

## ***Draft Systematic Review***

---

**Number XX**

### **Behavioral Programs for Diabetes Mellitus**

**Prepared for:**

Agency for Healthcare Research and Quality  
U.S. Department of Health and Human Services  
540 Gaither Road  
Rockville, MD, 20850  
www.ahrq.gov

This information is distributed solely for the purposes of predissemination peer review. It has not been formally disseminated by the Agency for Healthcare Research and Quality. It does not represent and should not be construed to represent an Agency for Healthcare Research and Quality or Department of Health and Human Services (AHRQ) determination or policy.

**Contract No. xxx-xxxx-xxxxx**

**Prepared by:**

<Name> Evidence-based Practice Center  
<City, State>

**Investigators:**

First and Last Names, X.X.  
First and Last Names, X.X.

**AHRQ Publication No. xx-EHCxxx**  
**<Month Year>**

This report is based on research conducted by an Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. xxx-xxxx-xxxxx). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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

This report may be used, in whole or in part, as the basis for development of clinical practice guidelines and other quality enhancement tools, or as a basis for reimbursement and coverage policies. AHRQ or U.S. Department of Health and Human Services endorsement of such derivative products may not be stated or implied.

This report may periodically be assessed for the urgency to update. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at [www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov). Search on the title of the report.

This document is in the public domain and may be used and reprinted without permission except those copyrighted materials that are clearly noted in the document. Further reproduction of those copyrighted materials is prohibited without the specific permission of copyright holders.

Persons using assistive technology may not be able to fully access information in this report. For assistance contact [EffectiveHealthCare@ahrq.hhs.gov](mailto:EffectiveHealthCare@ahrq.hhs.gov)

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

**Suggested citation:** <Authors>. <Behavioral Programs for Diabetes>. <Report Series Name No.> <#>. (Prepared by the <EPC Name> Evidence-based Practice Center under Contract No. <##>.) AHRQ Publication No. XX-EHCXXX-EF. Rockville, MD: Agency for Healthcare Research and Quality. <Month Year>. [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm).

## 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](http://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](http://www.effectivehealthcare.ahrq.gov)) to see draft research questions and reports or to join an e-mail 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](mailto:epc@ahrq.hhs.gov).

Richard G. Kronick, Ph.D.  
Director  
Agency for Healthcare Research and Quality

David Meyers, M.D.  
Acting Director, Center for Evidence and  
Practice Improvement  
Agency for Healthcare Research and Quality

Stephanie Chang M.D., M.P.H.  
Director, EPC Program  
Center for Evidence and Practice  
Improvement  
Agency for Healthcare Research and Quality

Aysegul Gozu, M.D., M.P.H.  
Task Order Officer  
Center for Evidence and Practice  
Improvement  
Agency for Healthcare Research and Quality

## **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 Task Order Officer (TOO) and the EPC work to balance, manage, or mitigate any conflicts of interest.

The list of Key Informants who participated in developing this report follows: *to be inserted following peer-review*

## **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.

Technical Experts 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 conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

The list of Technical Experts who participated in developing this report follows: *to be inserted following peer-review*

## **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 does 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 non-financial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential non-financial conflicts of interest identified.

The list of Peer Reviewers follows: *to be inserted following peer-review*

# Behavioral Programs for Diabetes

## Structured Abstract

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

**Data Sources.** MEDLINE®, Cochrane Central Register of Controlled Trials, EMBASE, CINAHL®, PsycINFO, and PubMed® (January 1, 1993 to early June, 2014); conference proceedings (2011- Spring 2014); reference lists of relevant studies.

**Methods.** Two reviewers independently assessed studies for fit with predetermined selection criteria and assessed risk of bias. One reviewer extracted data, with verification by a second reviewer. For T1DM, we conducted pair-wise meta-analysis to assess program effectiveness; subgroup analyses to examine patient variables (e.g., age, race/ethnicity, glycemic control); and meta-regressions 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 to assess potential moderation of program effectiveness, and subgroup analyses to assess the impact of patient variables. Strength of the body of evidence (SOE) for key outcomes in T1DM was assessed to determine our confidence in the results.

**Results.** The searches identified 45,075 citations, of which we included 32 studies for T1DM and 123 RCTs for T2DM. All trials had a medium or high overall risk of bias.

For T1DM, there was moderate SOE showing greater reductions in HbA<sub>1c</sub> at 6-month postintervention followup for individuals receiving a behavioral program compared with usual care (0.33 percent HbA<sub>1c</sub>) or an active control (0.43); both were statistically significant and the latter was considered clinically important based on our prespecified threshold of  $\geq 0.4$  unit change in percent HbA<sub>1c</sub>. There was low SOE showing no difference in HbA<sub>1c</sub> at end of intervention and at 12-month or longer followup. There was either low SOE of no difference, or insufficient SOE, for all other outcomes including self-management and lifestyle behaviors, body composition, quality of life, and complications. There were no conclusive findings from subgroup analyses. None of the program factors were shown to significantly influence the effectiveness of behavioral programs.

For T2DM, effect sizes for all minimally intensive ( $\leq 10$  contact hours) DSME programs were not considered clinically important for glycemic control. DSME, DSME plus support, and lifestyle programs having greater effect on HbA<sub>1c</sub> were more often delivered in person. For body mass index, lifestyle programs provided the largest effect sizes. Variability in effectiveness was shown across subgroups, with more benefit for participants with suboptimal glycemic control ( $\geq 7$  percent HbA<sub>1c</sub>), adults  $< 65$  years, and minority participants ( $\geq 75$  percent nonwhite).

**Conclusion.** Behavioral programs for T1DM offer some benefit for glycemic control when followup extends to 6 months, but more evidence is required to draw conclusions about long-term effects. More evidence is required to determine the effects for other key outcomes. For T2DM, our analyses showed limited benefit in glycemic control from DSME programs offering  $\leq 10$  hours of contact with delivery personnel, and suggested that in-person delivery of behavioral programs is more beneficial than 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 beneficial. Prospero Registration No. CRD42014010515

# Contents

<b>Executive Summary</b> .....	ES-1
<b>Introduction</b> .....	1
Background.....	1
Pathophysiology.....	1
Epidemiology and Burden of Disease.....	1
Diabetes Care and Self-Management.....	2
Rationale for Evidence Review.....	3
Scope of Review and Key Questions.....	4
Analytic Frameworks.....	6
Organization of This Report.....	6
<b>Methods</b> .....	9
Topic Refinement and Review Protocol.....	9
Literature Search Strategy.....	9
Inclusion and Exclusion Criteria.....	10
Study Selection.....	13
Data Extraction.....	13
Risk of Bias Assessment of Individual Studies.....	14
Data Synthesis.....	14
Strength of the Body of Evidence.....	19
Applicability.....	20
Peer Review and Public Commentary.....	20
<b>Results</b> .....	21
Literature Search and Screening.....	21
Type 1 Diabetes Mellitus.....	22
Literature Search and Screening.....	22
Characteristics of Included Studies.....	22
Risk of Bias of Individual Studies.....	26
KQ 1. Behavioral Programs and Behavioral, Clinical, and Health Outcomes; Diabetes-Related Health Care Utilization; and Program Acceptability.....	27
Key Points: HbA <sub>1c</sub> .....	27
Key Points: Other Clinical and Behavioral Outcomes.....	27
Key Points: Health Outcomes.....	28

Key Points: Diabetes-Related Health Care Utilization .....	28
Key Points: Program Acceptability .....	28
Detailed Synthesis.....	28
Summary of Key Findings and Strength of Evidence for KQ 1 .....	40
KQ 2. Subgroups for Effectiveness in T1DM.....	42
Key Points .....	43
Detailed Synthesis.....	43
KQ 3. Potential Moderation of Effectiveness for T1DM: Components, Intensity, Delivery Personnel, Method of Communication, Degree of Tailoring, and Level of Community Engagement.....	44
Key Points:.....	44
Detailed Synthesis.....	44
KQ4. Harms .....	45
Type 2 Diabetes Mellitus .....	45
Literature Search and Screening .....	45
Characteristics of Included Studies .....	46
Risk of Bias of Individual Studies .....	47
Effectiveness of Behavioral Programs Across Outcomes .....	47
KQ 5. Potential Moderation of Effectiveness for T2DM: Components, Intensity, Delivery Personnel, Method of Communication, Degree of Tailoring, and Level of Community Engagement.....	51
Key Points: HbA1c .....	51
Key Points: Body Mass Index .....	51
Detailed Synthesis.....	52
KQ 6. Subgroups for Factors Moderating Effectiveness in T2DM.....	60
Key Points .....	60
Detailed Synthesis.....	60
<b>Discussion</b> .....	63
Key Findings and Discussion for Type 1 Diabetes Mellitus (Key Questions 1-4) .....	63
Key Findings and Discussion for Type 2 Diabetes (KQs 5 and 6).....	65
Findings in Relation to What is Already Known .....	69
Applicability .....	71
Limitations of the Comparative Effectiveness Review Process .....	73
Limitations of the Evidence Base .....	74

Research Gaps .....	75
Conclusions .....	76
<b>References</b> .....	78
<b>Abbreviations and Acronyms</b> .....	95

## Tables

Table A. Categorization of program components and implementation factors.....	ES-10
Table B. Type 1 diabetes: Summary of key findings and strength of evidence for behavioral programs compared with an usual care.....	ES-14
Table C. Type 1 diabetes: Summary of key findings and strength of evidence for behavioral programs compared to an active control.....	ES-16
Table D. Results of the network meta-analysis for HbA <sub>1c</sub> : Nodes in rank order with description of associated program factors and mean differences in effect relative to usual care.....	ES-18
Table E. Potential research needs, by Key Question.....	ES-24
Table 1. Inclusion criteria for Type 1 diabetes (Key Questions 1-4).....	11
Table 2. Inclusion criteria for Type 2 diabetes (Key Questions 5-6).....	12
Table 4. Other clinical and behavioral outcomes.....	36
Table 5. Behavioral programs for diabetes compared with usual care: Health-related quality of life at 6-, 12-, and 24-month postintervention.....	38
Table 6. Behavioral programs for diabetes compared with usual care: Diabetes-related health care utilization at end of intervention, 6-, 12-, and 24-month post-intervention followup .....	39
Table 7. Type 1 diabetes: Summary of key findings and strength of evidence for behavioral programs compared with usual care .....	41
Table 8. Type 1 diabetes: Summary of key findings and strength of evidence for behavioral programs compared with an active control.....	42
Table 9. Results from univariate meta-regressions analyzing the association between different program factors and the effectiveness of behavioral programs in improving HbA <sub>1c</sub> .....	44
Table 10. Network meta-analysis for HbA <sub>1c</sub> : Description of nodes and results.....	54
Table 11. Network meta-analysis for body mass index: Description of nodes and results .....	57
Table 12. 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 <sub>1c</sub> .....	62
Table 13. Potential research needs, by Key Question.....	75

