of Evidence
HbA_{1c}	EOI	16 (1,155)[82-84,89,93-96,98,99,101,105,106,108,110,112]	MD, -0.11; 95% CI, -0.33 to 0.11	Low for no significant difference
HbA_{1c}	6m followup	12 (1,463)[84,86,88,93,94,100,102-104,108,109,111]	MD, -0.31; 95% CI,-0.47 to -0.15	Moderate for benefit[b]
HbA_{1c}	12m followup	7 (1,333)[83,85,102-104,108,111]	MD, -0.22; 95% CI, -0.49 to 0.05	Low for no significant difference
HbA_{1c}	>12m followup	4 (1,138)[85,94,103,104]	MD, -0.40; 95% CI, -0.92 to 0.12 (>12m, <24m) MD, -0.08; 95% CI, -1.96 to 1.8 (≥24m)	Low for no significant difference
Adherence to diabetes self-management	EOI	4(282);[84,88,93,96] SMBG (tests per day; higher better) 1 (74);[82] SDSCA (days per week) 1 (54);[108] DSMP (higher scores better) 1 (74);[82] DSCI (higher scores better)	MD, 0.15; 95% CI, -0.54 to 0.84 MD, 1.4; 95% CI, 0.35 to 2.43 MD, 5.00; 95% CI, 0.60 to 9.40 MD, 0.22; 95% CI, -0.60 to 1.04	Low for no significant difference
Adherence to diabetes self-management	6m followup	5 (252);[84,86,88,93,109] SMBG 1 (244);[94] SDSCA 2 (471);[103,104] DSMP	MD, 0.40; 95% CI, -0.36 to 1.16 MD, -0.06; 95% CI, -0.60 to 0.48 No difference (different measures)	Low for no significant difference
Adherence to diabetes self-management	12m followup	1 (54);[108] DSMP 1 (180);[85] skipping one or more doses in past month	MD, 4.00; 95% CI, -1.69 to 9.69 OR, 0.82; 95% CI, 0.48 to 0.1.38	Insufficient
Adherence to diabetes self-management	>12m followup	1 (390); SMBG [104] 1 (190);[85] skipping one or more doses in past month	MD, -0.36; 95% CI, -0.69 to -0.03 (≥24m) OR, 1.30; 95% CI, 0.78 to 2.17 (24m)	Insufficient
Change in body composition (BMI [$kg.m^{-2}$])	EOI	1 (60)[89]	MD, 0.08; 95% CI, -0.35 to 0.51	Insufficient
Change in body composition (BMI) [$kg.m^{-2}$])	6m followup	1 (227)[94]	MD, -0.21; 95% CI, -0.62 to 0.20	Insufficient
Change in body composition (kg)	EOI	1 (61)[105]	MD, -0.50; 95% CI, -5.69 to 4.69	Insufficient

Table 7. Type 1 diabetes: summary of key findings and strength of evidence for behavioral programs compared with usual care (continued)

Outcome	Outcome Timing	# Trials (# Subjects); Tool if Applicable	Mean Difference or Standardized Mean Difference[a]	Strength of Evidence
Change in physical activity (fitness – VO_2 max)	EOI	1 (43)[105]	MD, 0.59; 95% CI, 0.22 to 0.96	Insufficient
Change in physical activity (intensity/duration)	EOI	2 (91)[82,84]	SMD, 0.16; 95% CI, -0.25 to 0.57	Insufficient
Change in physical activity (intensity/duration)	6m followup	2 (272)[84,94]	SMD, -0.26; 95% CI, -1.00 to 0.49	Insufficient
Change in dietary or nutrient intake (energy [kcal/day])	EOI	1 (61)[105]	MD, -247.10; 95% CI, -281.7 to -212.5	Insufficient
Change in dietary or nutrient intake (% saturated fat)	EOI	1 (61)[105]	MD, -1.80; 95% CI, -3.53 to -0.07	Insufficient
Generic HRQL	EOI	7 (474)[82,93,95-98,110]	SMD, 0.10; 95% CI, -0.18 to 0.38	Moderate for no significant difference
Generic HRQL	6m followup	1 (53)[93]	SMD, -0.29; 95% CI, -0.83 to 0.26	Insufficient
Generic HRQL	12m followup	2 (405)[85,98]	SMD, 0.02; 95% CI, -0.11 to 0.15	Insufficient
Generic HRQL	≥12m followup	1 (291)[85]	SMD, -0.04; 95% CI, -0.27 to 0.19	Insufficient
Diabetes-specific quality of life	EOI	3 (212)[97,110,112]	SMD, 0.08; 95% CI, -1.44 to 1.60	Insufficient
Diabetes distress	EOI	4 (209)[82,84,93,95]	SMD, -0.31; 95% CI, -0.83 to 0.21	Low for no significant difference
Diabetes distress	6mo followup	4 (236)[84,93,109,111]	SMD, -0.28; 95% CI, -0.94 to 0.38	Low for no significant difference

BMI = body mass index; CI = confidence interval; DSCI = Diabetes Self Care Inventory; DSMP = Diabetes Self-Management Profile; EOI = end of intervention - <1 month followup (interventions lasted 1.5-25 months); HbA_{1c} = hemoglobin A_{1c}; HRQL = health-related quality of life; kcal=kilocalories; m=month; MD = mean difference; SDSCA = Summary of Diabetes Self-Care Activities; SMBG = self-monitoring of blood glucose; SMD = standardized mean difference

[a]Negative values are favorable for MDs or SMDs for HbA_{1c}, change in body composition, change in dietary intake, and diabetes distress.

[b]This point estimate did not meet threshold for clinical significance, although the 95% CI included clinically important difference.

There was moderate SOE showing differences in HbA_{1c} at 6-month postintervention followup with a clinically important reduction in HbA_{1c} for individuals who were enrolled in behavioral programs compared with those receiving an active control (Table 8). At end of intervention and 12-month followup, there was low SOE showing no difference in HbA_{1c}; because the 95% CIs included our threshold for a clinically important effect, we cannot rule out a benefit for behavioral programs. There was insufficient evidence for adherence to diabetes self-management at any followup timepoint.

Table 8. Type 1 diabetes: summary of key findings and strength of evidence for behavioral programs compared with an active control

Outcome	Outcome Timing	# Trials (# Subjects)	Mean Difference[a]	Strength of Evidence
HbA_{1c}	EOI	4 (529)[87,92,107,108]	MD, -0.32; 95% CI, -0.97 to 0.33	Low for no significant difference
HbA_{1c}	6m followup	4 (467)[91,92,107,108]	MD, -0.44; 95% CI, -0.69 to -0.19	Moderate for benefit
HbA_{1c}	12m followup	3 (305)[92,107,108]	MD, -0.44; 95% CI, -1.04 to 0.16	Low for no significant difference
Adherence to diabetes self-management	EOI	1 (54);[108] DSMP (higher scores better) 1 (149);[92] DBRS (higher scores better)	MD, 2.40; 95% CI, -2.46 to 7.26 No data reported; those in behavioral program did more poorly	Insufficient
Adherence to diabetes self-management	6m followup	1 (149);[91] SMBG (tests per day; higher better) 1 (149);[92] DBRS	MD, -0.20; 95% CI, -0.76 to 0.36 No data reported; those in behavioral program did more poorly	Insufficient
Adherence to diabetes self-management	12m followup	1 (54); DSMP 1 (149);[92] DBRS	MD, 2.00; 95% CI, -3.78 to 7.78 No data reported; those in behavioral program did more poorly	Insufficient

CI = confidence interval; DBRS = Diabetes Behavior Rating Scale; DSMP = Diabetes Self-Management Profile; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; m = month; MD = mean difference; SDSCA = Summary of Diabetes Self-Care Activities; SMBG = self-monitoring of blood glucose; SMD = standardized mean difference

[a]Negative values are favorable for HbA_{1c}.

KQ 2. Subgroups for Effectiveness in T1DM

This KQ evaluated whether behavioral programs differed in effectiveness for subgroups of patients with T1DM. For this question, we searched for subgroup analyses reported by individual trials that focused on whether a particular program was more or less effective in reducing HbA_{1c} (the outcome reported by the most studies) based on age (children and adolescents [≤18 years], young adults [19-30 years], adults [31-64 years], older adults ≥65 years]), race or ethnicity, socioeconomic status, time since diagnosis (≤1 year vs. >1 year), and level of glycemic control (HbA_{1c} <7 vs. ≥7 percent). We also looked at subgroups at the study level, for example when the mean age of participants fell within one of the age categories, or the majority (≥75 percent) of the participants was stated as racial/ethnic minorities. We evaluated the SOE for the subgroups based on age (Figures 5-10); insufficient data were reported or available for other subgroups.

Key Points

- Based on between-study results for comparisons with usual care, results were consistent with the general trend when looking at all studies. At 6 months, behavioral programs reduced HbA_{1c} in studies of youth by a statistically significant 0.28 percent and in studies of adults by a non-statistically significant 0.38 percent. At end of intervention, the point estimates indicated greater benefit for adults (0.28) than youth (0.00), although neither of these values reached statistical significance. None of the point estimates exceeded the a priori established clinically important difference of 0.4 percent HbA_{1c}.

- The effectiveness of behavioral programs compared with active controls appeared higher for youth than for adults at12-month followup; the effectiveness for youth was clinically important. The small number of studies in most subgroups provided insufficient SOE.
- One trial reported results separately for youth with baseline $HbA_{1c} \geq 8$ percent and found favorable results for this subgroup.
- No trials reported on HbA_{1c} by race or ethnicity, socioeconomic status, or time since diagnosis.

Detailed Synthesis

Age

In KQ 1, we presented our results by age groups (youth and adults). Behavioral programs appeared to be more effective in reducing HbA_{1c} for adults than for youth at end of intervention when compared to usual care (Figure 5); the effect size in the meta-analysis for adults[82,94,95,105,112] was greater in absolute terms than for the youth[83,84,89,93,96,98,99,101,106,108,110] (MD = -0.28 vs. 0.00 respectively); the results for adults approached statistical significance and the 95% CI contained our threshold for clinical importance. At 6-month followup, the effect sizes for youth[84,86,88,93,100,102-104,108,111] and adults[94,109] appeared similar (MD = -0.28 vs. MD = -0.38, respectively); only the results for youth reached statistical significance, although the 95% CIs in both groups included a clinically important effect size favoring behavioral programs. No study in adults reported at 12-month followup; the youth results showed no difference (MD, -0.22; 95% CI, -0.49 to 0.05) although the 95% CI included a clinically important effect for behavioral programs.

When compared with active controls at end of intervention, the effect sizes for youth (MD, -0.33; 95% CI -1.65 to 0.99) and adults (MD, -0.35; 95% CI -0.81 to 0.11) were both similar to the overall effect size and nonsignificant with imprecise 95% CIs. At 6-month followup, the effect size was larger for the youth[92,108] than for the adults[91,107] (MD -0.60 vs. -0.38) but both results failed to reach statistical significance. At 12-month followup, results for youth were statistically significant and clinically important (MD, -0.52; 95% CI, -1.04 to 0.00);[92,108] for adults there was no difference at 12-month followup (MD, -0.14; 95% CI, -1.28 to 1.00).[107].

In the studies that included adults only, the mean age across the studies ranged from 30.3–49.2 years. None of the studies reported results separately for young adults or older adults.

Level of Glycemic Control

One RCT (101 youth) conducted a subgroup analysis of 54 youth with suboptimal baseline glycemic control ($HbA_{1c} \geq 8$ percent).[96] At the end of intervention, Katz et al.[96] found that those receiving the behavioral program had greater odds of maintaining or improving their HbA_{1c} compared with those receiving usual care (odds ratio, 3.4; 95% CI, 1.0 to 11.9). This compares favorably to the overall study results which found no difference in change in glycemic control for the group receiving the behavioral program (MD, 0.30; 95% CI, -0.22 to 0.82). No data were reported for the subgroup of youth with optimal baseline HbA_{1c}. Subgroup analysis at the study level was not conducted because the mean baseline HbA_{1c} was >7 percent for all studies.

Other Subgroups

No data were reported for any of our other pre-specified subgroups: race or ethnicity, socioeconomic status, or time since diagnosis.

Summary of Key Findings and Strength of Evidence for KQ 2

At end of intervention, there was low SOE of no significant difference for both youth and adults, but the effect size appeared greater for adults, approached statistical significance, and its 95% CI included a clinically important value favoring behavioral programs (Table 9). The pooled effect estimate for youth was precise, but there was inconsistency in the individual study results with clinically important effects both for and against behavioral programs. Similar to the SOE when combining studies of youth and adults at 6-month followup (KQ 1), there was moderate SOE showing greater reduction in HbA_{1c} for youth attending behavioral programs compared with usual care. The SOE for adults was low for no difference due to high risk of bias and imprecision (related to low sample size); nevertheless, the 95% CI included a large effect size suggesting there may be some benefit. There were no changes to the SOE at 12-month followup because of the lack of adult studies reporting this data.

Table 9. Type 1 diabetes: summary of key findings and strength of evidence for subgroups (by age) receiving behavioral programs compared with usual care

Outcome	# Trials (# Subjects)	Mean Difference	Strength of Evidence
Youth			
HbA_{1c} (EOI)	11 (653)[83,84,89,93,96,98,99,101,106,108,110]	MD, 0.00; 95% CI -0.33 to 0.33	Low for no significant difference
HbA_{1c} (6m)	10 (1,213)[84,86,88,93,100,102-104,108,111]	MD, -0.28; 95% CI -0.51 to -0.05	Moderate for benefit[a]
HbA_{1c} (12m)	7 (1,333)[83,85,102-104,108,111]	MD, -0.22; 95% CI -0.49 to 0.05	Low for no significant difference
Adults			
HbA_{1c} (EOI)	5 (502)[82,94,95,105,112]	MD, -0.28; 95% CI -0.57 to 0.01	Low for no significant difference
HbA_{1c} (6m)	2 (250)[94,109]	MD, -0.38; 95% CI -0.82 to 0.06	Low for no significant difference
HbA_{1c} (12m)	NR	NR	Insufficient

CI = confidence interval; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; m = month; MD = mean difference
[a]This point estimate did not meet threshold for clinical significance, although the 95% CI included clinically important difference.

For subgroups based on age in comparisons with active controls, the small number of studies (and sample sizes) led to wide pooled 95% CIs which in some cases included values of clinical importance both for and against behavioral programs; because of these factors, the SOE was graded as insufficient in all but two cases (Table 10). In studies of youth with followup to 12 months, there was low SOE of a clinically important benefit for behavioral programs; in studies of adults with 6-month followup, there was low SOE for no difference in HbA_{1c}.

Table 10. Type 1 diabetes: summary of key findings and strength of evidence for subgroups (by age) receiving behavioral programs compared with active controls

Outcome	# Trials (# Subjects)	Mean Difference	Strength of Evidence
Youth			
HbA_{1c} (EOI)	3 (419)[87,92,108]	MD, -0.33; 95% CI -1.65 to 0.99	Insufficient
HbA_{1c} (6m)	2 (208)[92,108]	MD, -0.60; 95% CI -2.56 to 1.36	Insufficient
HbA_{1c} (12m)	2 (195)[92,108]	MD, -0.52; 95% CI -1.04 to 0.00	Low for benefit
Adults			
HbA_{1c} (EOI)	1 (110)[107]	MD, -0.35; 95% CI -0.81 to 0.11	Insufficient
HbA_{1c} (6m)	2 (259)[91,107]	MD, -0.38; 95% CI -0.93 to 0.17	Low for no difference
HbA_{1c} (12m)	1 (110)[107]	MD, -0.14; 95% CI -1.04 to 0.16	Insufficient

CI = confidence interval; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; m = month; MD = mean difference

KQ 3. Potential Moderation of Effectiveness for T1DM: Components, Intensity, Delivery Personnel, Method of Communication, Degree of Tailoring, and Level of Community Engagement

To assess whether the effectiveness of behavioral programs differed based on various program factors (i.e., intensity, delivery personnel, method of communication, degree of tailoring, and level of community engagement), we performed univariate meta-regressions for comparisons between behavioral programs and usual care at longest followup (Table 11). See Table 3 in Methods for our classification scheme. See the Characteristics of Included Studies section for a summary, and the description of interventions for each study in the summary tables in Appendix F.

We did not have enough studies to conduct a multiple variable meta-regression analysis, nor were there sufficient studies for analysis of those comparing behavioral programs with active controls or other behavioral programs. We conducted the analysis for HbA_{1c}; other outcomes did not have sufficient studies (≥10 studies) associated with them to support meaningful analyses. All but one study[105] fell under the category of DSME, therefore we did not conduct a regression analysis on program components.

Key Points

- Program intensity, including duration, contact hours, and frequency of contacts, appeared not to influence program effectiveness; the results were not statistically significant but were very precise (i.e., narrow 95% CIs) for no incremental effect when increasing intensity.
- Although not reaching statistical significance, delivery of programs to individuals appeared beneficial compared with delivery to groups.

Detailed Synthesis

Table 11 summarizes the results of the univariate meta-regressions conduced with 25 studies.[82-86,88,89,93-96,98-106,108-112] Duration of intervention (months), intensity (contact hours) and frequency of contacts were analyzed as continuous variables. Frequency of contacts is a composite variable combining duration and contact hours (contact hours per month). The delivery personnel variable had three categories. The remaining variables were dichotomized as shown in Table 11. The analysis for support persons assessed the impact of programs targeted at youth alone compared with those targeted at both youth and their parents or families; adult

studies[82,94,95,105,109,112] were not included in this analysis. The results indicated that the variables of duration, contact hours, and contact frequency appear not to influence program effectiveness; the coefficients are essentially zero (e.g., an additional month of program duration would not reduce HbA_{1c} to any greater extent) and the 95% CIs are very precise without any indication of potentially producing a clinically important effect considering our threshold of 0.4. Delivery to individuals appears to be beneficial compared with delivery to groups (i.e., positive coefficient indicating switching to group delivery increased HbA_{1c}); the result approached statistical significance and the 95% CI included a value meeting our threshold for clinical importance. Evidence was insufficient for other program factors; the lack of reporting for community engagement precluded any interpretation of the results.

Table 11. Results from univariate meta-regressions analyzing the association between different program factors and the effectiveness of behavioral programs in improving HbA_{1c} for T1DM

Program Factors	# Studies	Coefficient and 95% CI	P value
Duration of intervention (continuous: months)	25	0.01; 95% CI, -0.01 to 0.03	0.462
Intensity (continuous: contact hours)	25	-0.01; 95% CI, -0.02 to 0.01	0.269
Frequency (continuous: hours/month)	25	-0.02; 95% CI, -0.06 to 0.03	0.508
Method of communication (dichotomous: in-person/ mix of in-person & technology)	25	-0.02; 95% CI, -0.30 to 0.26	0.885
Delivery method (dichotomous: individual/ group)	25	0.22; 95% CI, -0.03 to 0.46	0.084
Delivery personnel (3 categories)	25		
Non-health professionals only		-0.12; 95% CI, -0.48 to 0.23	0.479
One health professional		-0.053; 95% CI, -0.39 to 0.28	0.745
Multidisciplinary team		-0.16; 95% CI, -0.42 to 0.095	0.203
Community engagement (dichotomous: present/none or NR)	25	-0.31; 95% CI, -0.65 to 0.025	0.068
Support person present (dichotomous: yes/no)	19	-0.04; 95% CI, -0.40 to 0.33	0.843

CI = confidence interval; NR = not reported

KQ4. Harms for T1DM

No studies reported on the associated harms (i.e. activity-related injury) of behavioral programs.

Type 2 Diabetes Mellitus

This section begins with a description of the results of our literature search and screening, a general description of the included RCTs and the behavioral programs investigated, and a summary of our ROB assessment. We follow this by presenting an overview on the effectiveness of behavioral programs for key outcomes, and then presenting the results for KQs 5 and 6. The results on effectiveness are grouped by outcome category (i.e., clinical, behavioral, and health) and then by comparison group (i.e., usual care, active control, and other interventions [comparative effectiveness]), and postintervention followup timepoint. For this section, results are presented as MD, SMD, or RR, with associated 95% CIs. Where statistical heterogeneity was considered substantial (>50 percent) we report the I^2 Statistic (I^2%). For results on KQs 5 and 6 for which we performed network meta-analysis, we describe the creation of groups (nodes) of interventions, and present the results including the MD and associated 95 percent credibility intervals, the rank order of each node, and a percentage referring to the node's "probability of being best" (PB). The analysis for KQ 6 also included a set of univariate meta-regressions; we present these results in a summary table.

For each KQ, we provide key points and then present a detailed synthesis of the evidence. Table E2 in Appendix E includes the ROB assessments for each RCT. A summary table describing the studies and interventions is included in Appendix F (Table F3). Appendix I contains summary tables of the effectiveness for all outcomes of behavioral programs compared with usual care (Table I1), active controls (Table I2), and other behavioral programs (Table I3). The results for the network meta-analyses for HbA_{1c} in the subgroup analyses for KQ 6 are found in Appendix J. The Supplementary File includes figures (forest plots) of pairwise meta-analyses between behavioral programs and usual care and active control groups, for all outcomes across all timepoints where more than one study reported findings.

Literature Search and Screening

For T2DM, we included 132 primary reports of RCTs,[107,135-265] and 29 associated publications[266-294] (including one abstract)[293] providing information related to the study methodology, outcomes, or description of the interventions (Figure 3). One of the studies was also included in the section on T1DM because it provided data on HbA_{1c} outcomes separately for T1DM and T2DM.[107]

Characteristics of Included Studies

The majority of RCTs were two-arm trials with the following comparisons: 1) DSME with usual care (55 trials)[135,136,138-143,147,149,153,155,158,162,163,171,173,176-179,183,187,193-197,203,206,211,213,215,218-220,223-226,228,229,231,233,235,238,242,245-247,253,257-260] or an active control (7 trials),[146,154,181,182,198,201,202] 2) DSME and support with usual care (8 trials)[151,189,207,208,210,216,217,222] or with an active control (1 trial),[164] 3) lifestyle programs with usual care (18 trials)[137,143,145,157,160,167,190,205,236,239,240,249,251,254,255,261-263] or an active control (7 trials),[156,161,165,166,169,186,252] and, 4) between two behavioral programs (21 trials).[144,150,152,159,170,172,180,185,188,199,204,209,212,221,232,237,243,244,248,250,256,264] Thirteen three-arm RCTs were included, with eight comparing behavioral programs with usual care,[188,200,214,234,241] or active control,[168,192,230] and five having one intervention arm compared with two controls.[107,174,175,184,265] Three four-arm trials[148,191,227] examined (1) two lifestyle programs compared with two dietary interventions,[148] (2) one lifestyle program compared with two active controls (dietary and physical activity interventions) and a usual care arm,[191] and (3) the comparative effectiveness between DSME and three DSME and support programs delivered by different personnel.[227] Trials were conducted in 16 countries but the majority (63 percent) were undertaken in the United States. The primary reports of nine RCTs (7.3 percent) were published prior to the year 2000,[137,140,159,165,204,213,232,245,251] and 57 (46 percent) were published since 2010.[107,135,139,146,148,152-155,162,164,167,168,170-173,175,179,181,182,191,193,194,198,199,201,202,206-211,214,216-219,221,224,227,228,233,234,236,237,240-242,244,247-249,252,253,256]

The mean age of the participants was between 45 and 72 years (median=58). Six studies did not report age.[139,160,193,224,242,245] The percentage of males ranged from 0–100 percent (median=40 percent). The proportion of nonwhite participants was between 0 and 100 percent; the majority (≥75 percent) of participants in 32 trials reported nonwhite race/ethnicity,[137,141,143,151,153,162,171,179,188,189,195,197,205-208,210,215-219,222,228,229,231,233,240,246,247,257,262] and 9 trials included few (<10 percent) people of nonwhite race /ethnicity.[149,183-185,212,239,249,251,256] Baseline HbA_{1c} was between 6.3 and 12.3 percent (median=8 percent); five trials did not report this information.[138,238,242,245,251] Median duration of diabetes was 8.1 years (range 1-18 years). The median percentage of participants prescribed treatment with insulin was 19.5 percent; one study assessed the effectiveness of a lifestyle program in a sample of patients who were all initiated on insulin therapy,[145] and another

studied a DSME program in patients receiving ongoing intensive insulin treatment.[181] Body mass index ranged from 23.8–39.1 kg/m^2 (median=33.0 kg/m^2).

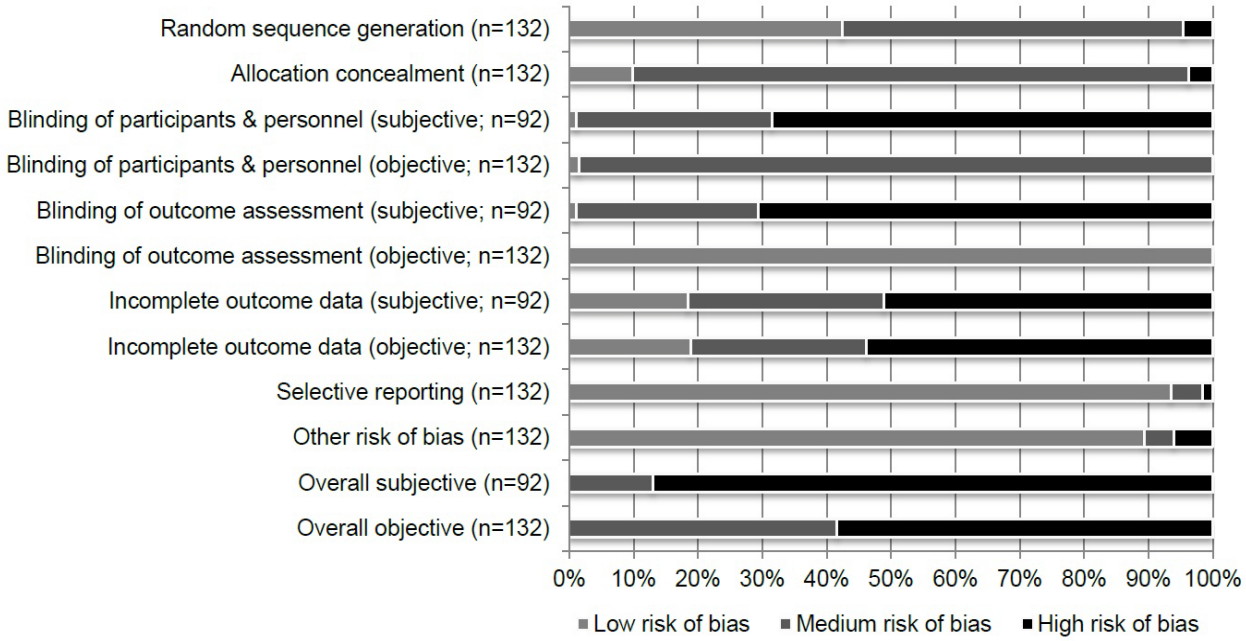
Table F3 in Appendix F includes details on each behavioral program studied. Several trials evaluated more than one behavioral program; there were 166 intervention arms in total. Overall, median program duration was 6 months (range 1–96) and median number of contact hours was 12 (range 1–208). Technology was the primary method of communication for 17 programs studied in 16 trials,[138,139,147,167,171,179,185,187,194,241,247,253,258,259,264,265] and was used alone or in combination with in-person communication in 42 programs; based on our inclusion criteria, all programs were delivered with some form of communication with delivery personnel. Sixty-four programs were delivered to individuals only, 56 to groups only, and 44 had some mixture of individual and group delivery (see Table F3 for details). Half (83 of 166; 50 percent) of programs were delivered by one health care professional, with (n=16) or without (n=67) the assistance of a non-health care professional; other programs were delivered by a multidisciplinary team (48 arms; 29 percent) or solely by non-health care professionals (31 arms; 19 percent) (see Table F3). Data on the delivery personnel could not be determined for two studies.[187,236]

Risk of Bias of Individual Studies

A summary of the ROB assessments for the 132 trials is presented in Figure 18; the consensus assessments for all domains in each study are presented in Appendix E. All trials were assessed as having a medium (unclear) or high overall ROB. For objective outcomes (e.g., HbA_{1c}, weight, blood pressure), 42 percent of trials had a medium ROB and 58 percent had a high risk. The assessment of high ROB was largely driven by incomplete outcome data (i.e., loss to followup). For trials (n=92) reporting on subjective outcomes of interest for this review (e.g., HRQL, depression), 13 percent had a medium ROB; the remainder (87 percent) had a high ROB. This was primarily due to lack of blinding of participants, study personnel, and outcome assessors (see Methods section and the Supplementary File for a description of decision rules for these assessments).

Twenty-four trials (18 percent) received funding from industry. One-hundred-six (80 percent) received funding from non-industry sources (e.g., government or foundations); of these, 15 (11 percent) received funding from both industry and non-industry sources. Funding was not reported for seven (0.5 percent) studies.

Figure 18. Risk of bias summary for trials of behavioral programs for type 2 diabetes



Effectiveness of Behavioral Programs Across Outcomes

We report on the overall effectiveness of behavioral programs before describing our results for KQs 5 and 6. This serves to summarize the findings on outcomes that did not contribute to the analyses for KQ 5 or 6, and to provide information for interpreting the results for KQs 5 and 6. We provide a summary of the results for our key outcomes, based on outcome category, comparison group, and timepoint. Because several trials studied more than one behavioral program, results are usually characterized by the number of comparisons rather than trials. The results for all outcomes are presented in summary tables in Appendix I; Table I1 contains results for behavioral programs compared with usual care and Table I2 contains those for comparisons with active controls. Most of these results are based on meta-analyses for two or more comparisons, and we indicate when no outcome data were available. Behavioral programs are not analyzed based on their components for these analyses; KQs 5 and 6 focused on potential moderation in effect by program components and other factors. Table I3 contains the results for key outcomes at longest followup (i.e., up to 12 months) from studies reporting on comparative effectiveness between different behavioral programs. This table is organized by outcome category and is grouped by comparisons in the manner the behavioral programs differed (e.g., comparing delivery personnel or intensity).

Key Clinical Outcomes: HbA_{1c} and Change in Body Composition

HbA_{1c}

Individuals receiving behavioral programs compared with usual control improved their glycemic control (i.e., reduced percent HbA_{1c}) at end of intervention (66 comparisons; 8,715 subjects; MD, -0.35; 95% CI, -0.56 to -0.14;

I^2=74%),[135,137,139,141,142,145,147,151,153,155,160,162,171,173,175-177,179,184,188-191,197,203,205-208,210,213-220,222-226,228,229,231,233,236,239-241,247,249,253-255,257-262,265] but not at 6-month (23 comparisons; 4,138 subjects; MD, -0.16; 95% CI, -0.36 to 0.04; I^2=61%)[136,140,143,146,163,173,178,183,193-196,211,215,229,234,235,241,246,249,259] or 12-month followup (9 comparisons; 1,494 subjects; MD, -0.14; 95% CI, -0.4 to 0.12; I^2=59%).[146,158,163,173,178,193,223,234] The results were of a smaller magnitude when behavioral programs were compared with active control groups at end of intervention (25 comparisons; 7,518 subjects; MD, -0.24; 95% CI, -0.41 to -0.07; I^2=70%).[107,154,161,164-166,168,169,174,175,184,186,191,192,198,202,230,252,265] For 6-month followup, the effect size was similar but the results reached statistical significance (6 comparisons; 595 subjects; MD, -0.19; 95% CI, -0.37 to -0.01).[107,156,181,182,201] The estimate was nonsignificant and imprecise at 12-month followup (6 comparisons; 486 subjects; MD, -1.10; 95% CI, -2.56 to 0.36).[107,164,192,201] No result was clinically important based on our prespecified threshold of 0.4 unit change in percent HbA_{1c}. The meta-analyses for HbA_{1c} indicated high heterogeneity in effect between studies across timepoints (I^2 ranged from 61–98 percent). As described in the Methods, we performed sensitivity analyses to explore this issue; however, none of the prespecified variables reduced the heterogeneity to below 50 percent so we present the original results.

In three trials (701 subjects) providing comparative effectiveness between DSME delivered to groups compared with delivery to individuals or via a mixture of individual and group delivery, there was a beneficial effect for those individuals receiving DSME in groups at up to 12-months followup (MD, -0.36; 95% CI, -0.63 to -0.08).[192,212,234] In contrast, there was a benefit at end of intervention shown in a trial comparing individual DSME and motivational interviewing with group-based empowerment DSME and supervised group exercise (143 subjects; MD, -0.30; 95% CI, -0.58 to -0.02).[244] Several comparative effectiveness studies found no difference in HbA_{1c} changes between groups. Some examples include the addition of an additional treatment (e.g., problem solving therapy,[168] music therapy[199]) or a support aspect to a DSME or lifestyle program;[172,227,230] others include comparisons between peer and health professional delivery of a program component (see Appendix I).[144,172,227,256]

Six trials reported on HbA_{1c} but did not provide data suitable for inclusion in the meta-analysis. Five trials comparing a behavioral program with usual care did not find a significant difference between groups.[149,157,167,187,200] One trial comparing two behavioral interventions with different delivery methods also found no difference between groups.[159]

Visualization of funnel plots did not suggest publication bias, and using the Egger test[78] for this outcome resulted in no significant indication of bias for comparisons with usual care (p=0.25) or active controls (p=0.21) at end of intervention.

Change in Body Composition

Compared with usual care, behavioral programs assisted participants in reducing their BMI ($kg \cdot m^{-2}$) at all three timepoints—end of intervention (36 comparisons; 4,280 subjects; MD, -0.51; 95% CI, -0.66 to -0.36),[135,137,139,145,151,153,155,162,171,175,179,184,189,190,206,208,210,214,215,224,226,233,239-242,246,249,251,255,257,259-61] 6-month followup (14 comparisons, 1,840 subjects; MD, -0.21; 95% CI, -0.32 to -0.1),[136,143,146,163,183,193,211,215,241,246,249,251,259] and 12-month followup (5 comparisons; 867 subjects; MD, -0.92; 95% CI, -1.44 to -0.4).[146,157,163,193,238] When compared to active controls, behavioral programs did not reduce BMI at any followup timepoint. Body weight (kg) was reduced at end of intervention in those receiving behavioral programs compared with those receiving usual care (37 comparisons; 4,070 subjects; MD, -1.68; 95% CI, -2.06 to -1.30),[137,141,145,147,153,160,167,176,178,184,188,190,191,200,203,205,213,214,217,222,224-226,239,246,249,254,258-263,265] or

active control (15 comparisons; 6,212 subjects; MD, -1.30; 95% CI, -2.48 to -0.12; I^2=78%).[148,154,165,166,169,174,184,186,191,198,202,252,265] There was no reduction in weight at other timepoints; one trial showed an increase in weight at 12-month followup for the behavioral program compared with active control arm (95 subjects; MD, 3.70; 95% CI, 1.67 to 5.73).[201] Waist circumference (cm) was reduced at end of intervention (17 comparisons, 1,521 subjects),[145,153,162,167,190,203,214,215,224,226,241,254,255,259,261] in those comparisons with usual care—MD = -3.17 (95% CI, -4.36 to -1.98; I^2=64%). One study found significant reduction in waist circumference at 6-month followup for those receiving a behavioral program compared to an active control (38 subjects; MD, -5.70; 95% CI, -6.54 to -4.86).[156] There was no difference found in two studies comparing behavioral programs to usual care at 12-month followup;[157,163] no data were available at 12-month followup for studies comparing behavioral programs to active control.

One comparative effectiveness trial (99 subjects) found that BMI was reduced (MD, -1.80; 95% CI, -2.51 to -1.09) at end of intervention for individuals receiving a cognitive-behavioral-therapy based lifestyle program including a portion-controlled diet compared with DSME including a meal plan.[170] Participants in this study who received the lifestyle program also reduced their weight and waist circumference more than those receiving the DSME program—MD = -5.10kg (95% CI, -7.22 to -2.98) and MD = -3.60cm (95% CI, -5.33 to -1.87), respectively.

Behavioral Outcomes: Change in Dietary Intake and Physical Activity; Medication Adherence

Participants receiving behavioral programs compared with usual care reduced their energy intake (daily intake of kilocalories) to a small extent at end of intervention (11 comparisons; 1,164 subjects; MD, -149.62; 95% CI, -243.01 to -56.23; I^2=68%)[135,137,155,167,188,191,215,216,245,261] and 6-month followup (3 comparisons; 469 subjects; MD, -64.05; 95% CI, -96.44 to -31.66).[163,167,215] There was no significant change at any timepoint in energy intake for comparisons with active controls, and no effect reached statistical significance for percent kilocalories from saturated fat.

Changes in intensity/duration of physical activity were measured by subjective (e.g., days per week in most cases) and objective (via accelerometers) means. Fifty percent of the studies reporting days per week of physical activity used the Summary of Diabetes Self-care Activities (SDSCA) questionnaire. Two trials (382 subjects) found that participants of behavioral programs increased the number of days per week of physical activity to a greater extent than those in usual care arms at 12-month followup (MD, 0.90; 95% CI, 0.90 to 0.90).[163,238] These and several other trials[138,163,184,219,226,236,238-240,253] did not find any difference at end of intervention or 6-month followup. One trial with 40 participants showed a negative affect for a behavioral program compared with an active control at end of intervention (MD, -1.06; 95% CI, -1.82 to -0.31).[184] There was no difference reported for objective measurements of exercise duration/intensity (7 comparisons), or for measures of fitness (5 comparisons) in trials comparing behavioral programs to usual care or active controls.

Two comparative effectiveness trials found significant benefit for changes in physical activity. Based on self-report of days per week of engaging in moderate-to-intense physical activity, Vadstrup et al.[244] found improvement (121 subjects; MD, 1.30; 95% CI, 0.80 to 1.80) for the group provided individual DSME and motivational interviewing compared with group-based empowerment DSME and supervised group exercise. Using the Modified Canadian

Aerobic Fitness Test which estimates relative maximal oxygen consumption, Plotnikoff et al.,[209] found improved fitness levels from supplementing DSME and support with a physical activity intervention (88 subjects; SMD, 0.62; 95% CI, 0.19 to 1.05).

Measurement of medication adherence was undertaken using various tools including the SDSCA,[138,171] the Hill-Bone Compliance Scale,[168,175] and the Morisky Adherence Scale.[253] A significant effect for medication adherence—in favor of the usual care group—was maintained from end of intervention to 12-month followup in one trial (191 subjects; SMD, -0.50; 95% CI -0.79 to -0.21);[238] other studies comparing behavioral programs to usual care found no difference at end of intervention or 6-month followup. Comparisons with active controls also found no difference at any followup timepoint.

Health Outcomes: Quality of Life, Micro- and Macrovascular Complications, All-Cause Mortality

Quality of Life

Outcomes for quality of life were categorized into five subcategories based on their focus (i.e., generic vs. diabetes-specific) and the similarity between studies in measurement scales. Groups of studies reported outcome data based on the SF-36 Health Survey (physical and mental component scores), and the Problem Areas in Diabetes (PAID) scale (0–100; lower score favorable) measuring diabetes distress. Accordingly, three of our subcategories represent these tools (i.e., Quality of Life–SF36 Physical, Quality of Life–SF36 Mental, and Diabetes Distress), for which we present results as MD. Other subcategories were created to combine other generic (Quality of Life–Other; e.g., WHO Quality of Life Brief, W-BQ12, EuroQol 5D) and diabetes-specific (Diabetes-specific Quality of Life; e.g., Diabetes Quality of Life, Diabetes Distress Scale, Appraisal of Diabetes, Diabetes Symptom Checklist) quality of life questionnaires; these results are presented as SMDs.

There was no difference in Quality of Life-SF36 (Physical) or Quality of Life-SF36 (Mental) when measured at end of intervention for comparisons with usual care,[155,214,222,239] or up to 6-months followup for comparisons with active controls.[169,181,252] There was no difference found for Quality of Life–Other in comparisons (n=7) with usual care up to 6-month followup,[195,196,206,226,249,253] or in comparisons (n=4) with active controls up to 12-months followup.[154,192] Results favored behavioral programs compared with usual care for Diabetes Distress (8 comparisons, 1,384 subjects) at end of intervention (MD, -1.82; 95% CI, -3.43 to -0.21),[142,147,211,218,225,226,228,233] but not at longer followup.[146,211,234] The result at end of intervention is not clinically important based on our prespecified threshold of a 0.5 SD using the mean SD of the included studies. One study (167 subjects) evaluating this outcome in a comparison to active controls found no difference at 6-month followup.[181] There was no difference in Diabetes-specific Quality of Life at any followup timepoint to 12-month followup when comparing behavioral programs to usual care,[146,163,175,177,189,215,253] or at end of intervention for programs compared with active controls.[154,168,175]

One trial assessed the effects on quality of life when the support phase of a DSME and support program was delivered by peers, clinical practice staff, or health care professionals (diabetes educators). Siminerio et al.[227] found that Diabetes Distress worsened for the group receiving support from peers when compared to the group receiving support from the educators (74 subjects; MD, 24.70; 95% CI, 15.02 to 34.38). This effect is considered clinically important.

There was no difference in Diabetes Distress when delivery of nonprofessional clinic staff was compared to that by health care professionals.

Micro- and Macrovascular Complications

Authors of the LookAHEAD trial (5,145 subjects) studied outcomes of myocardial infarctions, stroke, heart failure, diabetic nephropathy, diabetic retinopathy, and diabetic neuropathy. Diabetic retinopathy was reduced by 14% (hazard ratio, 0.86; 95% CI, 0.75 to 0.98) in participants receiving their intensive lifestyle program compared with an active control (didactic education and support) over a median of 8 years.[278] A secondary analysis of nephropathy using a post hoc outcome of very-high-risk chronic kidney disease—a combination of the a priori outcomes albuminuria and estimated glomerular filtration rate, found a lower incidence of nephropathy for the intensive lifestyle program at the 8 year end-of-intervention timepoint (risk difference 0.27 cases per 100 person-years; hazard ratio, 0.69; 95% CI, 0.55 to 0.87).[293] Results for the other outcomes in this trial did not reach statistical significance—myocardial infarction (RR, 0.86; 95% CI, 0.70 to 1.05), stroke (RR, 1.06; 95% CI, 0.79 to 1.44), heart failure (RR, 0.83; 95% CI, 0.64 to 1.08), and diabetic neuropathy (RR, 1.13; 95% CI, 0.92 to 1.38).

All-Cause Mortality

One study examined all-cause mortality as an pre-specified outcome;[252] there were enough data in 27 reports to calculate a difference in all-cause mortality for the associated comparisons. There was no difference in all-cause mortality between participants receiving behavioral programs and usual care (25 comparisons; 4,659 subjects; RR, 1.28; 95% CI, 0.84 to 1.94); mortality between behavioral programs and active control groups (5 comparisons, 6,050 subjects) was 14 percent lower for those receiving behavioral programs (RR, 0.86; 95% CI, 0.77 to 0.96).