## Figures

Figure A. Analytic framework for behavioral programs for type 1 diabetes mellitus.....	ES-6
Figure B. Analytic framework for behavioral programs for type 2 diabetes mellitus.....	ES-7
Figure C. Flow diagram of study retrieval and selection.....	ES-13
Figure 1. Analytic framework for behavioral programs for type 1 diabetes mellitus.....	7
Figure 2. Analytic framework for behavioral programs for type 2 diabetes mellitus.....	8
Figure 3. Flow diagram of study retrieval and selection .....	21
Figure 4. Risk of bias summary for trials of behavioral programs for type 1 diabetes .....	27
Figure 5. Behavioral programs for diabetes compared with usual care: HbA <sub>1c</sub> at the end of intervention .....	29

Figure 6. Behavioral programs for diabetes compared with usual care: HbA <sub>1c</sub> at 6-month postintervention.....	30
Figure 7. Behavioral programs for diabetes compared with usual care: HbA <sub>1c</sub> at 12-month postintervention (youth only).....	30
Figure 8. Behavioral programs for diabetes compared with active control: HbA <sub>1c</sub> at end of intervention .....	32
Figure 9. Behavioral programs for diabetes compared with active control: HbA <sub>1c</sub> at 6-month postintervention.....	32
Figure 10. Behavioral programs for diabetes compared with active control: HbA <sub>1c</sub> at 12-month postintervention.....	33
Figure 11. Behavioral programs for diabetes compared with usual care: Self-monitoring of blood glucose (tests per day) at end of intervention .....	34
Figure 12. Behavioral programs for diabetes compared with usual care: Self-monitoring of blood glucose (tests per day) at 6-month postintervention .....	34
Figure 13. Behavioral programs for diabetes compared with usual care: Health-related quality of life at end of intervention .....	38
Figure 14. Behavioral programs for diabetes compared with usual care: Participant attrition.....	40
Figure 15. Risk of bias summary for trials of behavioral programs for type 2 diabetes .....	47
Figure 16. Plot of network meta-analysis results for HbA <sub>1c</sub> .....	56
Figure 17. Plot of network meta-analysis results for body mass index .....	59

# 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 transferred from hospitals to outpatient settings, and several guidelines and diabetes management programs have been developed to improve diabetes care in the community.<sup>1</sup> However, an evaluation of initiatives to implement guidelines and processes of care in community health centers did not find improved glucose control, reflected in reduced hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels, for patients with diabetes.<sup>2</sup>

Approaches for supporting diabetic patients to change behaviors include interventions such as diabetes self-management education (DSME) with or without support, 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.<sup>3-7</sup> In contrast, there is a diverse evidence base supporting 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.

## Epidemiology and Burden of Disease

In 2012, 29.1 million Americans had 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).<sup>8</sup> About 208,000 Americans younger than 20 years had diagnosed diabetes in 2012.<sup>8</sup> 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 diabetes compared to non-Hispanic whites.<sup>8</sup> Specific to T1DM, non-Hispanic white youth are affected more often than all other racial or ethnic groups.<sup>9</sup>

Diabetes-related care accounts for 11 percent of all U.S. health care expenditure<sup>10</sup> equating to \$245 billion in total costs in 2012.<sup>8</sup> Average medical expenses are more than twice as high for a person with diabetes as they are for someone without diabetes.<sup>11</sup> Complications from diabetes include cardiovascular disease, retinopathy, neuropathy, nephropathy, and cerebrovascular disease, as well as comorbidities such as depression and other mental health conditions.<sup>12</sup>

## 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.<sup>13</sup> 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 (EDIC) study.<sup>14, 15</sup> Recently, these findings have extended to demonstrate reduced mortality.<sup>16</sup> 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.<sup>17</sup>

People with T2DM are often treated progressively through diet (e.g., calorie and fat reduced while controlling carbohydrate intake) and then, if needed, one or more oral hypoglycemic medications. Many T2DM patients eventually require the addition (or sole use) of insulin to obtain good 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.<sup>18, 19</sup> 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.<sup>20</sup>

Reducing the risk for diabetes-related complications often requires lifestyle and/or pharmacological management of body weight, blood pressure, and cholesterol levels.<sup>13, 21-23</sup> For instance, intensive lowering of blood pressure has shown to reduce major cardiovascular events by 11%.<sup>24</sup> The responsibility for this extensive, multicomponent disease management falls to both the diabetes health care team and, most notably, the patient. Patients are encouraged to adopt and adhere to several self-care or self-management and lifestyle behaviors.<sup>25, 26</sup> 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.<sup>27</sup>

A critical element of diabetes care is education and support to enable patients to engage in self-care and self-management behaviors. Because knowledge acquisition alone is not enough for behavioral changes,<sup>28, 29</sup> 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.<sup>30-33</sup> 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.”<sup>30</sup> 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.<sup>34</sup>

Despite the availability of new medications and treatment 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<sup>35</sup> and few (as low as 16 percent<sup>36</sup>) patients carry out all self-management recommendations.

## **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 community health settings. 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;<sup>37-44</sup> 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 which fall short of meeting current recommendations, and others which incorporate some enhancement of medical management 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,<sup>37, 39, 43, 45, 46</sup> and even fewer analyzed the data in a manner to assess multiple factors simultaneously<sup>45</sup>—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. For T2DM we built upon previous systematic reviews by identifying 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 moderation of effectiveness, by factors such as delivery personnel, effective community linkages, and demographics. This review will help inform decisions regarding what combination of program components and delivery methods are most effective for implementation of these programs in community health settings.

## Scope and Key Questions

For the purpose of this review we developed an operational definition of behavioral programs that encompasses DSME as well as other programs incorporating interactive components that target multiple important behavioral changes (e.g., diet and physical activity). 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  $\geq 4$  weeks, to improve disease control and/or patient health outcomes, and consisting of at least one of: a) DSME; or 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).*

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 [ $\leq 18$  years] and their families, young adults [19-30 years], adults [31-64 years], older adults ( $\geq 65$  years])
- b. Race or ethnicity
- c. Socioeconomic status (e.g., family income, education level, literacy)
- d. Time since diagnosis ( $\leq 1$  year vs.  $> 1$  year)
- e. Level of glycemic control ( $HbA_{1c} < 7$  vs.  $\geq 7$  percent])

**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

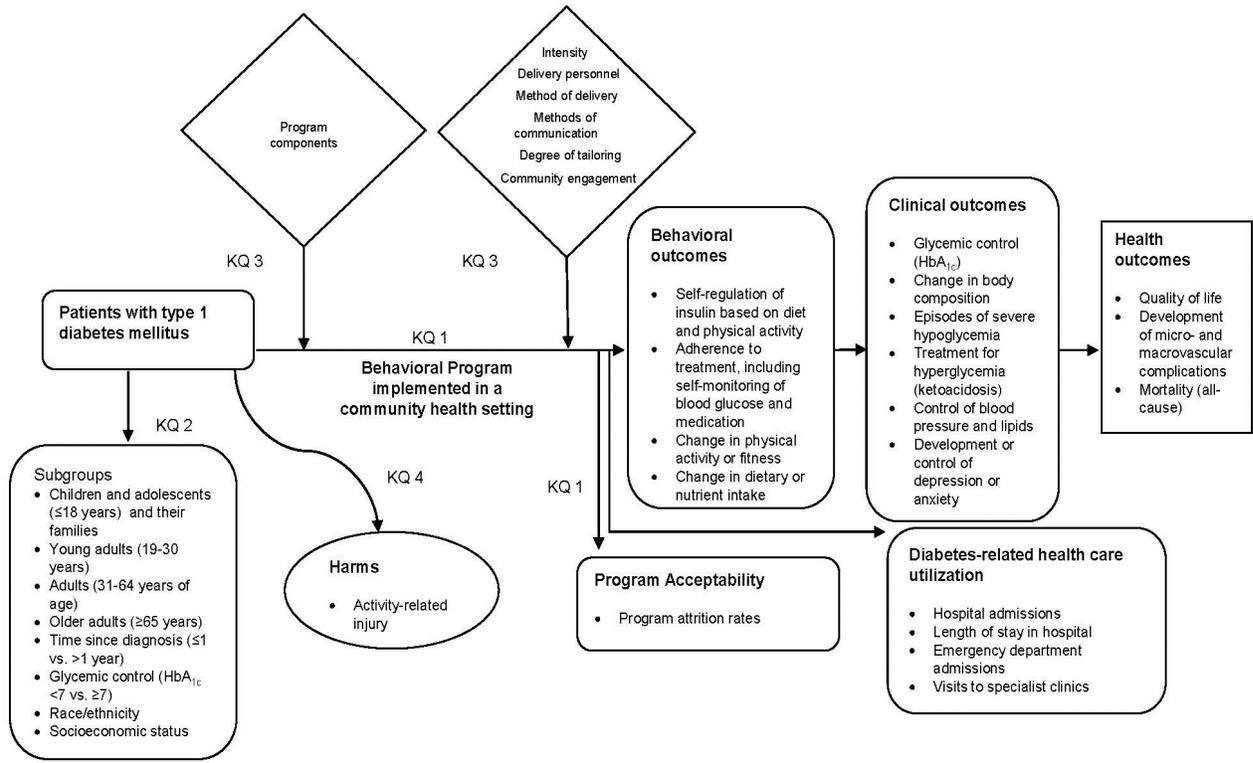
**Key Question 6.** Do the factors that contribute to program effectiveness for patients with T2DM vary across the following subpopulations?

- a. Age (young adults [19-30 years], adults [31-64 years], older adults [ $\geq 65$  years])
- b. Race or ethnicity
- c. Socioeconomic status (e.g., family income, education level, literacy)
- d. Time since diagnosis ( $\leq 1$  year vs.  $> 1$  year)
- e. Level of glycemic control ( $\text{HbA}_{1c} < 7$  vs.  $\geq 7$  percent)

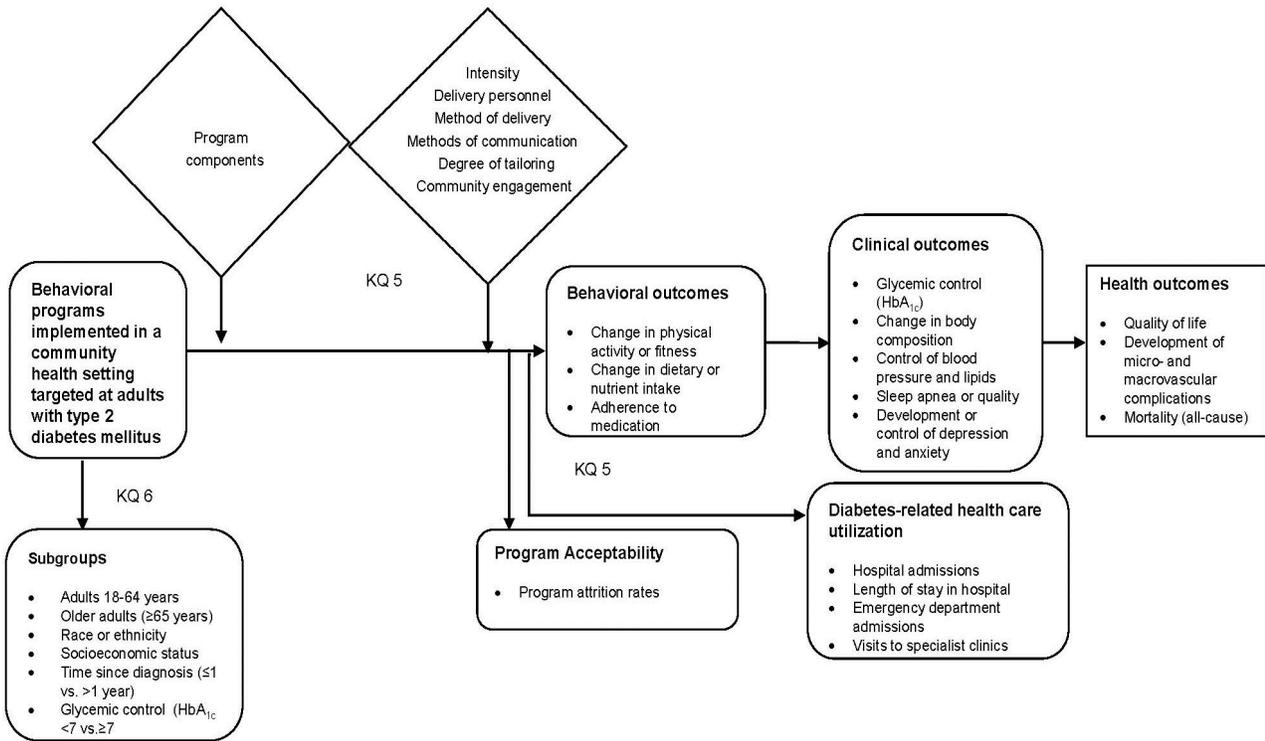
## **Analytical Frameworks**

We developed two analytic frameworks to guide the systematic review process (Figure A and Figure B). 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**



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



## 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, Scopus®, and PubMed® via the National Center for Biotechnology Information Databases. We limited the search to prospective controlled studies published in English.