KQ 5. Potential Moderation of Effectiveness for T2DM: Components, Intensity, Delivery Personnel, Method of Communication, Degree of Tailoring, and Level of Community Engagement

Key Points: HbA_{1c}

- In a network meta-analysis with usual care serving as the reference, behavioral programs showing effect sizes above our threshold for clinical importance represented all three major program component categories of DSME, DSME and support, and lifestyle.
- The effect sizes of all minimally intensive DSME programs (≤10 contact hours) were lower than our threshold for clinical importance, but were all higher than that for educational interventions not meeting our criteria for a behavioral program (e.g., didactic education programs).
- Programs having the higher effect sizes and probabilities of being best (≥5 percent) were more often delivered in person rather than including technology.

Key Points: Body Mass Index

- Lifestyle programs resulted in the highest effect sizes for BMI.
- Program intensity appeared less important than method of delivery; providing some individual (rather than solely group-based) delivery appears beneficial.

Detailed Synthesis

We conducted network meta-analyses for the outcomes of HbA_{1c} and BMI. These outcomes represent two of our key outcomes that were reported by the most studies. Tables 12 (HbA_{1c}) and 13 (BMI) provide descriptions of the nodes (no two containing the same combination of variables), and include the results including the rank order of each node, the MD relative to usual care, the associated 95 percent credibility interval, and a percentage referring to the node's "probability of being best" (PB). These tables also indicate which studies contributed to each node, with the sample size of the applicable study arms, although it should be noted that the network approach accounts for direct and indirect comparisons such that other information contributes to the results. We summarize our approach and the results for each outcome below. Figures 19 and 20 contain the plots showing the relative ranking of the different nodes; the studies within each node are cited in the accompanying tables. A consistency analysis was performed for the HbA_{1c} analysis and it was found that only two quadratic loops (of a total of 43 total quadratic and triangular loops) showed statistically significant inconsistency.

HbA_{1c}

Accounting for all variables of program components and delivery variables (Table 3) when creating the network was deemed not appropriate for various reasons. When choosing which variables to use, we prioritized them by considering factors including the: reliability and specificity with which we could categorize programs in each variable based on extent of reporting, overlap in meaning between variables, and the ability to inform those individuals making decisions to implement these programs in community settings. Deciding between program duration (months) and intensity (contact hours), the latter was chosen because it accounts for duration to some extent, aligns with our focus on interactive programs, and better enables one to estimate resource requirements in terms of personnel and space. Degree of tailoring was not chosen because every program incorporated this to some extent and categorizing this (e.g., minimal versus moderate in terms of content and delivery) was considered unreliable based on study reporting. Moreover, the use of technology (captured in the delivery method variable) was also considered a way to tailor the program to individuals, particularly in cases of poor access due to travel or time constraints. The level of community engagement was also not used because, when incorporated, this was largely via use of lay or peer providers which was captured in the delivery personnel variable. The remaining variables were placed in order (program components, program intensity, method of communication, method of delivery, and delivery personnel) and we then created nodes trying to incorporate as many variables as possible without having numerous nodes either empty (a theoretical grouping of variables that did not represent a studied program), or with only one or two programs. Dividing the data by the first variable of program components (DSME, DSME and support, and lifestyle) resulted in a relatively large number of DSME comparisons. For this group, we were able to use all five variables to create 24 potential nodes (18 which contained comparisons). We did not capture the variable of delivery personnel for the DSME and support, and lifestyle groups because most nodes would in this case contain at most one comparison.

When interpreting the results, we relied primarily on the relative ranking of the nodes, and looked for trends in the findings based on program variables that appeared to determine whether the effects would offer clinical benefit. Some nodes had very few studies, small sample sizes, and/or wide credibility intervals, thus we did not make any firm conclusions for a single node (or for differences in 561 potential comparisons) but rather from looking across nodes with similar features.

The results of the network meta-analysis indicated that, in comparison to the reference of usual care, 14 nodes produced MDs which fell at or above our clinically important threshold (0.4) for change in percent $HbA_{1c.}$ Four of these nodes represent DSME, five represent DSME and support, and five represent lifestyle programs. Six nodes represent medium-intensity programs (11–26 contact hours), six represent high-intensity programs (≥26 contact hours), and two (one DSME and support, and one lifestyle) represent low-intensity programs (≤10 contact hours). The mean contact hours for the programs represented by these effective nodes was 26.4 (range 7-40.5 hours); the mean total program duration was 8 months (range 2-12). None of the nodes representing low-intensity DSME programs showed clinically important effects; all had greater impact on HbA_{1c} than basic educational controls, but lower impact than a stand-alone dietary or physical activity intervention. Three of four nodes representing DSME programs with MDs showing clinically important effect were delivered by health care professionals.

Eleven of the 14 nodes representing clinically important effects were delivered in person rather than incorporating some form of technology. Behavioral programs in the nodes with the highest PB (36 and 10.7 percent, respectively) were delivered in person rather than by incorporating technology. Similar observations were noted for the other four nodes having PB≥5 percent, of which three were delivered in person and one was delivered using some form of technology; the latter group of studies provided supportive telephone calls between in-person sessions during lifestyle interventions tailored to minorities.[143,160] All effective nodes representing some use of technology were of moderate or high intensity.

An outlier having an MD of 2.80 (95% CI, 1.14 to 4.48) represented a study by Brown et al.[152] which found greater HbA_{1c} reduction at end of intervention in a group receiving DSME compared with one receiving DSME with the addition of a care manager.

Body Mass Index

We created nodes using four variables for BMI (i.e., program component, program intensity, method of communication, and method of delivery). Of the 39 plausible nodes (each differing by only one level of one variable), there were studies with data to populate 26 nodes.

Averaging the baseline values in the studies, BMI at baseline was similar for programs classified as DSME (32.4 $kg{\cdot}m^2$), DSME and support (33.0 $kg{\cdot}m^2$), and lifestyle (32.9 $kg{\cdot}m^2$). The effect sizes for BMI from behavioral programs relative to usual care ranged between -1.77 $kg{\cdot}m^2$ and 3.29 $kg{\cdot}m^2$. The node with the most beneficial MD only represented one study[157] evaluating a low-intensity lifestyle program with multiple brief contacts over 6 months. Nodes with rank orders 2 and 3 were both lifestyle programs of low and medium intensity, respectively. The node having the most studies (n=12) represented a DSME program of medium intensity (11–26 hours) which was delivered in person to groups; the results indicated this program to have 0 percent PB. One difference between the programs in this node and those with higher PB is that the higher PB all offered some individual delivery, rather than relying only on group delivery. Likewise, the majority of nodes having the highest MDs (i.e., 8 of the highest 10) offered some individual delivery.

Table 12. Network meta-analysis for effect moderation on HbA_{1c} results in T2DM: description of nodes and results

Arm Description	Rank Order of Effect, Studies & Sample Size of Study Arms	Intensity	Method of Communication	Delivery Method	Delivery Personnel	MD (%HbA_{1c}), 95% Credibility Interval	Probability of Being Best
Usual care (reference category)	**NA**[135-137,139-143,145,147,151,153,155,158,160,162,163,171,173,175-179,183,184,188-191,193-197,203,205-208,210,211,213-220,222-226,228,229,231,233-236,238-241,246,247,249,253-255,257-262,265] N = 6,448	NA	NA	NA	NA	0 [NA, NA]	0.0%
Active comparator (non-DSME)	**31**[107,146,154,164,168,169,175,181,182,184,192,198,201,252,265] N = 3,913	NA	NA	NA	NA	0.10 [-0.23, 0.43]	0.0%
Active comparator (other)	**15**[156,161,165,166,174,186,191,202,230] N = 241	NA	NA	NA	NA	-0.39 [-0.89, 0.10]	0.0%

Table 12. Network meta-analysis for effect moderation on HbA_{1c} results in T2DM: description of nodes and results (continued)

Arm Description	Rank Order of Effect, Studies & Sample Size of Study Arms	Intensity	Method of Communication	Delivery Method	Delivery Personnel	MD (%HbA_{1c}), 95% Credibility Interval	Probability of Being Best
DSME	**19**[135,153,154,178,185,212,225,231,234,238,243,244,257] N= 1,161	≤10h	In person	Individual & mixed	HCP	-0.29 [-0.61, 0.04]	0.0%
	22[107,144,146,172,173,182,199,211,212,234] N = 1,160	≤10h	In person	Group only	HCP	-0.22 [-0.61, 0.16]	0.0%
	29[144] N = 40	≤10h	In person	Group only	Non-HCP	-0.05 [-1.27, 1.16]	0.9%
	27[171,175,179,185,203,226,241,259,265] N = 532	≤10h	Some technology	Individual & mixed	HCP	-0.11 [-0.50, 0.27]	0.0%
	26[168,176,177,183,194,218-220,247,253] N = 1,679	≤10h	Some technology	Individual & mixed	Non-HCP	-0.16 [-0.53, 0.21]	0.0%
	24[192,206,213] N = 222	11-26h	In person	Individual & mixed	HCP	-0.17 [-0.81, 0.47]	0.0%
	21[136,141,155,158,163,170,181,192,193,199,223,224,235,243,260,264] N = 1,216	11-26h	In person	Group only	HCP	-0.25 [-0.53, 0.04]	0.0%
	20[195,196,228,229,246] N = 531	11-26h	In person	Group only	Non-HCP	-0.27 [-0.76, 0.21]	0.0%
	25[139,142,147,162,258] N = 611	11-26h	Some technology	Individual & mixed	HCP	-0.17 [-0.66, 0.31]	0.0%
	5[197,233] N = 159	11-26h	Some technology	Individual & mixed	Non-HCP	-0.78 [-1.57, 0.02]	3.7% [a]
	28[293] N = 46	11-26h	Some technology	Group only	HCP	-0.09 [-1.39, 1.20]	1.5%
	7[215] N= 15	≥27h	In person	Individual & mixed	HCP	-0.73 [-1.86, 0.41]	8.1% [a]
	1[201,202,244] 271	≥27h	In person	Group only	HCP	-1.37 [-2.03, -0.71]	36.0% [a]
	11[198] N = 30	≥27h	Some technology	Individual & mixed	HCP	-0.49 [-1.69, 0.70]	4.0% [a]

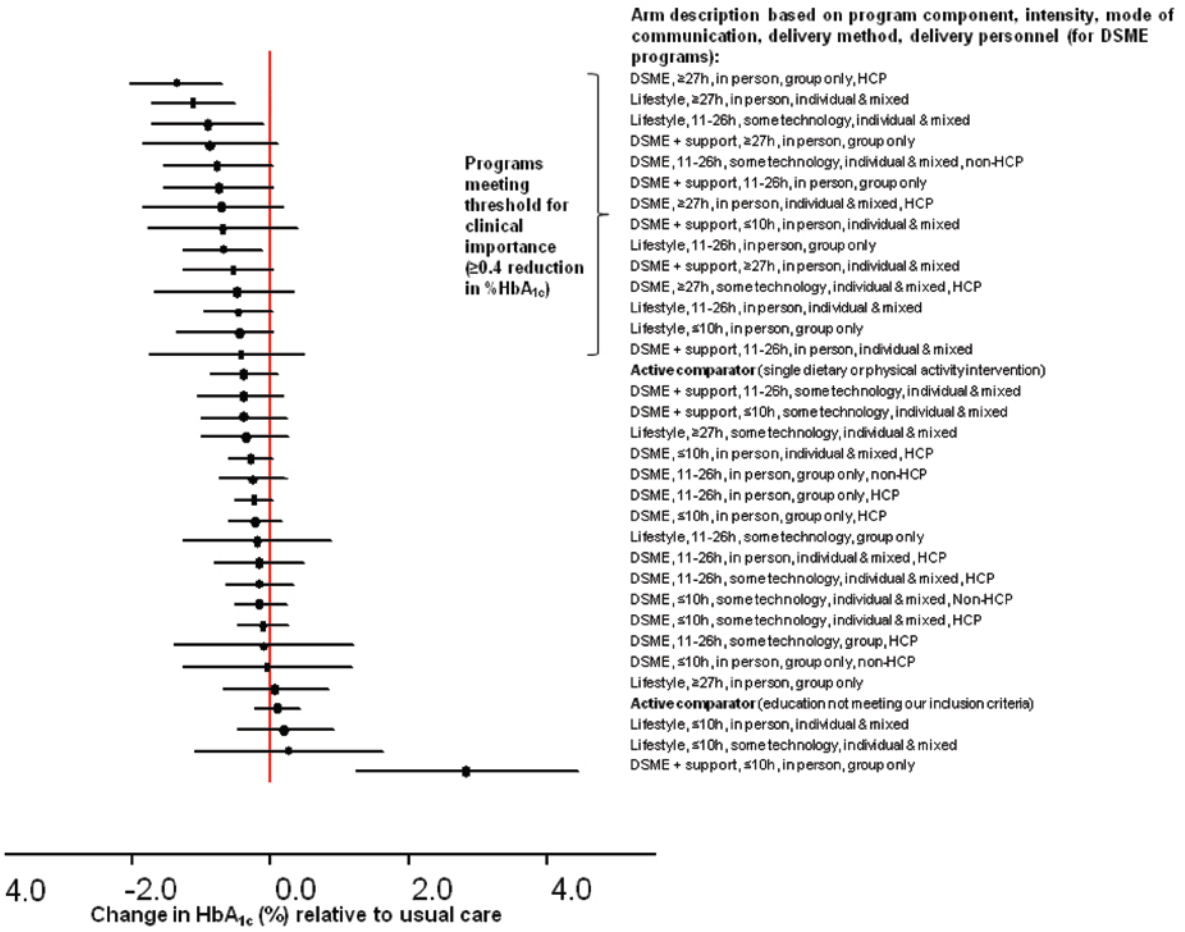
Table 12. Network meta-analysis for effect moderation on HbA_{1c} results in T2DM: description of nodes and results (continued)

Arm Description	Rank Order of Effect, Studies & Sample Size of Study Arms	Intensity	Method of Communication	Delivery Method	Delivery Personnel	MD (%HbA_{1c}), 95% Credibility Interval	Probability of Being Best
DSME + Support	**8**[210] N = 90	≤10h	In person	Individual & mixed	NA	-0.70 [-1.80, 0.40]	6.8% [a]
	34[152] N = 48	≤10h	In person	Group only	NA	2.83 [1.22, 4.43]	0.0%
	17[172,207,230] N = 334	≤10h	Some technology	Individual & mixed	NA	-0.38 [-0.99, 0.23]	0.0%
	14[164] N = 52	11-26h	In person	Individual & mixed	NA	-0.44 [-1.76, 0.86]	4.8% [a]
	6[150,208,209] N = 267	11-26h	In person	Group only	NA	-0.74 [-1.56, 0.08]	2.8% [a]
	16[152,189,209,222] N = 240	11-26h	Some technology	Individual & mixed	NA	-0.39 [-1.06, 0.28]	0.1%
	10[216,217] N = 197	≥27h	In person	Individual & mixed	NA	-0.54 [-1.28, 0.20]	0.8% [a]
	4[150,151] N = 230	≥27h	In person	Group only	NA	-0.88 [-1.86, 0.09]	9.4% [a]
Lifestyle	**32**[145,188,249] N = 171	≤10h	In person	Individual & mixed	NA	0.20 [-0.50, 0.92]	0.0%
	13[156,186] N = 44	≤10h	In person	Group only	NA	-0.45 [-1.35, 0.45]	0.9% [a]
	33[188] N = 67	≤10h	Some technology	Individual & mixed	NA	0.25 [-1.11, 1.62]	0.5%
	12[165,184,190,191,232,236] N = 138	11-26h	In person	Individual & mixed	NA	-0.47 [-0.99, 0.05]	0.0% [a]
	9[169,170,205,232,255] N = 161	11-26h	In person	Group only	NA	-0.69 [-1.25, -0.12]	0.5% [a]
	3[143,160] N = 76	11-26h	Some technology	Individual & mixed	NA	-0.91 [-1.72, -0.10]	7.4% [a]
	23[254] N = 74	11-26h	Some technology	Group only	NA	-0.20 [-1.28, 0.88]	0.9%
	2[137,161,174,214,261] N = 233	≥27h	In person	Individual & mixed	NA	-1.12 [-1.72, -0.53]	10.7% [a]
	30[239,240] N = 305	≥27h	In person	Group only	NA	0.07 [-0.67, 0.83]	0.0%
	18[166,252,262] N = 2643	≥27h	Some technology	Individual & mixed	NA	-0.37 [-1.01, 0.27]	0.1%

DSME = diabetes self-management education; h = hour(s); HbA_{1c} = hemoglobin A_{1c}; HCP = health care professional; MD = mean difference; NA = not applicable

[a] Highlighted rows represent those nodes having effect sizes meeting or exceeding our criteria for clinical importance.

Figure 19. Plot of network meta-analysis results for effect moderation on HbA_{1c} in T2DM



This plot depicts the results from our network meta-analysis for the outcome of HbA_{1c} (negative values favorable) when comparing groups ("nodes") of interventions, with each group differing by at least one level in the categories of program component, intensity, mode of communication, delivery method, and (for DSME programs only) delivery personnel (see Table 3 for categorization schema and the figure legend for a description of each node). The dots and lines represent the mean difference (MD) and 95 percent credibility intervals for the represented programs relative to usual care; the figure indicates which MDs meet or exceed our predetermined threshold for clinical importance (reduction in HbA_{1c} of ≥0.4%). The estimated MDs and 95% credibility intervals are included in Table 12.

Table 13. Network meta-analysis for effect moderation on body mass index results for T2DM: description of nodes and results

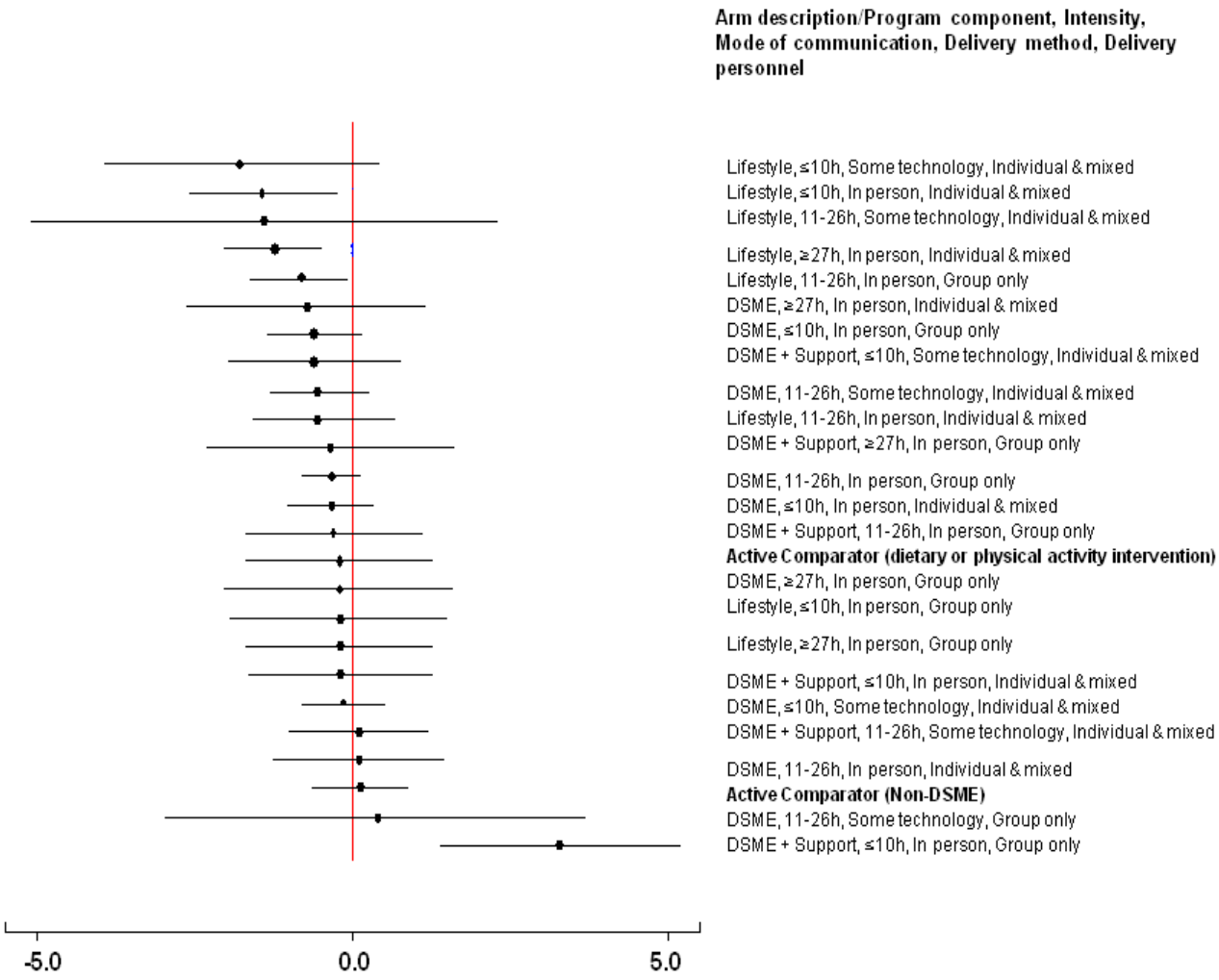
Arm Description	Rank Order of Effect, Studies & Sample Size of Study Arms	Intensity	Method of Communication	Delivery Method	MD ($kg \cdot m^{-2}$), 95% Credibility Interval	Probability of Being Best
Usual care (reference category)	**NA**[135-137,139,141,143,145,151,153,155,157,162,163,171,173,175,179,183,184,189,190,193,206,208,210,211,214,215,224,226,233,238-242,246,249,251,255,257,259-261] N = 3,341	NA	NA	NA	0 [NA, NA]	0.0%
Active comparator (non-DSME)	**23**[146,154,169,175,184,192] N = 684	NA	NA	NA	0.13 [-0.64, 0.88]	0.0%
Active comparator (other)	**15**[156,174,186,202] N = 99	NA	NA	NA	-0.21 [-1.69, 1.26]	0.1%
DSME	**13**[135,153,154,212,238,257] N = 629	≤10h	In person	Individual & mixed	-0.32 [-1.03, 0.33]	0.0%
	7[146,172,173,199,211,212] N = 771	≤10h	In person	Group only	-0.61 [-1.37, 0.17]	0.1%
	20[171,175,179,183,226,241,259] N = 470	≤10h	Some technology	Individual & mixed	-0.14 [-0.81, 0.53]	0.0%
	22[192,206] N = 194	11-26h	In person	Individual & mixed	0.10 [-1.27, 1.47]	0.1%
	12[136,141,155,163,170,192,193,199,224,246,260,264] N = 939	11-26h	In person	Group only	-0.33 [-0.80, 0.12]	0.0%
	9[162,233,242] N = 379	11-26h	Some technology	Individual & mixed	-0.55 [-1.29, 0.25]	0.1%
	24[264] N = 15	11-26h	Some technology	Group only	0.38 [-2.97, 3.72]	5.2%
	16[139,215] N = 161	≥27h	In person	Group only	-0.21 [-2.03, 1.60]	1.8%
	6[202] N = 3	≥27h	In person	Individual & mixed	-0.71 [-2.62, 1.19]	5.0%

Table 13. Network meta-analysis for effect moderation on body mass index results for T2DM: description of nodes and results (continued)

Arm Description	Rank Order of Effect, Studies & Sample Size of Study Arms	Intensity	Method of Communication	Delivery Method	MD ($kg \cdot m^{-2}$), 95% Credibility Interval	Probability of Being Best
DSME + Support	**19**[210] N = 90	≤10h	In person	Individual & mixed	-0.19 [-1.66, 1.26]	0.6%
	25[152] N = 48	≤10h	In person	Group only	3.29 [1.39, 5.19]	0.0%
	8[172] N = 93	≤10h	Some technology	Individual & mixed	-0.61 [-1.99, 0.78]	1.7%
	14[208,209] N = 153	11-26h	In person	Group only	-0.31 [-1.69, 1.12]	0.7%
	21[152,189,209] N = 123	11-26h	Some technology	Individual & mixed	0.09 [-1.00, 1.21]	0.0%
	11[151] N = 128	≥27h	In person	Group only	-0.34 [-2.29, 1.63]	3.0%
Lifestyle	**2**[145,249] N = 105	≤10h	In person	Individual & mixed	-1.44 [-2.59, -0.24]	11.9%
	17[156,186,251] N = 79	≤10h	In person	Group only	-0.20 [-1.94, 1.48]	0.8%
	1[157] N = 50	≤10h	Some technology	Individual & mixed	-1.77 [-3.93, 0.42]	32.5%
	10[184,190]	11-26h	In person	Individual & mixed	-0.54 [-1.58, 0.67]	0.5%
	5[169,170,255] N = 115	11-26h	In person	Group only	-0.80 [-1.63, -0.06]	0.5%
	3[143] N = 49	11-26h	Some technology	Individual & mixed	-1.38 [-5.08, 2.29]	31.6%
	4[137,174,214,261] N = 212	≥27h	In person	Individual & mixed	-1.24 [-2.03, -0.48]	3.1%
	18[239,240] N = 305	≥27h	In person	Group only	-0.20 [-1.68, 1.28]	0.7%

DSME = diabetes self-management education; h = hour(s); MD = mean difference; NA = not applicable

Figure 20. Plot of network meta-analysis results for effect moderation on body mass index for T2DM



DSME = diabetes self-management education; h = hours
This plot depicts the results from our network meta-analysis for the outcome of body mass index (BMI) when comparing groups ("nodes") of interventions with usual care as the referent. Each group differs by at least one level in the categories of program component, intensity, mode of communication, and delivery method (see Table 3 for categorization schema). The dots and lines represent the effect size in mean difference (MD) and 95% credibility intervals for the represented programs relative to usual care. The MDs and 95% credibility intervals are included in Table 13.

KQ 6. Subgroups for Factors Moderating Effectiveness in T2DM

Key Points

Glycemic Control

- In terms of overall effectiveness at longest followup for HbA_{1c}, participants with suboptimal glycemic control (≥7 percent HbA_{1c}) appear to benefit more than those with good control (<7 percent) from behavioral programs when compared to usual care and active controls. The effect sizes were not clinically important for either group.

- Few differences were evident when evaluating potential moderation by program factors in a subgroup of studies having participants with suboptimal baseline glycemic control. Of the two nodes representing low-intensity programs that were found to have clinically important effects in the original network analysis, one was shown not effective for participants with suboptimal glycemic control. Active controls of dietary or physical activity interventions were not as effective for participants with suboptimal control.

Age

- Older adults (≥65 years) did not benefit at longest followup in terms of reduction in HbA_{1c} from behavioral programs in comparison with usual care or active controls. In adults <65 years, the effect size for behavioral programs compared with active controls at longest followup was clinically important.

Race/Ethnicity

- Subgroup analysis of our meta-analyses comparing behavioral programs to usual care and active controls indicated that programs offered to predominantly minority participants (≥ 75 percent nonwhite) appear to provide more benefit than those offered to populations with a lower proportion (<75 percent) of nonwhite individuals. The effect size for minority participants reached clinical importance.
- Based on univariate regression analyses for the subgroups based on race/ethnicity, none of the program factors (e.g., intensity, delivery personnel) reached statistical significance for influencing the effectiveness of behavioral programs compared to usual care on HbA_{1c}. The subgroup of majority/white participants appeared to benefit more from lifestyle programs than from DSME or DSME plus support programs.
- Glycemic control appeared to be worse for the minority (HbA_{1c}=8.8 percent) compared with the majority/white (HbA_{1c}=7.6 percent) subgroup.

Detailed Synthesis

As is common with systematic reviews, all of our results for this KQ relied on between-study rather than within-study comparisons, such that the effect of randomization is removed and the results are considered observational and possibly biased through confounding by other study-level characteristics.

Glycemic Control

Initially, we conducted a subgroup analysis on the outcome of HbA_{1c} by baseline glycemic control (HbA_{1c} <7 vs. ≥7 percent) using the pair-wise meta-analysis results for HbA_{1c} at longest followup timepoint (data not shown). For behavioral programs compared with usual care, our meta-analysis showed a small benefit (MD, -0.12; 95% CI, -0.22 to -0.01; I^2=3%) for HbA_{1c} for participants with a baseline HbA_{1c} <7 percent (6 trials, 1,239 subjects);[194,196,223,246,249,260] the analysis showed greater benefit (although not clinically important) for participants with a baseline HbA_{1c} ≥7 percent (76 trials; 11,086 subjects; MD, -0.32; 95% CI, -0.42 to -0.21; I^2=71%). There was no difference in change in HbA_{1c} for persons with baseline HbA_{1c} <7 percent receiving a behavioral program compared with an active control (3 trials, 169 participants; MD, -1.43; 95% CI, -3.57 to 0.71; I^2=99%);[174,186,201] persons with HbA_{1c} ≥7 percent at baseline had greater reduction in HbA_{1c} after receiving behavioral programs compared with an

active comparator (20 trials, 7,709 subjects; MD, -0.18; 95% CI -0.30 to -0.06; I^2=38%), but this was not clinically important.

To explore potential moderation of effect based on the factors of interest, we performed a subgroup analysis of our network meta-analysis described in the section for KQ5. We removed the studies in which baseline HbA_{1c} was <7 percent (n=9)[174,186,194,196,201,223,246,249,260] and repeated the analysis for a subgroup with baseline HbA_{1c} ≥7 percent; there were an insufficient number of studies with baseline HbA_{1c} <7 percent to run the analysis using these studies, or to perform meta-regression analysis. The results are presented in Table J1 in Appendix J. The categorization of all nodes remained the same in relation to the variables of interest. The changes in this subgroup analysis include: 1) the effect sizes for nodes ranked 1 and 13 reduced substantially to ranks of 31 and 23 (from -1.37 to 0.09 and from -0.45 to -0.15, respectively), and 2) the active (dietary or physical activity) control became less effective (MD -0.14 vs. -0.39) for participants having ≥7 percent HbA_{1c}.

Age

The same set of subgroup analyses performed for baseline glycemic control was conducted for our age subgroups; the study population in nine studies reporting on HbA_{1c} had a mean age ≥65 years.[147,155,166,196,203,218,221,223,230,236] We first performed subgroup analyses by age group (≥65 years vs. <65 years) using the pair-wise meta-analyses results for HbA_{1c} at longest followup timepoint in comparisons between behavioral programs and both usual care and active control (data not shown). For behavioral programs compared with usual care, the meta-analysis for participants <65 years indicated that HbA_{1c} reduced to a statistically significant extent at longest followup (76 comparisons; 11.491 subjects; MD, -0.31; 95% CI, -0.42 to -0.21; I^2=72%); for older adults the results indicated no difference (7 comparisons; 734 subjects; MD, -0.24; 95% CI, -0.50 to 0.03; I^2=55%). For comparisons with active controls for participants <65 years, the benefit of behavioral programs was statistically and clinically significant (26 comparisons; 7,669 subjects; MD, -0.41; 95% CI -0.70 to -0.12; I^2=93%). For older adults, behavioral programs compared with an active control (3 comparisons, 206 subjects) failed to reduce HbA_{1c} (MD, -0.23; 95% CI, -0.60 to 0.14; I^2=0%).

Subsequently, we performed a subgroup analysis for populations <65 years by removing the data from the studies (n= 9)[147,155,166,196,203,218,223,230,236] having mean age ≥65 from our network meta-analysis described in the section for KQ5. The results are presented in Table J2 in Appendix J. The categorization of all nodes remained the same in relation to the variables of interest. The only notable change in this subgroup analysis was that the effect size for the active control of a dietary or physical activity intervention became clinically important (MD, - 0.55) although the PB remained at 0 percent.

Race/Ethnicity

We conducted subgroup analyses based on race/ethnicity (i.e. ≥75 percent nonwhite [minorities] and <75 percent nonwhite participants) for the outcome of HbA_{1c} at longest followup for behavioral programs compared to usual care and active controls (data not shown). Using the pairwise meta-analysis for HbA_{1c} when comparing behavioral programs to usual care, there was a clinically important effect for minority participants (33 comparisons; 4,774 participants; MD, -0.42; 95% CI -0.56 to -0.27; I^2=55%)[137,141,143,151,153,162,171,179,188,189,195,197,205-208,210,215-219,222,228,229,231,233,240,246,247,257,262] which was greater than that seen for the comparisons with <75 percent minorities (24 comparisons; 5,110 participants; MD, -0.16, 95% CI -0.31 to

0.00; I^2=75%).[139,142,147,160,175-177,183,184,194,196,214,220,224,234,235,239,249,253,254,258,259] For comparisons between behavioral programs and active control groups, there was no statistically significant reduction in HbA_{1c} among minorities (5 comparisons, 400 participants; MD, -0.32; 95% CI -0.67 to 0.04; I^2=0%);[164,173,182,198,230] studies with a larger proportion of white participants also showed no difference (10 comparisons, 6,214 participants; MD, -0.50; 95% CI -1.24 to 0.23; I^2=99%).[107,168,169,175,184,201,202,252] Glycemic control at baseline appeared to be worse for the minority (8.8 percent HbA_{1c}) compared with the majority/white (7.6 percent HbA_{1c}) subgroup.

We also conducted univariate meta-regressions for each race/ethnicity subgroup. For this analysis, we used outcome data for changes in HbA_{1c} at longest followup in comparisons between behavioral programs and usual care. Table 14 shows the results for each variable examined. No statistically significant finding was generated. The subgroup of majority/white participants appeared to benefit more (with a difference near our threshold of change in HbA_{1c}) from lifestyle programs compared with DSME or DSME plus support, but the results did not reach statistical significance.

Table 14. Results for race/ethnicity subgroups using univariate meta-regressions analyzing the association between different program factors and the effectiveness of behavioral programs compared to usual care in improving HbA_{1c} for T2DM

Program Factors	# Studies	Coefficient and 95% CI	P Value
Program component (dichotomous: DSME and DSME plus support/lifestyle)	<75% nonwhite (24)	-0.35; 95% CI, -0.73 to 0.032	0.07
	≥75% nonwhite (33)	0.31; 95% CI, -0.15 to 0.76	0.17
Duration of intervention (continuous: months)	<75% nonwhite (24)	-0.016; 95% CI,-0.05 to 0.02	0.38
	≥75% nonwhite (33)	0.013; 95% CI,-0.015 to 0.036	0.41
Intensity (continuous: contact hours)	<75% nonwhite (24)	-0.003; 95% CI, -0.011 to 0.004	0.36
	≥75% nonwhite (33)	0.003; 95% CI, -0.0007 to 0.008	0.096
Frequency (continuous: hours/month)	<75% nonwhite (24)	-0.006; 95% CI, -0.05 to 0.05	0.78
	≥75% nonwhite (33)	0.009; 95% CI, -0.042 to 0.059	0.73
Method of communication (dichotomous: in-person/ some use of technology)	<75% nonwhite (24)	-0.17; 95% CI, -0.57 to 0.22	0.37
	≥75% nonwhite (33)	0.076; 95% CI, -0.24 to 0.39	0.63
Delivery method (dichotomous: individual & mixed/ group only)	<75% nonwhite (24)	0.12; 95% CI, -0.30 to 0.54	0.56
	≥75% nonwhite (33)	0.15; 95% CI, -0.19 to 0.49	0.37
Delivery personnel (dicotomous: non-health professionals only/health professional(s))	<75% nonwhite (24)	0.001; 95% CI, -0.40 to 0.42	0.96
	≥75% nonwhite (33)	-0.15; 95% CI, -0.46 to 0.16	0.33
Community engagement (dichotomous: present/none or NR)	<75% nonwhite (24)	0.038; 95% CI, -0.40 to 0.48	0.86
	≥75% nonwhite (33)	0.12; 95% CI, -0.27 to 0.51	0.54

CI = confidence interval

Discussion

Key Findings and Discussion for Type 1 Diabetes Mellitus (Key Questions 1–4)

This section presents the main findings, followed by a discussion of the findings for key questions (KQs) 1-4 evaluating the effectiveness of behavioral programs for type 1 diabetes mellitus (T1DM). The key findings for KQs 1 and 2 include a summary of the strength of evidence (SOE) assessments. Further discussion is included in the subsequent sections of this chapter focusing on (1) the applicability of the findings, (2) contextualizing our results within previous literature, and (3) future research needs.

KQ 1. Behavioral Programs for T1DM and Behavioral, Clinical, and Health Outcomes; Diabetes-Related Health Care Utilization; and Program Acceptability

There was moderate SOE showing reduction in hemoglobin A_{1c} (HbA_{1c}) at 6-month postintervention followup with percent HbA_{1c} reduced by 0.31 for individuals who were enrolled in behavioral programs compared with those receiving usual care. For all other timepoints, there was no significant difference in HbA_{1c}; the SOE was low due to risk of bias and imprecise effect estimates. For followup timepoints of 12 months or longer, the 95% CIs included our threshold for clinical importance such that we cannot rule out benefit for behavioral programs based on the available evidence. For individuals who were enrolled in behavioral programs compared with those receiving an active control, there was moderate SOE showing a clinically important reduction in HbA_{1c} of 0.44 percent at 6-month postintervention followup. There was no difference in HbA_{1c} at other timepoints, however the SOE was low and we cannot rule out a benefit for behavioral programs.

There was low SOE showing no difference in adherence to diabetes self-management (i.e., frequency of blood glucose checks or overall self-management behaviors) at end of intervention and 6-month followup for comparisons with usual care. For comparisons with active controls there was insufficient SOE for adherence to diabetes self-management at all followup timepoints. There was moderate SOE of no difference at the end of intervention for generic HRQL, and insufficient evidence at longer followup. In comparisons with usual care, there was insufficient SOE to assess whether there was any effect on diabetes-specific HRQL at any timepoint, and low SOE of no difference for diabetes distress at end of intervention and 6-month followup. There were no data on HRQL for comparisons of behavioral programs with active controls. No trials reported on micro- and macrovascular complications or on all-cause mortality. The SOE grading was highly influenced by the moderate or high risk of bias (ROB) of individual studies, the imprecise estimates of effect, and (for insufficient SOE grades) the limited amount of data.

Evidence was insufficient to determine whether behavioral programs increased or decreased the number of diabetes-related hospital admissions, emergency department admissions, episodes of severe hypoglycemia, or episodes of severe hyperglycemia. Behavioral programs appear to be acceptable to patients with T1DM based on a proxy measure; our meta-analysis showed a 21 percent increased risk of attrition usual care compared with behavioral programs.

KQ 2. Subgroups for Effectiveness in T1DM

For the KQ, we examined the differential effect of patient characteristics on the effectiveness of behavioral programs for T1DM. In comparisons with usual care, results were consistent with those from KQ 1 when combining all studies of youth and adults. At 6 months, behavioral programs reduced HbA_{1c} in youth by a statistically significant 0.28 percent and in adults by a non-statistically significant 0.38 percent. At end of intervention, the point estimates indicated greater benefit within the adult subgroup (0.28) than the youth subgroup (0.00), although neither of these values reached statistical significance. None of the point estimates exceeded the a priori established clinically important difference of 0.4 percent HbA_{1c}.

For subgroups based on age in comparisons with active controls, the small number of studies (and sample sizes) led to wide pooled 95% CIs which in some cases included values of clinical importance both for and against behavioral programs; the SOE was thus graded as insufficient in all but two cases. In studies of youth with followup to 12 months, there was low SOE of a clinically important (reduction by 0.52) benefit for behavioral programs; in studies of adults with 6-month followup, there was low SOE of no difference in HbA_{1c}.

KQ 3. Potential Moderation of Effectiveness for T1DM: Components, Intensity, Delivery Personnel, Method of Communication, Degree of Tailoring, and Level of Community Engagement

To assess whether program factors (i.e., intensity, delivery personnel, method of communication, degree of tailoring, and level of community engagement) moderated the effectiveness of behavioral programs for T1DM, we performed univariate meta-regressions for comparisons between behavioral programs and usual care at longest followup. Program intensity, including duration, contact hours, and frequency of contacts, appeared not to influence program effectiveness; individual delivery appeared more favorable than group delivery of programs but the results did not reach statistical significance. We did not have enough studies to perform multivariable analysis, neither did we have enough to perform the univariate regressions for outcomes other than HbA_{1c}.

KQ4. Harms for T1DM

No studies reported on the associated harms (i.e., activity-related injury) of behavioral programs.

Discussion of Key Findings for T1DM

Overall, behavioral programs seem to have some benefit in T1DM for reducing $HbA_{1c,}$ when followup extends beyond the immediate postintervention period up to 6 months. The delay in benefit may in part reflect the time required for this marker of glycemic control, indicating control over the past 2-3 months, to demonstrate change. Notable though, is the large diversity in program duration whereby end of intervention was anywhere between 1.5 and 25 months. Another contributor may be that a period of time is needed to integrate newly learned self-management behaviors into one's life; however, our findings of no differences in self-management behaviors at any followup timepoint when behavioral programs were compared to usual care do not support this hypothesis. The beneficial findings for HbA_{1c} at 6 months appear

to be tempered by the findings of no difference at longer followup timepoints, although we are unable to confidently rule out benefit at long-term followup. An argument that the findings of benefit could be an artifact of differential attrition between groups—with those more motivated to or more successful in making positive changes returning for followup assessment—appears to be unlikely because of the lower (21%) attrition rate found for behavioral programs compared to usual care.

There are at least a couple reasons why our findings may underestimate the effect of these programs should they be implemented in routine practice. The usual care group in several studies received some form of attention from the investigators (e.g., periodic telephone calls to maintain contact and encourage study participation), and this may have resulted in improved glycemic control for the comparator group and reduced the relative effects of the behavioral program. Participants (or their providers) in the usual care or active control groups (not being blinded to group assignment in most studies) may have become more motivated to practice better self-management (including blood glucose regulation using insulin titrations), which could also attenuate differences between groups. Differences in the "usual care" provided may have also played a role, although this affect may be minimal considering recent evidence that variations in standard care in studies of behavioral interventions for youth with T1DM did not significantly impact study results.[295]

Our finding of a statistically significant and clinically important reduction by 0.44 percent HbA_{1c} at 6-month followup for comparisons between behavioral programs and active controls is notable. As per our operational definition, behavioral programs consisted of interactive programs having a duration ≥4 weeks with the inclusion of behavior change techniques; because of this, traditional, didactic educational[91,92,107,108] or support interventions[87] were considered comparators rather than interventions. By offering an intervention to both study arms, these studies may have introduced less potential bias from lack of allocation concealment and blinding. Although quite promising, when drawing conclusions regarding the overall benefits of behavioral programs, this finding needs to be interpreted in light of results showing no differences for HbA_{1c} at other timepoints and insufficient evidence to make conclusions about several other outcomes.

Many of the included studies were directed at adolescents. Self-management of T1DM during adolescence is complex, often characterized by personal challenges and uncertainty, transitions to adult care, less frequent health care visits, and diminished parental involvement; consequently, glycemic control deteriorates over the course of childhood and adolescence for many youth with T1DM.[296-299] For these reasons, many of the studies included in this review aimed to prevent deterioration of glycemic control rather than to improve it. The statistically significant reductions in HbA_{1c} at 6-month followup (versus usual care), and the clinically important reductions in HbA_{1c} at 6- and 12-month followup (0.60 and 0.52 percent, respectively) in comparisons with active controls in youth lend substantial support for these programs. Likewise, incorporating more demanding self-management behaviors may negatively impact social and emotional functioning, such that our findings of no difference in generic HRQL at end of intervention may be interpreted as positive.

Most studies for T1DM were undertaken in populations with baseline glycemic control ≥8.5 percent HbA_{1c}. While this may affect the applicability of the findings to some extent, clinicians may view this as highly relevant to their patient population of which many—particularly in their pubertal years—are struggling to achieve optimal control. Furthermore, the Diabetes Control and Complications Trial (DCCT)[20] found that these individuals receive the greatest benefit from HbA_{1c} reduction.

For T1DM, there was evidence that effectiveness appears not to be moderated by program intensity (i.e., duration, contact hours, or frequency of contacts), and that delivery to individuals compared with groups may be beneficial. We were unable to undertake any analysis to comment on the difference between educational and lifestyle programs, or the addition of a support component to DSME programs. Many individuals with T1DM under good glycemic control may have other risk factors (e.g., overweight, hyperlipidemia, hypertension) for which lifestyle programs may be warranted. Although some behavioral programs were of fairly long duration with highly intense contact with patients,[88] only one explicitly incorporated a support component.[82]

Our pair-wise meta-analyses used the Hartung-Knapp-Sidik-Jonkman random effects model[73-75] that typically provides a more conservative estimate of the 95% CI around pooled effect sizes than the common DerSimonian and Laird approach; the latter approach has been shown to lead to too many statistically significant results especially in the face of heterogeneity and few studies. The effect of our approach is that some results—especially those pooling few studies—are found statistically nonsignificant when another approach may find significance; moreover, the 95% CI in some cases spreads wider than those of the individual studies. For example, our reported 95% CI for the effect on HbA_{1c} for youth receiving a behavioral program compared with an active control at 6-month followup is -2.56 to 1.36 (not significant due to inclusion of 0 [no effect]), although the DerSimonian and Laird approach provided an estimate of -0.95 to -0.25 (significant). This factor also applies those findings for T2DM on the overall effectiveness of behavioral programs across all outcomes.

Key Findings and Discussion for Type 2 Diabetes (KQs 5 and 6)

This section presents the key findings for type 2 diabetes mellitus (T2DM). We begin by summarizing the effectiveness of behavioral programs across our key outcomes, based on comparator (i.e., usual care or active controls) and followup timepoint. Thereafter, we provide a brief summary and discussion of the findings for KQs 5 and 6 evaluating the potential of program components and delivery factors to moderate the effectiveness of behavioral programs for T2DM. Further discussion is included in the subsequent sections of this chapter focusing on (1) the applicability of the findings, (2) contextualizing our results within previous literature, and (3) potential needs for future research.

Effectiveness of Behavioral Programs Across Outcomes

There is evidence showing a beneficial effect of behavioral programs, compared to both usual care and other active interventions, at end of intervention for glycemic control; however, at longer followup results were only statistically significant at 6 months for comparison with active controls, and none of the results were considered to be clinically important based on our threshold of a 0.4 percent change in HbA_{1c}. There was substantial statistical heterogeneity in these pairwise meta-analyses, supporting our subsequent analysis for KQs 5 and 6 to determine which program factors, and population characteristics, influence (and optimize) the effects.

Behavioral programs showed some benefits in terms of reducing BMI (0.21-0.92 kg/m^2 to 12-month followup), weight (1.3-1.68 kg; end of intervention) and waist circumference (3.2 cm; short term), and daily energy intake (64-150 kilocalories per day to 6 months)—mainly when

compared with usual care. There was little evidence around the outcomes related to changes in physical activity and medication adherence, and findings were consistently of no difference.

Health-related quality of life was reported by fewer studies than anticipated. On average, findings of no difference were found for most studies and outcomes, except for Diabetes Distress where results favored behavioral programs compared with usual care at end of intervention but not at longer followup. Effects on diabetes complications were only reported for one study. Diabetic retinopathy was reduced by 14% and very-high-risk kidney disease by 31% in participants receiving a ≥8 year-long intensive lifestyle program compared with didactic education and support in the largest trial, conducted by the LookAHEAD research group.[278,292] Mortality between behavioral programs and active control groups (5 comparisons; 6,050 participants) was 14 percent lower for those receiving behavioral programs (RR, 0.86; 95% CI, 0.77 to 0.96). There was no difference for comparisons with usual care (25 comparisons; 4,659 participants; RR, 1.28; 95% CI, 0.84 to 1.94).

KQ 5. Potential Moderation of Effectiveness for T2DM: Components, Intensity, Delivery Personnel, Method of Communication, Degree of Tailoring, and Level of Community Engagement

In a network meta-analysis with usual care serving as the main reference, programs demonstrating effect sizes for HbA_{1c} at or above our threshold for clinical importance (i.e., 0.4 percent HbA_{1c} difference between groups) represented all three major program component categories of diabetes self-management education (DSME), DSME and support, and lifestyle. The effect sizes of minimally intensive DSME programs (≤10 contact hours) were less than our threshold for clinical importance, but were all higher than that of educational interventions not meeting our criteria for a behavioral program (e.g., didactic education programs represented by many active controls). Programs having larger effect sizes and higher probabilities of being best (≥5 percent) were more often delivered in person rather than including technology. All effective programs using some form of technology were of moderate or high intensity.

Lifestyle programs resulted in the largest effect sizes for BMI. Program intensity appeared less important than method of delivery; providing some individual (rather than solely group-based) delivery appears beneficial for improvements in BMI at longest followup.

KQ 6. Subgroups for Factors Moderating Effectiveness in T2DM

All of our results for this KQ relied on between-study rather than within-study comparisons, such that the effect of randomization is removed and the results are considered observational and possibly biased through confounding by other study-level characteristics.

In terms of overall effectiveness at longest followup for HbA_{1c}, participants with suboptimal or poor glycemic control (≥7 percent HbA_{1c}) appear to benefit more than those with good control (<7 percent) from behavioral programs when compared to usual care and active controls. The effect sizes were not clinically important for either group. Few differences were evident when evaluating potential moderation by program factors after rerunning the network meta-analysis of KQ 5 with a subgroup of studies having participants with suboptimal or poor baseline glycemic control.

Older adults (≥65 years) did not benefit at longest followup in terms of reduction in HbA_{1c} from behavioral programs in comparison with usual care or active controls. In adults <65 years,

the effect size for behavioral programs compared with usual care was statistically significant (reduction of 0.31 percent) and compared with active controls at longest followup was clinically important (0.43 percent). In a subgroup analysis of our original network meta-analysis of HbA_{1c}—removing the studies of participants with a mean age ≥65—the most noticeable change was the increase in effect size for active controls incorporating dietary or physical activity interventions, which produced clinically important effects (0.55 percent reduction in HbA_{1c}). The active controls still showed zero probability of success, perhaps due to the heterogeneity between, or small sample sizes of, the associated comparisons.

In comparison to usual care and active controls, behavioral programs offered to predominantly minority participants (≥ 75 percent nonwhite) appear to provide more benefit for glycemic control than those offered to populations with a lower proportion (<75 percent) of nonwhite individuals. The effect size for minority participants reached clinical importance when comparing behavioral programs to usual care (0.43 percent reduction in HbA_{1c}). Based on univariate regression analyses for the subgroups based on race/ethnicity, none of the program factors (e.g., intensity, delivery personnel) reached statistical significance for influencing the effectiveness of behavioral programs compared to usual care on HbA_{1c}. Lifestyle programs appeared favorable over DSME or DSME plus support for the group of studies (n=24) with predominantly white individuals (p=0.07).

Discussion of Key Findings for T2DM

The focus of our review for T2DM was on identifying factors contributing to the effectiveness of multicomponent programs. Our review includes the highest number of studies to date, and focuses on programs meeting current recommendations to change patient behaviors and patient-important outcomes (e.g., HRQL). We relied on strict inclusion criteria to study interactive programs incorporating behavioral strategies aiming to change multiple behaviors, without confounding by changes to medical management (e.g., medication changes, differing frequency of provider visits). Another strength of the review is our analytical approach; the network meta-analysis enabled differentiation of the various comparators, and incorporation of comparisons (e.g., intervention vs. intervention) often not amenable to other strategies. Moderate- and high-intensity (≥11 hours contact time) programs appear to be necessary to provide individuals with clinically important effects on HbA_{1c}; this outcome may also benefit from in-person delivery rather than using technology. For BMI, providing some individual delivery, rather than solely relying on group formats, appears beneficial.

Our review adds to previous findings in that lifestyle programs—not specifically training people in diabetes related self-care behaviors but focusing more on weight reduction and increases in physical activity—may provide similar or more benefit than DSME programs for improving glycemic control for individuals with T2DM. A feature of behavioral programs that may be particularly attractive to patients is that unlike some common drug therapies used in the management of type 2 diabetes, behavioral programs have the potential to reduce HbA_{1c} without contributing to weight gain. Our review confirms previous suggestions that programs with an interactive nature, employing behavioral approaches and covering multiple behaviors, are beneficial when compared with didactic educational interventions. Although perhaps not to a clinically important degree for individuals, the burgeoning growth of this disease means that even small gains in glycemic control from behavioral programs may serve as a substantial benefit for public health.

Our finding that single-topic, non-educational interventions (active controls of dietary or physical activity interventions) offer more benefit than do basic education interventions, supports the need to carefully distinguish and account for different comparators during the systematic review process. We used longest followup timepoint for the analyses to answer KQ 5 and 6, which may capture the "durability" of the programs better than restricting the analysis to the immediate postintervention period.

It appears from our network meta-analysis results for HbA_{1c}, that both individual and group delivery can be beneficial; this agrees with other work in this area[300] (also see below section on Findings in Relation to What is Already Known). Our results for KQ6 suggest that other factors (or combination of factors) may influence the effects of this variable; for instance, delivery format may be highly dependent upon the population served and program content. Studies within nodes having high effect sizes which offered programs in groups tended to be those offered to minorities, including Mexican Americans,[150,152,208] where support from peers was incorporated as a key program feature.

We were unable to draw any conclusions about the choice of delivery personnel from the network meta-analysis when answering KQ 5; there were too few studies in the categories of DSME and support, and lifestyle to account for this variable when creating the nodes. Drawing from the pair-wise meta-analysis results for those trials comparing two or more interventions (i.e. comparative effectiveness), there may be no difference when program delivery is conducted by heath care professionals or by lay providers (e.g., peers with diabetes, community health workers). Four trials (575 subjects) found no difference (MD, 0.00; 95% CI, -0.23 to 0.23)[144,172,227,256] in effectiveness when programs were delivered by peers compared with health care professionals. One trial (72 subjects) found no difference when the support phase of DSME was provided by clinic staff compared with diabetes educators (MD, 0.02; 95% CI, -0.60 to 0.64).[227] Most trials reported on extensive training programs for those delivering their programs. One reason why programs delivered by health care professionals were not superior may be that physicians, nurses, and dietitians receive little or no training in behavioral techniques as part of their formal education. This may be particularly true when extensive knowledge and expertise in theoretically guided approaches (e.g. motivational interviewing), or several behavior change techniques are required. Diabetes educators, highly regarded for their thorough knowledge and skills in diabetes education, may require substantial training and supervision when starting to apply advanced behavioral techniques such as motivational interviewing; to date this technique has shown benefit for improved glycemic control in the short term when delivered by clinical psychologists[232,250] but not by diabetes educators.[248] It could be speculated that the benefits for glycemic control may improve with time after those delivering the programs gain experience.

Our findings for KQ 6 suggest that people with good baseline glycemic control (<7 percent HbA_{1c}), advancing age (≥65 years), and white/European ancestry (studies not having a majority of minority participants) may not benefit to the same extent as participants with suboptimal or poor glycemic control, racial/ethnic minorities, and those of younger age. The finding of better success for patients with poorer glycemic control has been found in previous systematic reviews (for one example see Duke et al.[300]). Intuitively, individuals with good glycemic control may not achieve as much benefit from behavioral programs—there is little room for improvement and good self-management behaviors may already be practiced regularly. Our findings may have been different if we had chosen a different level of glycemic control for subgroup analysis; after consultation with several experts we were unable to define a "poor control" cut-point. Some caution is warranted when considering our findings for the age subgroups; there were limited

studies where the average participant age was ≥65 years, as specified for our subgroup analysis. Moreover, we relied on between-study differences for these subgroup analyses rather than within-study analysis for individual programs. Many trials included a broad range of ages up to 72 years, and the median age of the entire sample in this review was 58; the overall applicability of the results for KQ5 appear to apply to middle- and older-aged adults. Results may have differed for other patient-important outcomes such as quality of life; however, there were insufficient data for these analyses.

The findings for ethnicity need to be interpreted in light of our method of analysis and differences in baseline glycemic control between subgroups. Glycemic control appeared to be worse for the minority (HbA_{1c}=8.80 percent) compared with the majority/white (HbA_{1c}=7.60 percent) subgroup; it is thus hard to distinguish if ethnicity or glycemic control is more likely to have the greater influence in moderating program effectiveness. Ethnic minority groups have been shown to have higher HbA_{1c} levels than Caucasian groups; this finding holds after adjusting for factors affecting glycemic control (i.e., age, sex, BMI, duration of disease, mean plasma glucose) and thus may not be influenced by behavioral programs.[301] Conversely, a systematic review by Nam et al.[302] which found benefit for culturally tailored diabetes education, found that lower baseline HbA_{1c} levels better predicted positive responses to the programs. There are likely additional factors involved. Many investigators enrolling a large proportion of ethnic minorities in the trials included in this review adapted programs in ways to make them more culturally and linguistically acceptable—often including peers in the delivery or social support groups—which may have enhanced their effectiveness. Our reliance on study-level data to create subgroups (i.e., the entire study was delivered to minorities) may have limited our ability to capture differences in effects from programs delivered to a wider population base, which may reflect routine practice in many community health settings.

Although our discussion has centered on our findings related to our KQs, which focus on effect moderation, the important benefits shown by the LookAHEAD research group[252] should be highlighted. Reduction in retinopathy by 14 percent and nephropathy by 31 percent in those participating in a long-duration, intensive lifestyle program cannot be ignored.[278,293] Additionally, our findings from pairwise meta-analysis of 14 percent reduced mortality between those receiving behavioral programs and active controls was heavily influenced by the large weight (contributing to >50 percent of the pooled effect) of this study in the analysis.

Findings in Relation to What Is Already Known

For T1DM, this review provides a current examination of the effectiveness of behavioral programs for multiple outcomes and across all age groups. Few systematic reviews have been conducted over the past decade,[3,5,6] and most reviews have assessed the effects of a broad range of interventions (some of which were didactic education or single topic interventions) in diverse settings.[3,4,6,7] All we identified have focused on children and adolescents, and several included newly diagnosed patients. When calculated, effect sizes for glycemic control and psychosocial outcomes in general demonstrated very modest improvement at longest followup.[4,5] [Of note, much previous work reports results using a standardized effect size measure, rather than an unstandardized mean difference in absolute value of percent HbA_{1c}, as used in this review. Our results of 0.31 (vs. usual care) and 0.43 (vs. active control) percent reduction at 6-month followup represent approximately a 0.22 and 0.28 standardized effect size, respectively, which are commonly considered small].[303] Our results which incorporate more recent and larger studies confirm the findings of previous reviews.

In their systematic review and meta-analysis in 2006, Murphy et al.[6] called for larger, multicenter trails to better investigate the effects of psychoeducational interventions for T1DM. They also stated that no adequately powered RCT had proven effective for patients with poor glycemic control. Our review included reports from two multicentre trials (one by these authors) comparing behavioral programs (clinic-integrated group family sessions focused on family teamwork,[102] and DSME with motivational interviewing and solution-focused brief therapy[85]) to standard care and enrolling patients with poor glycemic control (baseline HbA_{1c} ≥9 percent in both trials).[85,102] Neither study found benefit in terms of HbA_{1c}. These authors also noted a need to determine if content or contact was what mattered most; studies (n=2) in their review that compared intervention to attention/active controls showed little effect due to improvements for the comparator group.[6] Our finding of a higher effect size for comparisons with active controls than with usual care (at 6 months) suggest that content may have an effect. In a 2000 review, Hampson et al.[4] noted that outcomes should be evaluated at an appropriate time to reflect the impact of the intervention. Our results for glycemic control seem to agree with this assertion; HbA_{1c} improved at 6-month followup but not at end of intervention which may have reflected the sensitivity of this outcome marker.

Several systematic reviews have performed some form of analysis to identify factors moderating the effectiveness of self-management and educational programs for T2DM. In 2002, Norris et al.[51] reported on a meta-regression examining several factors including intervention characteristics (e.g., program duration, number of contacts, contact time, group vs. individual delivery) on effectiveness of self-management education for HbA_{1c} from 37 comparisons; the authors also evaluated the effectiveness based on baseline glycemic control and age. The only significant factor was the total contact time, with the authors concluding that HbA_{1c} was reduced by 0.04 percent for every additional hour of contact time, over the range 1-28 hours. However, the meta-regression was conducted for comparisons of the educational interventions with a combination of usual care and active controls ("additional care delivered")—several of which received the same contact time as the intervention group. When considering this factor, there was a nonsignificant positive relationship between the differences in contact time and improved HbA_{1c}. Although our review took a different approach by using a network meta-analysis to incorporate a large suite of comparisons, we found very similar results—most programs showing effect sizes at longest followup (to 12-months) in the clinically important range have contact times in the moderate- or high-intensity categories (≥11h) and the mean contact time was 26.4 hours. We were also able to confirm that active controls (especially didactic educational programs) offer less benefit in reducing HbA_{1c} than do behavioral programs meeting our operational definition.

Another group led by Norris[31] undertook regression analysis to investigate similar factors for 22 weight loss interventions for people with T2DM. The authors found no significant interaction with followup interval, duration of intervention, intervention contacts, or baseline weight. Unlike the previous work, the authors separated out comparisons by comparator group and thus had little data (2-6 studies) for each analysis. Both reviews led by this author[31,51] included studies evaluating interventions focusing on one behavior (e.g., diet only), and studies where the effects of the intervention could not be clearly distinguished from that of additional disease/care management components.[304,305] This may explain in part why our effect sizes for HbA_{1c} at end of intervention are smaller than that (0.76 percent) found by Norris et al.[51]

Shortly after the work by Norris and colleagues, another group used a similar approach to analyze which variables within an educational intervention best explained the variance in

glycemic control. Evaluating HbA_{1c} results assessed immediately after 28 interventions, Ellis et al.[54] found a similar effect size as our results (0.32 percent reduction) and that face-to-face (i.e., in-person) delivery, cognitive reframing teaching method, and inclusion of exercise content collectively explained 44 percent of the variance in HbA_{1c}. Their failure to obtain significance for the "dose" of the interventions was suggested by the authors to reflect the lack of variation in the dose of interventions; they suggested that a better marker than number of contacts or duration of intervention may have been total contact hours or a combined variable (such as our use of contacts per month for the univariate meta-regressions). Since all of the interventions examined included a diet component, the benefit from adding an exercise component would seem to suggest these were what we usually classified as lifestyle interventions. Our results for KQ 5 are similar, in that they suggest in-person (face-to-face) delivery may be more efficacious than delivery via technology for patients with T2DM.

We can also compare our findings to those of three more recent reviews. Chodosh et al.[46] examined essential components of chronic disease self-management programs (diabetes, hypertension, and osteoarthritis) and found statistically significant differences for diabetes programs (n=26) that provided feedback (e.g., support after self-management program completion); this effect was consistent across the outcomes of HbA_{1c}, blood glucose, and weight. This finding reflects our results—suggesting DSME and support programs have higher efficacy than DSME programs—although the overall effect reported by these authors (0.81 percent) is higher than ours; again this difference in effect size may reflect an overestimate of effects of self-management interventions by inclusion of studies which include changes to medical management.[306,307] In a qualitative examination of 11 interventions showing beneficial effects for socially disadvantaged populations, Glazier et al.[55] observed several factors contributing to effectiveness, including one-to-one interventions, providing feedback, and high intensities with >10 contact times delivered over a longer period of time (≥6 months). These are consistent with our findings. The findings for feedback, or "booster sessions", and providing >10 contact hours were also found by Fan and Sidani[48] in another qualitative comparison of effect sizes of 50 RCTs. These authors also observed that larger effect sizes were found for one-on-one or mixed formats versus group formats; our results with respect to delivery method were inconclusive.

Our findings for KQ 5 are similar to those of previous work, although we have provided some new insight from use of a larger sample of studies, exclusion of programs not meeting current recommendations or introducing possible confounding by medical care variation, and an innovative analytical approach to assess multiple variables and account for a suite of comparisons not always applicable to other techniques.

Applicability

Type 1 Diabetes

The inclusion criteria for most studies did not specify a minimum HbA_{1c} level; however, for all studies the mean HbA_{1c} was over 7 percent. For most (70 percent), the mean HbA_{1c} was over 8.5 percent. The results of this report may only be applicable to individuals with suboptimal and poor glycemic control.

For studies targeting youth, the mean age across most studies ranged from 12 to 15 years. Therefore, the results should be generally applicable to older children and adolescents. One trial targeted younger children (8 to 12 years);[100] it is unclear whether the results of this report are applicable to younger children.

For studies targeting adults, the mean age across studies ranged from 30 to 49 years. No studies specifically targeted older adults (≥65 years), therefore it is unclear if the results are applicable to older adults.

Approximately 50 percent of studies specified that participants have a minimum duration of T1DM of ≥1 year. For studies that targeted youth, the mean duration of diabetes ranged from 2.7 to 7.3 years. The results of this report may only be applicable to children and adolescents who have been diagnosed with T1DM for at least 2 years. For studies that targeted adults, the mean duration of diabetes ranged from 7.5-23 years. It is unclear whether the results of this report are applicable to adults whose T1DM has been recently diagnosed.

We did not find evidence to confirm or refute whether behavioral programs are more or less efficacious for other subgroups, including sex or racial or ethnic minorities.

All of the studies targeting adults were conducted in the United Kingdom, Europe, or New Zealand. It is unclear whether the results from these studies are applicable to community health settings in the United States. For youth, most studies (70 percent) were conducted in the United States; the remaining studies were conducted in Europe and Australia. Despite potential differences in settings and health systems, results were similar across the studies.

The studies were conducted primarily in outpatient diabetes clinics affiliated with a secondary or tertiary care hospital. Our findings are generally applicable to these settings in the United States.

Type 2 Diabetes

The range of baseline HbA_{1c} in the included RCTs was 6.3-12.3 percent (median=8.0) which would appear to make the results of this review applicable to the majority of people enrolling in behavioral programs. We conducted subgroup analyses for KQ 6 based on baseline glycemic control (<7 vs. ≥7 percent HbA_{1c}) at the study level, which provided some insight into the relative effectiveness based on this level of glycemic control. This analysis may be limited by the small number of studies in the <7 percent subgroup (n=9 RCTs) and because the analysis was based on between-study rather than within-study variability in glycemic control which may not accurately reflect differences for individual programs. The results of this report are therefore most applicable to people having HbA_{1c} levels ≥7 percent.

The range of mean ages in the included studies was 45-72 years (median=58), therefore the results of the pairwise meta-analyses on overall effectiveness and of the analysis for KQ 5 are most applicable to middle- and older-aged adults. Our subgroup analysis for KQ 6 based on age (<65 vs. ≥65 years) provided some data on the relative effectiveness for these age groups, but similar to that for baseline HbA_{1c}, may be limited by the small sample of studies on older adults (n=9) and our analytical approach. Our exclusion criteria related to duration of diabetes (mean <1 year)—implemented in order to capture programs providing training in ongoing self-management and lifestyle behaviors—limits the relevance of this review for newly diagnosed patients. The mean duration of diabetes ranged from 1-18 years with a median of 8.1 years. No study performed subgroup analysis based on duration of diagnosis (≤1 vs. >1 year) and we were unable to perform this at the study level because the mean in all cases was above 1 year. The results appear to be applicable to both men and women, and for people on a variety of diabetes treatment regimens (19.2 percent were on insulin). Overall, there was fairly good representation of individuals reporting a minority racial/ethnic background. Subgroup analysis based on those studies reporting of race/ethnicity (24 comparisons for <75 percent minorities vs. 33

comparisons for ≥75 percent minorities) was conducted to increase the relevancy of the findings to these population groups.

The results seem applicable to community health settings in the United States. The majority (63 percent) of trials were conducted in the United States, and based on our inclusion criteria related to Human Development Index[62] all studies were performed in countries of similar development status. Some trials were conducted in academic settings in health fields—thought to have application in community health settings—although there may be some differences if these programs were delivered in different settings. Although details were reported inconsistently, health systems differences (i.e., usual care) may vary widely between study populations and could potentially influence the results obtained from behavioral programs. The effect from this difference should be minimal for this review, since we limited our results to changes from baseline between groups randomly assigned and judged to receive similar medical care.

Limitations of the Comparative Effectiveness Review Process

This review followed rigorous methodological standards, which were detailed a priori. Nevertheless, several limitations are inherent within systematic reviews in general.

First, there is a possibility of selective reporting bias (e.g., researchers only reporting positive outcomes) and publication bias, whereby unexpectedly strong results from large trials are selectively reported. In terms of selective outcome reporting, we were able to locate several trial registries and protocols to compare planned and published outcome reporting; most studies included in this review were judged as having low bias in this respect. We may have missed some reports of behavioral programs in diabetes, particularly those showing weak results. We believe publication bias is minimal: (1) our literature search was comprehensive, systematic, and included published and unpublished literature (e.g., some reports were located by contacting authors of studies published in abstract form[256] or without data on our outcomes of interest);[90] (2) there was large variation in effect sizes reported; and (3) we did not have a minimum sample size for inclusion, and several of the included studies were small. Visualization of funnel plots did not suggest publication bias, and using the Egger test[78] for our outcome with the most data (HbA_{1c}) resulted in no significant indication of bias for comparisons with usual care (p=0.25) or active controls (p=0.21) at end of intervention. Selected studies were confined to the English language because we felt that these reports would be most applicable to the end-users of this review who create recommendations or implement programs for people with diabetes within the United States. Moreover, effect sizes in language restricted reviews have shown to not differ significantly (overestimating effect sizes by 2 percent) from those not having restrictions.[308] Study selection bias was limited by having two independent reviewers perform screening and selection; we feel confident that study exclusion was based on explicit and appropriate reasoning which was clearly understood by reviewers.

Our decisions on study design were based largely on the availability of studies employing designs having lowest potential for bias. For T1DM, we expected to have a limited amount of evidence from RCTs, so we included other controlled studies. For T2DM, we only included RCTs which may have left out some studies evaluating outcomes and issues of relevance to this review. The body of evidence from RCTs was known in advance to be large, and provided 132 primary reports of trials undertaken in many health settings with diverse populations. In addition, adding non-RCT evidence would have substantially increased the potential bias in results. Behavioral interventions are already moderately complex—in terms of variability in social and

environmental contextual factors—and trials of such interventions rarely include blinded allocation or outcomes assessment; because of these factors we thought it desirable to avoid additional limitations arising from selection bias and confounding, for which non-RCTs and observational studies are more prone.

The interventions evaluated in the included trials were highly diverse in their content, delivery, and setting. Our inclusion criteria attempted to reduce some of the diversity by including studies of interventions meeting a fairly rigid operational definition of a behavioral program. We also excluded studies where the effects of the behavioral program could not be isolated (e.g., due to confounding by differences between groups in medical care management), where the patient population would not have already received previous basic education (e.g., enrollment of only newly diagnosed patients), and when the setting was not applicable to community health settings in the United States. Furthermore, we categorized the comparators into three groups to avoid further complexity in comparisons. Our categorization of the comparators and interventions was based on the factors of interest in this review, was informed by previous literature and input from our Key Informants and Technical Expert Panel, and was based in several cases on multiple reviewer deliberation and consensus. Nevertheless, we likely did not capture all factors of importance to some stakeholders. The diversity in programs and other contextual factors was apparent when considering the high heterogeneity in results from the pairwise meta-analysis for HbA_{1c} and some other outcomes in T2DM. Our analyses in KQs 3, 5 and 6 related to factors influencing the effectiveness of behavioral programs for both T1DM and T2DM.

Our analyses for T2DM should be interpreted based on our approaches to address program durability and the relatively high-level categorization of program components. Our network meta-analyses and subgroup analyses used outcome data at longest postintervention followup, which for the majority of studies was end of intervention (i.e., after all contact between participants and program personnel ceased) or, for fewer, between 1-6 months followup. Only 8 of 112 trials had followup longer than 6 months. This approach was used to include as many studies as possible (i.e., those that did report data for end of intervention) and also to reflect the durability of the programs in terms of their potential for impacting long-term health. Our results from the pairwise meta-analyses for HbA_{1c} in T2DM at each followup timepoint indicated reduced effectiveness at followup durations longer than end of intervention; this suggests that the mean effect sizes from our network meta-analysis at longest followup may underestimate the effects at end of intervention.

One of the reasons to differentiate between DSME and DSME plus support was to account for the variation in intensity between these categories, due to the support or maintenance phases (having lower contact frequency) in DSME plus support programs. Our definition of end of intervention was standardized for all programs, rather than taking into account any distinct phases within programs. There was large variation between programs in terms of the distribution of contacts, including the reporting of such, and attempting to capture effects based on relative intensity within programs or specific to the maintenance phase would have been difficult and unreliable. Because of this, one might have anticipated that the effects from DSME programs (without a maintenance phase) would have been higher than other programs having the same overall contact time. This does not appear to be the case, and our results would suggest that adding a support phase (often offering psychosocial support and/or behavior change strategies targeting behavior maintenance) was an important program feature of many lifestyle and DSME plus support programs regardless of the distribution of visits.

As stated in the Results chapter, we did not include program tailoring and degree of community engagement in the analysis for KQ5; these factors were considered to overlap in meaning to some extent with delivery method (e.g., use of technology enhancing tailoring) and delivery personnel (e.g., use of non-health providers providing community engagement), and the ones we used were thought to better represent the differences between the programs assessed in this review. With our focus on programs incorporating interaction with program personnel, we cannot comment on the effects of programs delivered entirely by way of technology which may provide sophisticated mechanisms to interact with and motivate participants or closely monitor disease management. Cost analysis of implementing differing behavioral programs was not addressed in this review.

Limitations of the Evidence Base

The evidence base was inadequate to fully answer the Key Questions, particularly with respect to the limited number of outcomes evaluated in several studies. We were unable to fully evaluate all outcomes of interest for several KQs. For KQ 1 for T1DM, there were limited data available to assess the SOE for many outcomes, including behavioral outcomes related to changes in dietary intake or physical activity, and clinical and health outcomes apart from HbA_{1c} and HRQL. Our assessment of factors contributing to effectiveness of behavioral programs for T1DM (KQ 3) was limited to the outcome of HbA_{1c} and to univariate meta-regressions (rather than network meta-analysis to simultaneously examine multiple comparisons and factors) because too few studies provided data on other outcomes. No studies contributed data for our assessment of harms (KQ 4). For KQs 5 and 6 related to T2DM, our network meta-analysis allowed for multiple comparisons but there were still too few studies reporting on outcomes besides HbA_{1c} and BMI to enable meaningful groupings into nodes to examine multiple factors simultaneously. Considering that behavioral changes are the key mediators to achieving clinical and health outcomes, analysis based on valid outcomes of changes to physical activity or diet would be ideal; greater use of these outcomes, especially via objective means, would be beneficial. The meta-regressions used for the subgroup analysis on ethnicity in KQ 6 are limited by comparator (only usual care) and did not allow us to capture multiple variables in a single analysis. In addition, our subgroup analyses for KQ 2 and 6 were mostly limited to indirect methods (i.e., relying on between-study rather than within-study comparisons). Several outcomes of importance to patients and policymakers, such as quality of life, development of complications, and health care utilization, were reported by few studies to confidently support conclusions of effect, or to analyze in terms of moderation by program factors.

Many trials had methodological limitations introducing some ROB. Blinding of participants and personnel are arguably difficult for trials of behavioral programs especially when the comparator is usual care. According to our decision rules for assessing ROB, a low ROB for participant and personnel blinding was granted if the comparator was an attention or active control and the authors stated some means to blind the study hypothesis from participants, and if there was a structured training and protocol followed for the personnel. Participant blinding in this manner was rarely reported. Lack of blinding of participants, and their healthcare providers, may result in underestimation of the effects of behavioral programs compared to comparators, due to cointervention; adjustments of insulin or oral antidiabetic medications may have been performed to a greater extent in the comparison groups than in the intervention groups. This effect may have been heightened because none of the studies we reviewed included any limitations or restrictions on adjustment of insulin or other medications. Blinding of outcome

assessors was also rarely reported, despite the high feasibility of ensuring this procedure. These two domains resulted in medium or high ROB being assigned for most trials for their subjective outcomes. For both subjective and objective outcomes, medium or high ROB was assigned in many cases from lack of intention-to-treat analysis (e.g., only reporting on results for completers) and/or from high participant attrition. Despite our inclusion of only RCTs, some studies had small sample sizes and a few failed to achieve adequate baseline comparability in demographic or clinical characteristics.

Research Gaps

Table 15 highlights some potential research needs based on our KQs.

Table 15. Potential research needs, by Key Question

KQ	Potential Research Needs
1 Effectiveness for T1DM	There were limited data to determine the effectiveness of behavioral programs for T1DM at durations of followup beyond 6 months. Future studies should strive to assess outcomes at longer term followup, to better determine the effects of these programs for periods of time that may better influence long-term outcomes of complications and quality of life.
1 Effectiveness for T1DM	There was insufficient evidence to demonstrate whether lifestyle programs (i.e., combining structured dietary and physical activity interventions) are effective for T1DM. Many individuals with T1DM under good glycemic control may have other risk factors (e.g., overweight, hyperlipidemia, hypertension) for which these programs may be warranted. Trials of lifestyle programs enrolling people with both types of diabetes should undertake subgroup analysis.
1 & 3 Effectiveness and moderating factors for T1DM	The effectiveness of adding a clinical, behavioral, psychosocial, or educational support component to programs in T1DM is unknown. These may be useful for prolonging the effects of behavioral programs, and to address some of the psychosocial aspects of the disease (particularly in adolescents) to a greater extent.
3 Moderating factors for T1DM	Only one study in T1DM compared behavioral programs delivered in person with those delivered via some form of technology allowing for interaction between the provider and patient. Transitioning individuals with diabetes between pediatric and adult care facilities and providers can be challenging, hampered by the scheduling structure of traditional clinics at a time in life when contact information and location of home, work and education is often changing frequently. As a result further research on providing behavioral programs via technology or creative scheduling is warranted for adolescents and young adults with diabetes.
3 Moderating factors for T1DM	Several studies for T2DM included a small sub-sample of people with T1DM. Trials of lifestyle programs that incorporate exercise need to perform subgroup analysis by type of diabetes particularly when evaluating the outcome of glycemic control; adjustment of insulin in individuals with T1DM for exercise can be challenging and could result in differential effects of lifestyle programs on glycemic control depending on the type of diabetes and medical management of the participants.
3 & 5 Moderating factors for T1DM & T2DM	There was large diversity in the reporting and use of behavior change techniques employed within the programs. An evaluation of the effects of different strategies may shed additional light on the factors (within components) determining effectiveness for behavioral programs.
5 Moderating factors for T2DM	The identification of what combination of providers (e.g., physician, nurse, dietitian, pharmacists, social workers, psychologist, and trained lay individuals) is best for implementation of behavioral programs for T2DM deserves further evaluation.

Table 15. Potential research needs, by Key Question (continued)

KQ	Potential Research Needs
5 Moderating factors for T2DM	Clinical psychologists are often employed to deliver program components that incorporate advanced behavioral approaches, such as motivational interviewing; this approach may not be feasible for all settings or within all program budgets. More research is required to determine the effectiveness of similar programs when delivered by other personnel trained to use these behavioral techniques.
5 Moderating factors for T2DM	Few trials directly compared interactive programs delivered in person to those delivered via technology. Because a technology-based approach may lessen resource burden, help to reach patients living in rural areas, and/or be desirable for younger adults more familiar with technology, its effectiveness needs further evaluation.
6 Effectiveness for different subgroups in T2DM	Trials including populations of diverse ethnic backgrounds should perform subgroup analysis based on age, ethnicity, and baseline glycemic control to further explore outcomes for these groups from programs that are not designed specifically for them, as might be common in most community health settings.
All	Few trials evaluated outcomes important to patients and decisionmakers (e.g. quality of life, micro- and macrovascular complications, health care utilization) in a manner that allowed pooling of results across studies. Use of widely accepted generic quality of life measures would be beneficial.
All	Study attrition rates affected the overall risk of bias substantially; more research on methods for maintaining study participation is required.
All	The risk of bias from participant and personnel blinding was high in most trials. Although many trials compared behavioral programs to active controls (limiting risk of bias due to blinding) comparisons with usual care would benefit from some mechanism to blind participants from the study hypothesis. Blinding of outcome assessors should always be attempted for subjective outcomes.
All	There is a need for consensus on what constitutes clinically important differences in outcomes for behavioral programs, such that they can be interpreted in meaningful ways for clinicians and patients.

KQ = Key Question; T1DM = type 1 diabetes; T2DM = type 2 diabetes

Conclusions

This systematic review found that behavioral programs (especially DSME) for T1DM have some benefit on glycemic control when followup extends beyond the immediate postintervention period up to 6 months after the program. There was no significant difference at end of intervention or followup longer than 6 months, although our confidence in these findings is low and we cannot rule out benefit. There was no difference in generic HRQL at end of intervention, or in diabetes distress or self-management behaviors at up to 6-month followup, although the SOE was low for these findings with the exception of generic HRQL at end of intervention (moderate SOE). Data were insufficient to draw any conclusions for other timepoints for generic HRQL, diabetes distress, and self-management, and for other outcomes including diabetes-specific HRQL, change in body composition or lifestyle behaviors, micro- and macrovascular complications, and mortality. Encouraging patients with T1DM to participate in behavioral programs to improve outcomes apart from HbA_{1c} is not supported by the current evidence.

For T2DM, our analyses showed limited benefit in glycemic control from DSME programs offering ≤10 hours of contact with delivery personnel, and suggested that in-person delivery of behavioral programs is more beneficial than incorporation of technology. We found that programs focused on lifestyle or on DSME can have similar benefit in terms of glycemic control, and that lifestyle programs appear better for reducing BMI. Whether the behavioral program is delivered by a health care professional or a trained lay person, or via individual or group format appears less important based on the available evidence. Behavioral programs seem to benefit individuals having suboptimal or poor glycemic control more than those with optimal control.

Tailoring programs to ethnic minorities—such as offering culturally appropriate materials and incorporating group interaction with peers—appears beneficial. While efforts should be made to provide culturally sensitive programs, community health settings that serve populations that are diverse in language and ethnicity may not have the opportunity to provide this flexible programming to meet each group's needs.

The finding that behavioral programs offer some benefit in terms of glycemic control in individuals with diabetes underscores the need for care providers to be educated in behavioral techniques, and related topics such as facilitating support groups and family communication training—something that is often missing within the formal training of physicians, nurses, dietitians, and pharmacists. This review was unable to assess the differential effects on program success by single versus multiple health care providers, or by delivery teams having differing compositions of providers (including trained lay professionals)—this topic deserves further evaluation. Few trials evaluated patient-important outcomes (e.g., quality of life) in a manner to pool results across studies. Use of widely accepted quality of life measures would be beneficial.

Efforts at integrating behavioral programs into care settings that incorporate the latest management guidelines should be prioritized. Program evaluation is an important component to build into the implementation of any behavioral program for diabetes, to ensure that it is the correct fit to be effective for the population that it is attempting to serve. At this time, there remains a need for clinicians to evaluate each patient's success after participating in these programs, should additional means be necessary to control their disease more adequately to prevent devastating complications.

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Abbreviations and Acronyms

95% CIs	95 percent confidence intervals
AC	active control
AHRQ	Agency for Healthcare Research and Quality
BMI	body mass index
CDC	Centers for Disease Control and Prevention
DSME	diabetes self-management education
DSMP	Diabetes Self-Management Profile questionnaire
EOI	end of intervention
EPC	Evidence-based Practice Center
h	hour
HbA_{1c}	hemoglobin A_{1c}
HRQL	health-related quality of life
I^2	I squared statistic (measure of statistical heterogeneity)
KIs	Key Informants
KQ	key question
m	month
MD	mean difference
n	number
NA	not applicable
NMA	network meta-analysis
NR	not reported
OR	odds ratio
PAID	Problem Areas in Diabetes questionnaire
PB	"probability of being best"
PICOTS	populations, interventions, comparators, outcomes, timing, settings
QOL	quality of life
RCT	randomized controlled trial
ROB	risk of bias
RR	risk ratios
SD	standard deviation
SDSCA	Summary of Diabetes Self-Care Activities
SMBG	self-monitoring of blood glucose
SMD	standardized mean differences
SOE	strength of evidence
SRDR	Systematic Review Data Repository
T1DM	type 1 diabetes mellitus
T2DM	type 2 diabetes mellitus
TEP	Technical Expert Panel
TOO	Task Order Officer
U.S.	United States
UC	usual care
UK	United Kingdom
VO_2max	maximal oxygen uptake
yr	year

Appendix A. Operational Definitions

Behavioral Program

An organized, multicomponent diabetes-specific program with repeated interactions by one or more trained individuals, with a duration of ≥4 weeks, to improve disease control and/or patient health outcomes, and consisting of at least one of: a) diabetes self-management education (DSME); b) a structured dietary intervention (related to any of weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; or c) a structured exercise or physical activity intervention together with one or more additional components. Additional components for (b) and (c) above may include interventions related to: diet or physical activity; behavioral change (including but not limited to goal setting, problem solving, motivational interviewing, coping skills training, cognitive behavioral therapy strategies); relaxation or stress reduction; blood glucose regulation; medication adherence; or self-monitoring for diabetic complications (foot, eye and renal tests).

Interventions must include contact with those delivering the program, rather than sole reliance on "interactive behavior change technology" (e.g., patient-centered websites, automated telephone calls, DVDs, touch screen kiosks). While these tools show great promise for helping health systems meet the growing demand for diabetes management and support, they have been shown to be most effective when they support human contact.[35]

Below, we expand on specific elements of the above operational definition. They are presented in the order in which they appear in the definition.

Trained Individual

This can be an individual who has either received formal education and training in diabetes management and/or education, or has received some form of training to provide the specific program offered. There is no requirement to have a certain degree level or certification. This may include what is described as a lay health worker, "expert patient," "promotores" (Spanish term), or peer, as long as training is provided.

Repeated Interaction

There must be more than one interactive session—via face-to-face or indirect means—with the personnel providing the program.

Duration of ≥4 Weeks

The minimum duration of 4 weeks does not include post-intervention follow-up assessments for outcome ascertainment.