We reviewed the reference lists of relevant systematic reviews and of all included studies. We searched the following trial registries: metaRegister of Controlled Trials (includes ClinicalTrials.gov, the International Standard Randomised Controlled Trial Number Register, Action Medical Research, the Wellcome Trust, and UK Trials) and the World Health Organization International Clinical Trials Registry Platform. We 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.

### 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,<sup>47</sup> published in the English language after 1993. For T1DM, we included prospective comparative studies (i.e., RCTs, nonrandomized controlled trials [non-RCTs], prospective cohort studies, controlled before-after studies). For T2DM, we included RCTs.

For T1DM, we included studies of patients (any age) diagnosed with T1DM and 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), 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.<sup>48</sup> 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 risk of bias. Each domain was rated having “low,” “unclear (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.<sup>49</sup> 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™ (SRDR; <http://srdhr.gov/>).<sup>50</sup> 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 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. All outcome data were extracted and reported in figures of meta-analyses (if pooled) or outcomes tables.

We focused on the following key outcomes: HbA<sub>1c</sub>, 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. For key outcomes we defined a threshold for clinical importance when there was literature to provide guidance. For HbA<sub>1c</sub>, we used a difference of 0.4 unit change in percent HbA<sub>1c</sub> (e.g., 7.6% vs. 8.0%).<sup>51</sup> For quality of life measures and other subjective outcomes reported using a continuous scale, we used a value of one-half standard deviation (0.50 standard deviation).<sup>52, 53</sup>

With input from our Technical Expert Panel, we categorized various components and delivery methods as outlined in Table 3. Many behavioral programs comprised DSME with or without the addition of a support component; those programs not considered DSME were considered as “lifestyle” programs.

**Table A. Categorization of program components and delivery factors**

<b>Program Factors</b>	<b>Categories and Description Variables</b>
Program Components*	DSME DSME + Support: DSME plus an added phase to extend program duration and support; often clinically focused but may be psychosocial, educational or behavioral 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 was used as a continuous variable for the regression analyses for KQs 3 and 6
Intensity* (contact hours; where contact hours could not be calculated, we used #contacts as a proxy)	≤10h 11 to 26h (e.g., weekly for up to 6m) ≥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 for T1DM
Method of communication†	In person only Mixture of in person and technology All technology with minimal interaction with providers
Method of delivery‡	Individual Mixed individual and group Group
Delivery personnel§	Delivered entirely by non-health professional (e.g., lay/community health worker, undergraduate students) after training and under some supervision One health professional for large majority (>75%) of delivery Provision by multidisciplinary team of health professionals
Degree of tailoring**	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) 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	Present, e.g., peer delivering program or peer support groups for support stage, use of community resources (infrastructure) for delivery or maintenance stages Absent, e.g., nothing reported or, at most, providing written information about community resources
Presence of support person††	Family or parent involved in >1 session No family or parent involvement in sessions

\*for network meta-analysis in KQ 5 and 6 only; † 2 and 3 were combined for analysis; ‡ 1 and 2 were combined for analysis; §2 and 3 were combined for KQ 5 and 6; \*\*used in summary tables and the analysis for T1DM; ††for T1DM only

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

## Synthesis for T1DM (KQs 1-4)

For each comparison of interest, we conducted a pair-wise 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<sup>54, 55</sup> for all meta-analyses using Stata 11.2 and Excel 2010 software. We calculated pooled mean differences, standardized mean differences, and risk ratios with corresponding 95% CIs, as appropriate. We analyzed outcomes at different postintervention time points.

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 with the most data (i.e., HbA<sub>1c</sub>) 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 component or delivery factors (KQ 3), we performed univariate meta-regressions for comparisons between behavioral programs and usual care for HbA<sub>1c</sub> from each study's longest followup timepoint. Each behavioral program was coded using the categorization scheme in Table 3 and these variables were used in the analysis. For harms (i.e., activity-related injury) (KQ 4) we planned to descriptively summarize all outcomes presented in studies.

## **Synthesis for T2DM (KQs 5-6)**

Before synthesizing findings to answer KQs 5 and 6, we performed pair-wise 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 having enough data (HbA<sub>1c</sub> and BMI). A network meta-analysis allows for simultaneous evaluation of a suite of comparisons and considers both direct and indirect evidence. A network of different comparisons is constructed (with “nodes” representing groupings of sufficiently similar interventions and comparators). We grouped the behavioral programs into nodes based on the categories of program factors described in Table 3. 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 (MD) 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”).

Key Question 6 focused on whether variability between population groups affected the role of potential factors moderating the effectiveness of behavioral programs for key outcomes with the most data (i.e., HbA<sub>1c</sub>). We first conducted subgroup analyses of the pair-wise meta-analysis results for HbA<sub>1c</sub> for behavioral programs compared with usual care and active controls at longest followup; subgroups based on baseline glyceic control (HbA<sub>1c</sub>), age, and ethnicity were performed. For glyceic control and age, we then performed subgroup analysis of the network meta-analysis used for KQ 5. For subgroups based on race/ethnicity ( $\geq 75$  vs.  $< 75$  percent nonwhite), the number of trials in either subgroup was not sufficient to perform a meaningful network meta-analysis so we conducted a set of univariate meta-regressions using the variables in Table 3 and methods outlined for KQ 2.

## **Strength of the Body of Evidence**

We followed the Methods Guide<sup>56</sup> 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 select behavioral and clinical outcomes (i.e., glyceic control, adherence to diabetes self-management behaviors, change in body composition, change in physical activity or fitness, and change in dietary or nutrient intake). 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 core 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 unsuspected). 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 due to no or very little evidence.

## **Applicability**

We assessed applicability of the body of evidence following guidance from the Methods Guide.<sup>56</sup> We used the PICOTS framework to explore factors that may affect applicability.

## **Results**

Searches of all sources identified a total of 45,075 citations. For T1DM, we included 32 studies described in 42 publications; there were 28 RCTs, 1 non-RCT and 3 controlled before-after studies. For T2DM, we included 123 RCTs described in 151 publications. Figure 3 describes the flow of literature through the screening process.

## **Type 1 Diabetes Mellitus: Description and Risk of Bias of Studies**

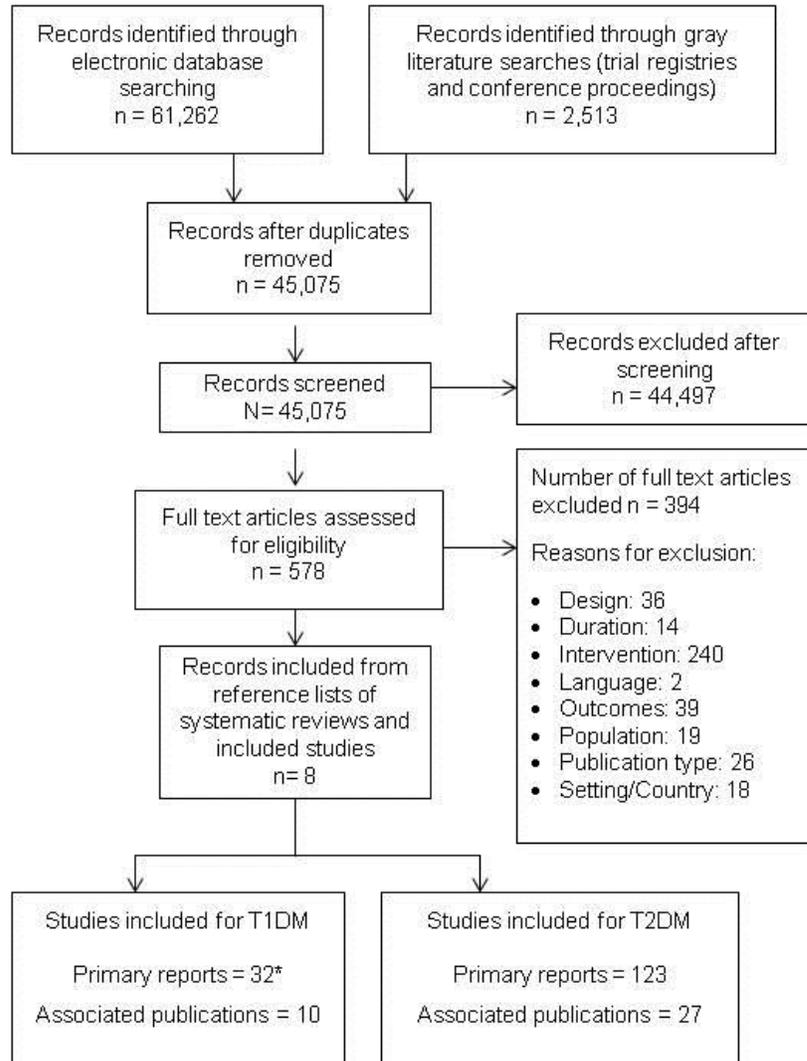
Twenty-three studies were conducted in youth; nine were conducted in adults. Most trials were two-arm trials comparing DSME to usual care.

The total duration of the behavioral programs for youth ranged from 1.5–25 months (median=6). The number of contact hours ranged from 2–48 hours (median=8). Five trials delivered the programs to youth only; 16 delivered the programs to both youth 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 1.5–12 months (median=6 months), and the number of contact hours ranged from 9–52 hours (median=16). 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 a moderate of high overall low risk of bias. For objective outcomes (e.g., HbA<sub>1c</sub>), 55 percent of trials had a medium (unclear) risk of bias and 45 percent had a high risk. The assessment of high risk was largely driven by incomplete outcome data (i.e., loss to followup). For subjective outcomes (e.g., health-related quality of life [HRQL]), all but two trials had a high risk of bias (93 percent). This was primarily due to lack of blinding of participants, study personnel, and outcome assessors.

**Figure C. Flow diagram of study retrieval and selection**



\* One study was included for both T1DM and T2DM

## **Type 1 Diabetes Mellitus: Results for Key Questions 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.

There was moderate SOE showing reduction in hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) at 6-month postintervention followup with percent HbA<sub>1c</sub> reduced by 0.33 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<sub>1c</sub>; 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<sub>1c</sub> of 0.43 percent at 6-month postintervention followup. There was no difference in HbA<sub>1c</sub> 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 any followup timepoint. For generic health-related quality of life, there was low SOE of no difference at the end of intervention. There was insufficient SOE for other key outcomes (i.e., micro- or macrovascular complications, changes to body composition, changes to dietary intake or physical activity).

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; our meta-analysis found a 17 percent increased 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 <sub>1c</sub>	EOI	15 (1,097)	MD, -0.11; 95% CI, -0.35 to 0.13	Low for no difference
HbA <sub>1c</sub>	6m followup	11 (1,316)	MD, -0.33; 95% CI, -0.51 to -0.15	Moderate for benefit
HbA <sub>1c</sub>	12m followup	6 (1,186)	MD, -0.21; 95% CI, -0.54 to 0.12	Low for no difference
HbA <sub>1c</sub>	≥12m followup	4 (1,138)	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 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 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 difference
Adherence to diabetes self-management	12m followup	1 (54); DSMP 1 (180); 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 1 (190); 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)	EOI	1 (60)	MD, 0.08; 95% CI, -0.35 to 0.51	Insufficient
Change in body composition (BMI)	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	EOI	1 (43)	MD, 0.59; 95% CI, 0.22 to 0.96	Insufficient

Outcome	Outcome Timing	# Trials (# Subjects); Tool if Applicable	Mean Difference or Standardized Mean Difference	Strength of Evidence
(fitness – VO <sub>2</sub> max)				
Change in physical activity (intensity/duration)	EOI	2 (91)	SMD, 0.16; 95% CI, -0.25 to 0.57	Insufficient
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 (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	6 (419)	SMD, 0.15; 95% CI, -0.16 to 0.46	Low 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	1 (26)	SMD, -0.77; 95% CI, -1.57 to 0.04	Insufficient
Diabetes-specific quality of life	EOI	1 (131)	SMD, 0.44; 95% CI, 0.08 to 0.81	Insufficient

BMI = body mass index; CI = confidence interval; DSMP = Diabetes Self-Management Profile; EOI = end of intervention; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; HRQL = health-related quality of life; MD = mean difference; SDSCA = Summary of Diabetes Self-Care Activities; SMBG = self-monitoring of blood glucose (frequency); SMD = standardized mean 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 <sub>1c</sub>	EOI	4 (566)	MD, -0.32; 95% CI, -0.78 to 0.14	Low for no difference
HbA <sub>1c</sub>	6m followup	4 (504)	MD, -0.43; 95% CI, -0.62 to -0.24	Moderate for benefit
HbA <sub>1c</sub>	12m followup	3 (342)	MD, -0.34; 95% CI, -0.71 to 0.03	Low for no 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; DSMP = Diabetes Self-Management Profile; EOI = end of intervention; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; MD = mean difference; SMBG = self-monitoring of blood glucose (frequency); SMD = standardized mean difference

For KQ 2, the effectiveness of behavioral programs compared with usual care for HbA<sub>1c</sub> appeared higher for adults than for youth at end of intervention. The effectiveness of behavioral programs compared with active controls appeared higher for youth than for adults at 12-month

followup, but few studies were included in the pooled results for these subgroups. One trial reported results separately for youth with baseline HbA<sub>1c</sub> ≥ 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<sub>1c</sub> > 8.5 percent). No trials reported on HbA<sub>1c</sub> by race or ethnicity, socioeconomic status, or time since diagnosis.

For KQ 3, none of the program factors (e.g., intensity, delivery personnel) was shown to significantly influence the effectiveness of behavioral programs compared with usual care on HbA<sub>1c</sub>. No studies reported on the associated harms (i.e. activity-related injury) of behavioral programs (KQ 4).

## **Type 2 Diabetes Mellitus: Description and Risk of Bias of Studies**

The majority of RCTs were two-arm trials, with many comparing DSME with usual care (51 trials) or an active control (7 trials); 15 two- and three-arm trials were included, as were several trials comparing two different behavioral programs (20 trials). Trials were conducted in 16 countries but the majority (63 percent) were undertaken in the United States. Several trials evaluated more than one behavioral program; there were 156 intervention arms in total. The mean age of the participants was between 45 and 72 years (median=58). Baseline HbA<sub>1c</sub> was between 6.3 and 12.3 percent (median=8 percent). Median duration of diabetes was 8.1 years (range 1-18 years).

Overall, median program duration was 6 months (range 1–96) and median number of contact hours was 12 (range 1–208). Fifty nine programs were delivered to individuals only, 54 to groups only, and 42 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.

None of the trials were assessed as having an overall low risk of bias. For objective outcomes (e.g., HbA<sub>1c</sub>), 42 percent of trials had a medium (unclear) 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). For subjective outcomes (e.g., HRQL), 14 percent had a medium risk of bias; the remainder (86 percent) had a high risk of bias. This was primarily due to lack of blinding of participants, study personnel, and outcome assessors.

## **Type 2 Diabetes Mellitus: Overall Effectiveness of Behavioral Programs, and Results for Key Questions 5 and 6**

### **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, in the short-term (up to 6 months) for glycemic control; however, results at 12-month followup were not statistically significant and none of the results were considered to be clinically important based on our identified threshold of a 0.4 percent change in HbA<sub>1c</sub>. 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, moderate the effects.

Behavioral programs showed some benefits in terms of reducing BMI (0.2-0.9 kg/m<sup>2</sup> to 12-month followup, weight (1.4-1.9 kg) and waist circumference (3cm) [short-term], and daily energy intake (120 kilocalories per day at 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. Results for Diabetes Distress 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% in participants receiving a  $\geq 8$  year-long intensive lifestyle program compared with didactic education and support in the largest trial, conducted by the LookAHEAD research group.<sup>57</sup> Mortality between behavioral programs and active control groups (4 RCTs; 5,949 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 (20 RCTs, 4,775 participants; RR, 1.32; 95% CI, 0.82 to 2.21).

## **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<sub>1c</sub> above our threshold for clinical importance (i.e. 0.4 percent) represented all three major program component categories of DSME, DSME and support, and lifestyle. The effect sizes of all minimally intensive DSME programs ( $\leq 10$  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). 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 ( $\geq 10$  contact hours). Table D summarizes the results of the network meta-analysis for HbA<sub>1c</sub>.

**Table D. Results of the network meta-analysis for HbA<sub>1c</sub>: Nodes in rank order with description of associated program factors and mean differences in effect relative to usual care**

Category of Components	Node	Intensity	Method of Communication	Delivery Method	Delivery Personnel	Rank Order in NMA	MD, 95% Credibility Interval (%HbA <sub>1c</sub> )
DSME	15	$\geq 27$ h	In person	Group only	HCP	1	-1.35 [-2.07, -0.65]
Lifestyle	32	$\geq 27$ h	In person	Individual & mixed	NA	2	-1.14 [-1.92, -0.38]
Lifestyle	30	11-26h	Some technology	Individual & mixed	NA	3	-0.90 [-1.75, -0.05]
DSME + Support	24	$\geq 27$ h	In person	Group only	NA	4	-0.89 [-1.89, 0.12]
DSME	13	11-26h	Some technology	Individual & mixed	Non-HCP	5	-0.78 [-1.61, 0.06]
DSME + Support	21	11-26h	In person	Group only	NA	6	-0.74 [-1.59, 0.10]
DSME	14	$\geq 27$ h	In person	Individual & mixed	HCP	7	-0.73 [-1.92, 0.47]
DSME + Support	17	$\leq 10$ h	In person	Individual & mixed	NA	8	-0.70 [-1.86, 0.46]
Lifestyle	29	11-26h	In person	Group only	NA	9	-0.67 [-1.27, -0.08]
DSME + Support	23	$\geq 27$ h	In person	Individual & mixed	NA	10	-0.54 [-1.32, 0.24]

Lifestyle	<b>28</b>	11-26h	In person	Individual & mixed	NA	<b>11</b>	-0.47 [-1.01, 0.08]
DSME	<b>16</b>	≥27h	Some technology	Individual & mixed	HCP	<b>12</b>	-0.46 [-1.71, 0.80]
Lifestyle	<b>26</b>	≤10h	In person	Group only	NA	<b>13</b>	-0.44 [-1.41, 0.52]
DSME + Support	<b>20</b>	11-26h	In person	Individual & mixed	NA	<b>14</b>	-0.40 [-1.77, 0.97]
DSME + Support	<b>22</b>	11-26h	Some technology	Individual & mixed	NA	<b>15</b>	-0.39 [-1.11, 0.31]
<b>Active comparator (e.g., dietary or physical activity intervention)</b>	<b>3</b>	NA	NA	NA	NA	<b>16</b>	-0.38 [-0.93, 0.16]
DSME + Support	<b>19</b>	≤10h	Some technology	Individual & mixed	NA	<b>17</b>	-0.38 [-1.02, 0.26]
Lifestyle	<b>34</b>	≥27h	Some technology	Individual & mixed	NA	<b>18</b>	-0.31 [-1.16, 0.52]
DSME	<b>4</b>	≤10h	In person	Individual & mixed	HCP	<b>19</b>	-0.30 [-0.66, 0.06]
DSME	<b>11</b>	11-26h	In person	Group only	Non-HCP	<b>20</b>	-0.28 [-0.79, 0.24]
DSME	<b>12</b>	11-26h	Some technology	Individual & mixed	HCP	<b>21</b>	-0.25 [-0.82, 0.32]
DSME	<b>10</b>	11-26h	In person	Group only	HCP	<b>22</b>	-0.24 [-0.55, 0.08]
DSME	<b>5</b>	≤10h	In person	Group only	HCP	<b>23</b>	-0.22 [-0.63, 0.19]
Lifestyle	<b>31</b>	11-26h	Some technology	Group only	NA	<b>24</b>	-0.20 [-1.34, 0.93]
DSME	<b>8</b>	≤10h	Some technology	Individual & mixed	Non-HCP	<b>25</b>	-0.15 [-0.55, 0.23]
DSME	<b>7</b>	≤10h	Some technology	Individual & mixed	HCP	<b>26</b>	-0.15 [-0.63, 0.31]
DSME	<b>9</b>	11-26h	In person	Individual & mixed	HCP	<b>27</b>	-0.15 [-0.83, 0.53]
DSME	<b>6</b>	≤10h	In person	Group only	Non-HCP	<b>28</b>	-0.05 [-1.32, 1.23]
Lifestyle	<b>33</b>	≥27h	In person	Group only	NA	<b>29</b>	0.08 [-0.71, 0.87]
<b>Active comparator (non-DSME)</b>	<b>2</b>	NA	NA	NA	NA	<b>30</b>	0.14 [-0.24, 0.52]
Lifestyle	<b>25</b>	≤10h	In person	Individual & mixed	NA	<b>31</b>	0.21 [-0.53, 0.96]
Lifestyle	<b>27</b>	≤10h	Some technology	Individual & mixed	NA	<b>32</b>	0.26 [-1.14, 1.66]
DSME + Support	<b>18</b>	≤10h	In person	Group only	NA	<b>33</b>	2.80 [1.14, 4.48]

The nodes (representing groupings of programs) are sorted by rank order (highest to lowest effect sizes), and each node is categorized by the components and features of the programs evaluated by the associated trials. The highlighted nodes have a rank order of ≤14 and effect sizes at or above our threshold for clinical importance. When choosing which variables to consider for creating the nodes, we used a hierarchical approach based on the categories in Table A. 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 decided to use four additional variables (i.e. intensity, method of communication, delivery method, and delivery personnel) to create 24 potential nodes (16 which contained data from 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.