Diabetes Self-Management Education

A program will be considered DSME if the authors state that it meets the standards for DSME in the country in which the program is delivered (i.e., the program does not just cover a set of recommended topics of education). We also will include programs aiming to change patient (not provider) behaviors that are reported to: 1) include individualized assessment of needs/behaviors (performed by the provider and/or patient); 2) provide education on multiple self-care/management behaviors using interactive approaches (these may be combined with didactic and/or collaborative approaches); and 3) incorporate some form of behavior change strategy

(e.g., goal setting) whereby patients are trained to make informed decisions to self-manage their disease.
Not all topics must be provided to all patients and not all patients will receive the same duration/number of sessions, that is, there may be some tailoring of topics and delivery based on the needs assessment.

Structured Dietary Intervention

Dietary interventions may related to weight loss (e.g., caloric restriction), glycemic control (e.g., carbohydrate counting, controlling glycemic index of foods), and/or reducing risk for complications or comorbidities (e.g., reduced saturated and trans fats, increased fiber). The intervention must include interactive education/training methods (i.e., must be more than the provision of information or advice) on more than one occasion. The diet composition may either be personalized to the patient or follow a predetermined composition (e.g., low calorie diet with <30 percent fat).

Structured Physical Activity Intervention

Physical activity interventions must include either 1) personalized programs based on patient assessment and/or a patient's goals to train and facilitate behavior change, or 2) a structured intervention with a pre-determined program of activity (i.e., type, frequency, intensity and duration). The intervention must include interactive education/training methods (i.e., must be more than the provision of information or advice) on more than one occasion.

Activities that do not provide considerable energy expenditure (moderate intensity or more; goal to reach >40 percent aerobic capacity) or strength training potential will not be included (e.g., yoga, tai chi, stretching) but may be considered relaxation or stress reduction interventions.

Blood Glucose Regulation

This includes self-regulation of medication, diet, physical activity and so forth, based on results of blood glucose monitoring or awareness training. The intervention must consist of more than didactic teaching of blood glucose monitoring, teaching how to use pumps or other diabetes treatment technology, or teaching how to inject insulin. It may, for example, include practicing skills and problem solving on how to use the test results or to increase self-awareness to improve control through behaviors.

Relaxation or Stress Reduction

This includes interactive training or teaching related to meditation, yoga and other forms of non-aerobic or resistance training, or specific relaxation exercises or techniques (e.g., biofeedback). It may or may not include supervised practice.

Behavior Change Strategies

These include strategies to change behaviors but are not solely focused on emotional well-being. Strategies include, but are not limited to, motivational interviewing, coping skills training, cognitive behavioral therapy or techniques, problem-solving, goal setting, behavioral contracting, support groups, use of incentives or rewards, environmental change or barrier reduction, parent simulation, family therapy (related to problems with disease management behaviors), or anchored instruction. They must be directed at more than the single behavior in

the structured diet or physical activity interventions. For example, a diet intervention with goal setting and motivational interviewing that are only related to diet will not be considered two separate interventions. The strategies do not have to be based on theory but, where they are, this will be noted during data extraction. They do not include interventions limited to screening or therapeutic counseling for mental health diagnoses or emotional issues, although general psychosocial aspects and adaptation to disease will be included.

Medication Adherence

Any ongoing or intermittent intervention (i.e., not one-time provision of advice or information) that is intended to increase adherence to medication for hyperglycemia or risk factor reduction (e.g., lipid-lowering medications). This can be technology-based (e.g., text reminders via cell phone).

Self-Monitoring for Diabetic Complications

Any ongoing or intermittent intervention (i.e., not one-time provision of advice or information) that is intended to increase self-monitoring or screening for micro- or macrovascular complications (e.g., training on home foot care, reminders to attend screening appointments). This can be technology-based (e.g., text reminders via cell phone).

Note on Classification During Data Synthesis

Because there were very few studies evaluating programs with dietary and another (non-physical activity) component, or physical activity and another (non-dietary) component, we collapsed all programs that were not DSME into a “lifestyle” category which largely contained programs focusing on diet and physical activity.

Community Health Setting

A clinical practice setting with the primary purpose of providing health care to community-dwelling individuals (i.e., not hospital inpatients). Community health settings include ambulatory care clinics, outpatient clinics, primary care clinics, family physician clinics, and federally qualified health centers (i.e., Community Health Centers and Rural Health Centers). Programs that will be excluded are those delivered in inpatient settings and those offered in the community but without a link to a health clinic or center.

Comparators

Usual (or Routine/Standard) Care

These consist of usual medical management of study participants, whether this was provided by the study investigators or other health care professionals; because medical care is so diverse, these groups could receive a minimally intense intervention such as provision of pamphlets or one individual session with an educator. Interventions which are very minimal (e.g. delivery of pamphlets) will be included in this category.

Active Comparator

Controls that were beyond usual care but not meeting our operational definition of a behavioral program were considered active controls (e.g., stand-alone dietary intervention, basic education program of short duration or not including behavioral approaches).

Other Intervention

Anything that meets our definition of behavioral health program will be categorized as an intervention.

Appendix B. Literature Search Strategies

MEDLINE

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present
Search Title: Behavioral Health Programs for Diabetes_1
Search Date: 28 May 2014
Results: 15064

1. exp Diabetes Mellitus/
2. exp hypoglycemia/
3. diabet*.mp.
4. (noninsulin depend* or non insulin depend* or insulin depend*).mp.
5. (T1DM or T2DM or IDDM or NIDDM).mp.
6. or/1-5
7. exp Diabetes Insipidus/
8. (diabet* adj3 (insipidus not mellitus)).mp.
9. or/7-8
10. 6 not 9 (473318)
11. Behavior Therapy/
12. Blood Glucose Self-Monitoring/
13. Cognitive Therapy/
14. Community Health Centers/
15. Disease Management/
16. exp Exercise/ and (counsel* or intervention* or program* or train*).mp.
17. exp Exercise Therapy/
18. exp Directive Counseling/
19. Health Behavior/ and (counsel* or intervention* or program* or train*).mp.
20. Health Education/
21. Health Promotion/
22. exp Nutrition Therapy/
23. "Outcome Assessment (Health Care)"/
24. exp Patient Care Team/
25. exp Patient Compliance/
26. Patient Education as Topic/
27. Program Evaluation/
28. Relaxation Therapy/
29. Self Administration/
30. Self Medication/
31. Self Care/
32. Weight Loss/
33. (behavio?r adj2 therap*).mp.
34. (blood glucose adj2 monitor*).mp.
35. (cognitive adj2 therap*).mp.
36. (communit* adj2 (center* or centre*)).mp.

37. disease management.mp.
38. directive counsel*.mp.
39. ((behavio* or exercis* or diet* or fitness or life style* or lifestyle* or nutrition or physical activit* or problem solving or relax*) adj3 (counsel* or intervention* or program* or therap* or train* or treat*)).mp.
40. motivation* interview*.mp.
41. (self manag* or selfmanag* or self car* or selfcar*).mp.
42. or/11-41 (655126)
43. 10 and 42 (43958)
44. randomized controlled trial.pt.
45. controlled clinical trial.pt.
46. randomi?ed.ab.
47. placebo.ab.
48. drug therapy.fs.
49. randomly.ab.
50. trial.ab.
51. groups.ab.
52. or/44-51
53. exp animals/ not humans.sh.
54. 52 not 53
55. 43 and 54 (16442)
56. cohort studies/
57. follow-up studies/
58. longitudinal studies/
59. prospective studies/
60. cohort analy*.tw.
61. (cohort adj (study or studies)).tw.
62. (control* adj5 (before adj2 after)).tw.
63. (control* adj5 (pre* adj2 post*)).tw.
64. (follow up adj (study or studies)).tw.
65. longitudinal.tw.
66. (observational adj (study or studies)).tw.
67. prospective.tw.
68. or/56-67 (1252385)
69. exp animals/ not humans.sh.
70. 68 not 69
71. 43 and 70 (5831)
72. 55 or 71 (19002)
73. limit 72 to yr="1993-2014" (16423)
74. limit 73 to english language (15064)

CENTRAL

Database: CENTRAL via Cochrane Library
Search Title: Behavioral Health Programs for Diabetes
Date Searched: 30 May 2014
Results: 8010

1. MeSH descriptor: [Diabetes Mellitus] explode all trees
2. MeSH descriptor: [Hypoglycemia] explode all trees
3. diabet*:ti,ab,kw
4. ("noninsulin depend*" or "non insulin depend*" or "insulin depend*"):ti,ab,kw
5. (T1DM or T2DM or IDDM or NIDDM):ti,ab,kw
6. #1 or #2 or #3 or #4 or #5
7. exp Diabetes Insipidus/
8. (diabet* near/3 (insipidus not mellitus)):ti,ab,kw
9. #7 or #8
10. #6 not #9 (31905)
11. MeSH descriptor: [Behavior Therapy] this term only
12. MeSH descriptor: [Blood Glucose Self-Monitoring] this term only
13. MeSH descriptor: [Cognitive Therapy] this term only
14. MeSH descriptor: [Community Health Centers] this term only /
15. MeSH descriptor: [Disease Management] this term only
16. MeSH descriptor: [Exercise] explode all trees
17. (counsel* or intervention* or program* or train*):ti,ab,kw
18. #16 and #17
19. MeSH descriptor: [Exercise Therapy] explode all trees
20. MeSH descriptor: [Directive Counseling] explode all trees
21. MeSH descriptor: [Health Behavior] this term only
22. (counsel* or intervention* or program* or train*):ti,ab,kw
23. #21 and #22
24. MeSH descriptor: [Health Education] this term only
25. MeSH descriptor: [Health Promotion] this term only
26. MeSH descriptor: [Nutrition Therapy] explode all trees
27. MeSH descriptor: [Outcome Assessment (Health Care)] this term only
28. MeSH descriptor: [Patient Care Team] explode all trees
29. MeSH descriptor: [Patient Compliance] explode all trees
30. MeSH descriptor: [Patient Education as Topic] this term only
31. MeSH descriptor: [Program Evaluation] this term only
32. MeSH descriptor: [Relaxation Therapy] this term only
33. MeSH descriptor: [Self Administration] this term only
34. MeSH descriptor: [Self Medication] this term only
35. MeSH descriptor: [Self Care] this term only
36. MeSH descriptor: [Weight Loss] this term only
37. (behavio*r near/2 therap*):ti,ab,kw
38. (“blood glucose” near/2 monitor*):ti,ab,kw
39. (cognitive near/2 therap*):ti,ab,kw
40. (communit* near/2 (center* or centre*)):ti,ab,kw
41. “disease management”:ti,ab,kw
42. “directive counsel*”:ti,ab,kw
43. ((behavio* or exercis* or diet* or fitness or “life style*” or lifestyle* or nutrition or “physical activit*” or “problem solving” or relax*) near/3 (counsel* or intervention* or program* or therap* or train* or treat*)):ti,ab,kw
44. “motivation* interview*”:ti,ab,kw

45. (“self manag*” or selfmanag* or “self car*” or selfcar*):ti,ab,kw
46. #11 or #12 or #13 or 14 or #15 or #18 or #19 or #20 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 (175091)
47. #10 and #46 (9944)
limit: Publication Date from 1993 to 2014, in Trials (8010)

CINAHL

Database: CINAHL
Search Title: Behavioral Health Programs for Diabetes
Date Searched: 30 May 2014
Results: 8881

1. (MH "Diabetes Mellitus+")
2. (MH "Hypoglycemia+")
3. diabet*
4. "noninsulin depend*" or "non insulin depend*" or "insulin depend*"
5. T1DM or T2DM or IDDM or NIDDM
6. S1 OR S2 OR S3 OR S4 OR S5
7. (MH "Diabetes Insipidus+")
8. diabet* N3 (insipidus not mellitus)
9. S7 OR S8
10. S6 not S9 (120,132)
11. (MH "Behavior Therapy")
12. (MH "Blood Glucose Self-Monitoring")
13. (MH "Cognitive Therapy")
14. (MH "Community Health Centers")
15. (MH "Diabetes Education")
16. (MH "Diet Therapy+")
17. (MH "Disease Management")
18. (MH "Exercise+") AND (counsel* or intervention* or program* or train*)
19. (MH "Health Behavior") AND (counsel* or intervention* or program* or train*)
20. (MH "Health Education")
21. (MH "Health Promotion")
22. (MH "Motivational Interviewing")
23. (MH "Multidisciplinary Care Team+")
24. (MH "Outcome Assessment")
25. (MH "Patient Compliance+")
26. (MH "Patient Education")
27. (MH "Program Evaluation")
28. (MH "Self Administration")
29. (MH "Self Medication")
30. (MH "Self Care")
31. (MH "Therapeutic Exercise+")
32. (MH "Weight Loss")
33. behavio#r N2 therap*

35. “blood glucose” N2 monitor*
36. cognitive N2 therap*
36. communit* N2 (center* or centre*)
37. “disease management”
38. “directive counsel*”
39. (behavio* or exercis* or diet* or fitness or “life style*” or lifestyle* or nutrition or “physical activit*” or “problem solving” or relax*) N3 (counsel* or intervention* or program* or therap* or train* or treat*)
40. “motivation* interview*”
41. “self manag*” or selfmanag* or “self car*” or selfcar*
42. S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 (334531)
43. S10 AND S42 (27139)
44. (MH "Clinical Trials+")
45. PT Clinical trial
46. TX clinic* n1 trial*
47. TX ((singl* n1 blind*) or (singl* n1 mask*)) or TX ((doubl* n1 blind*) or (doubl* n1 mask*)) or TX ((tripl* n1 blind*) or (tripl* n1 mask*)) or TX ((trebl* n1 blind*) or (trebl* n1 mask*))
48. TX randomi* control* trial*
49. (MH "Random Assignment")
50. TX random* allocat*
51. TX placebo*
52. (MH "Placebos")
53. (MH "Quantitative Studies")
54. TX allocat* random*
53. (MH "Quantitative Studies")
54. TX allocat* random*
55. S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54
56. (MH "Animals+") NOT (MH "Human")
57. S55 NOT S56
58. S43 AND S57 (7921)
59. (MH “Concurrent Prospective Studies”)
60. (MH “Nonexperimental Studies”)
61. (MH “Prospective Studies”)
62. “cohort analy*”
63. cohort N1 (study or studies)
64. control* N5 (before N2 after)
65. control* N5 (pre* N2 post*)
66. “follow up” N1 (study or studies)
67. longitudinal
68. observational N1 (study or studies)
69. prospective
70. S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69

71. (MH "Animals+") NOT (MH "Human")
72. S70 not S71
73. S43 AND S72 (2627)
74. S58 OR S73 (9468)
75. S74 Limiters – English Language; Publication Date: 19930101-20141231 (8881)

Ovid Embase

Database: Ovid Embase 1988 to 2014 Week 21
Search Title: Behavioral Health Programs for Diabetes_2
Date Searched: May 29, 2014
Results: 24629

1. exp diabetes mellitus/
2. exp hypoglycemia/
3. diabet*.mp.
4. (noninsulin depend* or non insulin depend* or insulin depend*).mp.
5. (T1DM or T2DM or IDDM or NIDDM).mp.
6. or/1-5
7. exp diabetes insipidus/
8. (diabet* adj3 (insipidus not mellitus)).mp.
9. or/7-8
10. 6 not 9 (613880)
11. behavior therapy/
12. blood glucose monitoring/
13. cognitive therapy/
14. diabetes education/
15. exp diet therapy/
16. directive counseling/
17. disease management/
18. drug self administration/
19. exp Exercise/ and (counsel* or intervention* or program* or train*).mp.
20. Health Behavior/ and (counsel* or intervention* or program* or train*).mp.
21. health center/
22. health education/
23. health promotion/
24. exp kinesiotherapy/
25. nutrition education/
26. outcome assessment/
27. patient care/
28. exp patient compliance/
29. patient education/
30. exp program evaluation/
31. rapid response team/
32. relaxation training/
33. self care/
34. weight reduction/

35. (behavio?r adj2 therap*).mp.
36. (blood glucose adj2 monitor*).mp.
37. (cognitive adj2 therap*).mp.
38. (communit* adj2 (center* or centre*)).mp.
39. disease management.mp.
40. directive counsel*.mp.
41. ((behavio* or exercis* or diet* or fitness or life style* or lifestyle* or nutrition or physical activit* or problem solving or relax*) adj3 (counsel* or intervention* or program* or therap* or train* or treat*)).mp.
42. motivation* interview*.mp.
43. (self manag* or selfmanag* or self car* or selfcar*).mp.
44. or/11-43 (1217935)
45. 10 and 44 (121429)
46. random*.mp.
47. animals/ not (animals/ and humans/)
48. 46 not 47
49. 45 and 48 (18450)
50. cohort analysis/
51. longitudinal study/
52. prospective study/
53. (cohort adj (study or studies)).tw.
54. (control* adj5 (before adj2 after)).tw.
55. (control* adj5 (pre* adj2 post*)).tw.
56. (follow up adj (study or studies)).tw.
57. (prospective adj (study or studies)).tw.
58. or/50-57
59. animals/ not (animals/ and humans/)
60. 58 not 59
61. 45 and 60 (9212)
62. 49 or 61 (25875)
63. limit 62 to yr="1993-2014" (25632)
64. limit 63 to english language (24629)

Ovid PsycINFO

Database: Ovid PsycINFO 1987 to May Week 4 2014
Search Title: Behavioral Health Programs for Diabetes_3
Date Searched: 29 May 2014
Results: 4008

1. exp Diabetes/
2. Hypoglycemia/
3. diabet*.mp.
4. (noninsulin depend* or non insulin depend* or insulin depend*).mp.
5. (T1DM or T2DM or IDDM or NIDDM).mp.
6. or/1-5
7. Diabetes Insipidus/

8. (diabet* adj3 (insipidus not mellitus)).mp.
9. or/7-8
10. 6 not 9 (18569)
11. Behavior Therapy/
12. Client Centered Therapy/
13. Client Education/
14. Cognitive Therapy/
15. exp Community Services/
16. exp Compliance/
17. exp Counseling/
18. Disease Management/
19. Drug Self Administration/
20. exp Exercise/ and (counsel* or intervention* or program* or train*).mp.
21. Health Behavior/ and (counsel* or intervention* or program* or train*).mp.
22. exp Health Care Delivery/
23. Health Care Services/
24. Health Education/
25. Health Promotion/
26. Movement Therapy/
27. Motivational Interviewing/
28. Physical Activity/
29. exp Program Evaluation/
30. Recreation Therapy/
31. exp Relaxation Therapy/
32. Self Monitoring/
33. Self Care Skills/
34. Weight Control/
35. Weight Gain/
36. Weight Loss/
37. (behavio?r adj2 therap*).mp.
38. (blood glucose adj2 monitor*).mp.
39. (cognitive adj2 therap*).mp.
40. (communit* adj2 (center* or centre*)).mp.
41. disease management.mp.
42. directive counsel*.mp.
43. ((behavio* or exercis* or diet* or fitness or life style* or lifestyle* or nutrition or physical activit* or problem solving or relax*) adj3 (counsel* or intervention* or program* or therap* or train* or treat*)).mp.
44. motivation* interview*.mp.
45. (self manag* or selfmanag* or self car* or selfcar*).mp.
46. or/11-45 (258474)
47. 10 and 46 (5964)
48. control*.tw.
49. random*.tw.
50. exp treatment/
51. or/ 48-50

52. exp animals/ not humans.sh.
53. 51 not 52
54. 47 and 53 (4248)
55. cohort analy*.tw.
56. (cohort adj (study or studies)).tw.
57. (control* adj5 (before adj2 after)).tw.
58. (control* adj5 (pre* adj2 post*)).tw.
59. (follow up adj (study or studies)).tw.
60. longitudinal.tw.
61. (observational adj (study or studies)).tw.
62. prospective.tw.
63. or/55-62
64. exp animals/ not humans.sh.
65. 63 not 64
66. 47 and 65 (502)
67. 54 or 66 (4367)
68. limit 67 to yr="1993-2014" (4103)
69. limit 68 to english language (4010)
70. remove duplicates from 69 (4008)

PubMed

Database: PubMed
Search Title:
Date Searched: 30 May 2014
Results: 670

1. "Diabetes Mellitus"[Mesh]
2. "Hypoglycemia"[Mesh]
3. diabet*[tiab]
4. "noninsulin dependent"[tiab] OR "non insulin dependent"[tiab] OR "insulin dependent"[tiab]
5. T1DM[tiab] OR T2DM[tiab] OR IDDM[tiab] OR NIDDM[tiab]
6. #1 OR #2 OR #3 OR #4 OR #5
7. "Diabetes Insipidus"[Mesh]
8. diabet*[tiab] AND (insipidus[tiab] NOT mellitus[tiab])
9. #7 OR #8
10. #6 NOT #9 (472248)
11. "Behavior Therapy"[Mesh:NoExp]
12. "Blood Glucose Self-Monitoring"[Mesh]
13. "Cognitive Therapy"[Mesh:NoExp]
14. "Community Health Centers"[Mesh:NoExp]
15. "Disease Management"[Mesh:NoExp]
16. "Exercise"[Mesh] AND (counsel* or intervention* or program* or train*)
17. "Exercise Therapy"[Mesh]
18. "Directive Counseling"[Mesh]
19. "Health Behavior"[Mesh] AND (counsel* or intervention* or program* or train*)
20. "Health Education"[Mesh:NoExp]

21. "Health Promotion"[Mesh:NoExp]
22. "Nutrition Therapy"[Mesh]
23. "Outcome Assessment (Health Care)"[Mesh:NoExp]
24. "Patient Care Team"[Mesh]
25. "Patient Compliance"[Mesh]
26. "Patient Education as Topic"[Mesh:NoExp]
27. "Program Evaluation"[Mesh:NoExp]
28. "Relaxation Therapy"[Mesh:NoExp]
29. "Self Administration"[Mesh]
30. "Self Medication"[Mesh] /
31. "Self Care"[Mesh:NoExp]
32. "Weight Loss"[Mesh:NoExp]
33. "behavior therapy"[tiab] OR "behaviour therapy"[tiab] OR "behavior therapies"[tiab] OR "behaviour therapies"[tiab] OR "behavioral therapy"[tiab] OR "behavioural therapy"[tiab] OR "behavioral therapies"[tiab] OR "behavioural therapies"[tiab]
34. "blood glucose monitoring"[tiab]
35. "cognitive therapy"[tiab] OR "cognitive therapies"[tiab]
36. "community centre"[tiab] OR "community centres"[tiab] OR "community center"[tiab] OR "community centers"[tiab]
37. "disease management"[All Fields]
38. "directive counseling"[All Fields]
39. ((behavio*[tiab] or exercis*[tiab] or diet[tiab] or fitness[tiab] or "life style"[tiab] or "life styles"[tiab] or lifestyle*[tiab] or nutrition[tiab] or "physical activity"[tiab] or "problem solving"[tiab] or relax*[tiab]) AND (counsel*[tiab] or intervention*[tiab] or program*[tiab] or therap*[tiab] or train*[tiab] or treat*[tiab]))
40. "motivational interviewing"[tiab] OR "motivational interview"[tiab] OR "motivational interviews"[tiab]
41. "self manage"[tiab] OR "self managed"[tiab] OR selfmanag*[tiab] or "self care"[tiab] or selfcar*[tiab]
42. #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 (965205)
43. #10 AND #42 (56413)
44. randomized controlled trial [pt]
45. controlled clinical trial [pt]
46. randomized [tiab]
47. placebo [tiab]
48. drug therapy [sh]
49. randomly [tiab]
50. trial [tiab]
51. groups [tiab]
52. #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51
53. animals [mh] NOT humans [mh]
54. #52 NOT #53
55. #43 AND #54 (20350)
56. "Cohort Studies"[Mesh:NoExp]

57. "Follow-Up Studies"[Mesh]
58. "Longitudinal Studies"[Mesh:NoExp]
59. "Prospective Studies"[Mesh]
60. "cohort analysis"[tiab] OR "cohort analyses"[tiab]
61. "cohort study"[tiab] OR "cohort studies"[tiab]
62. "controlled before and after"[tiab] OR "controlled before after"[tiab]
63. control*[tiab] AND pre[tiab] AND post[tiab] AND (study[tiab] OR studies[tiab])
64. "follow up study"[tiab] OR "follow up studies"[tiab]
65. longitudinal[tiab]
66. "observational study"[tiab] OR "observational studies"[tiab]
67. prospective[tiab]
68. #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67
69. animals [mh] NOT humans [mh]
70. #68 NOT #69
71. #43 AND #70 (7284)
72. #55 OR #71 (23770)
73. #72 Filters activated: Publication date from 2014/01/01 to 2014/12/31 (685)
74. #73 Filters activated: English (670)

Single search string:
Search: (((((("Diabetes Mellitus"[Mesh]) OR ("Hypoglycemia"[Mesh]) OR (diabet*[tiab]) OR ("noninsulin dependent"[tiab] OR "non insulin dependent"[tiab] OR "insulin dependent"[tiab]) OR (T1DM[tiab] OR T2DM[tiab] OR IDDM[tiab] OR NIDDM[tiab])) NOT ((diabet*[tiab] AND (insipidus[tiab] NOT mellitus[tiab])) OR ("Diabetes Insipidus"[Mesh]))) AND (("self manage"[tiab] OR "self managed"[tiab] OR selfmanag*[tiab] OR "self care"[tiab] OR selfcar*[tiab]) OR ("motivational interviewing"[tiab] OR "motivational interview"[tiab] OR "motivational interviews"[tiab]) OR ((behavio*[tiab] OR exercis*[tiab] OR diet[tiab] OR fitness[tiab] OR "life style"[tiab] OR "life styles"[tiab] OR lifestyle*[tiab] OR nutrition[tiab] OR "physical activity"[tiab] OR "problem solving"[tiab] OR relax*[tiab]) AND (counsel*[tiab] OR intervention*[tiab] OR program*[tiab] OR therap*[tiab] OR train*[tiab] OR treat*[tiab])) OR ("directive counseling"[All Fields]) OR ("disease management"[All Fields]) OR ("community centre"[tiab] OR "community centres"[tiab] OR "community center"[tiab] OR "community centers"[tiab]) OR ("cognitive therapy"[tiab] OR "cognitive therapies"[tiab]) OR ("blood glucose monitoring"[tiab]) OR ("behavior therapy"[tiab] OR "behaviour therapy"[tiab] OR "behavior therapies"[tiab] OR "behaviour therapies"[tiab] OR "behavioral therapy"[tiab] OR "behavioural therapy"[tiab] OR "behavioral therapies"[tiab] OR "behavioural therapies"[tiab]) OR ("Weight Loss"[Mesh:noexp]) OR ("Self Care"[Mesh:noexp]) OR ("Self Medication"[Mesh]) OR ("Self Administration"[Mesh]) OR ("Relaxation Therapy"[Mesh:noexp]) OR ("Program Evaluation"[Mesh:noexp]) OR ("Patient Education as Topic"[Mesh:noexp]) OR ("Patient Compliance"[Mesh]) OR ("Patient Care Team"[Mesh]) OR ("Outcome Assessment (Health Care)"[Mesh:noexp]) OR ("Nutrition Therapy"[Mesh]) OR ("Health Promotion"[Mesh:noexp]) OR ("Health Education"[Mesh:noexp]) OR ("Health Behavior"[Mesh] AND (counsel* OR intervention* OR program* OR train*)) OR ("Directive Counseling"[Mesh]) OR ("Exercise Therapy"[Mesh]) OR ("Exercise"[Mesh] AND (counsel* OR intervention* OR program* OR train*)) OR ("Disease Management"[Mesh:noexp]) OR ("Community Health

Centers"[Mesh:noexp]) OR ("Cognitive Therapy"[Mesh:noexp]) OR ("Blood Glucose Self-Monitoring"[Mesh]) OR ("Behavior Therapy"[Mesh:noexp]))) AND (((randomized controlled trial[pt]) OR (controlled clinical trial[pt]) OR (randomized[tiab]) OR (placebo[tiab]) OR (drug therapy[sh]) OR (randomly[tiab]) OR (trial[tiab]) OR (groups[tiab])) NOT (animals[mh] NOT humans[mh]))) OR (((((("Diabetes Mellitus"[Mesh]) OR ("Hypoglycemia"[Mesh]) OR (diabet*[tiab]) OR ("noninsulin dependent"[tiab] OR "non insulin dependent"[tiab] OR "insulin dependent"[tiab]) OR (T1DM[tiab] OR T2DM[tiab] OR IDDM[tiab] OR NIDDM[tiab])) NOT ((diabet*[tiab] AND (insipidus[tiab] NOT mellitus[tiab])) OR ("Diabetes Insipidus"[Mesh]))) AND (("self manage"[tiab] OR "self managed"[tiab] OR selfmanag*[tiab] OR "self care"[tiab] OR selfcar*[tiab]) OR ("motivational interviewing"[tiab] OR "motivational interview"[tiab] OR "motivational interviews"[tiab]) OR ((behavio*[tiab] OR exercis*[tiab] OR diet[tiab] OR fitness[tiab] OR "life style"[tiab] OR "life styles"[tiab] OR lifestyle*[tiab] OR nutrition[tiab] OR "physical activity"[tiab] OR "problem solving"[tiab] OR relax*[tiab]) AND (counsel*[tiab] OR intervention*[tiab] OR program*[tiab] OR therap*[tiab] OR train*[tiab] OR treat*[tiab])) OR ("directive counseling"[All Fields]) OR ("disease management"[All Fields]) OR ("community centre"[tiab] OR "community centres"[tiab] OR "community center"[tiab] OR "community centers"[tiab]) OR ("cognitive therapy"[tiab] OR "cognitive therapies"[tiab]) OR ("blood glucose monitoring"[tiab]) OR ("behavior therapy"[tiab] OR "behaviour therapy"[tiab] OR "behavior therapies"[tiab] OR "behaviour therapies"[tiab] OR "behavioral therapy"[tiab] OR "behavioural therapy"[tiab] OR "behavioral therapies"[tiab] OR "behavioural therapies"[tiab]) OR ("Weight Loss"[Mesh:noexp]) OR ("Self Care"[Mesh:noexp]) OR ("Self Medication"[Mesh]) OR ("Self Administration"[Mesh]) OR ("Relaxation Therapy"[Mesh:noexp]) OR ("Program Evaluation"[Mesh:noexp]) OR ("Patient Education as Topic"[Mesh:noexp]) OR ("Patient Compliance"[Mesh]) OR ("Patient Care Team"[Mesh]) OR ("Outcome Assessment (Health Care)"[Mesh:noexp]) OR ("Nutrition Therapy"[Mesh]) OR ("Health Promotion"[Mesh:noexp]) OR ("Health Education"[Mesh:noexp]) OR ("Health Behavior"[Mesh] AND (counsel* OR intervention* OR program* OR train*)) OR ("Directive Counseling"[Mesh]) OR ("Exercise Therapy"[Mesh]) OR ("Exercise"[Mesh] AND (counsel* OR intervention* OR program* OR train*)) OR ("Disease Management"[Mesh:noexp]) OR ("Community Health Centers"[Mesh:noexp]) OR ("Cognitive Therapy"[Mesh:noexp]) OR ("Blood Glucose Self-Monitoring"[Mesh]) OR ("Behavior Therapy"[Mesh:noexp]))) AND ((("Cohort Studies"[Mesh:noexp]) OR ("Follow-Up Studies"[Mesh]) OR ("Longitudinal Studies"[Mesh:noexp]) OR ("Prospective Studies"[Mesh]) OR ("cohort analysis"[tiab] OR "cohort analyses"[tiab]) OR ("cohort study"[tiab] OR "cohort studies"[tiab]) OR ("controlled before and after"[tiab] OR "controlled before after"[tiab]) OR (control*[tiab] AND pre[tiab] AND post[tiab] AND (study[tiab] OR studies[tiab])) OR ("follow up study"[tiab] OR "follow up studies"[tiab]) OR (longitudinal[tiab]) OR ("observational study"[tiab] OR "observational studies"[tiab]) OR (prospective[tiab])) NOT (animals[mh] NOT humans[mh])))

AADE Proceedings

Conference Proceeding: AADE Proceedings
Search Title: N/A
Date Searched: 27 June 2014
https://event.crowdcompass.com/aade14/custom-list/Schedule

URL provided by Michelle Crain, AADE Marketing and Communications Coordinator
mcrain@aadenet.org

Note: No availability to abstracts from 2011-2013 meetings.

ADA Proceedings

Conference Proceeding: ADA Proceedings (via Embase)
Search Title: N/A
Date Searched: 26 June 2014
Results: 3 PDFs

1. american diabetes association.ti.
2. limit 1 to (yr=2011 –Current" and (conference abstract or conference paper or conference proceeding or "conference review")) (3)

CDA Proceedings

Conference Proceeding: CDA Proceedings
Search Title: N/A
Date Searched: 27 June 2014
Results: 3 journal issues

Hand searched issues of the Canadian Journal of Diabetes on ScienceDirect:
http://www.sciencedirect.com/science/journal/14992671/

EASD Proceedings

Conference Proceeding: EASD (European Association for the Study of Diabetes) Proceedings
Search Title: N/A
Date Searched: 27 June 20143
Results: 3 links

Meeting abstracts available through the EASD website:
http://www.easd.org/index.php?option=com_content&view=article&id=69&Itemid=509

IDF Proceedings

Conference Proceeding: IDF Proceedings
Search Title: N/A
Date Searched: 27 June 2014
Results: 2 links (2012 conference not available)

Meeting abstracts available through the IDF website:
http://www.idf.org/final-programme

SMB Proceedings

Conference Proceeding: SBM Proceedings
Search Title: N/A

Date Searched: 27 June 2014
Results: 4 links to program PDFs

Meeting abstracts/programs available through the SBM website:
http://www.sbm.org/meetings/past

ISBNPA Proceedings

Conference Proceeding: ISBNPA (International Society for Behavioral, Nutrition and Physical Activity) Proceedings
Search Title: N/A
Date Searched: 27 June 2014
Results: 4 links to programs/abstracts

Meeting abstracts/programs available through the ISBNPA website:
https://secure.isbnpa.org/annual-meeting/index.cfm

ClinicalTrials.gov

Trial Registry: ClinicalTrials.gov
Date Searched: 25 – 26 June, 2014
Results: 2070

1. "Diabetes Mellitus" [DISEASE] AND (life style OR lifestyle OR life styles OR lifestyles) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (291)
2. "Diabetes Mellitus" [DISEASE] AND (self management) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (197)
3. "Diabetes Mellitus" [DISEASE] AND (behavior OR behaviour OR behavioral OR behavioural) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (710)
4. "Diabetes Mellitus" [DISEASE] AND (education OR educational) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (403)
5. "Diabetes Mellitus" [DISEASE] AND (blood glucose regulation) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (14)
6. "Diabetes Mellitus" [DISEASE] AND (medication adherence) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (61)
7. "Diabetes Mellitus" [DISEASE] AND ((exercise OR physical activity) AND (diet OR dietary)) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (273)
8. "Diabetes Mellitus" [DISEASE] AND ((exercise OR physical activity) AND (relaxation OR biofeedback OR yoga OR meditation)) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (10)
9. "Diabetes Mellitus" [DISEASE] AND ((diet OR dietary) AND (relaxation OR biofeedback OR yoga OR meditation)) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (7)
10. "Diabetes Mellitus" [DISEASE] AND (family) [TREATMENT] AND ("01/01/2009" : "12/31/2014") [FIRST-RECEIVED-DATE] (104)

WHO ICTRP

Trial Registry: WHO ICTRP
Date Searched: 26 June 2014
Results: 422

Advance search interface: http://apps.who.int/trialsearch/AdvSearch.aspx
> "Condition" field: diabetes
> "Intervention" field: lifestyle OR self management OR behavior OR education OR family
> "Recruitment status" field is: ALL
> Date of registration is between: 01/01/2009 and 31/12/2014 (422)

Appendix C. Very High Human Development Index Countries

These countries meet the category of Very-high Human Development Index status, as per the United Nations Development Program. (Human Development Report 2013 Team. Table 1. Human Development Index and its components. In: Human Development Report 2013. The Rise of the South: Human Progress in a Diverse World. United Nations Development Programme, 2013; pp 144-7. http://hdr.undp.org/en/content/human-development-report-2013. Accessed March 3, 2014.)

Andorra
Argentina
Australia
Austria
Barbados
Belgium
Brunei Darussalam
Canada
Chile
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hong Kong, China (SAR)
Hungary
Iceland
Ireland
Israel
Italy
Japan
Korea (Republic of)
Latvia
Liechtenstein
Lithuania
Luxembourg
Malta
Netherlands
New Zealand
Norway
Poland
Portugal
Qatar
Seychelles
Singapore
Slovakia
Slovenia
Spain
Sweden
Switzerland
United Arab Emirates
United Kingdom
United States

Appendix D. Studies Excluded After Full-Text Review

1. Aas AM, Bergstad I, Thorsby PM, et al. An intensified lifestyle intervention programme may be superior to insulin treatment in poorly controlled type 2 diabetic patients on oral hypoglycaemic agents: results of a feasibility study. Diabet Med. 2005 Mar;22(3):316-22. PMID: 15717881. Exclude: Intervention.

2. Abolfotouh MA, Kamal MM, El-Bourgy MD, et al. Quality of life and glycemic control in adolescents with type 1 diabetes and the impact of an education intervention. Int J Gen Med. 2011;4:141-52. PMID: 21475630. Exclude: Setting/Country.

3. Adams KF, Sperl-Hillen JaM, Davis H, et al. Factors influencing patient completion of diabetes self-management education. Diabetes Spectrum. 2013;26(1):40-5. PMID: Not available. Exclude: Outcomes.

4. Adepoju OE, Bolin JN, Ohsfeldt RL, et al. Can chronic disease management programs for patients with type 2 diabetes reduce productivity-related indirect costs of the disease? Evidence from a randomized controlled trial. Popul Health Manag. 2014;17(2):112-20. PMID: 24152055. Exclude: Intervention.

5. Adepoju OE, Bolin JN, Phillips CD, et al. Effects of diabetes self-management programs on time-to-hospitalization among patients with type 2 diabetes: a survival analysis model. Patient Educ Couns. 2014 Apr;95(1):111-7. PMID: 24468198. Exclude: Intervention.

6. Adkins JW, Storch EA, Lewin AB, et al. Home-based behavioral health intervention: use of a telehealth model to address poor adherence to type-1 diabetes medical regimens. Telemed J E Health. 2006 Jun;12(3):370-2. PMID: 16796506. Exclude: Design.

7. Agema P, Sherifali D. Determining the impact of an intervention to increase problem-solving skills in diabetes self-management: the diabetes problem-solving passport pilot study. Can. 2012 August;36(4):199-203. PMID: Not available. Exclude: Intervention.

8. Aikens JE, Rosland AM, Piette JD. Improvements in illness self-management and psychological distress associated with telemonitoring support for adults with diabetes. Prim Care Diabetes. 2014 Jul 22. PMID: 25065270. Exclude: Design.

9. Al Mazroui NR, Kamal MM, Ghabash NM, et al. Influence of pharmaceutical care on health outcomes in patients with type 2 diabetes mellitus. Br J Clin Pharmacol. 2009 May;67(5):547-57. PMID: 19552750. Exclude: Intervention.

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Appendix E. Risk of Bias

Table E1. Risk of bias for studies on type 1 diabetes mellitus

Author, Year	SG	AC	Blinding of PP		Blinding of OA		IOD		SOR	Other	Overall	
			Subjective	Objective	Subjective	Objective	Subjective	Objective			Subjective	Objective
Amsberg, 2009	M	M	H	M	H	L	H	H	L	L	H	H
Anderson, 1999	M	M	NA*	M	NA	L	NA	L	L	L	NA	M
Boardway, 1993	M	M	H	M	H	L	H	H	L	L	H	H
Christie, 2014	L	L	H	M	H	L	H	M	L	L	H	M
Cook, 2002	M	M	H	M	H	L	H	H	L	L	H	H
Ellis, 2007	M	M	NA	M	NA	L	NA	M	L	L	NA	M
Ellis, 2012	L	M	M	M	M	L	M	M	M	L	M	M
Franklin, 2006	L	M	H	M	H	L	M	M	L	L	H	M
Freeman, 2013	M	M	M	M	M	L	H	H	L	L	H	H
Hermanns, 2013	L	L	H	M	H	L	L	L	L	L	H	M
Holmes, 2014	M	M	NA	M	NA	L	NA	N	L	L	NA	H
Husted, 2014	L	L	H	M	H	L	H	H	L	H	H	H
Ismail, 2008	L	H	H	M	H	L	H	M	M	H	H	H
Karlsen, 2004	M	M	H	M	H	L	H	H	L	L	H	H
Katz, 2014	M	M	H	M	H	L	L	L	L	L	H	M
Kichler, 2013	M	M	H	M	H	L	H	M	L	L	H	M
Laffel, 2003	M	M	H	M	H	L	L	L	L	L	H	M
Lehmkuhl, 2010	L	M	NA	M	NA	L	NA	H	L	L	NA	H
Mannucci, 2005	H	H	H	M	H	L	H	H	L	H	H	H
Mayer-Davis, 2014	L	M	H	M	H	L	L	L	L	L	H	M
McNabb, 1994	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Murphy, 2007	M	M	NA	M	NA	L	NA	M	M	L	NA	M
Murphy, 2012	L	L	NA	M	NA	L	NA	L	M	L	NA	M
Nansel, 2007	L	M	H	M	H	L	L	L	L	L	H	M
Nansel, 2012	L	M	H	M	H	L	L	L	L	L	H	M
Perry, 1997	M	M	H	M	H	L	H	H	L	L	H	H
Serlachius, 2014	L	M	H	M	H	L	H	L	L	M	H	M
Viklund, 2007	M	M	NA	M	NA	L	NA	L	L	L	NA	M

Weinger, 2011	L	M	NA	M	NA	L	NA	L	L	L	NA	M
Wysocki, 2007	M	M	H	M	H	L	M	M	L	L	H	M
Zoffmann, 2006	H	L	H	M	H	L	H	H	L	L	H	H

*These trials may have reported on subjective (i.e., patient reported) outcomes but they were either not of interest to the review or not included in the analysis because of lacking data.