DSME = diabetes self-management education; h = hours; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; HCP = health care professional; MD = mean difference; NA=not applicable; NMA = network meta-analysis

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). Behavioral programs changed BMI by -1.75 kg·m<sup>2</sup> to 3.31 kg·m<sup>2</sup>. Lifestyle programs resulted in the highest effect sizes for BMI. Program intensity appeared less important than method of delivery; providing some in-person delivery appears beneficial.

## **KQ 6. Subgroups for Factors Moderating Effectiveness in T2DM**

In terms of overall effectiveness at longest followup for HbA<sub>1c</sub>, participants with suboptimal glycemic control ( $\geq 7$  percent HbA<sub>1c</sub>) 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 (via a network meta-analysis) potential moderation by program factors in a subgroup of studies having participants with suboptimal baseline glycemic control.

Older adults ( $\geq 65$  years) did not benefit at longest followup in terms of reduction in HbA<sub>1c</sub> 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. There was little change in the findings of the network meta-analysis when based on the studies where the mean age was  $< 65$  years.

Programs offered to predominantly minority participants ( $\geq 75$  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. 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<sub>1c</sub>. In line with our results for KQ 5, results for the variable of program intensity approached statistical significance ( $p=0.082$ ).

## **Discussion**

### **Type 1 Diabetes**

Overall, behavioral programs have some benefit in T1DM for reducing HbA<sub>1c</sub> when followup extends beyond the immediate postintervention period up to 6 months. The delay in benefit likely in part reflects the time required for this marker of glycemic control, indicating control over the past 2 to 3 months, to demonstrate change. 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 difference in self-management behaviors at any followup timepoint do not support this hypothesis. These beneficial findings for HbA<sub>1c</sub> appear to be tempered by those of no difference at longer followup timepoints ( $\geq 12$  months), although we are unable to confidently rule out benefit at long-term followup.

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 youth with T1DM did not significantly impact study results.<sup>58</sup>

Our finding of a statistically significant and clinically important reduction by 0.43 percent HbA<sub>1c</sub> at 6-month followup for comparisons between behavioral programs and active controls is 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. 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 in HbA<sub>1c</sub> at other timepoints, and the lack of sufficient evidence supporting conclusions for many 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.<sup>59-62</sup> For these reasons, many of the studies included in this review aimed to prevent deterioration of glycemic control rather than to improve it. The clinically important reductions in HbA<sub>1c</sub> at 6- and 12-month followup (0.60 and 0.54 percent, respectively) when behavioral programs were compared with active controls in youth lend substantial support for these programs.

Due to insufficient data, we were unable to examine the difference between educational and lifestyle programs, or the addition of a support component to DSME programs.

## **Type 2 Diabetes**

Moderate and high intensity ( $\geq 11$  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 beneficial.

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. Our review also confirms previous suggestions that programs with an interactive nature, employing behavioral approaches and covering multiple behaviors, 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. In contrast, our pair-wise meta-analysis of three RCTs (701 subjects) comparing group to individual program delivery favored group therapy. Delivery format may be highly dependent upon the population served and program content. Studies having high effect sizes which offered programs in groups tended to be those offered to minorities 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. Drawing from the pair-wise meta-analysis of five RCTs (647 subjects) comparing two or more interventions, there may be no difference when program delivery is conducted by health care professionals or by lay providers (e.g., peers with diabetes, community

health workers). 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.

Our findings suggest that people with suboptimal, or poor, baseline glycemic control ( $\geq 7$  percent HbA<sub>1c</sub>), 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 ethnicity (i.e., 8.8 percent HbA<sub>1c</sub> in the  $\geq 75\%$  minority group vs. 7.6 percent in the HbA<sub>1c</sub> <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 is some evidence that ethnicity may be an independent predictor, based on genetic and contextual factors. 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. Ethnic minority groups have also been shown to have higher HbA<sub>1c</sub> 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.<sup>63</sup> Our reliance on study-level data to create subgroups (i.e., the entire study population was 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**

For most studies (70 percent), the mean HbA<sub>1c</sub> was over 8.5 percent; therefore, the results of this report may be most applicable to individuals with poor glycemic control. Nevertheless, 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. 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. For studies targeting adults, the mean age across studies ranged from 30 to 49 years. No studies specifically targeted older adults ( $\geq 65$  years).

The mean duration of diabetes ranged from 2.7 to 7.3 years among studies that targeted youth, and 2.5 to 23 years for those targeting adults. It is unclear whether the results are applicable to youth 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 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 (73 percent) were conducted in the United States; the remaining studies were conducted in Europe. 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<sub>1c</sub> in the included RCTs was 6.3-12.3 percent (median=8) which would appear to make the results applicable to the majority of people enrolling in behavioral programs. Subgroup analyses based on baseline glycemic control (< vs. ≥7 percent HbA<sub>1c</sub>) provided some insight into the relative effectiveness based on this patient variable; behavioral programs appear to be more effective for people with suboptimal or poor glycemic control.

The range of mean ages in the included studies was 45 to 75 years (median=58), therefore the results are most applicable to middle- and older-aged adults. Subgroup analyses based on age (<65 vs. ≥65 years) provided some data on the relative effectiveness for these age groups; adults ≥65 years of age do not seem to obtain as much benefit in glycemic control as do younger adults. 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 regimes (19.2 percent were on insulin). Overall, there was fairly good representation of individuals reporting a minority racial/ethnic background. Subgroup analysis for race/ethnicity (21 comparisons for <75 minorities vs. 31 comparisons for ≥ minorities) showed that minorities may benefit more for glycemic control.

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<sup>47</sup> 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**

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. Our pre-specified 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 percent) from those not having restrictions.<sup>64</sup> 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. Some of our statistical analyses indicated substantial heterogeneity, and this supported our analyses in KQs 5 and 6 to determine some of the factors leading to variability in success for behavioral programs.

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 was limited data available to assess the strength of evidence for many outcomes, including behavioral outcomes related to changes in dietary intake or physical activity, and clinical and health outcomes apart from HbA<sub>1c</sub>. 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<sub>1c</sub> and to univariate meta-regressions.

For KQs 5 and 6 related to T2DM, our network meta-analysis allowed for multiple comparisons (i.e., no restriction to usual care or active control comparators) but there were still too few studies reporting on outcomes besides HbA<sub>1c</sub> and BMI. 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. Several outcomes of importance to patients and policymakers, such as quality of life, development of complications, and health care utilization, were reported by too 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 risk of bias. Blinding of participants and personnel, or outcome assessors, was rarely reported or sufficient. These two domains resulted in medium or high risk of bias being assigned for most trials for their subjective outcomes. 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., only reporting on results for completers) and/or from high participant attrition. Some studies had small sample sizes and accordingly failed to achieve baseline comparability in their samples. Although we analyzed change from baseline scores when able, the differential effect of behavioral programs based on these baseline imbalances (e.g., HbA<sub>1c</sub>, age)—as suggested by our subgroup analyses—cannot be ruled out.

## Research Gaps

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

**Table E. Potential research needs, by Key Question**

KQ	Potential Research Needs
1	There was limited data for assessing the SOE for 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	There was insufficient evidence to demonstrate whether lifestyle programs 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.

<b>KQ</b>	<b>Potential Research Needs</b>
<b>1 &amp; 3</b>	The effectiveness of a support component added to programs in T1DM is unknown. These may be useful for more fully address some of the psychosocial aspects of the disease (particularly in adolescents), thereby increasing the effectiveness of behavioral programs.
<b>3</b>	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.
<b>3</b>	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 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.
<b>3 &amp; 5</b>	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.
<b>5</b>	The correct mix of providers (e.g., physician, nurse, dietitian, pharmacists, social workers, psychologist, and trained lay individuals) for implementation of behavioral programs for T2DM deserves further evaluation.
<b>5</b>	The impact of training level for health care professionals—apart from clinical psychologists—on outcomes from behavioral programs employing advanced behavioral approaches needs further investigation.
<b>5</b>	Few trials directly compared interactive programs delivered in person to those delivered via technology. Because a technology-based approach may lessen resource burden and help to reach patients living in rural areas, its effectiveness needs further evaluation.
<b>6</b>	Trials including populations of diverse ages and ethnic backgrounds should perform subgroup analysis based on age and ethnicity 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.
<b>All</b>	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.
<b>All</b>	Study attrition rates affected the overall risk of bias substantially; more research on methods for maintaining study participation is required.
<b>All</b>	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 requires some mechanism to blind participants from the study hypothesis. Blinding of outcome assessors should always be attempted for subjective outcomes.
<b>All</b>	There is a need for consensus in the field on what constitutes clinically important differences for patient important outcomes in the context of behavioral programs, such that outcomes can be interpreted in meaningful ways for clinicians, patients, and other decisionmakers.

## Conclusions

This systematic review suggests that behavioral programs (essentially DSME) for T1DM have some benefit on glycemic control when followup extends to 6 months after the program, but that more, good quality evidence is required to draw conclusions about long-term effects. The results showed no difference in generic quality of life at end of intervention, or for self-management behaviors at up to 6-month followup, although the SOE for these findings was low suggesting that results may change with additional research. Data was insufficient to draw conclusions for other outcomes including diabetes-specific quality of life, change in body composition or lifestyle behaviors, micro- and macrovascular complications, and mortality. Based on current evidence, it is unclear whether encouraging patients with T1DM to participate in behavioral programs will yield important benefits for most outcomes.

For T2DM, our analyses showed limited benefit in glycemic control from DSME programs offering  $\leq 10$  hours versus  $>10$  hours of contact with delivery personnel, and suggested that in-person delivery of behavioral programs is more beneficial than incorporation of technology. 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. Behavioral programs appear to benefit individuals having suboptimal or poor glycemic control more than those with good control. Tailoring programs to ethnic minorities—such as 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.

Efforts at integrating behavioral programs into care settings that incorporate the latest treatment 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 types of programs, should additional means be necessary to control their disease more adequately to prevent devastating complications.

## References

1. Renders CM, Valk GD, Griffin SJ, et al. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev.* 2000(4). PMID: 11279717.
2. Landon BE, Hicks LS, O'Malley AJ, et al. Improving the management of chronic disease at community health centers. *N Engl J Med.* 2007 Mar 1;356(9):921-34. PMID: 17329699.
3. Couch R, Jetha M, Dryden DM, et al. Diabetes education for children with type 1 diabetes mellitus and their families (structured abstract). Evidence Report/Technology Assessment No. 08-E011. Rockville, MD: Agency for Healthcare Research and Quality Database of Abstracts of Reviews of Effe, April, 2008. PMID: 18620470.
4. Gage H, Hampson SE, Skinner TC, et al. Educational and psychosocial programmes for adolescents with diabetes: approaches, outcomes and cost-effectiveness. *Patient Educ Couns.* 2004 Jun;53(3):333-46. PMID: 15186872.
5. Hood KK, Rohan JM, Peterson CM, et al. Interventions with adherence-promoting components in pediatric type 1 diabetes: meta-analysis of their impact on glycemic control. *Diabetes Care.* 2010 Jul;33(7):1658-64. PMID: 20587726.
6. Murphy HR, Rayman G, Skinner TC. Psycho-educational interventions for children and young people with type 1 diabetes. *Diabet Med.* 2006 Sep;23(9):935-43. PMID: 16922699.
7. Urban AD, Berry D, Grey M. Optimizing outcomes in adolescents with type 1 diabetes and their families. *Journal of Clinical Outcomes Management.* 2004;11(5):299-306. PMID: Not available.
8. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2014. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2014 [cited 2014 Nov. 27]; <http://www.cdc.gov/diabetes/data/statistics/2014statisticsreport.html>.
9. Search for Diabetes in Youth Study Group. The burden of diabetes mellitus among us youth: prevalence estimates from the search

- for diabetes in youth study. *Pediatrics*. 2006 Oct;118(4):1510-8. PMID: 17015542.
10. Dall TM, Zhang Y, Chen YJ, et al. The economic burden of diabetes. *Health Affairs*. 2010 Feb;29(2):297-303. PMID: 20075080.
  11. Centers for Disease Control and Prevention. Diabetes Report Card 2012. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2012 [cited 2013 Nov 15]; <http://www.cdc.gov/diabetes/pubs/pdf/diabetesreportcard.pdf>.
  12. Bystritsky A, Danial J, Kronemyer D. Interaction between diabetes and anxiety and depression: implications for treatment. *Endocrinol Metab Clin N Am*. 2014;43(1):269-83. PMID: 24582102.
  13. American Diabetes Association. Standards of medical care in diabetes--2014. *Diabetes Care*. 2014 Jan;37 Suppl 1:S14-80. PMID: 24357209.
  14. Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993 Sep 30;329(14):977-86. PMID: 8366922.
  15. Nathan DM. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: overview. *Diabetes Care*. 2014 Jan;37(1):9-16. PMID: 24356592.
  16. Orchard TJ, Nathan DM, Zinman B, et al. Association between 7 years of intensive treatment of type 1 diabetes and long-term mortality. *JAMA*. 2015 Jan 6;313(1):45-53. PMID: 25562265.
  17. Fullerton B, Jeitler K, Seitz M, et al. Intensive glucose control versus conventional glucose control for type 1 diabetes mellitus. *Cochrane Database Syst Rev*. 2014;2:CD009122. PMID: 24526393.
  18. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998 Sep 12;352(9131):837-53. PMID: 9742976.
  19. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet*. 1998 Sep 12;352(9131):854-65. PMID: 9742977.
  20. Hemmingsen B, Lund SS, Gluud C, et al. Targeting intensive glycaemic control versus targeting conventional glycaemic control for type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2013;11:CD008143. PMID: 24214280.
  21. Colhoun HM, Betteridge DJ, Durrington PN, et al. Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the collaborative atorvastatin diabetes study (cards): multicentre randomised placebo-controlled trial. *Lancet*. 2004 Aug 21-27;364(9435):685-96. PMID: 15325833.
  22. Heart Protection Study Collaborative Group. MRC/BHF heart protection study of cholesterol-lowering with simvastatin in 5963 people with diabetes: a randomised placebo-controlled trial. *Lancet*. 2003 Jun 14;361(9374):2005-16. PMID: 12814710.
  23. UK Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. *BMJ*. 1998;317(7160):703-13. PMID: Not available.
  24. Lv J, Neal B, Ehteshami P, et al. Effects of intensive blood pressure lowering on cardiovascular and renal outcomes: a systematic review and meta-analysis. *PLoS Med*. 2012;9(8):e1001293. PMID: 22927798.
  25. Griffin S. Diabetes care in general practice: meta-analysis of randomised control trials. *Bmj*. 1998 Aug 8;317(7155):390-6. PMID: 9694757.
  26. Tomky D, Cypress M, Dang D, et al. AADE7 self-care behaviors. *Diabetes Educ*. 2008 May-Jun;34(3):445-9. PMID: 18535317.
  27. Funnell M. Beyond the data: moving towards a new dawn in diabetes. *Diabet Med*. 2013 Jul;30(7):765-6. PMID: 23710971.
  28. Knight KM, Dornan T, Bundy C. The diabetes educator: trying hard, but must

- concentrate more on behaviour. *Diabet Med.* 2006;23(5):485-501. PMID: 16681557.
29. Norris SL, Zhang X, Avenell A, et al. Long-term effectiveness of lifestyle and behavioral weight loss interventions in adults with type 2 diabetes: a meta-analysis. *Am J Med.* 2004 Nov 15;117(10):762-74. PMID: 15541326.
  30. Haas L, Maryniuk M, Beck J, et al. National standards for diabetes self-management education and support. *Diabetes Care.* 2013;36(Supplement 1):S100-S8. PMID: 23264420.
  31. International Diabetes Federation. Position Statement: Self-management Education. Brussels, Belgium: International Diabetes Federation; 2011 [cited 2013 Nov. 15]; <http://www.idf.org/education/self-management-education>.
  32. Jones H, Berard LD, Macneill G, et al. Clinical practice guidelines: self-management education. *Can J Diabetes.* 2013;37(Suppl. 1):S26-S30. PMID: 24070958.
  33. National Institute for Health and Clinical Excellence. The management of type 2 diabetes. In: National Institute for Excellence in Health Care, editor. London: National Collaborating Centre for Chronic Conditions, Centre for Clinical Practice; 2010.
  34. Schellenberg ES, Dryden DM, Vandermeer B, et al. Lifestyle interventions for patients with and at risk for type 2 diabetes: a systematic review and meta-analysis. *Ann Intern Med.* 2013 Oct 15;159(8):543-51. PMID: 24126648.
  35. Hoerger TJ, Segel JE, Gregg EW, et al. Is glycemic control improving in u.S. Adults? *Diabetes Care.* 2008 Jan;31(1):81-6. PMID: 17934153.
  36. Funnell MM. The Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Clinical Diabetes.* 2006;24(4):154-5. PMID: Not available.
  37. Chodosh J, Morton SC, Mojica W, et al. Meta-analysis: chronic disease self-management programs for older adults. *Ann Intern Med.* 2005 Sep 20;143(6):427-38. PMID: 16172441.
  38. Deakin T, Mcshane CE, Cade JE, et al. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev.* 2005(2):CD003417. PMID: 15846663.
  39. Fan L, Sidani S. Effectiveness of diabetes self-management education intervention elements: a meta-analysis. *Can J Diabetes.* 2009;33(1):18-26. PMID: Not available.
  40. Gary TL, Genkinger JM, Guallar E, et al. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educ.* 2003 May-Jun;29(3):488-501. PMID: 12854339.
  41. Medical Advisory Secretariat. Behavioural interventions for type 2 diabetes: an evidence-based analysis. *Ont Health Technol Assess Ser.* 2009;9(21):1-45. PMID: 23074526.
  42. Minet L, Moller S, Vach W, et al. Mediating the effect of self-care management intervention in type 2 diabetes: a meta-analysis of 47 randomised controlled trials. *Patient Educ Couns.* 2010 Jul;80(1):29-41. PMID: 19906503.
  43. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care.* 2002 Jul;25(7):1159-71. PMID: 12087014.
  44. Warsi A, Wang PS, Lavalley MP, et al. Self-management education programs in chronic disease: a systematic review and methodological critique of the literature. *Arch Intern Med.* 2004 Aug 9-23;164(15):1641-9. PMID: 15302634.
  45. Ellis SE, Speroff T, Dittus RS, et al. Diabetes patient education: a meta-analysis and meta-regression. *Patient Educ Couns.* 2004 Jan;52(1):97-105. PMID: 14729296.
  46. Glazier RH, Bajcar J, Kennie NR, et al. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care.* 2006 Jul;29(7):1675-88. PMID: 16801602.
  47. Malik K, Human Development Report 2013 Team. Human Development Report 2013. The rise of the south: human progress in a diverse world. N.Y., New York: United Nations Development Programme 2013.

48. Higgins JP, Green S. Section 8. Assessing risk of bias in included studies. The Cochrane Collaboration; 2011. <http://handbook.cochrane.org> Last accessed March 4, 2014.
49. Wells GA, Shea B, O'Connell D, et al. The Newcastle-Ottawa scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. 2000. [http://www.ohri.ca/programs/clinical\\_epidemiology/oxford.asp](http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp). Last accessed Feb 10, 2015.
50. Ip S, Hadar N, Keefe S, et al. A web-based archive of systematic review data. *Systematic Reviews*. 2012;1:15. PMID: 22588052.
51. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. Guidance for industry diabetes mellitus: developing drugs and therapeutic biologics for treatment and prevention. 2008: <http://www.fda.gov/downloads/Drugs/Guidances/ucm071624.pdf>. Last accessed May 27, 2014.
52. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Med Care*. 2003 May;41(5):582-92. PMID: 12719681.
53. Revicki D, Hays RD, Cella D, et al. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *J Clin Epidemiol*. 2008 Feb;61(2):102-9. PMID: 18177782.
54. Inthout J, Ioannidis JP, Borm GF. The Hartung-Knapp-Sidik-Jonkman method for random effects meta-analysis is straightforward and considerably outperforms the standard Dersimonian-Laird method. *BMC Med Res Methodol*. 2014;14:25. PMID: 24548571.
55. Sidik K, Jonkman JN. A simple confidence interval for meta-analysis. *Stat Med*. 2002 Nov 15;21(21):3153-9. PMID: 12375296.
56. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication No. 10(14)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality. January 2014.
- Chapters available at [www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)
57. Knowler WC. Impact of a lifestyle intervention on diabetes control and microvascular complications. American Diabetes Association 73rd Scientific Sessions; 2013 June; Chicago, IL.
58. Ayling K, Brierley S, Johnson B, et al. How standard is standard care? Exploring control group outcomes in behaviour change interventions for young people with type 1 diabetes. *Psychol Health*. 2015 Jan;30(1):85-103. PMID: 25118842.
59. Court JM, Cameron FJ, Berg-Kelly K, et al. Diabetes in adolescence. *Pediatr Diabetes*. 2009 Sep;10 Suppl 12:185-94. PMID: 19754629.
60. Ingerski LM, Anderson BJ, Dolan LM, et al. Blood glucose monitoring and glycemic control in adolescence: contribution of diabetes-specific responsibility and family conflict. *J Adolesc Health*. 2010 Aug;47(2):191-7. PMID: 20638012.
61. Schilling LS, Knafl KA, Grey M. Changing patterns of self-management in youth with type I diabetes. *J Pediatr Nurs*. 2006 Dec;21(6):412-24. PMID: 17101399.
62. Peters A, Laffel L. Diabetes care for emerging adults: recommendations for transition from pediatric to adult diabetes care systems: a position statement of the American Diabetes Association, with representation by the American College of Osteopathic Family Physicians, the American Academy of Pediatrics, the American Association of Clinical Endocrinologists, the American Osteopathic Association, the Centers for Disease Control and Prevention, Children with Diabetes, the Endocrine Society, the International Society for Pediatric and Adolescent Diabetes, Juvenile Diabetes Research Foundation International, the National Diabetes Education Program, and the Pediatric Endocrine Society (formerly Lawson Wilkins Pediatric Endocrine Society). *Diabetes Care*. 2011 Nov;34(11):2477-85. PMID: 22025785.
63. Herman WH, Dungan KM, Wolffenbutter BH, et al. Racial and ethnic differences in mean plasma glucose, hemoglobin A1c, and 1,5-anhydroglucitol in over 2000 patients with type 2 diabetes. *J Clin Endocrinol*

Metab. 2009 May;94(5):1689-94. PMID:  
19276235.