AC = allocation concealment; Blinding of OA = blinding of outcome assessors; Blinding of PP = blinding of participants and personnel; H = high risk of bias; IOD = incomplete outcome data; L = low risk of bias; M = medium or unclear risk of bias; NA = not applicable; Other = other sources of bias; Overall = overall risk of bias assessment; SG = sequence generation; SOR = selective outcome reporting

Table E2. Risk of bias for studies on type 2 diabetes mellitus

Author, Year	SG	AC	Blinding of PP		Blinding of OA		IOD		SOR	Other	Overall	
			Subjective	Objective	Subjective	Objective	Subjective	Objective			Subjective	Objective
Adachi, 2013	M	M	H	M	H	L	M	M	L	L	H	M
Adolfsson, 2007	M	L	NA*	M	NA	L	NA	H	L	H	NA	H
Agur-Collins, 1997	M	M	H	M	H	L	H	H	L	L	H	H
Amoako, 2008	H	H	H	M	H	L	M	M	L	L	H	H
Anderson, 1995	M	M	H	M	H	L	H	H	L	L	H	H
Anderson, 2005	M	M	H	M	H	L	L	L	L	L	H	M
Anderson, 2009	L	L	H	M	H	L	H	H	L	L	H	H
Anderson, 2010	M	M	NA	M	NA	L	NA	H	L	H	NA	H
Anderson-Loftin, 2005	L	M	H	M	H	L	H	H	L	L	H	H
Baksi, 2008	L	M	NA	M	NA	L	NA	H	L	L	NA	H
Barratt, 2008	L	M	NA	M	NA	L	NA	L	L	L	NA	M
Beverly, 2013	L	M	M	M	M	L	H	H	L	M	H	H
Bond, 2007	M	M	H	M	H	L	L	L	L	L	H	M
Bozzetto, 2014	L	M	M	M	M	L	H	H	L	L	H	H
Bradshaw, 2007	M	M	M	M	M	L	H	H	M	L	H	H
Brown, 2002	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Brown, 2005	M	M	M	M	M	L	L	L	L	L	M	M
Brown, 2011	M	M	NA	M	NA	L	NA	L	L	L	NA	M
Castejon, 2013	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Chan, 2012	L	M	H	M	H	L	H	H	L	L	H	H
Chan, 2014	L	L	M	M	M	L	L	L	L	L	M	M
Cheong, 2009	M	M	M	M	M	L	H	H	L	L	H	H
Chlebowy, 2014	M	M	H	M	H	L	H	H	L	L	H	H
Clark, 2004	L	M	H	M	H	L	L	L	L	L	H	M
Cooper, 2008	M	M	NA	M	NA	L	NA	H	H	M	NA	H
Corkery, 1997	M	M	NA	M	NA	L	NA	H	L	L	NA	H

Cramer, 2007	M	M	H	M	H	L	H	H	L	M	H	H
Dasgupta, 2006	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Davis, 2010	M	M	NA	M	NA	L	NA	M	L	L	NA	M
Deakin, 2006	M	M	H	M	H	L	L	L	L	L	H	M
D-Eramo Melkus, 2010	L	M	M	M	M	L	M	M	L	L	M	M
Dunstan, 1997	M	M	H	M	H	L	H	H	L	L	H	H
Dunstan, 2005	M	M	M	M	M	L	H	H	L	L	H	H
Eakin, 2014	L	M	H	M	H	L	M	M	L	L	H	M
Edelman, 2015	M	M	NA	M	NA	L	NA	M	L	L	NA	M
Fisher, 2013	L	M	M	M	H	L	H	H	M	L	H	H
Foster, 2009	L	M	H	M	H	L	L	L	L	L	H	M
Foster, 2013	L	M	NA	M	NA	L	NA	L	L	L	NA	M
Frosch, 2011	M	M	H	M	H	L	H	H	L	L	H	H
Gagliardino, 2013a	M	M	M	M	M	L	L	L	L	L	M	M
Gagliardino, 2013b	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Giannopoulou, 2005	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Glasgow, 2006a	M	M	H	M	H	L	M	M	L	L	H	M
Glasgow, 2006b	L	M	H	M	H	L	H	H	L	L	H	H
Glasgow, 2012	L	M	H	M	H	L	M	M	L	L	H	M
Goudswaard, 2004	L	M	NA	M	NA	L	NA	H	L	L	NA	H
Hawkins, 2010	L	L	NA	M	NA	L	NA	H	L	L	NA	H
Hendricks, 2000	M	M	M	M	M	L	H	H	L	L	H	H
Hermanns, 2012	L	M	M	M	M	L	H	H	L	L	H	H
Hill-Briggs, 2011	M	M	NA	M	NA	L	NA	L	L	L	NA	M
Holmen, 2014	L	M	H	M	H	L	M	M	L	M	H	M
Holtrop, 2002	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Huisman, 2009	M	M	H	M	H	L	H	H	L	L	H	H
Izquierdo, 2003	M	M	M	M	M	L	H	H	L	H	H	H

Johnson, 2009	L	M	M	M	M	L	M	M	L	L	M	M
Jones, 2003	M	M	NA	M	NA	L	NA	M	L	L	NA	M
Keyserling, 2002	L	M	M	M	H	L	H	H	L	H	H	H
Kim, 2006	M	M	NA	M	NA	L	NA	L	L	L	NA	M
Kim, 2009	L	M	H	M	H	L	L	L	L	L	H	M
Kim, 2014	M	M	H	M	H	L	H	H	L	L	H	H
Koo, 2010	M	M	NA	M	NA	L	NA	M	L	L	NA	M
Kulzer, 2007	M	M	H	M	H	L	M	M	L	L	H	M
Lee, 2011	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Lorig, 2008	M	M	H	M	H	L	H	H	L	L	H	H
Lorig, 2009	L	M	H	M	H	L	M	M	L	L	H	M
Lorig, 2010	L	M	H	M	H	L	M	M	L	L	H	M
Lujan, 2007	M	M	NA	M	NA	L	NA	L	L	L	NA	M
Lynch, 2014	M	M	M	M	M	L	H	H	L	H	H	H
Mandel, 2013	L	L	M	M	M	L	H	H	L	L	H	H
Mayer-Davis, 2004	M	M	NA	M	NA	L	NA	M	L	L	NA	M
McGowan, 2011	H	L	M	M	M	L	H	H	L	L	H	H
Miller, 2014	L	M	M	M	M	L	H	H	L	L	H	H
Moncrieft, 2014	M	M	H	M	H	L	M	M	L	M	H	M
Moriyama, 2009	H	H	H	M	H	L	H	H	L	L	H	H
Muchmore, 1994	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Murrock, 2009	L	M	NA	M	NA	L	NA	H	L	L	NA	H
Nashita, 2013	M	M	H	M	H	L	H	H	L	L	H	H
Palmas, 2014	L	L	NA	M	NA	L	NA	M	L	L	NA	M
Philis-Tsimikas, 2011	L	H	NA	M	NA	L	NA	H	L	L	NA	H
Plotnikoff, 2011	L	M	M	M	M	L	M	M	L	L	M	M
Prezio, 2013	L	M	NA	M	NA	L	NA	M	L	L	NA	M
Reaney, 2013	L	M	H	M	H	L	L	M	L	L	H	M
Rickheim, 2002	H	H	H	M	H	L	H	H	L	H	H	H

Ridgeway, 1999	M	M	H	M	H	L	H	H	M	L	H	H
Rock, 2014	L	M	H	M	H	L	M	M	L	L	H	M
Rosal, 2005	M	M	H	M	H	L	L	L	L	L	H	M
Rosal, 2011	M	M	H	M	H	L	M	M	L	M	H	M
Rosal, 2014	L	M	M	M	M	L	L	L	L	H	H	H
Rothschild, 2014	L	M	L	L	L	L	M	M	L	H	H	H
Ruggiero, 2010	M	M	H	M	H	L	H	H	L	L	H	H
Ruggiero, 2014	L	M	H	M	H	L	H	H	L	L	H	H
Sacco, 2009	H	M	H	M	H	L	H	H	L	L	H	H
Salinero-Fort, 2011	M	M	NA	M	NA	L	NA	L	L	L	NA	M
Samuel-Hodge, 2009	L	M	H	M	H	L	H	M	M	L	H	M
Sarkadi, 2004	L	L	H	M	H	L	M	M	L	L	H	M
Sevick, 2012	L	M	NA	M	NA	L	NA	H	L	L	NA	H
Shibayama, 2007	M	M	H	M	H	L	M	M	L	L	H	M
Sigurdardottir, 2009	L	L	H	M	H	L	L	L	L	L	H	M
Siminerio, 2013	M	M	M	M	M	L	M	M	L	L	M	M
Sinclair, 2013	L	M	H	M	H	L	H	H	L	L	H	H
Sixta, 2008	L	M	NA	M	NA	L	NA	H	L	L	NA	H
Skelly, 2005	L	M	H	M	H	L	H	H	L	L	H	H
Skelly, 2009	M	L	M	M	M	L	L	L	L	L	M	M
Smith, 1997	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Sorkin, 2014	M	M	H	M	H	L	L	L	L	M	H	M
Spencer, 2011	M	M	H	M	H	L	H	H	L	L	H	H
Sperl-Hillen, 2013	L	M	H	M	H	L	M	L	H	L	H	H
Steed, 2005	H	H	H	M	H	L	M	M	L	L	H	H
Sung, 2012	L	M	H	M	H	L	M	M	L	L	H	M
Tang, 2014	M	L	NA	L	NA	L	NA	H	M	L	NA	H
Thoolen, 2007	L	M	H	M	H	L	H	H	L	L	H	H
Toobert, 2003	M	M	H	M	H	L	H	H	L	L	H	H

Toobert, 2011	M	M	H	M	H	L	H	H	L	L	H	H
Trief, 2011	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Tucker, 2014	M	M	H	M	H	L	H	H	L	M	H	H
Utz, 2008	L	M	M	M	M	L	M	M	L	L	M	M
Vadstrup, 2011	L	M	M	M	M	L	M	M	L	L	M	M
Varney, 2014	L	M	H	M	H	L	H	H	L	M	H	H
Vazquez, 1998	M	M	H	M	H	L	M	M	L	L	H	M
Vincent, 2007	L	M	H	M	H	L	H	H	L	L	H	H
Walker, 2011	L	M	M	M	M	L	M	M	L	L	M	M
Weinger, 2011	L	M	M	M	M	L	M	M	L	M	M	M
Welch, 2011	M	M	NA	M	NA	L	NA	H	L	L	NA	H
Welschen, 2013	L	L	H	M	H	L	L	L	L	H	H	H
West, 2007	M	M	NA	M	NA	L	NA	L	L	L	NA	M
Wierenga, 1994	M	M	H	M	H	L	H	H	M	L	H	H
Wing, 2013	M	M	H	M	H	L	L	L	L	L	H	M
Wolever, 2010	M	M	H	M	H	L	H	H	L	L	H	H
Wolf, 2004	L	L	H	M	H	L	M	M	L	L	H	M
Yoo, 2007	L	M	NA	M	NA	L	NA	H	L	L	NA	H
Yuan, 2014	M	M	NA	M	NA	L	NA	H	L	M	NA	H
Zgibor, 2013	M	M	M	M	M	L	H	H	L	L	H	H

*These trials may have reported on subjective (i.e., patient reported) outcomes but they were either not of interest to the review or not included in the analysis because of lacking data.

AC = allocation concealment; Blinding of OA = blinding of outcome assessors; Blinding of PP = blinding of participants and personnel; H = high risk of bias; IOD = incomplete outcome data; L = low risk of bias; M = medium or unclear risk of bias; NA = not applicable; Other = other sources of bias; Overall = overall risk of bias assessment; SG = sequence generation; SOR = selective outcome reporting

Appendix F. Description of Studies and Interventions

Table F1. Description of studies and interventions for T1DM in youth

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Anderson, 1999 U.S. (MA)	I= 30 UC= 28 AC= 31	I= 12.7±1.4y, 50%, NR, 8.3±1.1% UC = 12.5±1.4y, 52%, NR, 8.6±0.9% AC= 12.7±1.4y, 50%, NR, 8.7±1.2%	DSME; office-based Parent Adolescent Teamwork intervention	12m, 4, 1.5-2h	In-person	Individual with family	Non-HCP (research assistant)	Minimal – Content & Delivery	None/NR
Boardway, 1993 U.S. (MI)	I= 13 UC= 18	I= 15.4±1.2y, 22%, 30%, 13.9±2.4% UC= 14.3±1.7y, 60%, 33%, 15.7±3.6%	DSME; stress management & regime adherence training with active SMBG	6m, 13, NR	In-person	Group	HCP (RN)	Moderate-to-High - Content	None/NR
Christie, 2014 United Kingdom	I= 182 UC= 183	I= 13.1±2.1y, 42.8%, 13.2%, 9.9±1.5% UC= 13.2±2.1y, 46.4%, 20.2%, 10.0±1.5%	DSME; CASCADE intervention with MI & solution-focused brief therapy	4m, 4, 8h	In-person	Group with families	Multidisciplinary (DSN with any HCP)	Moderate-to-High - Content	Yes
Cook, 2002 U.S. (IL, NY)	I= 26 UC= 27	I= 14.8±1.2y, 50%, 12%, 8.8±1.3% UC= 14.4±1.4y, 37%, 19%, 9.2±2.0%	DSME; Choices Diabetes Program focus on problem solving	1.5m, 6, 12h	In-person	Group	HCP (not specified)	Moderate-to-High - Content	None/NR
Ellis, 2007 U.S. (MI)	I= 64 UC= 63	I= 13.4±1.9y, 59%, 80%,	DSME; Multisystemic	5.7m, 48±19, 48h	In-person	Individual with family	HCP (therapists)	Moderate-to-High -	Yes

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		11.4±2.2% UC= 13.1±2.0y, 38%, 68%, 11.3±2.2%	Therapy (family-centered, home and community-based psychotherapy)					Content & Delivery	
Ellis, 2012 U.S. (MI)	I= 74 AC= 72	I= 14.2±2.2y, 43%, 82%, 11.6±2.5% AC= 14.1±2.4y, 44%, 78%, 11.8±2.6%	I= DSME; Multisystemic Therapy (family-centered, home and community-based psychotherapy) AC= Telephone support	I= 5.6m, 45.7±18.6, 46h AC= 4.9m, 14.0±6.3, 7h	I= In-person AC= Technology (telephone)	1= Individual with family AC= Individual	HCP (Psych or Social workers)	I= Moderate-to-High - Content & Delivery AC= Moderate-to-High - Content & Delivery	I= Yes AC= None
Franklin, 2006 Scotland	I= 33 UC= 28 Not reporting on Intensive insulin therapy (IIT) plus Sweet Talk arm	I= 14.1 (11.7-15.6)y, 45.5%, 3%, 9.8 (8.6-11.5) (Median IQR) UC= 12.7 (10.5-14.8)y, 63%, 3.7%, 10.1 (9.2-11.2) (Median, IQR)	DSME; Sweet Talk (automated weekly delivery of tailored text messages to reinforce/support goals made in clinics)	12m, 3-4, NR (during clinic visits)	Mixed	Individual	Multidisciplinary (RA & care team)	Minimal – Content & Delivery	None/NR
Freeman, 2013 U.S. (OR)	I_1= 44 I_2= 46	I_1= 15.0±1.8y, 47.3%, NR, 11.2±1.7% I_2= 14.9±1.8y, 52.7%, NR, 11.0±1.7%	I_1= DSME; BFST-D (Behavioral Family Systems Therapy for Diabetes) delivered in-person I_2= DSME; BFST-D delivered via videoconferencing	I_1= 3m, 7.56, 8-12h I_2= 3m, 7.03, 7-10.5h	I_1= In-person I_2= Technology	I_1= Individual with family I_2= Individual with family	I_1= HCP (Psych) I_2= HCP (Psych)	I_1=Moderate to High – Content & Delivery I_2= Moderate to High – Content & Delivery	I_1= Yes I_2= Yes

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Holmes, 2014 U.S.	I= 137 AC= 89	I= 13.0±1.2y, 44.5%, 32.1%, 8.8% AC= 12.7±1.2y, 53.9%, 24.7%, 8.9%	I= DSME; clinic-integrated low-intensity coping skills training, conflict resolution & communication AC= Non-DSME education	I= 12m, 4 + telephone contacts, 3h + telephone contact time AC= 12m; 4, 1h	I= Mixed AC= In-person	I= Individual with parent AC= Individual with parent	I= Non-HCP (graduate-level interventionists) AC= Non-HCP (bachelor-level facilitators)	I= Moderate-to-High – Content & Delivery AC= None	I= None/NR AC= None/NR
Husted, 2014 Denmark	I= 37 UC= 34	I= 14.9±1.5y, 38%, NR, 9.5±3.7% UC= 14.6±1.3y, 40%, NR, 8.8±3.0%	DSME; Guided Self-Determination-Youth (clinic-based intervention focused on life skills to facilitate empowerment)	20m, 12 (8-16), 8-12h	In-person	Individual with family	Multidisciplinary (RN or Physician and RD)	Moderate-to-High – Content & Delivery	None/NR
Katz, 2014 U.S. (MA)	I= 50 UC= 51 NR on active control	I= 12.7±2.2y, 42%, 10%, 8.4±1.4% UC= 12.5±2.3y, 55%, 2%, 8.4±1.3%	DSME; clinic-integrated family-based psychoeducation & Care Ambassador	25m, 9.4±1.5 + 25 Care Ambassador contacts, 4.75h + Care Ambassador contacts (4+h)	Mixed	Individual with family	Non-HCP (research assistant)	Moderate-to-High – Content & Delivery	None/NR
Kichler, 2013 U.S. (MI)	I= 16 UC= 15	NR by arm; 15.2±1.3y, 47%, 23%, 10±2.1%	DSME; Diabetes Adjustment and Coping Group Therapy Program - K.I.D.S. Project intervention with behavioral and family system strategies	1.5m, 6, 6h	In-person	Group with families	Non-HCP (trainee) & HCP (Pysch)	Moderate-to-High – Content & Delivery	None/NR
Laffel, 2003 U.S. (MA)	I= 50 UC= 50	I= 11.9±2.4y, 47%, NR, 8.4±1.7% (all	DSME; clinic integrated CBT-based family-	12m, 4, NR	In-person	Individual with family	Non-HCP (research assistant)	Minimal – Content & Delivery	None/NR

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		participants) UC= 12.2±2.2y, NR	focused teamwork intervention						
Lehmkuhl, 2010 U.S. (FL)	I= 18 UC= 14	I= 13.7±2.7y, 39%, NR, 10.8±2.1% UC= 13.4±2.2y, 14%, NR, 10.4±1.9%	DSME; Telehealth Behavioral Therapy (utilized some of the principles of BFST intervention)	2.8m, 36, 11h	Technology	Individual with family	Non-HCP (therapist interns)	Moderate-to-High – Content & Delivery	None/NR
Mayer-Davis, 2014 U.S. (CO, OH, NC)	I = 31 UC = 30	All 13.9±1.4y, NR, NR HbA_{1c} I= 9.8±1.6% UC= 9.5±1.3%	DSME; Flexible Lifestyles for Youth (FL3X) combining MI, problem-solving, and family systems therapy	3m, 5, 2.5h Plus short additional contacts	Mixed (In-person sessions with automated telephone reminders/ motivational boosters)	Individual with a family member	HCP (diabetes clinicians/educators)	Moderate-to-High – Content & Delivery	None/NR
McNabb, 1994 U.S. (IL)	I= 12 UC= 12	I= 9.7y, NR, NR, 10.5±2.9% UC= 10y, NR, NR, 12.9±3.8%	DSME; In Control program for children to gain self-care independence	1.5m, 6, 6h	In-person	Group with families	HCP (NR)	Minimal-to-High – Content	None/NR
Murphy, 2007 United Kingdom	I= 37 UC= 41	I= 12.6±2.3y, 55%, NR, 9.1±1.0% UC= 13.1±2.0y, 56%, NR, 9.1±1.5%	DSME; clinic-integrated group family sessions focused on family teamwork (Families, Adolescents and Children's Teamwork Study (FACTS))	12m, 4, 4h	In-person	Group with families	Multidisciplinary (DSN, RD, Physician)	Minimal - Delivery	None/NR

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Murphy, 2012 United Kingdom	I= 158 UC= 147	I= 13.1±1.9y, 47%, 7%, 9.2±1.7% UC= 13.2±2.0y, 49%, 9%, 9.4±2.1%	DSME; clinic-integrated group family sessions focused on family teamwork (FACTS)	6m, 6, 9h	In-person	Group with families	Multidisciplinary (DSN, RD, Physician)	Minimal - Delivery	None/NR
Nansel, 2007 U.S. (MD)	I= 40 UC= 41	I= 13.6±1.9, 42.5%, 17.5%, 46.3±34.1 (% above upper limit) UC= 13.9±1.6, 46.3%, 12.2%, 42.2±28.6 (% above upper limit)	DSME; Self-regulation and MI intervention using Diabetes Personal Trainers for self-monitoring, goal-setting and problem solving sessions	2m, 6 + telephone calls, NR	Mixed	Individual	Non-HCP (health field students)	Moderate-to-High – Content & Delivery	None/NR
Nansel, 2012 U.S. (MA, IL, FL, TX)	I= 201 UC= 189	I= 12.5±1.8y, 49.3%, 24%, 8.4±1.2% UC= 12.4±1.7y, 49,2%, 26%, 8.3±1.1%	DSME; WE*CAN Manage Diabetes program focusing on problem solving approach	21m, 6 + 12 telephone calls, 3h + telephone contact time	Mixed	Individual with family	Non-HCP (trained health advisors)	Moderate-to-High – Content & Delivery	None/NR
Serlachius 2014 Australia	I = 73 UC = 74	I= 14.4±1.1y, 42.5%, NR, 8.5±1.5% UC= 14.3±1.1y, 50%, NR, 8.6±1.4%	DSME; DM-specific CBT-based Best Coping programme with coping skills and problem-solving training, and cognitive restructuring	1.2m, 5, 10h Plus CD-ROM for maintenance	In-person	Group	HCP (health psychologist)	Minimal - Content	None/NR
Thomas-Dobersen, 1993	I= 11 UC= 9	I= 13.9y (12-17, range), 9.1%, NR, 12.2 (9-	Lifestyle; SHAPEDOWN (family-based	3m, 14, 21h (Each contact	In-person	Group (sessions for adolescents	Multidisciplinary (RD, Psych & child health	Minimal - Content	None/NR

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
U.S. (CO) Observ.		15.8)% UC= 15.2y (12-18, range), 0%, NR, 13.1 (9.9-16.9)%	multidisciplinary behavior modification program)	had separate sessions for adolescents and parents)		and parent separate)	associate)		
Viklund, 2007 Sweden	I= 28 UC= 27	I= 14.3±1.6y, 43%, NR, 7.4±1.2% UC= 14.1±0.8y, 39%, NR, 8.1±1.8%	DSME; empowerment program with problem-based learning	1.5m, 6, 12h	In-person	Group	HCP (DSN)	Moderate-to-High – Content	None/NR
Viner, 2003 United Kingdom Observ.	I= 21 UC= 20	I= 13.0, 28%, NR, 10.2 (SE 0.3) UC= 13.3, 60%, NR, 10.0 (SE 0.3)	DSME; motivational/solutions-focused group intervention	1.5m, 6 + 1 for parents, NR	In-person	Group (sessions for adolescents and parents separate)	NR	Moderate-to-High – Content & Delivery	None/NR
Wysocki, 2007 U.S. (MO, FL)	I= 36 AC= 36 UC= 32	I= 13.9±.9y, 58%, 39%, 9.6±1.6% AC= 14.4±1.9y, 56%, 25%, 9.7±1.6% UC= 14.2±1.9y, 50%, 47%, 9.5±1.5%	I= DSME; BFST-D AC= Non-DSME education	I= 6m, 12, 18h AC= 6m, 12, 18h	I= In-person AC= In-person	I= Individual with family AC= Group with families	I= Multidisciplinary AC= Multidisciplinary	I= Moderate-to-High – Content & Delivery AC= None	I= None/NR AC= None/NR

AC= active control; CBT= cognitive behavioral therapy; DSME= diabetes self-management education; DSN= diabetes specialist nurse; HCP= health care professional; I= Intervention; MI= motivational interviewing; NA= not applicable; NR= not reported; Observ.= observational study design; Pysch= psychologist; RA= research assistant; RD= registered dietitian; RN= registered nurse; SMBG= self-monitoring blood glucose; UC= usual care

Table F2. Description of studies and interventions for T1DM in adults

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Amsberg, 2009 Sweden	I= 46 UC= 48	I= 41.1±11.7y, 56%, NR, 8.5±0.9% C= 41.4±12.9y, 42%, NR, 8.5±0.8%	DSME + Support; CBT-based with CGMS ("Power to Choose Your Direction")	11, 12 + 5 telephone contacts, 18.25h + telephone contact time (Maintenance phase = 9m)	Mixed	Mixed	Multidisciplinary (RN, Pysch)	Moderate-to-High – Content & Delivery	None/NR
Forlani, 2006 Italy Observ.	I= 54 UC= 36	I= 43 (18–65)y (Median, Range), 33%, NR, 8.2±1.6% UC= 41 (26–65)y (Median, Range), 66%, NR, 8.1±1.2%	DSME; empowerment group teaching & situation simulation	4m, 8, 16h	In-person	Group	HCP (Physician or RD)	Moderate-to-High - Content	None/NR
Hermanns, 2013 Germany	I= 81 AC= 79	I= 45.9±13.8y, 61.7%, NR, 8.3±1.1% AC= 45.1±13.4y, 50.6%, NR, 8.0±0.9%	I= DSME; PRIMAS empowerment approach AC= Non-DSME education; standard in Germany	I= 1.5m, 12, 18h AC= 1.5m, 12, 18	I= In-person AC= In-person	I= Group AC= Group	I= HCP (CDE) AC= HCP (CDE)	I= Moderate-to-High – Content AC= None	I= None/NR AC= None/NR
Ismail, 2008 United Kingdom	I= 106 UC= 121 NR on Active control	I= 37.2±9.9y, 37.7%, 21%, 9.6±1.3% UC=36.4±11.3y, 45,4%, 14%, 9.7±1.2%	DSME; Motivational Enhancement Therapy & CBT	6m, 12, 10h	In-person	Individual	HCP (DSN)	Moderate-to-High - Content	None/NR

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Karlsen, 2004 Norway	I= 47 UC= 45	I= 49.2±14.7y, 52%, NR, 7.9±1.2% UC= 48.6±10.3y, 53%, NR, 8.4±1.2%	DSME; CBT-based program	6m, 6, 9h	In-person	Group	Non-HCP (peers) & HCP (DSN)	Moderate-to-High – Content & Delivery	Yes
Mannucci, 2005 Italy (Non-RCT)	I= 96 UC= 37	I= 30.7±8.4y, 44%, NR, 7.7±1.4% UC= 30.3±12.2y, 43%, NR, 7.9±1.6%	DSME; Interactive Educational and Support Group (IESG), physician-led long-term open group education program	12m, 26, 52h	In-person	Group	HCP (Physicians)	Moderate-to-High – Content & Delivery	None/NR
Perry, 1997 New Zealand	I= 31 UC= 30	I= 41.5±11.6y, 66.7%, NR, 8.9±2.6% UC= 42.8±12.6y, 48.4%, NR, 8.7±2.0%	Lifestyle; multiple topics with individualized diet and physical activity prescriptions	6m, 6 + additional sessions or telephone calls, NR	In-person	Individual	Multidisciplinary (RD & others in research team)	Moderate-to-High – Content & Delivery	None/NR
Weinger, 2011 U.S. (MA)	I=74 AC_1= 75 AC_2= 73	I= 51.8 (23.7-74.2)y 54%, 12% 9.0 (7.6-12.6)%, 50% AC_1= 54.7 (25.0-75.1)y 52%, 11% 8.8 (7.6-13.6)%, 50%	I= DSME; CBT-based group education program AC_1= Non-DSME (didactic group sessions) AC_2= Non-DSME (individual RN &	I= 1.5m, 5, 10h AC_1= 1.5, 5, 10h AC_2= 6m, NR, NR	I= In-person AC_1= In-person AC_2= In-person	I= Group AC_1= Group AC_2= Individual	I= Multidisciplinary (RN, RD) AC_1= RN AC_2= Multidisciplinary (RN, RD)	I= Moderate-to-High – Content AC_1= Minimal – Content AC_2= Minimal –	I= None/NR AC_1= None/NR AC_2= None/NR

Author, Year & Country	Comparison & Sample Size	Age, Males, Ethnic Minorities, HbA1c	Intervention Category & Description	Total Duration, # Contacts, Contact Time	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed)	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		AC_2= 56.2 (21.6-74.8)y 42%, 15% 8.6 (7.6-13.1)%, 49%	RD consults offered)					Content & Delivery	
Zoffmann, 2006 Denmark	I= 36 UC= 25	I= 36.8±1.7y, 46.5%, NR, 9.0±0.2% UC= 35.7±2.1y, 50%, NR, 9.1±0.2%	DSME; Guided Self-Determination Group Training	2m, 8, 16h	In-person	Group	Multidisciplinary (RN & researcher)	Moderate-to-High – Content & Delivery	None/NR

AC= active control; CBT= cognitive behavioral therapy; CDE= certified diabetes educator; CGMG= continuous glucose monitoring system; DSME= diabetes self-management education; DSN= diabetes specialist nurse; HCP= health care professional; I= Intervention; NA= not applicable; NR= not reported; Observ.= observational design; Psych= psychologist; RD= registered dietitian; RN= registered nurse; SMBG= self-monitoring blood glucose; UC= usual care

Table F3. Description of studies and interventions for T2DM

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Adachi, 2013 Japan	I= 100 UC= 93	I= 60.4±11.4y 45%, NR 26.3±4.6kg/m^2 7.6±1.4%, 11% UC= 62.3±10.1y 42%, NR 24.9±4.6kg/m^2 7.3±1.1%, 13%	DSME; SILE (Structured Individual-based Lifestyle Education), focus on diet but also self-management through activity and stress management	6m; 3.5; NR; NA	In-person	Individual	HCP (RD)	Moderate-to-High – Content	None/NR
Adolfsson, 2007 Sweden	I= 50 UC= 51	I= 62.4±8.9y 57%, NR 30.4±4.3 7.4±1.0%, 0% UC= 63.7±9.0y 61%, NR 29.6±3.3kg/m^2 7.1±0.8%, 0%	DSME; empowerment group education	7m; 4.7, 12h; NA	In-person	Group	Multidisciplinary (DSN, Physician)	Moderate-to-High – Content & Delivery	None/NR
Agurs-Collins, 1997 U.S. (DC)	I= 32 UC= 32	I= 62.4±5.9y 34%, 100% 33.9±5.1kg/m^2 11.0±1.7%, 40% UC= 61.0±5.7y 12%, 100% 34.9±6.8kg/m^2 10.0±1.9%, 50%	Lifestyle; hospital-based lifestyle program (Diabetic Exchange Lists) to achieve ≤0.9kg wt loss/wk & moderate physical activity ≥3 x/wk with weekly group exercises for 3m) tailored to older African Americans	6m; 19, 28h; 3m	In-person	Mixed with supports	HCP (RD) Minimal from exercise physiologist	Moderate-to-High – Content & Delivery	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Amoako, 2008 U.S. (NC)	I= 34 UC= 34	All= 61±9.5y 0%, 100% NR, 0%	DSME; psycho-educational uncertainty management intervention (DU-UMI) for older African American women	1m; 4, 1h; NA	Technology	Individual	HCP (NP)	Moderate-to-High – Content & Delivery	Yes
Anderson D, 2010 U.S. (CT)	I= 146 UC= 149	I= NR 41%, 72.6% 35.4±8.6 7.6±1.8%, NR UC= NR 43%, 73.8% 33.7±6.6 8.4±2.3%, NR	DSME; telephonic disease management in a community health center for medically underserved, predominantly Hispanic population	12m; 18, NR; NA	Technology	Individual	HCP (RN)	Moderate-to-High – Content & Delivery	None/NR
Anderson R, 1995 U.S. (MI)	I= 23 UC= 23	All= 50y 30%, NR 54% using insulin HbA1c I=11.75±3.0% UC= 10.8±2.9%	DSME; "Empowerment: Facilitating a Path to Personal Self-Care"	1.5m; 6, 12h; NA	In-person	Group with supports	HCP (CDE)	Moderate-to-High – Content & Delivery	None/NR
Anderson R, 2005 U.S. (MI)	I= 125 UC= 114	All= 61.0±11.4y 18%, 96% 91.3±20.6kg HbA1c	DSME; problem-based empowerment program for African Americans	1.5m; 6, 12h; NA	In-person	Group with supports	Multidisciplinary (RD, RN)	Moderate-to-High – Content & Delivery	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		I= 8.7±2.13% UC= 8.4±2.2%							
Anderson R, 2009 U.S. (MI)	I= 156 UC= 154	I= 55.5±11.3y 43.6%, 40.9% 34.9±9.0kg/m^2 7.7±2.1%, 27.7% UC= 55.7±11.5y 39%, 50% 33.8±7.8kg/m^2 7.5±1.8%, 26.3%	DSME; Diabetes Self-Management Consultant (DSMC) manager intervention based on empowerment approach	24m; 24; NR; NA	Mixed	Individual	HCP (RD or RN both CDE)	Moderate-to-High – Content & Delivery	None/NR
Anderson-Loftin, 2005 U.S. (SC)	I= 49 UC= 48	I= 58.9±10.1y 22%, 100% 35.4±8.1kg/m^2 7.5±1.6%, 17% UC= 55.7±12.1y 25%, 100% 34±8.3kg/m^2 8.3±2.6%, 13%	Lifestyle; Soul Food Light: culturally competent diabetes diet education and peer-professional support groups for rural black southerners	5m; 8+16 telephone followup calls, 10h + call duration; NA	Mixed	Mixed with supports	Multidisciplinary (RD, RN)	Moderate-to-High – Content & Delivery	Yes
Baksi, 2008 England	I_1= 43 I_2= 40	I_1= 59.3±13y 57.6%, NR 28.7±5.5kg/m^2 7.4±1.3%, 21.4% I_2= 60.5±11y 47.1%, NR 32.5±5.3kg/m^2	I_1= DSME; delivered by health professionals I_2= DSME; delivered by peers	I_1= 6m; 6, 9h; NA I_2= 6m; 6, 9h; NA	I_1= In-person I_2= In-person	I_1= Group I_2= Group	I_1= HCP (DSN) I_2= Non-HCP (peer) & HCP (DSN)	I_1= Minimal – Content & Delivery I_2= Minimal – Content & Delivery	I_1= None/NR I_2= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		7.6±1.6%, 33.3%							
Barratt, 2008 England	I= 27 UC= 26	I= 55.8±11.3y 44%, NR 33.8±5.3kg/m^2 9.6±1.7%, 100% UC= 55.8±11.3y 46%, NR 32.1±4.3kg/m^2 9.7±1.2%, 100%	Lifestyle; weight loss and lifestyle program (500kcal deficit and 150mins/wk PA) with MI to prevent weight gain following initiation of insulin	6m; 6, 4h; NA	In-person	Individual	HCP (RD)	Minimal – Content & Delivery	None/NR
Beverly, 2013 U.S. (MA)	I= 68 AC= 67	I= 59.9±8.5y 52.2%, 26.9% 34.6±7.0kg/m^2 8.5±1.4%, NR AC= 58.4±9.0y 44.7%, 29.8% 33.7±7.1kg/m^2 8.3±1.0%, NR	I= DSME; reinforcement of education using conversation map tools AC= Non-DSME education; Heart Healthy sessions	I= 1m; 4, 4h; NA AC= 1m; 2, 4h; NA	I= In-person AC= In-person	I= Group AC= Group	I= Multidisciplinary (RD, RN) AC= Multidisciplinary (RD, RN)	I= Minimal – Content AC= Minimal – Content	I= None/NR AC= None/NR
Bond, 2007 U.S. (WA)	I= 31 UC= 31	I= 66.2±5.7y 58%, 13% 90.7±16.3kg 7.0±1.1%, 94% UC= 68.2±6.2y 52%, 14% 92.5±18.1kg 7.1±0.9%, 94%	DSME; web-based DSME with self-management tracking, online education and support sessions and MSN communication for older adults	6m; 26+, NR; NA (Plus instant messaging, email & chats)	Technology	Mixed	HCP (RN)	Moderate-to-High – Content & Delivery	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		(T1DM 13%)							
Bozzetto, 2014 Italy	I_1= 11 I_2= 8 AC_1= 10 AC_2= 9	I_1= 63±5y 72.8%, NR 31±3kg/m^2 6.7±0.9%, 0% I_2= 59±8y 100%, NR 29±2.0kg/m^2 6.9±0.6%, 0% AC_1= 58±4y 70%, NR 30±2.0kg/m^2 6.3±0.3%, 0% AC_2= 56±7y 77.8%, NR 28±3kg/m^2 6.6±0.8%, 0%	I_1= Lifestyle; high-carbohydrate, high-fibre diet (no caloric restriction) plus supervised PA I_2= Lifestyle; high-MUFA diet (no caloric restriction) plus supervised PA AC_1= Diet; high-carbohydrate, high-fibre diet AC_2= Diet; high-MUFA diet	I_1= 1.8m; 16, NR; NA I_2= 1.8m; 16, NR; NA AC_1= 1.8m; 8, NR; NA AC_2= 1.8m; 8, NR, NA (Plus twice weekly telephone calls to check adherence)	I_1= Mixed I_2= Mixed AC_1= Mixed AC_2= Mixed	I_1= Individual I_2= Individual AC_1= Individual AC_2= Individual	I_1= Multidisciplinary (RD, exercise physiologist) I_2= Multidisciplinary (RD, exercise physiologist) AC_1=HCP (RD) AC_2= HCP (RD)	I_1= Minimal – Delivery I_2= Minimal – Delivery AC_1= Minimal & Delivery AC_2= Minimal – Delivery	I_1= None/NR I_2= None/NR AC_1= None/NR AC_2= None/NR
Bradshaw, 2007 U.S. (UT)	I= 30 UC= 37	I= 60.8±11.0y 32%, 0% NR 6.7±1.2%, 23% UC= 57.5±11.0y 38%, 17% NR 6.9±1.1%, 23%	DSME; DSME meeting standards with RTAD (Resiliency Training Approach for Diabetes)	1.2m; 10, 15h; NA	In-person	Group	Multidisciplinary (CDE, RD)	Minimal – Content	None/NR
Brown, 2002 U.S. (TX)	I= 128 UC= 128	I= 54.7±8.2y 40%, 100%	DSME + Support; culturally	12m; 27, 54h; 9m	In-person	Group with supports	Non-HCP (CHW) &	Moderate-to-High –	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		32.3±6.0kg/m^2 11.8±3.0%, 26% UC= 53.3±8.3y 32%, 100% 32.1±6.4kg/m^2 11.8±3.0%, 27%	competent, community-based self-management intervention for Mexican Americans				Multidisciplinary (RN, RD)	Content & Delivery	
Brown, 2005 U.S. (TX)	I_1= 114 I_2= 102	I_1= 49.6±7.6y 39.5%, 100% 32.2±5.8kg/m^2 11.8±3.4%, 9.6% I_2= 49.6±8.2y 40.2%, 100% 32.9±8.3kg/m^2 11.5±3.5%, 7.4%	I_1= DSME + Support; compressed version of culturally competent, community-based DSME for Mexican Americans I_2= DSME + Support; intense version of DSME + Support	I_1= 12m; 11, 22h; 10m I_2= 12m; 26, 52h; 9m	I_1= In-person I_2= In-person	I_1= Group with supports I_2= Group with supports	I_1= Non-HCP (CHW) & Multidisciplinary (RN, RD) I_2= Non-HCP (CHW) & Multidisciplinary (RN, RD)	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High – Content & Delivery	I_1= Yes I_2= Yes
Brown, 2011 U.S. (TX)	I_1= 48 I_2= 35	I_1= 49.7±9.2y 25.7%, 100% 32.2±5.4kg/m^2 10.6±3.0%, 21.3% I_2= 49.0±7.8y 35.4%, 100%	I_1= DSME + Support; culturally tailored group DSME for Mexican Americans I_2= DSME +	I_1= 6m; 10; 20h; 4m I_2= 6m; 15; 20h+; 4m	I_1= In-person I_2= Mixed	I_1= Group with supports I_2= Mixed with supports	I_1= Multidisciplinary (RN, RD) I_2= Multidisciplinary (RN, RD)	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High – Content &	I_1= Yes I_2= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		34.6±7.6kg/m^2 9.2±2.7%, 16.7%	Support; addition of case manager to coordinate care					Delivery	
Castejon, 2013 U.S. (FL)	I= 19 UC= 24	I= 54±9y 42%, 100% 31.2±1.9kg/m^2 8.3±0.4%, NR UC= 55±10y 21%, 100% 31.5±1.3kg/m^2 8.2±0.4%, NR	DSME; Pharmacist-centered Assessment and Reinforcement of Diabetes Self-efficacy (PARDS), community-based pharmacist intervention for Latinos	1.5m; 4, 4.5h; NA	In-person	Mixed with supports	Non-HCP (graduate student) & HCP (Pharmacist)	Moderate-to-High - Content	Yes
Chan, 2014 Hong Kong	I= 312 AC= 312	I= 54.5±9.9y 57.1%, NA 26.6±4.3kg/m^2 8.2±1.7%, 37.7% AC= 54.8±8.6y 56%, NA 27.1±4.6kg/m^2 8.2±1.6%, 32%	I= DSME; empowerment DM class followed by peer telephone support AC= Non-DSME education; empowerment DM class	I= 12m; 14; 7h; NA AC= 12m; 1, 2h; NA	I= In-person AC= In-person	I= Mixed AC= Group	I= Non-HCP (peer) & HCP (RN) AC=RN	I= Moderate-to-High – Content & Delivery AC= Minimal - Content	I= Yes AC= None/NR
Chan, 2012 Hong Kong	I= 107 UC= 101	I= 71.7±8.0y 34.3%, NA 24.8±3.6kg/m^2 7.4±1.5%, 22.2% UC= 72.0±7.9y 25.3%, NA	DSME; problem-solving group education with PA practice for older adults	2m; 8, 16h; NA	In-person	Group	HCP (allied HCP)	Minimal – Content & Delivery	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		24.6±3.8kg/m^2 7.0±1.2%, 25.3%							
Cheong, 2009 Canada	I= 22 AC= 22	I= 55.4±2.2y 58%, NR 32.6±1.3kg/m^2 7.2±0.3%, 0% AC= 54.8±1.4y 53, NR 35.5±1.4kg/m^2 7.2±0.2%, 0% (SEM used)	I= Lifestyle; First Step First Bite Program focused on walking more and low GI foods AC= PA portion of Lifestyle	I= 1m; 4, 4-6h; NA AC= 1m; 4, 4-6h; NA	I= In-person AC= In-person	I= Group AC= Group	I= Non-HCP (graduate student) AC=Non- HCP (graduate student)	I= Minimal – Content AC= Minimal - Content	I= None/NR AC= None/NR
Chlebowy, 2014 U.S. (KY)	I = 26 UC = 36	I= 55.8±2.1y NR, 100% 36.3±7.8 kg/m^2 7.8±0.2%, NR UC= 53.0±2.3y NR, 100% 33.0±7.6 kg/m^2 8.1±0.2%, NR	DSME; MI-based intervention focused on medication adherence, self-monitoring, and PA	3m; 6, 5h; NA	In-person	Individual	HCP (RN)	Moderate-to-High - Content	None/NR
Clark, 2004 United Kingdom	I= 50 UC= 50	All= 59.5y 58%, NR 31±4kg/m^2 8.4±1.6%, 21%	Lifestyle; individualized diet and PA goals with brief MI based on assessment of stage of change and barrier identification	6m; 12, 3h; NA	Mixed	Individual	HCP (interventionist)	Moderate-to-High- Content & Delivery	None/NR
Cooper, 2008	I= 53	All= 58.6 (35-	DSME; Looking	2m; 8, 16h; NA	In-person	Group	HCP (DSN)	Minimal –	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
United Kingdom	UC= 36	73)y 56% male HbA1C I= 8.5±2.3% UC= 7.8±2.2%	After Yourself, empowerment-based education program with focus on systems of motivation and relaxation training					Content	
Corkery, 1997 U.A. (NY)	I_1= 34 I_2= 30	All= 52.±11.7y 26%, 100% NR 11.7±3.7%, NR	I_1= DSME; ADA standards for low-income and literacy Hispanics I_2= DSME; addition of CHW for support and care coordination	I_1= 3.4m I_2= 3.4m	I_1= In-person I_2= In-person	I_1= Individual (30% with supports) I_2= Individual (30% with supports)	I_1= HCP (RN/CDE) I_2= Non-HCP (CHW) & HCP (RN/CDE)	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= Yes
Cramer, 2007 U.S. (NY)	I= 27 UC= 24	I= HbA1c ≥8% UC= HbA1c ≥8%	Lifestyle; Modified Diabetes Prevention Program (DPP) teaching plan	9m; 16, NR; NA	Mixed	Individual	HCP (RN)	Moderate-to-High – Content	None/NR
Dasgupta, 2006 Canada	I= 21 AC= 21	I= 54 (47-58)y 57%, NR 36.6(31.6-39.8) kg/m^2 7.2(6.1-7.7)%, 0% AC= 49 (46-55)y 43%, NR	I= Lifestyle; diet counseling and supervised aerobic moderate-intensity exercise 3x/wk tapering AC= Diet portion of Lifestyle	I= 6m; 54, 50.5h; NA AC= 6m; 6, 2.5h; NA	I= In-person AC= In-person	I= Mixed AC= Mixed	I= Multidisciplinary (RD, exercise physiologist) AC= HCP (RD)	I= Minimal – Content AC= Minimal - Content	I= None/NR AC= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		36.4 (32.8-41.8) kg/m^2 7.1 (6.3-7.4)%, 0% (Median, IQR)							
Davis, 2010	I= 85 UC= 80	I= 59.9±9.4y 27.1%, 75.3% 37.1±8.1kg/m^2 9.3±1.9%, 16.3% UC= 59.2±9.3y 23.7%, 72.5% 35.9±7.6 kg/m^2 8.9±1.8%, 22.8%	DSME; Diabetes TeleCare for underserved communities	12m; 13, NR; NA	Mixed	Mixed	Multidisciplinary (RN/CDE, RD, LPN)	Moderate-to-High – Content & Delivery	Yes
Deakin, 2006	I= 157 Att. C= 157	I= 61.3±9.7y 52%, NR 30.8±5.3kg/m^2 7.7±1.6%, 17% Att. C= 61.8±11.0y 52%, NR 30.6±5.7kg/m^2 7.7±1.6%, 17%	I= DSME; X-PERT Programme focused on empowerment and discovery learning Att. C= 3 booked contacts for RD, RN and GP	I= 1.5m; 6, 12h; NA Att. C= 1.5m; 1-3, 1h; NA	I= In-person Att. C= In-person	I= Group with supports Att. C= In-person	I= HCP (RD) Att. C= Multidisciplinary (RD, RN, GP)	I= Moderate-to-High – Content & Delivery Att. C= Minimal - Content	I= Yes Att. C= None/NR
D'Eramo-Melkus, 2010 U.S. (CT)	I= 52 AC= 57	I= 45±10y 0%, 100% 96±18kg 8.3±2.2%, 0%	I= DSME + Support; culturally relevant CBT-based behavioral DSMT plus coping	I= 12m; 13, 12.5h+3 NP support visits; 9m AC= 12m; 14,	I= In-person AC= In-person	I= Mixed AC= Mixed	I= Multidisciplinary (NP, Psych) AC= HCP (NP)	I= Moderate-to-High – Content AC= None	I= None/NR AC= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		AC= 45±10y 0%, 100% 96±18kg 8.3±2.2%, 0%	skills training and followup support AC= Non-DSME education and support	17+3 NP support visits; 9m					
Dunstan, 1997 Australia	I= 11 AC= 12	I= 52.3±8.3y 73%, NR 29.1±2.4kg/m^2 8.8±2.7%, 0% AC= 53.0±7.0y 75%, NR 29.7±4.3kg/m^2 8.1±1.4%, 0%	I= Lifestyle; low-fat diet with supervised moderate intensity stationary cycling 3x/wk for older adults AC= Diet; low fat diet with supervised stretching 3x/wk	I= 1.8m; 24, 16h+weekly RD interview duration; NA AC= 1.8m; 24, 16h+weekly RD interview duration; NA	I= In-person AC= In-person	I= Individual AC= Individual (NR for PA component)	I= Multidisciplinary (RD, Exercise physiologist) AC= Multidisciplinary (RD, Exercise physiologist)	I= Minimal – Content AC= Minimal - Content	I= None/NR AC= None/NR
Dunstan, 2005 Australia	I= 19 AC= 17	I= 67.6±5.2y 63%, NR 31.5±3.4kg/m^2 8.1±1.1%, 0% AC= 66.9±5.3y 46%, NR 32.5±3.8kg/m^2 7.5±1.1%, 0%	I= Lifestyle; moderate weight loss diet plus supervised and home-based high intensity (75-85% 1-RM) progressive resistance training AC= Diet; moderate weight loss diet with supervised and home-based	I= 12m; 86, 72h+ time for 14 calls; 6m AC=12m; 86, 72h+ time for 14 calls; 6m	I= Mixed AC= Mixed	I= Individual AC= Individual	I= Multidisciplinary (RD, Exercise physiologist) AC= Multidisciplinary (RD, Exercise physiologist)	I= Minimal – Content & Delivery AC= Minimal – Content & Delivery	I= None/NR AC= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
			stretching						
Eakin, 2014 Australia	I= 151 UC= 151	I= 57.7±8.1y 56%, 13.1% 33.1±6.3kg/m^2 7.6 (6.3-8.1)%, 15.2% UC= 58.3±9.0y 57%, 11.9% 33.2±6.0kg/m^2 7.0 (6.4-7.9)%, 13.2% (Median, IQR)	Lifestyle; Living Well with Diabetes, telephone-delivered program with MI for weight loss (5-10% initial weight) and PA (≥210min/wk & 2-3 resistance/wk)	18; 27, 11.25h; 12m	Technology	Individual	Non-HCP (telephone counselors)	Moderate-to-High – Content & Delivery	None/NR
Edelman, 2015 U.S. (NC)	I = 193 Att. C = 184	I= 57.8±10.9y 46%, 51% 36.2±7.9 kg/m^2 9.2±1.5%, NR Att. C= 59.6±10.7y 45%, 50% 36.4±7.5kg/m^2 9.0±1.4%, NR	I = DSME; telephonic behavioral nurse intervention (TEACH-DM) for DM and hypertension Att. C = General health information at same frequency	I = 24m; 12, NR; NA Att. C = 24m; 12, 2hr; NA	I = Technology Att. C = Technology	I = Individual Att. C = Individual	I = HCP (RN) Att. C = HCP (RN)	I = Moderate-to-High – Content & Delivery Att. C = None	I = None/NR Att. C = None/NR
Fisher, 2013 U.S. (CA)	I_1= 150 I_2= 146 AC= 96	I_1= 57±8.8y 52%, 58.7% 32.1±7.2kg/m^2 7.4±1.6% 15.3% I_2= 55.9±9.4y	I_1= DSME; My Path to Healthy Life, bilingual computer-assisted self-management program (CASM) focused on diet,	I_1= 12m; 10, 3h ;8m I_2= 12m; 10, 3.5h; 8m AC= 12m; 8, 2h;	I_1= Mixed I_2= Mixed AC= Technology	I_1= Individual I_2= Individual AC= Individual	I_1= Non-HCP (nonprofessional college graduates) I_2= Non-HCP (nonprofessional	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High –	I_1= None/NR I_2= None/NR AC=

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		44%, 58.2% 33.9±7.9kg/m^2 7.4±1.6%, 19.2% AC= 55.2±9.6y 41%, 64.6% 33.3±8.4kg/m^2 7.4±1.6%, 19.8%	PA and medication taking with followup calls I_2= DSME; CAPS (CASM plus problem solving therapy) AC= Non-DSME education; Computer health risk assessment, DM DVD and telephone contacts	NA			college graduates) AC= Non-HCP (nonprofessional college graduates)	Content & Delivery AC= None	None/NR
Foster, 2009 U.S. (PA)	I= 35 AC= 34	I= 52.1±7.7y 25.7%, 63% 39.1±5.5kg/m^2 7.6±1.6%, 0% AC= 52.8±11.2y 32.2%, 56% 38.9±6.1kg/m^2 7.5±1.7%, 0%	I= Lifestyle; portion-controlled diet, prescribed PA regime (1250-1550 kcal/d; 20-25% fat & 20-25% protein), ≥200 mins PA/wk) and CBT-based behavioral weight loss treatment AC= Non-DSME education; didactic group sessions	I= 2.8m; 12, NR; NA AC= 2.8m; 3, NR, NA	I= In-person AC= In-person	I= Group AC= Group	I= HCP (not specified) AC= HCP (not specified)	I= Minimal – Content AC= None	I= None/NR AC= None/NR
Foster, 2013	I_1=50	I_1= 55.5±10.3y	I_1= Lifestyle;	I_1= 6m; 9, 13.5h;	I_1= In-person	I_1= Group	I_1= Non-HCP	I_1= Minimal -	I_1=

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
U.S. (PA)	I_2=50	58%, 68% 35.3±4.6kg/m^2 7.6±1.3%, NR I_2= 55.7±11.0y 60%, 60% 36.2±5.8kg/m^2 7.9±1.3%, NR	behavioral lifestyle program with portion-controlled pre-packaged diet (1250-1550kcal/d; 20-25% fat & 20-25% protein), PA target ≥200 mins/wk and CBT-based behavioral training I_2= DSME; DSME meeting standards plus diet and exercise goals (as lifestyle arm) and meal plan	NA I_2= 6m; 9, 13.5h; NA	I_2= In-person	I_2= Group	(lifestyle counselor) I_2= HCP (CDE)	Content I_2= Minimal - Content	None/NR I_2= None/NR
Frosch, 2011 U.S. (CA)	I= 100 UC= 101	I= 56.7±8.3y 46%, 78.8% 33.3±8.0kg/m^2 9.4±1.1%, NR UC= 54.3±8.9y 57%, 92% 32.8±7.4kg/m^2 9.8±2.1%, NR	DSME; DVD program with health coaching via telephone for poorly controlled diabetes	5m; 5; 2.5h; NA	Technology	Individual	HCP (RN)	Moderate-to-High – Content & Delivery	None/NR
Gagliardino, 2013a Argentina	I_1= 105 I_2= 93	I_1= 60±10y 50%, NA 33±6kg/m^2 7.3±1.5%, NR	I_1= DSME; Diabetes Structured Education Courses for	I_1= 6m; 5, 7.5h+; NA I_2= 12m; 46, 7.5h+peer	I_1= In-person I_2= Mixed	I_1= Group I_2= Mixed	I_1= HCP (diabetes educator) I_2= Non-HCP	I_1= Minimal – Content I_2= Moderate – Content &	I_1= None/NR I_2= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		I_2= 62±9y 47%, NA 32±7kg/m^2 7.1±1.5%, NR	People with Type 2 Diabetes including low calorie (1000kcal) diet and SMBG delivered by educators I_2= DSME + Support; same program delivered by peers with ongoing support	support contact time; 11m			(peer)	Delivery	
Gagliardino, 2013b Argentina	I= 117 UC= 117 (Not reporting on arms with physician education)	I= 62.2±8.4y NR, NA 29.0kg/m^2 7.8±1.4%, NR UC= 62±8.4y NR, NA 29.3kg/m^2 7.8±1.2%, NR	DSME; Diabetes Structured Education Courses for People with Type 2 Diabetes including low calorie (1000kcal) diet and SMBG	6m; 5, 7.5h+; NA	In-person	Group	HCP (diabetes educators)	Minimal – Content	None/NR
Giannopoulou, 2005 U.S. (NY)	I= 11 AC_1= 11 AC_2= 11 (Analyzed)	I= 57.4±1.7y 0%, NR 33.7±1.9kg/m^2 6.8±0.5%, 0% AC_1= 55.5±1.7y 0%, NR 35.9±1.9kg/m^2 6.4±0.8%, 0%	I= Lifestyle intervention with nutritional consulting (high monounsaturated fat and 600kcal energy deficit) and supervised walking program (60mins 3-4x/wk)	I= 3.2; 42+, 42h+ nutritional counseling time; NA AC_1= 3.2m; 42+, 42h+; NA AC_2= 3.2m; 15, NR; NA	I= In-person AC_1= In-person AC_2= In-person	I= NR AC_1= NR AC_2= Individual	I= HCP (non specific) AC_1= HCP (non specific) AC_2= HCP (non specific)	I= Minimal – Content AC_1= Minimal – Content AC_2= Minimal – Content	I= None/NR AC_1= None/NR AC_2= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		AC_2= 58.5±1.7y 0%, NR 34.3±1.9kg/m^2 7.3±0.5%, 0%	AC_1= PA control AC_2= Diet control						
Glasgow, 2006a U.S. (CO)	I= 174 Att. C= 161	I= 62.0±11.7y 49.7%, 25.9% 31.3±7.0kg/m^2 7.4±1.6%, 24.2% Att. C= 61.0±11.0y 50%, 20.4% 31.9±7.2kg/m^2 7.5±1.6%, 19.2%	I= DSME; CBT-based computer-assisted tailored intervention focused on healthy eating and PA with followup Att. C= computer-generated general health risk appraisal with brief followup and counseling	I= 2m; 3, 1h+; NA (Plus tailored mail out) Att. C= NR	I= Mixed Att. C= Mixed	I= Individual Att. C= Individual	I= Non-HCP (health educators) Att. C= Non-HCP (health educators)	I= Minimal – Content & Delivery Att. C= NA	I= None/NR Att. C= NA
Glasgow, 2006b U.S. (CO)	I= 167 UC= 160	I= 61.1±11.4y 50%, 34% 32.1±7.0kg/m^2 7.3±1.5%, 27% UC= 61.1±11.4y 60%, 27% 33.3±8.0kg/m^2 7.2±1.3%, 22%	DSME; computer-assisted and tailored DSM intervention focused on diet and aerobic and strength PA	2m; 4, 1.5h; NA	Mixed	Individual	Non-HCP (graduates of health degrees)	Moderate-to-High – Content	None/NR
Glasgow, 2012 U.S. (CO)	I= 162 AC= 169 Att. C= 132	I= 57.8±9.3y 46.3%, 29.3% 35.3±0.5kg/m^2 8.3±0.1%, NR	I= DSME; My Path to Healthy Life, bilingual computer-assisted	I= 12m; 3+, 1h+; NA (Plus computer	I= Mixed AC= NA	I= Mixed AC= Individual	I= Non-HCP (research staff member) & HCP (RD)	I= Moderate-to-High – Content & Delivery	I= Yes AC= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		AC= 58.7±9.3y 55.4%, 25.9% 34.4±0.5kg/m^2 8.0±0.1%, NR Att. C= 58.7±9.1y 48.5%, 29.4% 34.8±0.6kg/m^2 8.2±0.2%, NR	self-management program (CASM) focused on diet, PA and medication taking with followup calls and group sessions AC= Non-DSME education via (CASM) with periodic automated motivational calls Att. C= Tailored health risk assessment and brief contacts	use and invitation to 3- 2h group sessions but only 36% attended one) AC= 12m; NA (Computer use only) Att. C= 12m; NR	Att. C= Technology	Att. C= Individual	AC= NA Att. C= NR	AC= Moderate-to-High – Content & Delivery Att. C= NA	Att. C= NA
Goudswaard, 2004 The Netherlands	I= 28 UC= 30	I= 62.6±9.0y 52%, NR 30.2±4.4 8.2±1.1%, 0% UC= 58.7±11.4y 44%, NR 29.8±5.5 8.8±1.5%, 0%	DSME; collaborative education with emphasis on SMBG interpretation for patients on maximal oral hypoglycemic agents	6m; 6, 2.5h; NA	In-person	Individual	HCP (RN)	Minimal - Content	None/NR
Hawkins, 2010 U.S. (CT)	I= 40 Att. C= 36	I= 64y 14.7%, 82.4%	I= DSME; videophone	I= 6m; 16, 4.5h; NA	I= Technology	I= Individual	I= HCP (NP)	I= Moderate-to-High –	I= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		37.7±8.5kg/m^2 9.0±2.3%, NR Att. C= 65.8±10.4y 12.5%, 84.4% 38.6±6.9kg/m^2 8.9±3.1%, NR	motivational program based on Life With Diabetes: A Series of Teaching Outlines and MI for older adults Att. C= handouts on general healthy living and monthly videophone calls	(Plus reminder calls) Att. C= 6m; 6, 0.5h; NA	Att. C= Technology	Att. C= Individual	Att. C= HCP (RN)	Content & Delivery Att. C= NA	Att. C= NA
Hendricks, 2000 U.S. (MD)	I_1= 15 I_2= 15	I_1= 57.4±13.0y 100%, 100% 25-29kg/m^2 (33%); >30kg/m^2 (54%) 8.3±2.0%, NR I_2= 58.9±10.5y 100%, 100% 25-29kg/m^2 (40%); >30kg/m^2 (60%) 7.8±1.9%, NR	I_1= DSME + Support; Lifeskills Diabetes Self-Management Training Program with empowerment approach and quarterly telephone support for African American men I_2= DSME + Support; Lifeskills Diabetes Self-Management Training Program with empowerment	I_1= 7m; 6, 8.5h; 6m I_2= 7m; 8, 9h; 6m	I_1= Mixed I_2= Mixed	I_1= Mixed I_2= Mixed	I_1= Multidisciplinary (NP, Psych both CDE) I_2= Multidisciplinary (NP, Psych both CDE)	I_1= Moderate-to-High – Content I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
			approach and monthly telephone support for African American men						
Hermanns, 2012	I= 94 AC= 92	I= 62.0±8.7y 47.9%, NR 33.3±5.6kg/m^2 8.4±1.5%, 100% (4.2±3.2 injections/day) AC= 63.9±7.8y 63%, NR 33.4±6.2kg/m^2 8.3±1.2%, 100% (3.7±1.2 injections/day)	I= DSME; MEDIAS 2 ICT for initiation of intensive insulin therapy using empowerment approach and focus on metabolic risk factors AC= Non-DSME education; didactic education	I= 1.25m; 10, 15h; NA AC= 1.25m; 10, 15h; NA	I= In-person AC= In-person	I= Group with supports for 1 session AC= Group	I= HCP (CDE) AC= HCP (CDE)	I= Minimal – Content AC= None	I= None/NR AC= None/NR
Hill-Briggs, 2011 U.S. (MD)	I= 29 AC= 27	I= 61.1±11.0y 48.3%, 100% NR 8.5%, 35.2% AC= 61.5±10.9y 33.3%, 100% NR 8.3%, 33.3%	I= DSME; Project DECIDE (Decision-making Education for Choices In Diabetes Everyday), problem-solving-based diabetes self-management training for low income and literacy patients	I= 4.5m; 9, NR; NA AC= 0.5m; 2, NR; NA	I= In-person AC= In-person	I= Group AC= Group	I= HCP (interventionist) AC= HCP (interventionist)	I= Moderate-to-High – Content AC= Moderate-to-High - Content	I= None/NR AC= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
			AC= Non-DSME; condensed 2-sessions of education and problem solving						
Holmen, 2014 Norway	I = 50 AC = 51 UC = 50	I= 57.4±12.2y 50%, NR 30.7±5.6kg/m^2 8.2±1.1%, 38% AC= 58.6±11.8y 67%, NR 32.4±6.5 kg/m^2 8.1±1.1%, 50% UC= 55.9±12.2y 60%, NR 32.0±6.0kg/m^2 8.3±1.2%, 48%	I = DSME; mobile-phone self-management system with telephone counseling AC = Non-DSME; mobile-phone self-management system	I = 12m; 5, 1.5h; NA	I = Technology AC = NA	I = Individual AC = Individual	I = Multidisciplinary (RN, RD) AC= NA	I = Moderate-to-High - Delivery	I = None/NR AC = None/NR
Holtrop, 2002 U.S. (MI)	I= 67 UC= 65	I= 58y 0%, 5% 35.4±5.8kg/m^2 8.0%, 25.4% UC= 65y 0%, 5% 37.9±8.1kg/m^2 7.7%, 34%	DSME; Sticking to it- Diabetes Mellitus, behavioral education program focused on diet and exercise	1.5; 6+6 supportive telephone contacts, 9h+telephone duration; NA (Plus supportive telephone contacts between sessions)	Mixed	Mixed	Non-HCP (lay health advisors from the community)	Minimal – Content & Delivery	Yes
Huisman, 2009	I= 53	I= 60.1±6.8y	I= Lifestyle; self-	I= 6m; 9, 17h;	I= In-person	I= Mixed	I= HCP (Psych)	I= Minimal –	I=

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
The Netherlands	AC= 38 UC= 38	52%, 0% 36.0±6.8kg/m^2 7.3±1.3%, NR AC= 56.7±10.3y 42%, 0% 35.7±6.1kg/m^2 7.6±1.5%, NR UC= 56.7±9.9y 46%, 0% 35.0±5.3kg/m^2 7.2±1.1%, NR	regulation program for weight reduction via MI to select personalized goals AC= Non-DSME education; self-help book with 12-week program with 1 in-person and 3 telephone consultations	NA AC= 6m; 4, NR; NA	AC= Mixed	with supports for 1 session AC= Individual	AC= HCP (RN)	Content & Delivery AC= Minimal – Content & Delivery	None/NR AC= None/NR
Izquierdo, 2003 U.S. (NY)	I_1= 27 I_2= 29	I_1= 61.4±8.9y 59%, 5% 31.3±6.2kg/m^2 8.3±1.6%, NR (9% T1DM) I_2= 53.9±10.1y 33%, 5% 35.9±9.2kg/m^2 8.7±2.2%, NR (12% T1DM)	I_1= DSME; in-clinic delivery of DSME meeting standards and including coping skills and empowerment approach I_2= DSME; telemedicine delivery of DSME meeting standards and including coping skills and empowerment approach	I_1= 3m; 3, 4h; NA I_2= 3m; 3, 4h; NA	I_1= In-person I_2= Technology	I_1= Individual I_2= Individual	I_1= Multidisci-plinary (RD, RN) I_2= Multidisci-plinary (RD, RN)	I_1= Minimal – Content & Delivery I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= None/NR
Johnson, 2009	I= 22	I= 56.2y	I= Lifestyle;	I= 3m; 8, NR; NA	I= In-person	I= Group	I= Non-HCP	I= Minimal –	I=

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Canada	AC= 19	42%, NR 32.7±5.9kg/m^2 6.5±1.3%, 0% AC= 56.2y 42%, NR 32.0±6.2kg/m^2 6.4±1.3%, 0%	walking program with supervised walking 1x/wk and goal to increase intensity by 10% and diet training to exchange foods having low for high glycemic index AC= basic walking program (no defined targets) and basic dietary education on glycemic load	AC= 3m; 8, NR (All participants received 12-week basic walking program in early phase)	AC= In-person	AC = Group	(health field graduate students) AC= non-HCP	Content AC= Minimal - Content	None/NR AC= None/NR
Jones, 2003 Canada	I= 250 UC= 250 (Not reporting on groups receiving free glucose testing strips)	I= 55.1y 56.4%, NR 32.2kg/m^2 8.43%, 32% UC= 54.6y 50%, NR 31.6kg/m^2 8.48%, 34.4%	DSME; Pathways to Change, stage-matched personalized assessment and counseling for SMBG, healthy eating and smoking cessation	12m; 5, NR; NA (Plus newsletters)	Technology	Individual	NR	Moderate-to-High – Content & Delivery	None/NR
Keyserling, 2002 U.S. (NC)	I_1= 66 I_2= 67 UC= 67	I_1= 59.8y 0%, 100% 34.6kg/m^2 11.1%, 40.9%	I_1= Lifestyle; clinic-based with diet (reduced fat), PA (30mins/ day)	I_1= 6m; 4, 3h; NA I_2= 12m; 19, 9.5h; 6m	I_1= Individual I_2= Mixed	I_1= Individual I_2= Mixed	I_1= HCP (RD) I_2= Non-HCP (peer) & HCP	I_1= Minimal – Content & Delivery	I_1= None/NR I_2= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		I_2= 58.5y 0%, 100% 36.2kg/m^2 10.8%, 43.3% UC= 59.2y 0%, 100% 36.5kg/m^2 11.3%. 41.8%	I_2= Lifestyle; clinic and community-based A New Leaf . Choices for Healthy Living with Diabetes for African American Women incorporating social support				(RD)	I_2= Moderate-to-High – Content & Delivery	
Kim, 2006 Korea	I= 32 UC= 26	I= 55.0±8.1y 19%, NR 25.8±3.8kg/m^2 8.5±1.4%, NR UC= 53.8±9.0y 31%, NR 26.2±4.0kg/m^2 8.6±1.3%, NR	Lifestyle; education and counseling for 5% weight loss including individualized diet and ≥150mins/wk moderate PA	6m; 18, NR; 2m	In-person	Individual	Non-HCP (exercise trainer) & HCP (RN)	Minimal – Content & Delivery	None/NR
Kim, 2009 U.S. (MD, DC)	I= 41 UC= 42	I= 56.2±8.4y 62.5%, 100% 25.9±3.4kg/m^2 9.4±1.5%, NR UC= 56.6±7.6y 48.7%, 100% 25.7±3.1kg/m^2 9.1±1.3%, NR	DSME + Support; community-based SHIP-DM (self-help intervention program for type 2 diabetes management) for Korean American immigrants	7m; 12, 13-15h; 5.6m (Plus reminder calls and newsletters)	Mixed	Mixed	Multidisciplinary (RD, RN)	Moderate-to-High - Delivery	Yes
Kim, 2014 Korea	I = 18 UC = 17	I= 48.8±8.6y 50%, NA 28.3±3.4kg/m^2	Lifestyle; diet and PA prescription with supervised	3m; 36, 36h+; NA	In-person	Individual	Multidisciplinary (RD, exercise physiologist)	Minimal - Content	None/NR

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		7.5±0.7%, 0% UC= 48.3±8.2y 59%, NA 28.1±3.4kg/m^2 7.7±0.7%, 0%	resistance training 3x/wk and self-performed aerobic exercise & educational sessions						
Koo, 2010 Korea	I= 14 AC_1= 19 AC_2= 13 UC= 18	I= 53±8y 0%, NR 29.4 (25.9-37.8) kg/m^2 8.0±1.8%, NR AC_1= 57±8y 0%, NR 27.1 (24.0-31.5) kg/m^2 7.5±1.1%, NR AC_2= 59±4y 0%, NR 25.5 (23.5-34.4) kg/m^2 7.8±1.0%, NR UC= 57±8y 0%, NR 28.5 (24.0-31.5) kg/m^2 7.5±1.1%, NR	I= Lifestyle; diet and PA prescriptions and education AC_1= Diet prescription (1200kcal) with education AC_2= PA prescription (120mins brisk walking /day) with monitoring	I= 3m; 13, NR; NA AC_1= 3m; 7, NR; NA AC_2= 3m; 7, NR, NA	I= In-person AC_1= In-person AC_2= In-person	I= Individual AC_1= Individual AC_2= Individual	I= HCP (exercise therapist) AC_1= NR AC_2= HCP (exercise therapist)	I= Minimal – Content AC_1= Minimal – Content AC_2= None	I= None/NR AC_1= None/NR AC_2= None/NR
Kulzer, 2007 Germany	I_1= 63 I_2= 66 AC= 64	I_1= 56.6±6.7y 53.6%, NR 31.8±3.3kg/m^2	I_1= DSME; empowerment group DSME	I_1= 3m; 12, 18h; NA	I_1= In-person I_2= In-person	I_1= Group I_2= Mixed AC= Group	I_1= HCP (Psych) I_2= HCP (Pscyh)	I_1= Minimal – Content	I_1= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		8.2±0.5%, 0% I_2= 55.4±6.5y 51.6%, NR 32.63±4.2kg/m^2 7.7±0.4%, 0% AC= 55.2±5.6y 45.9%, NR 32.1±3.9kg/m^2 7.6±0.5%, 0%	I_2= DSME; empowerment group & Individual DSME AC= Non-DSME education in groups	I_2= 3m; 12, 18h; NA AC= 3m; 4, 6h; NA	AC= In-person		AC= HCP (Psych)	I_2= Minimal – Content & Delivery AC= None	I_2= None/NR AC= None/NR
Lee, 2011 Hong Kong	I= 84 UC= 73	I= NR 39%, NR 25.1 8.18%, NR UC= NR 37%, NR 25.6 8.0%, NR	DSME; self-management training focused on self-efficacy	1.5m; 6, 15h; NA	In-person	Group	HCP (social worker)	Minimal - Content	None/NR
Lorig, 2008 U.S. (CA)	I= 219 UC= 198 Not considering 6-month RCT portion without reinforcement by automated	I= 52.9±13.2y 42.9%, 100% 80.0±18.5kg 7.4±2.0%, 8.7% UC= 52.8±13.4y 32.8%, 100% 77.9±13.4kg 7.4±1.9%, 12.1%	DSME; Spanish Diabetes Self-Management Program (SDSMP) delivered by peers for Spanish-speaking adults	1.5m; 6, 15h; NA	In-person	Group with supports	Non-HCP (Spanish-speaking peer)	Moderate-to-High – Content & Delivery	Yes

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	telephone)								
Lorig, 2009 U.S. (CA)	I= 186 UC= 159	I= 67.7±11.9y 37.6%, 36% 87.0±24.0kg 6.7±1.5%, 17.7% UC= 65.4±11.4y 33.8%, 29.4% 88.9±24.6kg 6.7±1.4%, 17%	DSME; community-based, peer-led DSMP using self-efficacy approach	1.5m; 6, 15h; NA	In-Person	Group with supports	Non-HCP (peers)	Minimal – Content	Yes
Lorig, 2010 U.S. (CA)	I= 491 UC= 270 (Intervention group includes IDSMP with+without listserve reinforcement)	I= 54.2±9.9y 26.3%, 22% NR 6.5±1.2%, NR UC= 54.4±10.6y 28.9%, 28.9% NR 6.4±1.3%, NR	DSME; Internet DSMP with discussion boards and facilitator support	1.5m; 6, NR; NA	Technology	Individual	Non-HCP (peers)	Moderate-to-High – Content & Delivery	Yes
Lujan, 2007 U.S. (TX)	I= 75 UC= 75	I= 57.0±9.8y 19%, 100% NR 8.2±2.2%, 4% UC= 59.6±10.3y 22%, 100% NR 7.7±1.5%, 5%	DSME; culturally specific diabetes intervention delivered by promotores for Mexican Americans	6m; 12, 16h+biweekly telephone support duration; NA (Plus 8 mailed postcards)	Mixed	Mixed	Non-HCP (Promotores)	Moderate-to-High – Content & Delivery	Yes
Lynch, 2014	I= 30	I= 53.4±11.4y	I= DSME; Lifestyle	I= 6m; 42,	I= Mixed	I= Mixed	I= Non-HCP	I= Moderate-	I= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
U.S. (IL)	AC= 31	40%, 100% 35.3±6.5kg/m^2 7.9±1.6%, 43.3% AC= 54.8±8.5y 25.8%, 100% 35.9±6.3kg/m^2 7.4±1.6%, 41.9%	Improvement Through Food and Exercise (LIFE), CBT-based intervention for African Americans with comorbid diabetes and hypertension plus telephone support calls from peers AC= minimal education classes	36+telephone support duration; NA AC= 6m; 2, 6h; NA	AC= In-person	AC= Group	(African American peers) & HCP (RD) AC= Non-HCP (CHW)	to-High – Content & Delivery AC= Minimal - Content	AC= None/NR
Mandel, 2013 U.S. (OH)	I_1= 64 I_2= 67	I_1= 57.1±9.7y 23.4%, NR 36.8±8.2kg/m^2 7.7±1.8%, NR I_2= 58.0±11.3y 31.3%, NR 34.5±8.5kg/m^2 7.4±1.6%, NR	I_1= DSME I_2= DSME (Music Therapy)	I_1= 1m; 4, 8h; NA I_2= 2m; 8, 14h; NA	I_1= In-person I_2= In-person	I_1= Group I_2= Group	I_1= HCP (CDE or RD) I_2= Multidisciplinary (CDE or RD, music therapist)	I_1= Minimal – Content I_2= Moderate-to-High – Content & Deivery	I_1= None/NR I_2= None/NR
Mayer-Davis, 2004 U.S. (SC)	I_1= 58 I_2= 67 UC= 64	I_1= 58.9±7.8y 15%, 89.4% 37.5±6.7kg/m^2 9.7±3.1%, 42.5% I_2= 59.7±8.6y 22%, 85.7% 37.6±6.5kg/m^2	I_1= Lifestyle; reimbursable intensive lifestyle program tailored to medically underserved I_2= Lifestyle; reimbursable	I_1= 12m; 4, 4h; NA I_2= 12m; 26, 26h; 8m	I_1= In-person I_2= In-person	I_1= Mixed I_2= Mixed	I_1= HCP (RD) I_2= HCP (RD)	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High – Content and Delivery	I_1= None/NR I_2= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		10.2±2.5%, 51% UC= 62.4±9.5y 21%, 73.2% 35.2±7.5kg/m^2 9.6±2.9%, 41%	intensive lifestyle program modeled after Diabetes Prevention Program tailored to medically underserved						
McGowan, 2011 Canada	I= 169 AC= 152	I= 55±12y 46%, 22% 80±15kg 6.8±1.2%, NR AC= 59±12y 45%, 18% 83±19kg 7.1±1.5%, NR	I= DSME; 2-day DM education and Stanford Chronic Disease Self-management Program AC= 2-day DM education	I= 1.5m; 8, 27+h; NA AC= 0.06m; 2, 6+h; NA	I= In-person AC= In-person	I= Group AC= Group	I= Non-HCP (lay program leaders) & Multidisciplinary (RN, RD) AC= Multidisciplinary (RN, RD)	I= Minimal – Content & Delivery AC= Minimal – Content	I= Yes AC= None/NR
Miller, 2014 U.S. (OH)	I= 32 AC= 36	I= 54.0±7.0y 36%, 28% 36.2±1.2kg/m^2 8.3±0.3%, 0% AC= 53.9±8.2y 37%, 18.5% 36.2±1.2kg/m^2 8.5±0.2%, 0%	I= DSME; Smart Choices AC= Mindfulness-based Eating Awareness Program with guided meditation	I= 6m; 12, 28h; NA AC= 6m; 12, 28h; NA	I= In-person AC= In-person	I= Group AC= Group	I= HCP (RD) AC= Multidisciplinary (RD, social worker)	I= Minimal – Content & Delivery AC= Minimal – Content & Delivery	I= None/NR AC= None/NR
Moncrieft, 2013 (FI)	I = 54 UC = 57	I= 54.8±8.3y 35.1%, 100% 32.2±3.7kg/m^2 7.7±1.4%, NR UC= 54.8±6.3y	Lifestyle; Community Approach to Lifestyle Modification for Diabetes (CALM-	12m; 17; 26+h; 9m Plus brief telephone contact between	Mixed	Mixed	Non-HCP (psychologist trainee)	I= Minimal – Content	I = None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		22.2%, 91% 32.9±5.4kg/m^2 7.8±1.2%, NR	D) with diet, PA and stress management training	sessions					
Moriyama, 2009 Japan	I= 50 UC= 25	I= 66.4±9.2y 40%, NR 60.0±11.0kg 7.5±1.5%, 7% UC= 65.2±8.5y 57%, NR 60.7±11.2kg 7.4±1.7%, 17%	DSME; Cognitive-behavior theory-based program focused on diet, PA and family support	12m; 12+24 telephone followups, 6h+telephone call duration; NA	Mixed	Individual (Plus family provided information)	HCP (RN)	Moderate-to-High – Content & Delivery	None/NR
Muchmore, 1994 U.S. (CA)	I_1= 12 I_2= 11	I_1= 57.3±2.3y 33%, NR 89.5±5kg 10.3±0.3%, 0% I_2= 60.1±2.2y 45%, NR 99±5kg 10.45±.04%, 0%	I_1= Lifestyle; behavioral weight loss program plus basic DM diet education I_2= Lifestyle; behavioral weight loss program plus diet and blood glucose regulation intervention	I_1= 6.5m; 23, 22+; 3.7m I_2= 6.5; 23, 22+; 3.7m	I_1= In-person I_2= In-person	I_1= Mixed I_2= Mixed	I_1= Multidisciplinary (RN, RD) I_2= Multidisciplinary (RN, RD)	I_1= Minimal – Content I_2= Moderate-to-High - Content	I_1= None/NR I_2= None/NR
Murrock, 2009 U.S. (OH)	I= 36 UC= 34	I= 58.5±12.2y 0%, 100% 94.8±26.9kg 7.7±1.2%, 21% UC= 67.1±7.9y 0%, 100%	Lifestyle; dance and peer support for African American women	2.8m; 24, 24+social support activity duration; NA	In-person	Group	Non-HCP (African American dance instructor) & HCP (RN)	Moderate-to-High – Content & Delivery	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		96.5±20.8kg 7.4±0.1%, 21%							
Nishita, 2013 U.S. (HI)	I= 128 UC= 62	I= 47.6±.09y 34.4%, 68.7% 32.4±0.7kg/m^2 7.8±0.2%, NR UC= 50.±1.2y 43.6%, 74.2% 34.2±1.1kg/m^2 7.7±0.2%, NR	DSME; life coaching and pharmacist counseling using empowerment approach for employed adults	12m; 14.0, 13h; NA (Plus nutritional counseling as appropriate)	In-person	Individual	Non-HCP (graduates of social sciences degrees) & HCP (Pharmacist)	Moderate-to-High – Content & Delivery	Yes
Palmas, 2014 U.S. (NY)	I= 181 Att. C= 179	I= 57.1±7.7y 39.2%, 100% NR 8.8±1.7%, NR Att. C= 58.1±7.8y 37.4%, 100% NR 8.5±1.6%, NR	I= DSME + Support; CHW-led intervention focused on problem solving and negotiating healthcare Att. C= mailed information and 4 telephone contacts	I= 12m; 13, 4.6h; 9m Att. C= 12m; 4+4 mail-outs, 0.7h; NA	I= Mixed Att. C= Technology	I= Mixed Att. C= Individual	I= Non-HCP (CHW) Att. C= Non-HCP (research assistant)	I= Moderate-to-High – Content & Delivery Att. C= None	I= Yes Att. C= None
Philis-Tsimikas, 2011 U.S. (CA)	I= 104 UC= 103	I= 49.2±11.8y 25.2%, 98.1% 32.1±5.9kg/m^2 10.3±1.7%, NR UC= 52.2±9.6y 33.7%, 94.2%	I= DSME + Support; Project Dulce, peer-led diabetes education program for high-risk Mexican	10m; 12, 16h; 8m	In-person (Plus telephone reminders)	Group	Non-HCP (Promotores)	Moderate-to-High – Content & Delivery	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		30.9±6.3kg/m^2 10.5±1.7%, NR	Americans						
Plotnikoff, 2011 Canada	I_1= 49 I_2= 47	I_1= 60 (25-75)y 40%, NR 34.3±5.7kg/m^2 7.8±2.2%, NR I_2= 60 (25-75)y 40%, NR 34.8±9.0kg/m^2 7.3±1.3%, NR (Mean, Range)	I_1= DSME + Support; I_2= DSME + Support; addition of individualized PA counseling with continual telephone support	I_1= 12m; 11, 16.5h+; 11m I_2= 12m; 32, 17.5h+time for telephone counseling; 10m	I_1= In-person I_2= Mixed	I_1= Group I_2= Mixed	I_1= HCP (CDE) I_2= Non-HCP (certified personal trainers) & HCP (CDE)	I_1= Minimal – Content I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= Yes
Prezio, 2013 U.S. (TX)	I= 90 UC= 90	I= 47.9±11.0y 33.3%, 77.8% 32.7±7.8kg/m^2 8.9±2.2%, NR UC= 45.7±10.7y 45.6%, 70% 33.9±8.2kg/m^2 8.7±2.3%, NR	DSME + Support; Community Diabetes Education (CoDE) for uninsured Mexican Americans	12m; 7, 7h; 10m	In-person	Individual	Non-HCP (CHW)	Moderate-to-High – Content & Delivery	Yes
Reaney, 2013 Germany & Spain (33 sites)	I= 330 UC= 351	I= 62±9.6y 54.2%, NR 31.2±5.4 7.2 (6.5-8.0)%, 47% UC= 61.9±8.7y 52.4%, NR 31.7±5.9kg/m^2 7.0 (6.4-7.8)%,	I= DSME; group DSME using Conversation Maps tools EU version	1.5m; 4, 8-12h; NA	In-person	Group	HCP (trained diabetes educator as per usual care at sites)	Minimal - Content	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		41.9% (Mean, IQR)							
Rickheim, 2002 U.S. (MN)	I_1= 87 I_2= 83	I_1= 51.6±9.2y 35.6%, 3.6% 33.8±6.1kg/m^2 8.9±1.9%, 0% I_2= 52.9±12.8y 32.5%, 10.5% 34.9±6.5kg/m^2 8.0±1.9%, 0%	I_1= DSME; group education meeting National Standards and informed by an integrated data evaluation system I_2= DSME; individual education meeting National Standards and informed by an integrated data evaluation system	I_1= 6m; 4, 7h; NA I_2= 6m; 4, 5h; NA	I_1= In-person I_2= In-person	I_1= Group I_2= Individual	I_1= Multidisciplinary (RD, RN) I_2= Multidisciplinary (RD, RN)	I_1= Minimal – Content I_2= Minimal – Content	I_1= None/NR I_2= None/NR
Ridgeway, 1999 U.S. (TN)	I= 28 UC= 28	I= 62y 33%, NR 88±16kg 12.3±2.2%, 17% UC= 65y 25%, NR 84.8±17kg 12.3±3.0%, 15%	DSME; Life Skills program with behavioral training	12m; 7, 10.5h; NA (Plus telephone reminders)	In-person	Mixed	Multidisciplinary (RD, RN CDEs with some physician contact)	Minimal – Content & Delivery	None/NR
Rock, 2014	I_1= 74	I_1= 55.5±9.2y	I_1= Lifestyle;	I_1 & I_2= 12m; 41,	I_1 & I_2= In-	I_1 & I_2=	I_1 & I_2= Non-HCP	I_1 & I_2=	I_1 & I_2=