64. Moher D, Pham B, Klassen TP, et al. What contributions do languages other than english make on the results of meta-analyses? J Clin Epidemiol. 2000 Sep;53(9):964-72. PMID: 11004423.

# 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.<sup>1</sup> However, an evaluation of initiatives to implement guidelines and processes of care in community health centers did not find improved control of hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels for patients with diabetes.<sup>2</sup>

Approaches for supporting diabetic patients to change behaviors include interventions such as diabetes self-management education (DSME) with or without added support, 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.<sup>3-7</sup> 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."<sup>8</sup> 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.<sup>8</sup> 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.<sup>8,9</sup> 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 (diagnosed and undiagnosed). This represents 9.3 percent of the entire population and 12.3 percent of the adult population (20 years or older).<sup>9</sup> About 208,000 people younger than 20 years had diagnosed diabetes in 2012.<sup>9</sup> 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 diabetes compared to non-Hispanic whites.<sup>9</sup>

Specific to T1DM, non-Hispanic white youth are affected more often than all other racial or ethnic groups.<sup>10</sup>

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<sup>2, 11</sup> and poorer diabetes outcomes for both T1DM and T2DM.<sup>12-14</sup>

Diabetes-related care accounts for 11 percent of all U.S. health care expenditure<sup>15</sup> equating to \$245 billion in total costs in 2012.<sup>9</sup> Average medical expenses are more than twice as high for a person with diabetes as they are for someone without diabetes.<sup>16</sup>

Complications from diabetes include cardiovascular disease, retinopathy, neuropathy, nephropathy, and cerebrovascular disease, as well as comorbidities such as depression and other mental health conditions.<sup>17</sup> 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.<sup>15</sup> 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.<sup>9</sup>

## **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.<sup>18</sup> 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 (EDIC) study.<sup>19, 20</sup> Recently, these findings have extended to demonstrate reduced mortality.<sup>21</sup> 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.<sup>22</sup>

People with T2DM are often treated progressively through diet (e.g., calorie and fat reduced while controlling carbohydrate intake) and then, if needed, one or more oral hypoglycemic medications. Many T2DM patients eventually require the addition (or sole use) of insulin to obtain good 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.<sup>23, 24</sup> 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.<sup>25</sup>

Reducing the risk for diabetes-related complications often requires lifestyle and/or pharmacological management of body weight, blood pressure, and cholesterol levels.<sup>18, 26-28</sup> For instance, intensive lowering of blood pressure has shown to reduce major cardiovascular events by 11%.<sup>29</sup> The responsibility for this extensive, multicomponent disease management falls to both the diabetes health care team and, most notably, the patient. Patients are encouraged to adopt and adhere to several self-care or self-management and lifestyle behaviors.<sup>30, 31</sup> For many,

a key behavior may be self-regulation of carbohydrate intake, physical activity and/or medication doses based on results of monitoring of blood glucose. In addition, 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.<sup>32-35</sup> 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.<sup>36</sup>

A critical element of diabetes care is education and support to enable patients to engage in self-care and self-management behaviors. 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.”<sup>37</sup> Because knowledge acquisition alone is not enough for behavioral changes,<sup>38,39</sup> 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.<sup>37,40-42</sup> 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.”<sup>40</sup> 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.<sup>33</sup>

Despite the availability of new medications and treatment 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<sup>43</sup> and few (as low as 16 percent<sup>44</sup>) patients carry out all self-management recommendations of their health care provider. 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.<sup>16</sup> 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).<sup>8</sup>

## **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.<sup>45-52</sup> 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,<sup>45, 47, 50, 53, 54</sup> and even fewer analyzed the data in a manner to assess multiple factors simultaneously<sup>53</sup>—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. For T2DM we built upon previous systematic reviews by identifying 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 demographics. This review will provide information regarding the effectiveness 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 as well as other programs incorporating interactive components that target multiple important behavioral changes (e.g., diet and physical activity) (see Appendix A). 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."<sup>55</sup> 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  $\geq 4$  weeks, to improve disease control and/or patient health outcomes, and consisting of at least one of: a) DSME; or 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).*

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.<sup>56</sup>

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 [ $\leq 18$  years] and their families, young adults [19-30 years], adults [31-64 years], older adults [ $\geq 65$  years])
- b. Race or ethnicity
- c. Socioeconomic status (e.g., family income, education level, literacy)
- d. Time since diagnosis ( $\leq 1$  year vs.  $> 1$  year)
- e. Level of glycemic control ( $HbA_{1c} < 7$  vs.  $\geq 7$  percent)

**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 [ $\geq 65$  years])
- b. Race or ethnicity
- c. Socioeconomic status (e.g., family income, education level, literacy)
- d. Time since diagnosis ( $\leq 1$  year vs.  $> 1$  year)
- e. Level of glycemic control ( $\text{HbA}_{1c} < 7$  vs.  $\geq 7$  percent)

## 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.

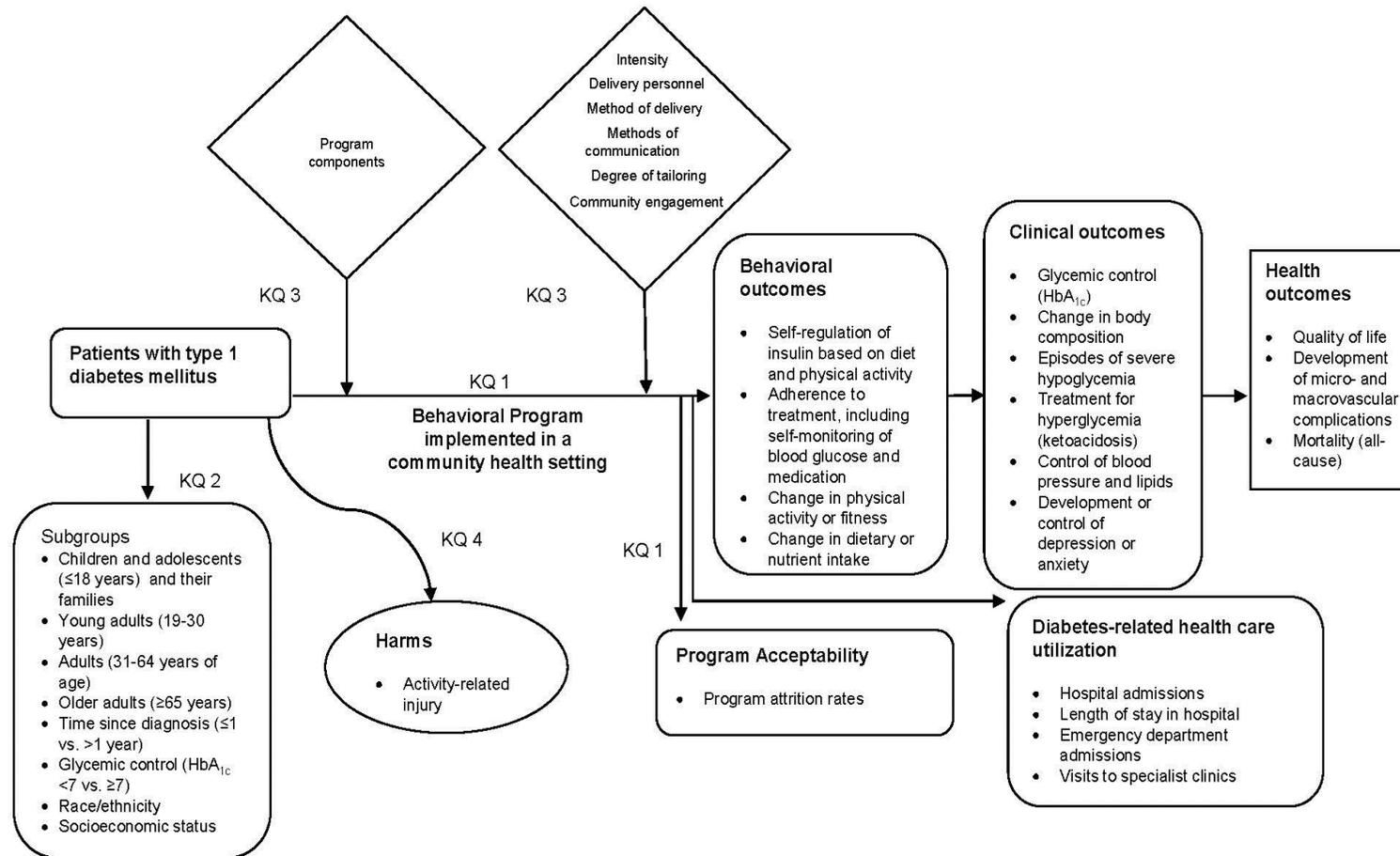
## Organization of This Report

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.