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
U.S. (CA, MN)	I_2= 77 Att. C= 76	52.7%, 20.3% 36.2±4.3kg/m^2 7.4±1.1%, 18% I_2= 57.3±8.6y 52.0%, 18.2% 36.2±4.7kg/m^2 7.3±1.4%, 18% Att. C= 56.8±9.3y 42.1%, 22.4% 36.3±4.4kg/m^2 7.4±1.1%, 18%	weight loss program incorporating low-fat diet with meal replacements I_2= Lifestyle; weight loss program incorporating low-carbohydrate diet with meal replacements Att. C= two one-to-one weight loss sessions with materials, tracking program and monthly check-in	NR; 3m (Plus telephone availability) Att. C= 12m; 2, 2h; NA (Plus monthly telephone check-ins)	person (Plus telephone availability but use NR) Att. C= Individual (Plus telephone check-ins)	Individual Att. C= Individual	(weight loss counselors) Att. C= HCP (RD)	Minimal – Content & Delivery Att. C= None	None/NR Att. C= None/NR
Rosal, 2005 U.S. (MA)	I= 15 UC= 10	I= 62.7±8.1y 20%, 100% 32.4±4.5kg/m^2 7.7±1.2%, 40% UC= 62.4±9.7y 20%, 100% 32.7±7.4kg/m^2 9.3±1.8%, 70%	DSME; community-based, literacy and culturally tailored program for low-income Spanish-speaking individuals of Puerto Rican heritage	3m; 13, 26.5-31.5h; NA	In-person	Mixed	Multidisciplinary (RN, RD)	Moderate-to-High – Content & Delivery	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Rosal, 2011 U.S. (MA)	I= 124 UC= 128	I= 18 - >65y 21.8%, 100% 34.5±6.5kg/m^2 8.9±1.8%, 42.8% UC= 18 - >65y 25%, 100% 34.5±6.5kg/m^2 9.1±2.0%, 54.7%	DSME + Support; Latinos en Control, community-based, culturally tailored self-management intervention for low-income, Spanish-speaking Latinos	12m; 21, 51h; 8m (Plus telephone reminders)	In-person	Mixed with supports	Non-HCP (trained lay person) & HCP (RD, health educator)	Moderate-to-High – Content & Delivery	Yes
Rosal, 2014 U.S. (MA)	I_1 = 43 I_2 = 46	I_1= 52±11y 0%, 100% 34.4±8.0kg/m^2 9.4±2%, 53.5% I_2= 53±10y 0%, 100% 36.4±8kg/m^2 9.6±2%, 45.7	I_1 = DSME; Adaptation of Power to Prevent I_2 = DSME; Virtual adaptation of Power to Prevent	I_1 = 2m; 8, 12h; NA I_2 = 2m; 8, 12h; NA	I_1 = In-person I_2 = Technology	I_1 = Group I_2 = Group	I_1 = Multidisciplinary (RD [CDE], NP) I_2 = Multidisciplinary (RD [CDE], NP)	I_1 = Moderate-to-high - Content, I_2 = Moderate-to-high – Content and Delivery	I_1 = None/NR I_2 = None/NR
Rothschild, 2014 U.S. (IL)	I= 73 Att. C= 71	I= 53.7±11.7y 35.6%, 100% 32.7±7.4kg/m^2 8.5±2.2%, 19.2% Att. C= 53.6±12.7y 29.6%%, 100% 34.2±9.5kg/m^2 8.1±1.6%, 12.7%	I= DSME + Support; Mexican Americans Trial of Community Health Workers (MATCH) providing in-home self-management training Att. C; 36 mailed bilingual diabetes self-management	I= 24m; 36, 54h; 12m Att. C = 24m; 36, Oh; NA	I= In-person Att. C= mail only	I= Individual Att. C= NA	I= Non-HCP (CHW) Att. C= NA	I= Moderate-to-High – Content & Delivery Att. C= Minimal - Content	I= Yes Att. C= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
			newsletters						
Ruggerio, 2010 U.S. (IL)	I= 25 UC= 25	All participants= 65.8±9.4y 34%, 100% 32.4±6.6kg/m^2 HbA1c: I= 8.5±1.7% UC= 8.9±1.6% Insulin use NR	DSME; Medical assistant self-care coaching intervention using empowerment approach for low-income racial/ethnic minorities	6m; 6, 2h; NA (Plus telephone reminders)	Mixed	Individual	Non-HCP (certified medical assistants)	Moderate-to-High – Content & Delivery	Yes
Ruggerio, 2014 U.S. (IL)	I= 136 UC= 134	I= 53.2±11.7y 32.1%, 100% 33.0±6.4kg/m^2 8.7±2.4%, NR UC= 53.1±13.0y 30.3%, 100% 33.4±6.4kg/m^2 8.5±2.3%, NR	DSME; Medical assistant self-care coaching intervention using empowerment approach for low-income racial/ethnic minorities	12m; 12, 4h; NA	Mixed	Individual	Non-HCP (certified medical assistants)	Moderate-to-High – Content & Delivery	Yes
Sacco, 2009 U.S. (FL)	I= 31 UC= 31	All participants = 52±8.6y 42%, 22.6% 35.8±7.7kg/m^2 8.5±1.7%, 53%	DSME; brief CBT-based coaching telephone intervention delivered by paraprofessional for T2DM ≥1 cardiovascular risk factors	6m; 16, 6h; NA	Mixed (1 in-person session)	Individual	Non-HCP (undergraduate psychology students)	Minimal – Content & Delivery	None/NR
Salinero-Fort, 2011 Spain	I_1= 304 I_2= 304	I_1= 67.3±19y 51%, NR 30.5±5.2kg/m^2	I_1= DSME; Conventional Health Promotion	I_1= 24m; 10, 6.7h; NA	I_1= In-person I_2= In-person	I_1= Individual I_2= Individual	I_1= HCP (RN) I_2= HCP (RN)	I_1= Minimal – Content & Delivery	I_1= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		7.4±1.2%, 14.4% I_2= 66.1±8y 46%, NR 29.6±4.6kg/m^2 7.1±1.3%, 14.2%	Education as per Spanish recommendation I_2 = DSME; PRECEDE model focusing on predisposing, enabling and reinforcing factors for behaviors identified via assessment	I_2= 24m; 10, 6.7h; NA				I_2= Moderate-to-High – Content & Delivery	I_2= None/NR
Samuel-Hodge, 2009 U.S. (NC)	I= 117 UC= 84	I= 57.0y 36%, 100% 34.6kg/m^2 7.7%, 51% UC= 61.3y 37%, 100% 35.1kg/m^2 7.9%, 38%	DSME + Support; church-based diabetes self-management program for African Americans	12m; 25, 19h+telephone call time;4m	Mixed	Mixed	Non-HCP (church health advisor) & Multidisciplinary (RD, other HCP)	Moderate-to-High – Content & Delivery	Yes
Sarkadi, 2004 Sweden	I= 39 UC= 38	I= 66.4±7.9y NR, NR 27.2±3.6kg/m^2 6.5+_0.5%, NR UC= 66.5±10.7y NR, NR 28.6±5.8kg/m^2 6.5±0.5%, NR	DSME; pharmacist-led, experience and empowerment-based group education	12m; 12, NR; NA	In-person	Group	HCP (Pharmacist)	Moderate-to-High - Content	None/NR
Sevick, 2012	I= 147	I= 25 - >75y	I=DSME; SCT-	I= 6m; 14, NR;	I= In-person	I= Group	I=	I= Moderate-	I=

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
U.S. (PA)	Att. C= 149	29.0%, 31.3% 34.0±7.3kg/m^2 7.7±2.2%, NR Att. C= 25 - >75y 34.8%%, 28.8% 35.1±7.7kg/m^2 7.5±1.7%, NR	based intervention with technology-based self-monitoring of SNBG, diet and PA Att. C= basic group education and mailed magazines; also received meter and pedometer	NA Att. C= 6m; 3, NR:NA	Att. C= In-person	Att. C= Group	Multidisciplinary (RD, RN) Att. C= HCP (RN)	to-High – Content Att. C= None	None/NR Att. C= None/NR
Shibayama, 2007 Japan	I= 67 UC= 67	I= 61±8y 65.2%, NR 26±5kg/m^2 7.4±0.7%, 0% UC= 62±7y 65.2%, NR 26±5kg/m^2 7.4±0.7%, 0%	DSME; nurse-led DSME	12m; 12, 5.5h; NA	In-person	Individual	HCP (RN)	Moderate-to-High – Content & Delivery	None/NR
Sigurdardottir, 2009 Iceland	I= 30 UC= 28	I= 57.8±10.9y 64%, NR 31.5±5.1kg/m^2 8.1±0.9%, 39% UC= 63.5±9.3y 72%, NR 32.7±5.0kg/m^2 7.9±8.9%, 20%	DSME; nurse-led empowerment approach using self-completed instruments on self-care and quality of life	1.5m; 6, 2.3-3.7h; NA	Mixed	Individual	HCP (RN)	Moderate-to-High – Content & Delivery	None/NR
Siminerio,	I_1= 32	I_1= 60±12y	I_1= DSME;	I_1= 6m; NR, NR;	I_1= In-person	I_1= Individual	I_1= HCP (CDE)	I_1= Moderate-	I_1=

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
2013 U.S. (PA)	I_2= 35 I_3= 36 I_4= 38	47%, 22% 34.6±6.1 8.7±1.9%, NR I_2= 60±13.4y 40%, 20% 36.2±8.2kg/m^2 9.0±2.1%, NR I_3= 64±10y 47%, 14% 34±8.7kg/m^2 8.6±2.4%, NR I_4= 60±10y 42%, 13% 35.7±8.8kg/m^2 8.3±1.8%, NR	empowerment based DSME, PRISM (Program Reinforcement Impacts Self-Management) I_2= DSME + Support; DSMS by practice staff I_3= DSME + Support; DSMS by peer I_4= DSME + Support; DSMS support by educator	NA I_2= 6m; 1.2+DSME, 0.25h+DSME; 4.5m I_3= 6m; 5.0+DSME, 2.25h+DSME; 4.5m I_4= 6m; 5.1+DSME, 1.5h+DSME; 4.5m	I_2= Mixed I_3= Mixed I_4= Mixed	I_2= Individual I_3= Individual I_4= Individual	I_2= Non-HCP (medical assistant or LPN) & HCP (CDE) I_3= Non-HCP (peer) & HCP (CDE) I_4= HCP (CDE)	to-High – Content & Delivery I_2= Moderate-to-High – Content & Delivery I_3= Moderate-to-High – Content & Delivery I_4= Moderate-to-High – Content & Delivery	None/NR I_2= None/NR I_3= Yes I_4= None/NR
Sinclair, 2013 U.S. (HI)	I= 48 UC= 34	I= 53±12y 37%, 100% 36±12kg/m^2 9.9±2.0%, 56% UC= 55±10y 38%, 100% 38±8kg/m^2 9.8±2.2%, 46%	DSME; Partners in Care; community-based, culturally adapted CBT-based DSME delivered by peers for Hawi'i Natives and Pacific Islanders	3m; 12, 12h; NA	In-person	Group	Non-HCP (peer)	Moderate-to-High – Content & Delivery	Yes
Sixta, 2008 U.S. (TX)	I= 68 UC= 63	I= 54.5 (30-77)y 29%, 100% NR	DSME; promotores-led culturally sensitive	2.3m; 10, 15h; NA	In-person	Group	Non-HCP (Promotores)	Moderate-to-High – Content &	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		7.32%, NR UC= 52.8 (26-81)y 29%, 100% NR 7.65%, NR (Mean, Range)	DSME for underserved Hispanic Americans					Delivery	
Skelly, 2005 U.S. (NC)	I= 23 UC= 18 (Analyzed)	I= 60.5±9.0y 0%, 100% NR 9.2±2.5%, 26.1% UC= 63.7±10.8y 0%, 100% NR 9.0±2.8%, 16.7%	DSME; symptom-focused teaching and counseling intervention for rural older African American women	2m; 4, 4h; NA	In-person	Individual	HCP (RN)	Moderate-to-High – Content & Delivery	None/NR
Skelly, 2009 U.S. (NC)	I_1= 60 I_2= 60 AC= 60	I_1= 65y (Median) 0%, 100% NR 8.3±1.6%, 18% I_2= 68.5y (Median) 0%, 100% NR 8.4±1.6%, 17%	I_1= DSME; symptom-focused teaching and counseling intervention for rural older African American women I_2= DSME + Support; symptom-focused teaching and	I_1= 2.8m; 4, 4h; NA I_2= 8.6m; 8, 5h; 5.8m AC= 2.8m; 4, 4h; NA	I_1= In-person I_2= Mixed AC= In-person	I_1= Individual with family I_2= Individual with family AC= Individual	I_1= HCP (RN) I_2= HCP (RN) AC= HCP (RN)	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High – Content & Delivery AC= Minimal – Content &	I_1= None/NR I_2= None/NR AC= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		AC= 68y (Median) 0%, 100% NR 8.1±1.6%, 17%	counseling intervention for rural older African American women with telephone booster sessions AC= skills-based weight management program focused on diet education					Delivery	
Smith, 1997 U.S. (AL)	I_1= 10 I_2= 6 (Analyzed)	All participants: 62.4±7.0y 0%, 41% 34.7±4.9kg/m^2 10.25±2.2%, 0%	I_1= Lifestyle; behavioral weight-control program for older obese women I_2= Lifestyle; behavioral weight-control program for older obese women with MI	I_1= 4m; 16, NR; NA I_2= 4m; 19, NR; NA	I_1= In-person I_2= In-person	I_1= Group I_2= Mixed	I_1= Multidisciplinary (RD, Psych, exercise physiologist) I_2= Multidisciplinary (RD, Psych, exercise physiologist) – Psych for MI	I_1= Minimal – Content I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= None/NR
Sorkin, 2014 U.S. (CA,	I = 53 UC = 36	All participants: 52.7±6.9y 0%, 100% NR, NR, NR	I = Lifestyle; United for Life (Unidas por la vida) modeled after DPP but community-based for Latino women (Mothers with	I = 4m; 16, NR; NA	Mixed	Mixed with supports	Non-HCP (CHW "Community Lifestyle Coaches")	I = Moderate-to-high – Conent and Delivery	I = Present

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
			T2DM and their daughters)						
Spencer, 2011 U.S. (MI)	I= 84 UC= 84	I= 50 (47, 52)y 25%, 100% 34 (32, 36)kg/m^2 8.6 (8.0, 9.1)%, 27% UC= 55 (53, 57)y 33%, 100% 35 (33, 37)kg/m^2 8.5 (8.0, 8.9)%, 29% (95% CI)	DSME; culturally tailored, behavioral theory-based CHW intervention for African Americans and Latinos	6m; 14 & biweekly telephone calls, 24h plus telephone contact time; NA	Mixed	Mixed	Non-HCP (CHW)	Moderate-to-High – Content & Delivery	Yes
Sperl-Hillen, 2013 U.S. (NM, MN)	I_1= 246 I_2= 243 UC= 134	I_1= 61.6±10.9y 50.4%, 37.3% 34.4±8.0 kg/m^2 8.1%, NR I_2= 61.2±11.8y 49%, 33.5% 34.4±7.0 kg/m^2 8.1%, NR UC= 63.3±1.5y 53.7%, 32.6 34.7±7.7 kg/m^2 8.0%, NR	I_1= DSME; individual DSME I_2= DSME; group DSME using U.S. Conversation Maps	I_1= 3m; 3, 3h; NA I_2= 2.5m; 4, 8h; NA	I_1= In-person I_2= In-person	I_1= Individual I_2= Group with supports	I_1= HCP (RN or RD CDE) I_2= HCP (RN or RD CDE)	I_1= Minimal – Content I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Steed, 2005 United Kingdom	I= 65 UC= 59	I= 59.2±8.8y 67.7%, 47.7% NR 8.2±1.3%, NR UC= 60.3±8.6y 74.6%, 56.2% NR 8.6±1.8%, NR	DSME; University College London diabetes self-management programme (UCL-DSMP)	3m; 6, 15h; NA	In-person	Group	HCP (DSN)	Minimal - Content	None/NR
Sung, 2012 Korea	I= 22 UC= 18	I= 70.2±4.7y 31.8%, NR 23.9kg/m^2 7.6±1.1%, 31.8% UC= 70.1±3.6y 38.9%, NR 25.5kg/m^2 7.6±1.4%, 44.4%	Lifestyle; Supervised walking program with basic education for the elderly	6m; 34, 24h; NA	In-person	Mixed	NR	Moderate-to-High – Content	None/NR
Tang, 2014 U.S. (MI)	I_1= 56 I_2= 60	I_1= 48.4±10.0y 35.7%, 100% 32.0±4.6kg/m^2 7.8±1.7%, 25% I_2= 50.2±11.2y 46.7%, 100% 33.0+/-7.6kg/m^2 8.2±2.2%, 20%	I_1= DSME + Support; CHW-led Partners in Care & DSMS led by CHWs for Latinos I_2= DSME + Support; CHW-led Partners in Care & DSMS led by peer leaders for Latinos	I_1= 18m; 16.9, 25.5h; 12m I_2= 18m; 17.7, 26h; 12m (Per protocol had many more contacts in DSMS phase)	I_1= Mixed I_2= Mixed	I_1= Mixed with supports I_2= Mixed with supports	I_1= Non-HCP (CHW) I_2= Non-HCP (CHW & peers)	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High – Content & Delivery	I_1= Yes I_2= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Thoolen, 2007 The Netherlands	I= 89 UC= 108	I= 62.0±4.9y 64%, NR NR NR, NR UC= 61.9±5.6y 55%, NR NR NR, NR	DSME; Beyond Good Intentions, focused on coping and self-regulation around diet, exercise and medications	3m; 6, 10h; NA	In-person	Mixed	HCP (RN)	Minimal – Content & Delivery	None/NR
Toobert, 2003 U.S. (OR)	I= 163 UC= 116	I= 61.6±8.0y 0%, 8% 35.1±7.75kg/m^2 7.4±1.3%, 20.4% UC= 60.7±7.8y 0%, 5.3% 35.6±8.85kg/m^2 7.4±1.5%, 21.6%	Lifestyle; Mediterranean Lifestyle Program (multicomponent program focusing on reduction of behavioral CHD risk factors of diet, PA, social support, stress management and smoking cessation)	6m; 29, 124h; NA	In-person (telephone followup for missed sessions)	Group	Non-HCP (>75%; lay leaders & RAs) & Multidisciplinary (RD, Exercise physiologist)	Minimal – Content & Delivery	Yes
Toobert, 2011	I= 142 UC= 138	I= 55.6±9.7y 0%, 100% 35.3±7.05kg/m^2 8.4±1.9%, 29.1% UC= 58.7±10.3y 0%, 100% 33.2±6.75kg/m^2	Lifestyle; Viva Bien (adaptation of Mediterranean Lifestyle Program for Latinos)	24m; 52, 208h; 18m	In-person	Group with supports during maintenance phase	Non-HCP (>75% trained bilingual facilitators) & Multidisciplinary (RD, Physician)	Moderate-to-High – Content & Delivery	Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		8.2±1.7%, 32.1%							
Trief, 2011 U.S. (NY)	I_1= 12 I_2= 12 UC= 13 (Analyzed)	I_1= 61.1±9.3y 50%, NR 33.0±5.4kg/m^2 8.1±1.2%, NR I_2= 60.3±8.6y 41.7%, NR 35.3±7.3kg/m^2 8.4±1.4%, NR UC= 61.1±11.1y 38.5%, NR 35.1±7.2kg/m^2 8.2±1.1%, NR	I_1= DSME; problem-solving approach delivered via telephone to individuals I_2= DSME; problem-solving approach delivered via telephone for couples	I_1= 3m; 9, NR; NA I_2= 3m; 9, NR; NA	I_1= Technology I_2= Technology	I_1= Individual I_2= Individual with spouse	I_1= HCP (CDE) I_2= Multidisciplinary (CDE, therapist)	I_1= Moderate-to-High – Content & Delivery I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= None/NR
Tucker, 2014 U.S. (FL)	I= 64 UC=	I= NR 27%, 70% 36.1(SE0.3)kg/m^2 NR, NR UC= NR 25%, 77% 36.2(SE0.3)kg/m^2 NR, NR	DSME; culturally sensitive, empowerment-focused, community-based health promotion program provided to racial/ethnic minorities	2m; 4, 12h+ telephone contact time; NA	Mixed	Mixed	Non-HCP (community leaders) & Multidisciplinary (RN, RD, Psych)	Moderate-to-High – Content & Delivery	Yes
Utz, 2008 U.S. (VA)	I_1= 8 I_2= 13	I_1= 56.6±14.7y 37.5%, 100% NR 8.1±1.6%, 25%	I_1= DSME; Individual DSME I_2= DSME; group-based, culturally	I_1= 2m; 3, 1h; NA I_2= 2m; 8, 16h; NA	I_1= In-person I_2= In-person	I_1= Individual I_2= Group	I_1= HCP (CDE) I_2= HCP (CDE)	I_1= Minimal – Content I_2= Moderate-to-High –	I_1= Yes I_2= Yes

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		I_2= 62.4±14.7y 23.1, 100% NR 8.1±1.4%, 46.2%	tailored DSME for rural African Americans					Content & Delivery	
Vadstrup, 2011 Denmark	I_1= 73 I_2= 70	I_1= 58.0±10.3y 60%, NR 98.2 +/- 24.8kg 7.8±0.9%, 14% I_2= 58.5±10.3y 59%, NR 96.2 +/- 15.2kg 7.9±0.8%, 19%	I_1= DSME; individualized counseling program with MI I_2= DSME; group-based rehabilitation program using an empowerment approach & supervised group aerobic exercise and resistance training	I_1= 6m; 8, 6.75h; NA I_2= 6m; 33, 53h; NA	I_1= In-person I_2= In-person	I_1= Individual I_2= Group with some spouse involvement	I_1= Multidisciplinary (RN, RD, Podiatrist) I_2= Multidisciplinary (RN, RD, Podiatrist, Physiotherapist)	I_1= Moderate-to-High – Content & Delivery I_2= Minimal - Content	I_1= None/NR I_2= None/NR
Varney, 2014 Australia	I = 47 UC = 47	I= 59 (56-62)y 72%, 2% 32.1 (30.3-33.9) kg/m^2 8.2 (8.0-9.7)%, 53% UC= 64 (61-66)y 64%, 21% 30.9 (29.1-32.6)	DSME; telephonic health coaching	6m; 6, 2.5h; NA	Technology	Individual	HCP (RD)	Moderate-to-High – Content & Delivery	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		kg/m^2 8.5 (8.1-8.9)%, 62% All 95% CI							
Vazquez, 1998 U.S. (MA)	I= 18 UC= 20	All participants 32-70y 55%, 100% 27-40kg/m^2 NR, NR	DSME; Buena Alimentacion, Buena Salud (Good Eating, Good Health) for Caribbean Latinos	3m; 12, NR; NA	In-person	Group	Multidisciplinary (RD, Psych)	Moderate-to-High – Content & Delivery	Yes
Vincent, 2007 U.S. (AZ)	I= 10 UC= 10	I= 56.7±10.6y 11%, 100% 30.6±2.7kg/m^2 6.6±1.2%, NR UC= 55.3±8.2y 50%, 100% 29.8±4.2kg/m^2 6.7±1.2%, NR	DSME; culturally tailored for Mexican Americans	2m; 8, 16h; NA (Plus telephone reminders)	In-person (with telephone reminders)	Group with supports	Non-HCP (Promotores) & HCP (not specified)	Moderate-to-High – Content & Delivery	Yes
Walker, 2011 U.S. (NY)	I= 262 UC= 265	I= 55.7±7.4y 31.7%, 94.3% 31.8±6.2kg/m^2 8.6 (8.0-9.6)%, 21% UC= 55.4±7.2y 34.1%, 93.9% 30.7±6.0kg/m^2 8.7 (8.0, 10.2)%, 25%	DSME; telephonic intervention focused on medication adherence and lifestyle behaviors with socio-ecological approach for low-income, insured urban diabetics	12m; 7.9±2.1, 2h; NA	Technology	Individual	Non-HCP (health educators)	Moderate-to-High - Delivery	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		(Mean, IQR)							
Weinger, 2011 U.S. (MA) both T1DM & T2DM 50:50%	I=74 AC_1= 75 AC_2= 73	I= 51.8 (23.7-74.2)y 54%, 12% 29.4 (18.6-51.5)kg/m^2 9.0 (7.6-12.6)%, 55.3% AC_1= 54.7 (25.0-75.1)y 52%, 11% 29.4 (20.3-57.8) kg/m^2 8.8 (7.6-13.6)%, 55.3% AC_2= 56.2 (21.6-74.8)y 42%, 15% 29.0 (17.8-50.4) kg/m^2 8.6 (7.6-13.1)%, 55.3%	I= DSME; CBT-based group education program AC_1= Non-DSME (didactic group sessions) AC_2= Non-DSME (individual RN & RD consults offered)	I= 1.5m; 5, 10h; NA AC_1= 1.5; 5, 10h; NA AC_2= 6m; NR, NR; NA	I= In-person AC_1= In-person AC_2= In-person	I= Group AC_1= Group AC_2= Individual	I= Multidisciplinary (RN, RD) AC_1= RN AC_2= Multidisciplinary (RN, RD)	I= Minimal – Content AC_1= Minimal – Content AC_2= Minimal – Content & Delivery	I= None/NR AC_1= None/NR AC_2= None/NR
		(Median, Range)							
Welch, 2011 U.S. (MA)	I_1=58 I_2=57 Only 2 of 4 arms – not	I_1= 54.4±10.3y 37.9%, 21% 34.9±6.7kg/m^2 8.8±1.3%, 40.4%	I_1= DSME; standard I_2= DSME; standard with MI	I_1= 6m; 4, 2.5h; NA I_2= 6m; 4, 2.5h; NA	I_1= In-person I_2= In-person	I_1= Individual I_2= Individual	I_1= HCP (CDE) I_2= HCP (CDE)	I_1= Minimal – Content & Delivery I_2= Moderate-	I_1= None/NR I_2= None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
	reporting on arms adding computer summary of barriers)	I_2= 54.9±9.3y 42.1%, 14% 34.1±5.6kg/m^2 9.1±1.5%, 31.6%	counseling and tools by CDEs					to-High – Content & Delivery	
Welschen, 2013 Netherlands	I= 78 UC= 76	I= 60.5±9.4y 59.5%, 2.7% 31.6±5.7kg/m^2 6.8±1.0, NR UC= 61.2±8.8y 64.2%, 5.1% 31.5±5.2kg/m^2 6.8±1.0%, NR	Lifestyle; CBT-based intervention with problem-solving training for diet, PA, smoking cessation	6m; 3±1.7, 1.5h; NA	In-person	Individual	Multidisciplinary (RN, RD)	Moderate-to-High- Content & Delivery	None/NR
West, 2007 U.S. (AL)	I_1= 108 I_2= 109	I_1= 52±10y 0%, 38% 36.5±5.4kg/m^2 7.6±1.4%, 0% I_2= 54±10y 0%, 39% 36.5±5.5kg/m^2 7.5±1.4%, 0%	I_1= Lifestyle; behavioral weight control program I_2= Lifestyle: behavioral weight control program + MI	I_1= 18m; 47, NR; 12m I_2= 18m; 47, NR; 12m	I_1= In-person I_2= In-person	I_1= Mixed I_2= Mixed	I_1= Multidisciplinary (RD, CDE, behaviorist, exercise physiologist) I_2= Multidisciplinary (RD, CDE, behaviorist, exercise physiologist , psychologist)	I_1= Minimal – Content I_2= Moderate-to-High – Content & Delivery	I_1= None/NR I_2= None/NR
Wierenga, 1994	I= 35 UC= 31	I= 30-86y NR, 6.1%	Lifestyle; behavioral	1.25m; 5, 7.5h; NA	In-person	Group	HCP (RN)	Minimal – Content	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
U.S. (WI)		28.7±6.9kg/m^2 NR, NR UC=30-86y NR, 6.1% 28.7±6.9kg/m^2 NR, NR (All except BMI for all participants)	modification program to promote gradual change						
Wing & LookAhead Study Group, 2013 U.S. (16 Sites)	I= 2570 AC= 2575	I= 58.6±6.8y 40.6%, 36.9% 35.3±5.7kg/m^2 (Male), 36.3±6.2 kg/m^2 (Female) 7.2±1.1%, 15.5% AC= 58.9±6.9y 40.3%, 36.7% 35.1± 5.2kg/m^2 (Male), 36.6± 6.0kg/m^2 (Female) 7.3±1.2%, 16.5%	I= Lifestyle; 3-phase intense lifestyle intervention for sustained weight loss including group and individual contacts, supportive sessions, and behavioral training AC= Non-DSME; diabetes support and education	I= 96+m; 202+, 86+h; 84m AC= 96+m; 16+, NR; 48+m	I= Mixed AC= In-person	I= Mixed AC= Group	I= Non-HCP (RA) & HCP (lifestyle counselors of various disciplines) AC= HCP (educator with background in DM education, exercise or nutiriton)	I= Moderate-to-High – Content & Deli very AC= Minimal – Content & Delivery	I= None/NR AC= None/NR
Wolever, 2010 U.S. (NC)	I= 30 UC= 26	I= 53.1±8.3y 27%, 66% NR 7.7±1.9%, NR	DSME; integrative health coaching using Wheel of Health	6m; 14, 7h	Technology	Individual	Non-HCP (trainees in social work or psychology)	Moderate-to-High - Content & Delivery	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
		UC= 52.8±7.6y 19%, 54% NR 8.2±1.9%, NR							
Wolf, 2004 U.S. (VA)	I= 74 UC= 73	I= 53.5±8.6y 38%, 15% 37.6±7.7kg/m^2 7.9±1.6%, 26% UC= 53.4±8.0y 42%, 26% 37.5±6.4kg/m^2 7.5 ±1.5%, 22%	Lifestyle; Dietician-led lifestyle case management with structured medical nutrition therapy and basic education on diet and PA	12m; 12 + monthly telephone contacts, 10h + monthly telephone support	Mixed	Group	HCP (RD)	Minimal – Content and Delivery	None/NR
Yoo, 2007 Korea	I= 30 UC= 30	I= 55.3±7.6y 32%, NR 26.1±4.1kg/m^2 8.7±1.3%, 0% UC= 55.3±7.6y 35%, NR 26.1±4.1kg/m^2 8.7±1.3%, 0%	Lifestyle; lifestyle modification program using self-efficacy approach with stress management training	13m; 25, 25h; 9m	In-person	Group	HCP (RN)	Minimal-Content	None/NR
Yuan, 2014 Hong Kong	I = 36 UC = 40	I= 58.9±8.4y 39%, NA 23.8±4.6kg/m^2 6.97±0.9%, NR UC= 57.8±8.2y 30%, NA 25.4±4.7kg/m^2 7.04±1.0%, NR	DSME; meeting standards but no identified behavioral approach	2m; 8, 16h; NA	In-person	Group	HCP (RD)	Minimal-Content	None/NR

Author, Year & Country	Comparison & Sample Size (Number randomized unless NR then # analyzed)	Age, Male, Non-White, BMI/KG, HbA1c, Insulin Treatment	Intervention Category & Description	Total Duration Including all Phases (m); Intensity (# contacts, total contact time); Maintenance/Support Phase Duration	Method of Communication (In-person, Mixed, Technology)	Method of Delivery (Individual, Group, Mixed) & Presence of Supports	Delivery Personnel (Non-HCP, Single HCP, Multidisciplinary)	Degree of Tailoring	Community Engagement
Zgibor, 2014	I_1= 102 I_2= 119	I_1= 64.5y 33.3%, 3.9% 34.3kg/m^2 7.4%, 35.0% I_2= 61.7y 38.7%, 2.5% 35.3kg/m^2 7.6%, 30.0%	I_1= DSME + Support; traditional DSME and support by CDE I_2= DSME + Support; DSME and support with peer leader	I_1= 13.5m; 16, NR; 12m I_2= 13.5m; 16, NR; 12m	I_1= Mixed I_2= Mixed	I_1= Mixed I_2= Mixed	I_1= HCP (RN CDE) I_2= Non-HCP (peer) & HCP (RN CDE)	I_1= Minimal - Content & Delivery I_2= Moderate-to-High - Content & Delivery	I_1= None/NR I_2= Yes

AC=active control; Att. C=attention control; CDE=certified diabetes educator; CHW=Community health worker; DSME=diabetes self-management education; DSMS=diabetes self-management support; DSN=diabetes specialist nurse; EU=European Union; GP=general practitioner; h=hour; HCP=health care professional; I=intervention (behavioral program); LPN=Licensed practical nurse; m=month; MI=motivational interviewing; NA=not applicable; NP=Nurse practitioner; NR=not reported; PA = physical activity; Psych=Psychologist; RD=registered dietitian; RN-registered nurse; SE=standard error; UC=usual care

Appendix G. Type 1 Diabetes Mellitus: Summary of Results From Observational Studies

Table G1. Summary of results from observational studies

Study, Year (# Subjects)	Outcome	Timepoint	Results	Conclusion
Thomas-Dobersen, 1993 (20 youth)	HbA_{1c}	EOI	MD, -0.50; 95% CI -1.84 to 0.84	No difference
Thomas-Dobersen, 1993 (20 youth)	HbA_{1c}	12m followup	MD, 0.67; 95% CI -1.47 to 2.81	No difference
Thomas-Dobersen, 1993 (20 youth)	Depression	EOI	SMD, -.43; 95% CI -0.84 to 0.75	No difference
Thomas-Dobersen, 1993 (20 youth)	Depression	12m followup	SMD, 0.05; 95% CI -0.86 to 0.96	No difference
Thomas-Dobersen, 1993 (20 youth)	BMI	EOI	MD, 0.29; 95% CI -1.06 to 0.48	No difference
Thomas-Dobersen, 1993 (20 youth)		12m followup	MD, -0.27; 95% CI -1.87 to 1.36	No difference
Thomas-Dobersen, 1993 (20 youth)	Weight	EOI	MD, -1.13; 95% CI -2.72 to 0.46	No difference
Thomas-Dobersen, 1993 (20 youth)		12m followup	MD, -0.40; 95% CI -4.54 to 3.74	No difference
Thomas-Dobersen, 1993 (20 youth)	Participant attrition	12m	RR, 1.64; 95% CI 0.16, 2.46	Increased risk of attrition for those receiving usual care
Viner, 2003 (41 youth)	HbA_{1c}	12m followup	MD, -1.20; 95% CI -2.24 to -0.16	Improved for those receiving behavioral program
Forlani, 2006 (90 adults)	HbA_{1c}	12m followup	MD, -0.70; 95% CI -1.31 to -0.09	Improved for those receiving behavioral program
Forlani, 2006 (90 adults)	HRQL	12m followup	SMD, 0.31; 95% CI -0.11 to 0.74	No difference
Forlani, 2006 (90 adults)	HRQL-diabetes specific	12m followup	SMD, 0.03; 95% CI -0.39 to 0.45	No difference

BMI = body mass index; EOI = end of intervention; m = month; MD = mean difference; QOL = quality of life; RR = risk ratio; SMD = standardized mean difference

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Appendix H. Strength of Evidence Tables for Type 1 Diabetes Mellitus

Table H1. Behavioral programs compared with usual care: strength of evidence for Key Question 1

Outcome	# Trials (# Subjects); Tool if Applicable	Risk of Bias	Consistency	Directness	Precision	Reporting Bias	Findings and Direction of Effects	Strength of Evidence
HbA_{1c} (EOI)	16 (1,155)[1-16]	Medium	Inconsistent	Direct	Precise	Un-suspected	MD, -0.11; 95% CI -0.33 to 0.11	Low
HbA_{1c} (6m)	12 (1,463) [3, 5, 6, 15, 17-24]	Medium	Consistent	Direct	Precise	Un-suspected	MD, -0.31; 95% CI -0.47 to -0.15 Favors behavioral programs	Moderate
HbA_{1c} (12m)	7 (1,333) [2, 15, 20-22, 24, 25]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.22; 95% CI -0.49 to 0.05	Low
HbA_{1c} (>12m)	4 (1,138)[6, 21, 22, 25]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.40; 95% CI -0.92 to 0.12 (>12m, <24m) MD, -0.08; 95% CI -1.96 to 1.8 (≥24m)	Low
Adherence to diabetes self-management (EOI)	4 (282);[3, 5, 8, 18] SMBG 1(74);[1] SDSCA 1 (54);[15] DSMP	High	Consistent	Direct	Imprecise	Un-suspected	MD, 0.15; 95% CI -0.54 to 0.84 MD, 1.4 days; 95% CI 0.35 to 2.43 MD, 5.00; 95% CI 0.60 to 9.40	Low
Adherence to diabetes self-management (6m)	5 (252);[3, 5, 17, 18, 23] SMBG 1 (244);[6] SDSCA 2 (471);[21, 22] DSMP	High	Consistent	Direct	Imprecise	Un-suspected	MD, 0.40; 95% CI -0.36 to 1.16 MD, -0.06; 95% CI -0.60 to 0.48 No difference (different summary measures)	Low
Adherence to diabetes self-management (12m)	1 (54);[15] DSMP 1 (180);[25] skipping one or more doses in past month	High	Consistent	Direct	Imprecise	Un-suspected	MD, 4.00; 95% CI -1.69 to 9.69 OR, 0.82; 95% CI, 0.48 to 0.1.38	Insufficient
Adherence to diabetes self-management (≥12m)	1 (390); SMBG 1 (190);[25] skipping one or more doses in past month	High	Inconsistent	Direct	Imprecise	Un-suspected	MD, -0.36; 95% CI -0.69 to -0.03 (≥24m) OR, 1.30; 95% CI, 0.78 to 2.17 (24m)	Insufficient
Change in body composition (BMI) (EOI)(6m)	1 (60)[4]	Medium	Unknown	Direct	Imprecise	Un-suspected	MD, 0.08; 95% CI, -0.35 to 0.51	Insufficient
Change in body composition (BMI)	1 (227)[6]	High	Unknown	Direct	Imprecise	Un-suspected	MD, -0.21; 95% CI, -0.62 to 0.20	Insufficient
Change in body composition (kg)	1 (61)[13]	High	Unknown	Direct	Imprecise	Un-suspected	MD, -0.50; 95% CI, -5.69 to 4.69	Insufficient
Change in	1 (43)[13]	High	Unknown	Direct	Imprecise	Un-	MD, 0.59; 95% CI 0.22 to 0.96	Insufficient

Outcome	# Trials (# Subjects); Tool if Applicable	Risk of Bias	Consistency	Directness	Precision	Reporting Bias	Findings and Direction of Effects	Strength of Evidence
physical activity (fitness–VO_2 max) (EOI)						suspected	Favors behavioral programs	
Change in physical activity (intensity/ duration) (EOI)	2 (91)[1, 3]	High	Consistent	Direct	Imprecise	Un-suspected	SMD, 0.16; 95% CI -0.25 to 0.57	Insufficient
Change in physical activity (intensity/ duration) (6m)	2 (272)[3, 6]	High	Inconsistent	Direct	Imprecise	Un-suspected	SMD, -0.26; 95% CI -1.0 to 0.49	Insufficient
Change in nutrient intake (kcal/day) (EOI)	1 (61)[13]	High	Unknown	Direct	Imprecise	Un-suspected	MD, -247.10; 95% CI -281.7 to -212.5 Favors behavioral programs	Insufficient
Change in nutrient intake (saturated fat) (EOI)	1 (61)[13]	High	Unknown	Direct	Imprecise	Un-suspected	MD, -1.80; 95% CI -3.53 to -0.07; favors behavioral programs	Insufficient
Generic HRQL (EOI)	7 (474)[1, 5, 7-9, 16, 26]	High	Consistent	Direct	Precise	Un-suspected	SMD, 0.10; 95% CI -0.18 to 0.38	Moderate
Generic HRQL (6m)	1 (53)[5]	High	Unknown	Direct	Imprecise	Un-suspected	SMD, -0.29; 95% CI -0.83 to 0.26	Insufficient
Generic HRQL (12m)	2 (405)[9, 25]	High	Unknown	Direct	Imprecise	Un-suspected	SMD, 0.02; 95% CI -0.11 to 0.15	Insufficient
Generic HRQL (≥12m)	1 (291)[25]	High	Unknown	Direct	Imprecise	Un-suspected	SMD, -0.04; 95% CI -0.27 to 0.19	Insufficient
Diabetes-specific quality of life (EOI)	3 (212)[11, 16, 26]	High	Inconsistent	Direct	Imprecise	Un-suspected	SMD, 0.08; 95% CI, -1.44 to 1.60	Insufficient
Diabetes Distress (EOI)	4 (209)[1, 3, 5, 7]	High	Consistent	Direct	Imprecise	Un-suspected	SMD, -0.31; 95% CI, -0.83 to 0.21	Low
Diabetes Distress (6m)	4 (236)[3, 5, 23, 24]	High	Consistent	Direct	Imprecise	Un-suspected	SMD, -0.28; 95% CI, -0.94 to 0.38	Low

Note: No study reported on complications or all-cause mortality. Only clinical trials were included in strength of evidence assessments. Lower scores beneficial for HbA_{1c}, Diabetes Distress, Change in Nutrient Intake, and Change in Body Composition; higher scores beneficial for Adherence to Diabetes Self-management, Change in Physical Activity, and Generic and Diabetes-specific Quality of Life.

CI = confidence interval; DSMP = Diabetes Self-Management Profile; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; HRQL = health-related quality of life; M = month; MD = mean difference; SDSCA = Summary of Diabetes Self-Care Activities; SMBG = self-monitoring of blood glucose

Table H2. Behavioral programs compared with an active control: strength of evidence for Key Question 1

Outcome	# Trials (# Subjects); Tool if Applicable	Risk of Bias	Consistency	Directness	Precision	Reporting Bias	Findings and Direction of Effects	Strength of Evidence
HbA_{1c} (EOI)	4 (529) [15, 27-29]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.32; 95% CI -0.97 to 0.33	Low
HbA_{1c} (6m)	4 (467)[15, 28-30]	Medium	Consistent	Direct	Precise	Un-suspected	MD, -0.44; 95% CI -0.69 to -0.19 Favors behavioral programs	Moderate
HbA_{1c} (12m)	3 (305)[15, 28, 29]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.44; 95% CI -1.04 to 0.16	Low
Adherence to diabetes self-management (EOI)	1 (54);[15] DSMP 1 (149);[28] DBRS	High	Inconsistent	Direct	Imprecise	Un-suspected	MD, 2.40; 95% CI -2.46 to 7.26 No data reported; those in behavioral program did more poorly	Insufficient
Adherence to diabetes self-management (6m)	1 (149);[30] SMBG 1 (149);[28] DBRS	High	Inconsistent	Direct	Imprecise	Un-suspected	MD, -0.20; 95% CI -0.76 to 0.36 No data reported; those in behavioral program did more poorly	Insufficient
Adherence to diabetes self-management (12m)	1 (54);[15] DSMP 1 (149);[28] DBRS	High	Inconsistent	Direct	Imprecise	Un-suspected	MD, 2.00; 95% CI -3.78 to 7.78 No data reported; those in behavioral program did more poorly	Insufficient

Note: Only clinical trials were included in strength of evidence assessments. Lower scores beneficial for HbA_{1c}; higher scores beneficial for adherence to diabetes self-management.

CI = confidence interval; DBRS = Diabetes Behavior Rating Scale; DSMP = Diabetes Self-Management Profile; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; M = month; MD = mean difference; SDSCA = Summary of Diabetes Self-Care Activities; SMBG = self-monitoring of blood glucose

Table H3. Behavioral programs compared with usual care: strength of evidence for Key Question 2 (age subgroups)

Outcome	# Trials (# Subjects); Tool if Applicable	Risk of Bias	Consistency	Directness	Precision	Reporting Bias	Findings and Direction of Effects	Strength of Evidence
Youth								
HbA_{1c} (EOI)	11 (653)[2-5, 8-10, 12, 14-16]	Medium	Inconsistent	Direct	Precise	Un-suspected	MD, 0.00; 95% CI -0.33 to 0.33	Low
HbA_{1c} (6m)	10 (1,213)[3, 5, 15, 17-22, 24]	Medium	Consistent	Direct	Precise	Un-suspected	MD, -0.28; 95% CI -0.51 to -0.05 Favors behavioral programs	Moderate
HbA_{1c} (12m)	7 (1,333)[2, 15, 20-22, 24, 25]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.22; 95% CI -0.49 to 0.05	Low
Adults								
HbA_{1c} (EOI)	5 (502)[1, 6, 7, 11, 13]	High	Consistent	Direct	Imprecise	Un-suspected	MD, -0.28; 95% CI -0.57 to 0.01	Low
HbA_{1c} (6m)	2 (250)[6, 23]	High	Consistent	Direct	Imprecise	Un-suspected	MD, -0.38; 95% CI -0.82 to 0.06	Low
HbA_{1c} (12m)	NR							Insufficient

CI = confidence interval; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; M = month; MD = mean difference

Table H4. Behavioral programs compared with active controls: strength of evidence for Key Question 2 (age subgroups)

Outcome	# Trials (# Subjects); Tool if Applicable	Risk of Bias	Consistency	Directness	Precision	Reporting Bias	Findings and Direction of Effects	Strength of Evidence
Youth								
HbA_{1c} (EOI)	3 (419)[15, 27, 28]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.33; 95% CI -1.65 to 0.99	Insufficient
HbA_{1c} (6m)	2 (208)[15, 28]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.60; 95% CI -2.56 to 1.36	Insufficient
HbA_{1c} (12m)	2 (195)[15, 28]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.52; 95% CI -1.04 to 0.00	Low
Adults								
HbA_{1c} (EOI)	1 (147)[29]	Medium	Unknown	Direct	Imprecise	Un-suspected	MD, -0.35; 95% CI -0.81 to 0.11	Insufficient
HbA_{1c} (6m)	2 (259)[29, 30]	Medium	Consistent	Direct	Imprecise	Un-suspected	MD, -0.38; 95% CI -0.93 to 0.17	Low
HbA_{1c} (12m)	1 (110)[29]	Medium	Unknown	Direct	Imprecise	Un-suspected	MD, -0.14; 95% CI -0.61 to 0.33	Insufficient

CI = confidence interval; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; M = month; MD = mean difference

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Appendix I. Effectiveness Across Outcomes for Type 2 Diabetes Mellitus

Notes: Bold text represents statistically significant findings.

Table I1. Effectiveness of behavioral programs compared with usual care for type 2 diabetes

Category	Outcomes	Timepoint					
		EOI		6m		12m	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
Clinical Outcomes	Glycemic Control (HbA_{1c})	66 (8,715)[1-63]	**MD, -0.35; 95% CI -0.56 to -0.14; I^2=74%**	23 (4,138)[14, 33, 45, 51, 53, 62, 64-78]	MD, -0.16; 95% CI -0.36 to 0.04; I^2=61%	9 (1,494)[14, 40, 67-69, 71, 78, 79]	MD, -0.14; 95% CI -0.4 to 0.12; I^2=59%
	Change in Body Composition (BMI)	36 (4,280)[1-3, 6, 8-10, 12, 13, 15, 18, 19, 21, 22, 27, 29, 30, 32, 33, 41, 43, 47, 49-51, 53, 56, 57, 60, 62, 63, 77, 80, 81]	**MD, -0.51; 95% CI -0.66 to -0.36; I^2=54%**	14 (1,840)[33, 51, 53, 62, 64, 66-68, 70, 71, 75, 77, 81]	**MD, -0.21; 95% CI -0.32 to -0.1; I^2=0%**	5 (867)[67, 68, 71, 82, 83]	**MD, -0.92; 95% CI -1.44 to -0.4; I^2=0%**
	Weight (kg)	37 (4,070)[2, 4, 6, 7, 9, 11, 17, 19, 20, 22, 23, 25, 26, 31, 32, 35, 39, 41-43, 49, 53, 55, 58-63, 69, 77, 84-86]	**MD, -1.68; 95% CI -2.06 to -1.30; I^2=53%**	8 (1,714)[53, 62, 68, 74, 77, 78, 84]	MD, -0.22; 95% CI -0.56 to 0.12; I^2=0%	1 (291)[68]	MD, -1.60; 95% CI -5.41 to 2.21; I^2=NA
	Change in Body Composition (% body fat)	2 (73)[26, 60]	MD, -3.34; 95% CI -4.57 to -2.11; I^2=0%	NA	NA	NA	NA
	Change in Body Composition (waist circumference [cm])	17 (1,521)[6, 9, 12, 22, 25, 32, 33, 41, 43, 51, 55, 56, 60, 62, 84]	**MD, -3.17; 95% CI -4.36 to -1.98; I^2=64%**	6 (690)[33, 51, 62, 68, 84]	MD, -1.09; 95% CI -2.7 to 0.52; I^2=10%	2 (385)[68, 82]	MD, -2.92; 95% CI -11.3 to 5.46; I^2=0%
	Total Cholesterol (mmol/l)	27 (2,633)[2, 6-9, 16-18, 20-22, 25, 29, 31-33, 42, 48, 49, 51, 55, 60, 62, 63]	**MD, -0.1; 95% CI -0.11 to -0.09; I^2=0%**	7 (686)[33, 51, 53, 62, 66, 68]	**MD, -0.24; 95% CI -0.39 to -0.09; I^2=0%**	1 (291)[68]	MD, -0.10; 95% CI -0.34 to 0.14; I^2=NA
	HDL Cholesterol (mmol/l)	25 (2,733)[1, 2, 6, 7, 9, 16-18, 20-22, 29-33, 41, 48, 49, 55, 60, 62, 63]	**MD, 0.02; 95% CI 0.02 to 0.02; I^2=7%**	4 (563)[33, 53, 62, 68]	**MD, -0.09; 95% CI -0.12 to -0.06; I^2=0%**	1 (291)[68]	MD, 0.00; 95% CI -0.20 to 0.20; I^2=NA
	LDL Cholesterol (mmol/l)	27 (3,063)[1-3, 6, 9, 12, 13, 18, 21, 22, 28-33, 41, 47-49, 51, 55, 60, 62, 63]	**MD, -0.03; 95% CI -0.03 to -0.03; I^2=59%**	5 (457)[33, 51, 62, 68]	MD, -0.19; 95% CI -0.47 to 0.09; I^2=49%	1 (291)[68]	MD, 0.00; 95% CI -0.09 to 0.09; I^2=NA
	Triglycerides	24 (2,561)[1, 2, 6, 9,	**MD, -0.17;**	5 (712)[14, 33, 53, 62,	MD, -0.18;	1 (291)[68]	MD, -0.20; 95%

Category	Outcomes	Timepoint					
		EOI		6m		12m	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
	(mmol/l)	14, 18, 21, 22, 25, 29-33, 41, 42, 48, 49, 55, 60, 62, 63	**95% CI -0.24 to -0.1; I^2=36%**	68	95% CI -0.37 to 0.01; I^2=6%		CI -0.45 to 0.05; I^2=NA
	Systolic Blood Pressure (mmHg)	36 (4,776)[1-4, 6, 7, 9, 10, 12-14, 18, 21, 22, 25, 26, 28-30, 32, 33, 39, 41, 42, 47, 49, 51, 53, 58, 60, 62, 63, 80, 84]	**MD, -0.78; 95% CI -1.3 to -0.26; I^2=23%**	10 (1,613)[14, 33, 51, 53, 62, 68, 78, 84]	MD, -1.08; 95% CI -2.9 to 0.74; I^2=0%	1 (291)[68]	MD, -2.80; 95% CI -7.69 to 2.09; I^2=NA
	Diastolic Blood Pressure (mmHg)	33 (4,583)[1-4, 6, 7, 9, 10, 12, 13, 18, 21, 22, 25, 26, 28-30, 32, 39, 41, 42, 47, 49, 53, 58, 60, 62, 63, 80, 84]	**MD, -0.94; 95% CI -1.32 to -0.56; I^2=32%**	7 (1,424)[33, 53, 62, 68, 78, 84]	**MD, -1.26; 95% CI -1.97 to -0.55; I^2=0%**	1 (291)[68]	MD, -2.20; 95% CI -4.73 to 0.33; I^2=NA
	Depression Symptoms	13 (1,751)[5, 7, 17, 21, 32-34, 38, 49, 53, 61, 62]	**SMD, -0.16; 95% CI -0.32 to 0; I^2=45%**	5 (1,189)[33, 53, 62, 72, 74]	SMD, -0.09; 95% CI -0.57 to 0.39; I^2=80%	NA	NA
	Anxiety Symptoms	NA	NA	NA	NA	NA	NA
Behavioral Outcomes	Change in Physical Activity - Duration/ Intensity (Subjective [days/week])	7 (1,176)[19, 37, 43, 49, 50, 54, 83]	MD, 0.56; 95% CI -0.1 to 1.22; I^2=79%	2 (270)[68, 87]	MD, 1.73; 95% CI -8.82 to 12.28; I^2=91%	2 (382)[68, 83]	**MD, 0.90; 95% CI 0.9 to 0.9; I^2=0%**
	Change in Physical Activity - Duration/ Intensity (Objective)	5 (373)[20, 23, 39, 48]	SMD, 0.49; 95% CI -0.24 to 1.22; I^2=74%	NA	NA	NA	NA
	Change in Physical Activity – Fitness	2 (329)[15, 60]	SMD, 0.67; 95% CI -7.37 to 8.71; I^2=90%	1 (134)[67]	SMD, 0.03; 95% CI -0.30 to 0.37; I^2=NA	1 (134)[67]	SMD, 0.11; 95% CI -0.23 to 0.44; I^2=NA
	Change in Physical	NA	NA	NA	NA	NA	NA

Category	Outcomes	Timepoint					
		EOI		6m		12m	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
	Activity – Strength						
	Change in Dietary Intake – Energy Intake (kcal/day)	11 (1,164)[1, 2, 10, 20, 23, 33, 34, 60, 84, 88]	**MD, -149.62; 95% CI -243.01 to -56.23; I^2=68%**	3 (469)[33, 68, 84]	**MD, -64.05; 95% CI -96.44 to -31.66; I^2=0%**	1 (191)[68]	MD, 114.00; 95% CI -308.19 to 536.19; I^2=NA
	Change in Dietary Intake – Saturated Fat Intake (% of daily kcal)	10 (1,208)[2, 10, 20, 33, 34, 49, 50, 60, 88]	MD, -0.24; 95% CI -0.73 to 0.25; I^2=44%	2 (232)[33, 68]	MD, -0.40; 95% CI -8.82 to 8.02; I^2=23%	1 (191)[68]	MD, -1.10; 95% CI -2.22 to 0.02; I^2=NA
	Adherence to Medication (higher scores desirable)	4 (742)[13, 15, 54, 83]	SMD, -0.17; 95% CI -0.7 to 0.36; I^2=75%	1 (54)[87]	SMD, 0.42; 95% CI -0.12 to 0.96; I^2=NA	1 (191)[83]	**SMD, -0.50; 95% CI -0.79 to -0.21; I^2=NA**
Health Outcomes	Quality of Life – SF-36 Physical (higher score desirable)	5 (787)[10, 32, 39, 49]	MD, 0.45; 95% CI -0.05 to 0.95; I^2=0%	NA	NA	NA	NA
	Quality of Life – SF-36 Mental (higher score desirable)	5 (787)[10, 32, 39, 49]	MD, 1.60; 95% CI -1.96 to 5.16; I^2=86%	NA	NA	NA	NA
	Quality of Life – Other (higher score desirable)	4 (447)[27, 43, 53, 54]	SMD, 0.12; 95% CI -0.26 to 0.5; I^2=40%	3 (789)[53, 73, 74]	SMD, 0.08; 95% CI -0.11 to 0.27; I^2=0%	NA	NA
	Diabetes-specific Quality of Life – Diabetes Distress (PAID) (lower scores	8 (1,384)[5, 7, 36, 42-44, 47, 75]	**MD, -1.82; 95% CI -3.43 to -0.21; I^2=0%**	4 (1,382)[67, 75, 78]	MD, -1.89; 95% CI -4.37 to 0.59; I^2=0%	3 (757)[67, 78]	MD, -1.30; 95% CI -5.84 to 3.24; I^2=0%

Category	Outcomes	Timepoint					
		EOI		6m		12m	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
	desirable)						
	Diabetes-specific Quality of Life – Other (lower scores desirable)	5 (753)[15, 17, 20, 21, 33, 54]	SMD, -0.21; 95% CI -0.55 to 0.13; I^2=51%	3 (366)[33, 67, 68]	SMD, -0.04; 95% CI -0.38 to 0.3; I^2=0%	2 (325)[67, 68]	SMD, -0.09; 95% CI -1.15 to 0.97; I^2=0%
	Mortality – All cause (longest followup)	25 (4,659)[5, 14, 20, 28, 35, 39-43, 53, 64, 68, 69, 78, 79, 82-84]	RR, 1.28; 95% CI 0.84 to 1.94; I^2=1%	NA	NA	NA	NA
Health Care Utilization	Emergency Department Visits (previous 6 months)	NA	NA	2 (762)[73, 74]	MD, -0.07; 95% CI -0.7 to 0.56	NA	NA
	Days of Hospital Stay (previous 6 months)	NA	NA	2 (646)[73, 74]	MD, 0.24; 95% CI -1.52 to 2.0	NA	NA
Program Acceptability	Participant Attrition (longest followup)	81 (14,154)[1-6, 8, 10-22, 24, 26-34, 36-44, 47, 49, 52-70, 72-87, 89]	RR, 1.11; 95% CI 0.82 to 1.49; I^2=43%	NA	NA	NA	NA

BMI = body mass index; CI = confidence interval; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; I^2 = statistical heterogeneity; kg = kilograms; m = month; MD = mean difference; NA = not applicable; RR = risk ratio; SMD = standardized mean difference

Table I2. Effectiveness of behavioral programs compared with active control for type 2 diabetes

Category	Outcomes	Timepoint					
		EOI		6m followup		12m followup	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
Clinical Outcomes	Glycemic Control (HbA_{1c})	25(7,518)[15, 19, 23, 59, 90-104]	**MD, -0.24; 95% CI -0.41 to -0.07; I^2=70%**	6 (595)[103, 105-108]	**MD, -0.19; 95% CI -0.37 to -0.01; I^2=0%**	6 (486)[92, 99, 103, 108]	MD, -1.10; 95% CI -2.56 to 0.36; I^2=98%
	Change in Body Composition (BMI)	10 (1,323)[15, 19, 90, 96-99, 101]	MD, -0.52; 95% CI -1.08 to 0.04; I^2=66%	1 (38)[105]	MD, -2.20; 95% CI -6.80 to 2.40; I^2=NA	2 (181)[99]	**MD, -0.30; 95% CI -0.3 to -0.3; I^2=0%**
	Weight (kg)	15 (6,212)[19, 23, 59, 90, 93, 94, 96-98, 100, 101, 104, 109]	**MD, -1.30; 95% CI -2.48 to -0.12; I^2=78%**	3 (439)[105, 106, 108]	MD, 0.14; 95% CI -3.41 to 3.69; I^2=67%	1 (95)[108]	**MD, 3.70; 95% CI 1.67 to 5.73; I^2=NA**
	Change in Body Composition (% body fat)	NA	NA	NA	NA	NA	NA
	Change in Body Composition (waist circumference [cm])	5 (5,332)[94, 96, 98, 101, 104]	MD, -2.54; 95% CI -5.78 to 0.7; I^2=79%	1 (38)[105]	**MD, -5.70; 95% CI -6.54 to -4.86; I^2=NA**	NA	NA
	Total Cholesterol (mmol/l)	8 (928)[90, 93, 96, 97, 99, 109]	**MD, -0.26; 95% CI -0.46 to -0.06; I^2=50%**	1 (167)[106]	MD, 0.08; 95% CI -0.15 to 0.30; I^2=NA	2 (181)[99]	MD, -0.15; 95% CI -0.79 to 0.49; I^2=0%
	HDL Cholesterol (mmol/l)	8 (6,005)[90, 93, 97, 99, 104, 109]	**MD, 0.02; 95% CI 0.0 to 0.04; I^2=0%**	2 (401)[106, 108]	MD, 0.03; 95% CI -0.84 to 0.9; I^2=54%	2 (181)[99]	MD, 0.1; 95% CI -0.22 to 0.02; I^2=0%
	LDL Cholesterol (mmol/l)	6 (5,824)[90, 93, 97, 104, 109]	MD, 0.02; 95% CI -0.03 to 0.07; I^2=0%	2 (401)[106, 108]	MD, 0.13; 95% CI -1.52 to 1.78; I^2=75%	NA	NA
	Triglycerides (mmol/l)	9 (6,073)[90, 93, 96, 97, 99, 104, 109]	MD, -0.16; 95% CI -0.41 to 0.09; I^2=72%	1 (167)[106]	MD, -0.05; 95% CI -0.40 to 0.30; I^2=NA	2 (181)[99]	MD, -0.36; 95% CI -0.99 to 0.27; I^2=0%

Category	Outcomes	Timepoint					
		EOI		6m followup		12m followup	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
	Systolic Blood Pressure (mmHg)	5 (5,895)[90, 96, 98, 100, 104]	MD, -0.63; 95% CI -3.13 to 1.87; I^2=19%	2 (205)[105, 106]	MD, 2.49; 95% CI -10.46 to 15.44; I^2=0%	NA	NA
	Diastolic Blood Pressure (mmHg)	5 (5,895)[90, 96, 98, 100, 104]	MD, -0.36; 95% CI -3.03 to 2.31; I^2=54%	2 (205)[105, 106]	MD, 0.06; 95% CI -8.6 to 8.72; I^2=0%	NA	NA
	Depression Symptoms	3 (4,982)[90, 101, 104]	SMD, -0.00; 95% CI -0.08 to 0.08; I^2=0%	NA	NA	NA	NA
	Anxiety Symptoms	3 (233)[99, 101]	**MD, -1.49; 95% CI -2.1 to -0.88; I^2=0%**	NA	NA	2 (181)[99]	**MD, -1.80; 95% CI -3.07 to -0.53; I^2=0%**
Behavioral Outcomes	Change in Physical Activity - Duration/ Intensity (Subjective [days/week])	1 (40)[19]	**MD, -1.06; 95% CI -1.82 to -0.31; I^2=NA**	NA	NA	NA	NA
	Change in Physical Activity - Duration/ Intensity (Objective)	2 (46)[23]	SMD, 1.24; 95% CI -12.99 to 15.47; I^2=89%	NA	NA	NA	NA
	Change in Physical Activity – Fitness	3 (102)[91, 93, 109]	SMD, 0.55; 95% CI -0.92 to 2.02; I^2=55%	NA	NA	NA	NA
	Change in Physical Activity – Strength	NA	NA	NA	NA	NA	NA

Category	Outcomes	Timepoint					
		EOI		6m followup		12m followup	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
	Change in Dietary Intake – Energy Intake (kcal/day)	7 (242)[23, 93, 94, 98, 100, 101]	MD, -158.94; 95% CI -333.73 to 15.85; I^2=38%	1 (38)[105]	MD, -70.00; 95% CI -847.59 to 707.59; I^2=NA	NA	NA
	Change in Dietary Intake – Saturated Fat Intake (% of daily kcal)	2 (74)[93, 101]	MD, -1.40; 95% CI -10.64 to 7.84; I^2=22%	1 (38)[105]	MD, 2.00; 95% CI -0.77 to 4.77; I^2=NA	NA	NA
	Adherence to Medication	4 (1,309)[15, 90, 95]	SMD, -0.05; 95% CI -0.17 to 0.07; I^2=0%	NA	NA	NA	NA
Health Outcomes	Quality of Life – SF-36 Physical (higher score desirable)	2 (4,432)[96, 104]	MD, 5.00; 95% CI -50.92 to 60.92; I^2=85%	1 (167)[106]	MD, 1.60; 95% CI -1.18 to 4.38; I^2=NA	NA	NA
	Quality of Life – SF-36 Mental (higher score desirable)	2 (4,432)[96, 104]	MD, -2.59; 95% CI -48.65 to 43.47; I^2=74%	1 (167)[106]	MD, -1.00; 95% CI -3.82 to 1.82; I^2=NA	NA	NA
	Quality of Life – Other (lower score desirable)	2 (767)[90, 99]	SMD, -0.08; 95% CI -0.47 to 0.31; I^2=11%	NA	NA	2 (181)[99]	SMD, -0.06; 95% CI -0.57 to 0.45; I^2=0%
	Diabetes-specific Quality of Life – Diabetes Distress (PAID)	NA	NA	1 (167)[106]	MD, 1.10; 95% CI -2.08 to 4.28; I^2=NA	NA	NA
	Diabetes-specific Quality of Life – Other (lower score desirable)	4 (1,309)[15, 90, 95]	SMD, 0.04; 95% CI -0.16 to 0.24; I^2=17%	NA	NA	NA	NA

Category	Outcomes	Timepoint					
		EOI		6m followup		12m followup	
		# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect	# Comparisons (# Subjects)	Study Effect
	Mortality – All cause (longest followup)	5 (6,050)[90, 102, 104]	**RR, 0.86; 95% CI, 0.77 to 0.96; I^2=0%**	NA	NA	NA	NA
Program Acceptability	Participant Attrition	21 (7,603)[15, 19, 59, 90-92, 94, 96, 98-107]	**RR, 0.87; 95% CI 0.78 to 0.97; I^2=0%**				

BMI = body mass index; CI = confidence interval; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; I^2 = statistical heterogeneity; kg = kilograms; m = month; MD = mean difference; NA = not applicable; RR = risk ratio; SMD = standardized mean difference

Table I3. Comparative effectiveness of behavioral programs for type 2 diabetes mellitus

Outcome	Category of Comparative Effectiveness	# Trials (# Subjects)	Study Effect at Longest Followup	Conclusion
HbA_{1c}	Addition of Support to DSME	3 (387)[102, 110, 111]	MD, -0.07; 95% CI -0.35 to 0.22	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
	Addition of Support to Lifestyle Program	1 (114)[20]	MD, 0.20; 95% CI -0.94 to 1.34	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
	Addition of Another Component to DSME	4 (547)[95, 112-114]	MD, 0.86; 95% CI -0.03 to 1.76	No difference when adding care coordination,[112] PST,[95] MT,[113] or PA[114] to DSME [95, 113]or DSME + Support[112, 114]
	Addition of Another Component to Lifestyle Program	3 (241)[115-117]	MD, -0.05; 95% CI -0.34 to 0.25	No difference when adding MI[116, 117] or blood glucose regulation[115] interventions to a lifestyle program
	High vs. Low Intensity	2 (209)[118, 119]	MD, -0.41; 95% CI -1.22 to 0.41	No difference between high and low intensity DSME and support programs
	Delivery of DSME via technology vs. in person	2 (126)[120, 121]	MD, 0.07; 95% CI -0.61 to 0.75	No difference when delivery of empowerment DSME with CST via telemedicine vs. in person at clinic,[120] or when social-cognitive theory-guided group DSME for African Americans delivered via virtual world online vs in person[121]
	Delivery of DSME to groups vs. individuals	3 (701)[78, 99, 122]	**MD, -0.36; 95% CI -0.63 to -0.08**	**Improved using group compared with individual delivery of DSME**

Outcome	Category of Comparative Effectiveness	# Trials (# Subjects)	Study Effect at Longest Followup	Conclusion
	Delivery by Peers vs. HCP	4 (575)[110, 111, 123, 124]	MD, 0.00; 95% CI -0.23 to 0.23	No difference when delivery of DSME[110, 123] or support phase[111, 124] by peer compared with HCP
	Delivery by non-HCPs vs. HCP	1 (72)[111]	MD, 0.02; 95% CI -0.60 to 0.64	No difference when support after DSME is provided by clinic staff vs. DM educators
	Addition of peers to CHW-led DSME + Support	1 (116)[125]	MD, -0.30; 95% CI -0.90 to 0.30	No difference when adding peer leaders to support phase of CHW-led DSME + Support (Partners in Care)
	Others	1 (99)[126]	MD, -0.30; 95% CI -0.72 to 0.12	No difference between CBT-based lifestyle program with portion-controlled diet and DSME with meal plan
		1 (600)[127]	MD, -0.07; 95% CI -0.22 to 0.08	No difference between DSME using PRECEDE model vs. conventional health promotion model
		1 (24)[51]	MD, 0.19; 95% CI -0.76 to 1.14	No difference between DSME with problem-solving approach using telephone delivery to couples vs. individuals
		1 (21)[128]	MD, 0.13; 95% CI -1.18 to 1.44	No difference between group-based culturally tailored DSME to individual DSME for rural African Americans
		1 (143)[129]	**MD, -0.30; 95% CI -0.58 to -0.02**	**Improved with individual DSME with MI vs. group-based empowerment DSME with supervised group exercise**
Change in Body Composition (BMI)	Addition of Support to DSME	2 (259)[110, 111]	MD, -0.08; 95% CI -0.58 to 0.41	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
	Addition of Another Component to DSME	3 (255)[112-114]	MD, 0.08; 95% CI -0.48 to 0.64	No difference when adding care coordination,[112] MT,[113] or PA[114] to DSME or DSME + Support
	Delivery of DSME to groups vs. individuals	2 (212)[99, 122]	MD, 0.16; 95% CI -1.12 to 1.44	No difference using group delivery compared with individual delivery of DSME
	Delivery by Peers vs. HCP	2 (263)[110, 111]	MD, 0.47; 95% CI -0.32 to 1.26	No difference when delivery of DSME[110] or support phase[111] by peer compared with HCP
	Delivery by non-HCPs vs. HCP	1 (73)[111]	MD, 0.31; 95% CI -0.72 to 1.34	No difference when support after DSME is provided by clinic staff vs. DM educators[111]
	Addition of peers to CHW-led DSME + Support	1 (116)[125]	MD, 0.50; 95% CI -0.24 to 1.24	No difference when adding peer leaders to support phase of CHW-led DSME + Support (Partners in Care)
	Other	1 (99)[126]	**MD, -1.80; 95% CI -2.51 to -1.09**	**Improved with CBT-based lifestyle program with portion-controlled diet compared with DSME with meal plan**
		1 (600)[127]	MD, 0.06; 95% CI -0.19 to 0.31	No difference between DSME using PRECEDE model vs. conventional health promotion model
		1 (24)[51]	MD, -0.04; 95% CI -5.27 to 5.19	No difference between DSME with problem-solving approach using telephone delivery to couples vs. individuals

Outcome	Category of Comparative Effectiveness	# Trials (# Subjects)	Study Effect at Longest Followup	Conclusion
Change in Body Composition (Weight [kg])	Addition of Support to Lifestyle Program	1 (112)[20]	MD, 0.41; 95% CI -7.21 to 8.03	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
	Addition of Another Component to Lifestyle Program	3 (241)[115-117]	MD, -1.14; 95% CI -2.80 to 0.52	No difference when adding MI[116, 117] or blood glucose regulation[115] interventions to a lifestyle program
	High vs. Low Intensity	1 (96)[85]	MD, -1.30; 95% CI -2.90 to 0.30	No difference between high and low intensity lifestyle program tailored to medically underserved
	Delivery of DSME to groups vs. individuals	2 (581)[78, 122]	MD, -0.15; 95% CI -0.87 to 0.58	No difference using group compared with individual delivery of DSME
	Other	1 (99)[78, 126]	**MD, -5.10; 95% CI -7.22 to -2.98**	**Improved with CBT-based lifestyle program with portion-controlled diet compared with DSME with meal plan**
		1 (121)[129]	MD, -0.10; 95% CI -1.30 to 1.10	No difference between individual DSME with MI and. group-based empowerment DSME with supervised group exercise
Change in Body Composition (waist circumference)	Addition of Another Component to DSME + Support	1 (88)[114]	MD -2.00; 95% CI -5.75 to 1.75	No difference when adding PA to DSME + Support
	Addition of peers to CHW-led DSME + Support	1 (116)[125]	MD, 0.25; 95% CI -2.44 to 2.95	No difference when adding peer leaders to support phase of CHW-led DSME + Support (Partners in Care)
	Others	1 (99)[126]	**MD, -3.60; 95% CI -5.33 to -1.87**	**Improved with CBT-based lifestyle program with portion-controlled diet compared with DSME with meal plan**
		1 (24)[51]	MD, -1.22; 95% CI -10.32 to 7.88	No difference between DSME with problem-solving approach using telephone delivery to couples vs. individuals
		1 (121)[129]	MD, -0.20; 95% CI -1.51 to 1.11	No difference between individual DSME with MI and. group-based empowerment DSME with supervised group exercise
Change in Dietary Intake (kcal/d)	Addition of Support to Lifestyle Program	1 (102)[20]	MD, -65.00; 95% CI -195.23 to 65.23	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
Change in Dietary Intake (% saturated fat/kcal)	Addition of Support to Lifestyle Program	1 (102)[20]	MD, 0.14; 95% CI -0.25 to 0.53	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
Medication Adherence	Addition of Another Component to DSME	1 (296)[95]	SMD, 0.05; 95% CI -0.18 to 0.28	No difference when adding PST to DSME

Outcome	Category of Comparative Effectiveness	# Trials (# Subjects)	Study Effect at Longest Followup	Conclusion
Change in Physical Activity – Intensity/ Duration (subjective; days per week)	Delivery of DSME to groups vs. individuals	1 (92)[122]	MD, 1.30; 95% CI -0.70 to 0.90	No difference in group compared with individual delivery of DSME
	Delivery by non-HCPs vs. HCP	1 (73)[111]	MD, 0.56; 95% CI -1.11 to 1.80	No difference when support after DSME is provided by clinic staff vs. DM educators
	Others	1 (121)[129]	**MD, 1.30; 95% CI 0.80 to 1.80**	**Improved between individual DSME with MI and group-based empowerment DSME with supervised group exercise**
Change in Physical Activity – Intensity/ Duration (objective)	Addition of Support to Lifestyle Program	1 (111)[20]	SMD, 0.23; 95% CI -0.15 to 0.60	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
Change in Physical Activity – Fitness	Addition of Another Component to DSME + Support	1 (88)[114]	**SMD, 0.62; 95% CI 0.19 to 1.05**	**Improved when adding a PA component to DSME + Support**
Quality of Life-Other	Delivery of DSME to groups vs. individuals	1 (120)[99]	SMD, -0.08; 95% CI -0.44 to 0.28	No difference using group compared with individual delivery of DSME
Quality of Life – SF-36 Physical	Delivery of DSME to groups vs. individuals	1 (92)[122]	MD, -0.80; 95% CI -4.04 to 2.44	No difference in group compared with individual delivery of DSME
Quality of Life – SF-36 Mental	Delivery by Peers vs. HCP	1 (221)[124]	MD, -0.20; 95% CI -2.21 to 1.81	No difference when delivery of support phase by peer compared with HCP
Diabetes-related Quality of Life (higher score desirable)	Addition of Another Component to DSME	1 (196)[95]	MD, 0.14; 95% CI -0.09 to 0.37	No difference when adding PST to DSME
	Delivery by Peers vs. HCP	1 (198)[110]	SMD, 0.11; 95% CI -0.17 to 0.38	No difference when delivery of DSME by peer compared with HCP
	Delivery of DSME via telemedicine vs. in person	1 (35)[120]	SMD, -0.06; 95% CI -0.72 to 0.61	No difference when delivery of empowerment DSME with CST via telemedicine vs. in person at clinic
	Addition of Support to Lifestyle Program	1 (119)[20]	SMD, 0.04; 95% CI -0.32 to 0.40	No difference when adding tailoring (African American women) and social support in community to clinic-based lifestyle program
	Other	1 (121)[129]	SMD, 0.15; 95% CI -0.20 to 0.51	Improved between individual DSME with MI and. group-based empowerment DSME with supervised group exercise
Diabetes Distress (lower score desirable)	Delivery of DSME via telemedicine vs. in person	1 (31)[120]	MD, 3.60; 95% CI -12.05 to 19.25	No difference when delivery of empowerment DSME with CST via telemedicine vs. in person at clinic
	Delivery by non-HCPs vs. HCP	1 (73)[111]	MD, 2.40; 95% CI -5.65 to 10.45	No difference when support after DSME is provided by clinic staff vs. DM educators
	Delivery by Peers vs. HCP	1 (74)[111]	**MD, 24.70; 95% CI 15.02 to 34.38**	**Increased distress with delivery of support phase by peers compared with HCP**

BMI = body mass index; CBT = cognitive-behavioral theory; CHW = community health worker; CI = confidence interval; CST = coping skills therapy; DM = diabetes mellitus; EOI = end of intervention; HbA_{1c} = hemoglobin A_{1c}; HCP = health care professional; m = month; MD = mean difference; MI = motivational interviewing; MT = music therapy; NA = not applicable; PA = physical activity; PST = problem-solving training; SMD = standardized mean difference

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Appendix J. Network Meta-Analysis Results for Glycemic Control and Age Subgroup Analyses

Table J1. Network meta-analysis results for HbA_{1c} for suboptimal glycemic control subgroup (HbA_{1c} ≥7%)

Arm Description	Rank Order of Effect & Studies (only those removed from original analysis)	Intensity	Method of Communication	Delivery Method	Delivery Personnel	MD, 95% Credibility Interval	Probability of Being Best
Usual care	NA[1-6]	NA	NA	NA	NA	0 [NA, NA]	0.0%
Active comparator (non-DSME)	28[7]	NA	NA	NA	NA	-0.10 [-0.34, 0.15]	0.0%
Active comparator (other)	24[8, 9]	NA	NA	NA	NA	-0.14 [-0.55, 0.26]	0.0%
DSME	22	≤10h	In person	Individual & mixed	HCP	-0.17 [-0.40, 0.07]	0.0%
	20	≤10h	In person	Group only	HCP	-0.20 [-0.47, 0.07]	0.0%
	29	≤10h	In person	Group only	Non-HCP	-0.03 [-0.96, 0.90]	0.4%
	26	≤10h	Some technology	Individual & mixed	HCP	-0.11 [-0.41, 0.18]	0.0%
	21[1]	≤10h	Some technology	Individual & mixed	Non-HCP	-0.18 [-0.48, 0.11]	0.0%
	17	11-26h	In person	Individual & mixed	HCP	-0.26 [-0.72, 0.20]	0.0%
	18[3, 6]	11-26h	In person	Group only	HCP	-0.26 [-0.48, -0.04]	0.0%
	15[2, 4]	11-26h	In person	Group only	Non-HCP	-0.34 [-0.78, 0.10]	0.0%
	25	11-26h	Some technology	Individual & mixed	HCP	-0.12 [-0.47, 0.22]	0.0%
	4	11-26h	Some technology	Individual & mixed	Non-HCP	-0.78 [-1.37, -0.18]	5.3%[a]
	27	11-26h	Some technology	Group only	HCP	-0.11 [-1.16, 0.93]	1.3%
	7	≥27h	In person	Individual & mixed	HCP	-0.73 [-1.61, 0.14]	10.1%[a]
	31[7]	≥27h	In person	Group only	HCP	0.09 [-0.49, 0.68]	0.0%
	9	≥27h	Some technology	Individual & mixed	HCP	-0.70 [-1.60, 0.21]	9.3%[a]
DSME + Support	8	≤10h	In person	Individual & mixed	NA	-0.70 [-1.52, 0.12]	7.7%[a]
	34	≤10h	In person	Group only	NA	2.83 [1.48, 4.20]	0.0%
	16	≤10h	Some technology	Individual & mixed	NA	-0.30 [-0.74, 0.13]	0.0%
	10	11-26h	In person	Individual & mixed	NA	-0.64 [-1.70, 0.43]	10.5%[a]
	6	11-26h	In person	Group only	NA	-0.73 [-1.38, -0.10]	4.0%[a]
	13	11-26h	Some technology	Individual & mixed	NA	-0.36 [-0.86, 0.12]	0.0%
	11	≥27h	In person	Individual & mixed	NA	-0.55 [-1.08, -0.02]	0.6%[a]
	3	≥27h	In person	Group only	NA	-0.88 [-1.66, -0.10]	14.4%[a]
Lifestyle	33[5]	≤10h	In person	Individual & mixed	NA	0.50 [-0.35, 1.34]	0.0%
	23[9]	≤10h	In person	Group only	NA	-0.15 [-1.16, 0.88]	1.4%
	35	≤10h	Some technology	Individual & mixed	NA	0.40 [-0.83, 1.62]	0.4%
	12	11-26h	In person	Individual & mixed	NA	-0.41 [-0.82, 0.01]	0.0%[a]

	5	11-26h	In person	Group only	NA	-0.76 [-1.19, -0.33]	1.8%[a]
	1	11-26h	Some technology	Individual & mixed	NA	-1.01 [-1.61, -0.40]	19.4%[a]
	19	11-26h	Some technology	Group only	NA	-0.20 [-0.99, 0.59]	0.4%
	2[8]	≥27h	In person	Individual & mixed	NA	-0.98 [-1.47, -0.50]	12.9%[a]
	30	≥27h	In person	Group only	NA	0.02 [-0.51, 0.57]	0.0%
	25	≥27h	Some technology	Individual & mixed	NA	-0.34 [-0.80, 0.11]	1.3%

DSME = diabetes self-management education; h = hour(s); HCP = health care professional; MD = mean difference; NA = not applicable

[a]Highlighted rows represent those nodes having effect sizes meeting or exceeding our criteria for clinical importance.

Table J2. Network meta-analysis results for HbA_{1c} for participants under 65 years of age

Arm Description	Rank Order of Effect & Studies(only those removed from original analysis)	Intensity	Method of Communication	Delivery Method	Delivery Personnel	MD, 95% Credibility Interval	Probability of Being Best
Usual care	NA[2, 3, 10-14]	NA	NA	NA	NA	0 [NA, NA]	0.0%
Active comparator (non-DSME)	31	NA	NA	NA	NA	0.12 [-0.23, 0.46]	0.0%
Active comparator (other)	12[15, 16]	NA	NA	NA	NA	-0.54 [-1.19, 0.10]	0.0%[a]
DSME	18[16]	≤10h	In person	Individual & mixed	HCP	-0.33 [-0.68, 0.02]	0.0%
	21	≤10h	In person	Group only	HCP	-0.22 [-0.63, 0.19]	0.0%
	29	≤10h	In person	Group only	Non-HCP	-0.05 [-1.31, 1.21]	0.8%
	27[12]	≤10h	Some technology	Individual & mixed	HCP	-0.09 [-0.51, 0.32]	0.0%
	25[13]	≤10h	Some technology	Individual & mixed	Non-HCP	-0.15 [-0.55, 0.24]	0.0%
	23	11-26h	In person	Individual & mixed	HCP	-0.17 [-0.83, 0.50]	0.0%
	20[3, 11]	11-26h	In person	Group only	HCP	-0.26 [-0.58, 0.06]	0.0%
	17[2]	11-26h	In person	Group only	Non-HCP	-0.38 [-0.97, 0.20]	0.0%
	28[10]	11-26h	Some technology	Individual & mixed	HCP	-0.06 [-0.63, 0.50]	0.0%
	5	11-26h	Some technology	Individual & mixed	Non-HCP	-0.78 [-1.60, 0.04]	3.4%[a]
	26	11-26h	Some technology	Group only	HCP	-0.11 [-1.46, 1.22]	1.6%
	7	≥27h	In person	Individual & mixed	HCP	-0.73 [-1.92, 0.45]	7.7%[a]
	1	≥27h	In person	Group only	HCP	-1.42 [-2.12, -0.72]	37.3%[a]
	13	≥27h	Some technology	Individual & mixed	HCP	-0.49 [-1.72, 0.75]	3.8%[a]
DSME + Support	8	≤10h	In person	Individual & mixed	NA	-0.71 [-1.85, 0.44]	6.5%[a]
	34	≤10h	In person	Group only	NA	2.82 [1.14, 4.48]	0.0%
	19[16]	≤10h	Some technology	Individual & mixed	NA	-0.27 [-1.05, 0.51]	0.1%
	15	11-26h	In person	Individual & mixed	NA	-0.43 [-1.77, 0.93]	4.2%[a]
	6	11-26h	In person	Group only	NA	-0.74 [-1.58, 0.10]	2.4%[a]
	16	11-26h	Some technology	Individual & mixed	NA	-0.39 [-1.09, 0.31]	0.1%
	11	≥27h	In person	Individual & mixed	NA	-0.54 [-1.32, 0.23]	0.8%[a]
	4	≥27h	In person	Group only	NA	-0.88 [-1.89, 0.12]	8.5%[a]
Lifestyle	32	≤10h	In person	Individual & mixed	NA	0.21 [-0.51, 0.95]	0.0%
	10	≤10h	In person	Group only	NA	-0.60 [-1.62, 0.41]	2.3%[a]
	33	≤10h	Some technology	Individual & mixed	NA	0.26 [-1.13, 1.65]	0.5%
	14[14]	11-26h	In person	Individual & mixed	NA	-0.45 [-1.06, 0.16]	0.0%[a]

	9	11-26h	In person	Group only	NA	-0.68 [-1.27, -0.09]	0.4%[a]
	3	11-26h	Some technology	Individual & mixed	NA	-0.91 [-1.75, -0.06]	6.6%[a]
	22	11-26h	Some technology	Group only	NA	-0.20 [-1.32, 0.92]	0.9%
	2	≥27h	In person	Individual & mixed	NA	-1.17 [-1.81, -0.55]	11.7%[a]
	30	≥27h	In person	Group only	NA	0.08 [-0.70, 0.86]	0.0%
	24[15]	≥27h	Some technology	Individual & mixed	NA	-0.16 [-0.94, 0.62]	0.1%

DSME = diabetes self-management education; h = hour(s); HCP = health care professional; MD = mean difference; NA = not applicable

[a]Highlighted rows represent those nodes having effect sizes meeting or exceeding our criteria for clinical importance.

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