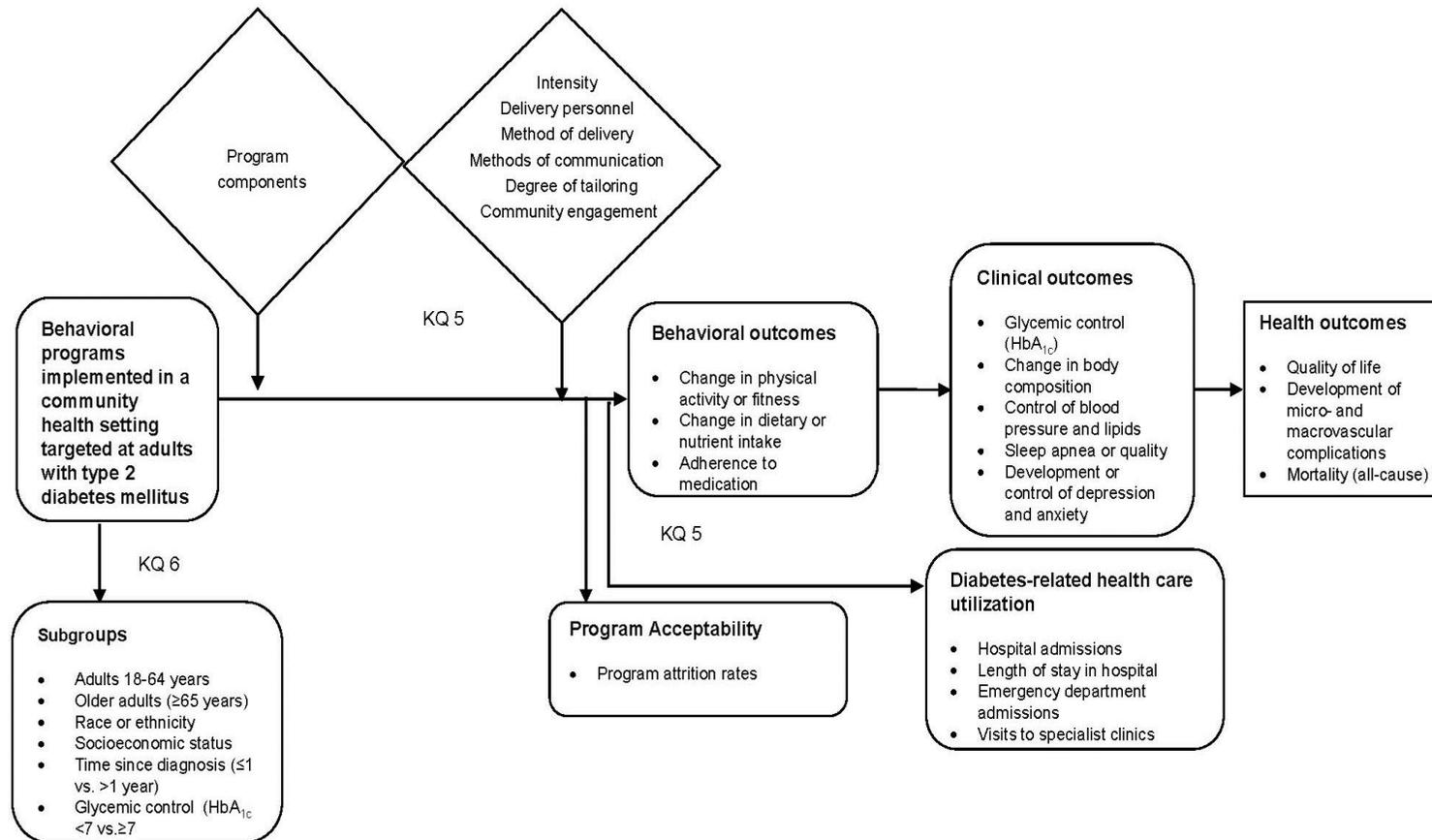
The report includes a number of appendices to provide further detail on our methods, the studies assessed, and the results not presented in the text. There is also reference to a supplementary file which may be accessed for additional information on the methods for study selection and risk of bias assessment,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

- Appendix A: Operational Definitions
- Appendix B: Literature Search Strategies
- Appendix C: Very High Human Development Index
- Appendix D: Excluded Studies
- Appendix E: Risk of Bias Assessments
- Appendix F: Summary Tables of Studies and Interventions
- Appendix G: Observational Study Results for T1DM
- Appendix H: Strength of Evidence Tables for T1DM
- Appendix I: Effectiveness of Behavioral Programs for T2DM Across Comparators and Outcomes
- 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

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



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



## 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).<sup>57</sup> The main sections in this chapter reflect the elements of the protocol established for the review.<sup>58</sup> 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.<sup>58</sup> 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, Scopus®, and PubMed® via the National Center for Biotechnology Information Databases.

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.<sup>59</sup> 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 the following trial registries: metaRegister of Controlled Trials (includes ClinicalTrials.gov, the International Standard Randomised Controlled Trial Number Register, Action Medical Research, the Wellcome Trust, and UK Trials) 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 (where available). When a protocol or abstract met our screening criteria, we 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.<sup>60</sup> 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.<sup>19, 28, 61</sup>

For T1DM, we included prospective comparative studies (i.e., RCTs, nonrandomized controlled trials [non-RCTs], prospective cohort studies, controlled before-after studies).<sup>62</sup> 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.<sup>63</sup> 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 of study participants, whether this was provided by the study investigators or other health care professionals; because medical care is so diverse between settings, these groups could receive a minimally intensive intervention such as provision of pamphlets or one individual session with an educator. Controls that were beyond usual care but not meeting our operational definition of a behavioral program were considered active controls (e.g., dietary intervention, 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)<sup>64</sup> or other quality improvement programs that incorporate strategies targeting health systems or providers.<sup>65</sup> 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 regimens 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)**

Population	<ul style="list-style-type: none"> <li>• Patients with T1DM (any age) who have undergone basic diabetes education</li> </ul>
Interventions	<ul style="list-style-type: none"> <li>• Multicomponent behavioral program that includes at least one of:               <ul style="list-style-type: none"> <li>- Diabetes self-management education; OR</li> <li>- Structured dietary intervention (related to any of weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; OR</li> <li>- Structured exercise/physical activity intervention together with one or more additional components.</li> <li>- 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).</li> </ul> </li> <li>• Repeated provision by one or more trained individuals</li> <li>• Duration of intervention: minimum 4 weeks</li> </ul>
Comparators	<ul style="list-style-type: none"> <li>• 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</li> <li>• Delivery methods (personnel, intensity, communication methods etc.) as reported for studies</li> </ul>
Outcomes	<ul style="list-style-type: none"> <li>• Behavioral outcomes               <ul style="list-style-type: none"> <li>- Self-regulation of insulin based on diet, physical activity, and glucose monitoring results</li> <li>- Change in physical activity (e.g., volume of activity per week) or fitness (e.g. cardiorespiratory fitness, strength)</li> <li>- Change in dietary or nutrient intake (i.e., energy intake, saturated fat consumption)</li> <li>- Adherence to treatment, including self-monitoring and medication</li> </ul> </li> <li>• Clinical outcomes               <ul style="list-style-type: none"> <li>- Glycemic control (HbA<sub>1c</sub>)</li> <li>- Change in body composition (i.e., weight, BMI, waist circumference, % body fat)</li> <li>- Episodes of severe hypoglycemia<sup>66</sup></li> <li>- Treatment for hyperglycemia (ketoacidosis)</li> <li>- Control of blood pressure and lipids</li> <li>- Development or control of depression or anxiety</li> </ul> </li> <li>• Health outcomes               <ul style="list-style-type: none"> <li>- Quality of life (e.g., validated tools for health-related quality of life, life satisfaction,</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>psychosocial adaptation to illness, patient satisfaction)</li> <li>- Development of micro- and macrovascular complications (i.e., retinopathy, nephropathy, neuropathy, cardiovascular outcomes)</li> <li>- Mortality (all-cause)</li> <li>• Diabetes-related health care utilization <ul style="list-style-type: none"> <li>- Hospital admissions</li> <li>- Length of stay in hospital</li> <li>- Emergency department admissions</li> <li>- Visits to specialist clinics</li> </ul> </li> <li>• Program acceptability as measured by participant attrition rates</li> <li>• Harms from program as reported for studies <ul style="list-style-type: none"> <li>- Activity-related injury</li> </ul> </li> </ul>
Timing	<ul style="list-style-type: none"> <li>• Any length of post-intervention followup</li> </ul>
Study design	<ul style="list-style-type: none"> <li>• 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</li> </ul>
Settings	<ul style="list-style-type: none"> <li>• Community health setting (i.e. ambulatory care clinics, outpatient clinics, primary care clinics, family physician clinics, Community Health Centers, Rural Health Centers)</li> <li>• United States or other high-income countries with a very high Human Development Index<sup>60</sup></li> </ul>
Language	<ul style="list-style-type: none"> <li>• English</li> </ul>

BMI = body mass index; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; T1DM = type 1 diabetes

**Table 2. Inclusion criteria for Type 2 diabetes (Key Questions 5-6)**

Population	<ul style="list-style-type: none"> <li>• Adults (≥18 years) with T2DM who have undergone primary diabetes education</li> </ul>
Interventions	<ul style="list-style-type: none"> <li>• Multicomponent behavioral programs that include at least one of: <ul style="list-style-type: none"> <li>- Diabetes self-management education; OR</li> <li>- Structured dietary intervention (related to any of weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; OR</li> <li>- Structured exercise/physical activity intervention together with one or more additional components.</li> <li>- 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).</li> </ul> </li> <li>• Repeated provision by one or more trained individuals</li> <li>• Duration of intervention: minimum 4 weeks</li> </ul>
Comparators	<ul style="list-style-type: none"> <li>• 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</li> <li>• Delivery methods (personnel, intensity, communication methods etc.) as reported for studies</li> </ul>
Outcomes	<ul style="list-style-type: none"> <li>• Behavioral outcomes <ul style="list-style-type: none"> <li>- Change in physical activity (e.g., volume of activity per week) or fitness (e.g., cardiorespiratory fitness, strength)</li> <li>- Change in dietary or nutrient intake (i.e., energy intake, saturated fat consumption)</li> <li>- Adherence to medication</li> </ul> </li> <li>• Clinical outcomes <ul style="list-style-type: none"> <li>- Glycemic control (HbA<sub>1c</sub>)</li> <li>- Change in body composition (i.e., weight, BMI, waist circumference, % body fat)</li> <li>- Control of blood pressure and lipids</li> <li>- Sleep apnea or sleep quality</li> <li>- Development or control of depression or anxiety</li> </ul> </li> <li>• Health outcomes <ul style="list-style-type: none"> <li>• Quality of life (e.g., validated tools for health-related quality of life, life satisfaction, psychosocial adaptation to illness, patient satisfaction)</li> <li>• Development of micro- and macrovascular complications (i.e., retinopathy, nephropathy, neuropathy, cardiovascular outcomes) <ul style="list-style-type: none"> <li>• Mortality (all-cause)</li> </ul> </li> </ul> </li> <li>• Diabetes-related health care utilization</li> </ul>

	<ul style="list-style-type: none"> <li>- Hospital admissions</li> <li>- Length of stay in hospital</li> <li>- Emergency department admissions</li> <li>- Visits to specialist clinics</li> </ul>
	<ul style="list-style-type: none"> <li>• Program acceptability as measured by participant attrition rates</li> </ul>
Timing	<ul style="list-style-type: none"> <li>• Any length of post-intervention followup</li> </ul>
Study design	<ul style="list-style-type: none"> <li>• Randomized controlled trials</li> </ul>
Settings	<ul style="list-style-type: none"> <li>• Community health setting (i.e., ambulatory care clinics, outpatient clinics, primary care clinics, family physician clinics, Community Health Centers, Rural Health Centers)</li> <li>• United States or other high-income country with a very high Human Development Index<sup>60</sup></li> </ul>
Language	<ul style="list-style-type: none"> <li>• English</li> </ul>

BMI = body mass index; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; 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 Supplementary File 1). 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<sub>1c</sub>, 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. 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 treatment. In studies where both types of patients were included and results were not reported separately, if more than 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 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.<sup>67</sup> 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 risk of bias.

Each domain was rated as having “low,” “unclear (medium),” or “high” risk of bias. We assessed blinding and incomplete outcome data separately for subjective outcomes (e.g., quality of life) and objective outcomes (e.g., HbA<sub>1c</sub>). We reported any additional sources of bias, such as baseline imbalances or design-specific risks of bias, in the “other” sources of bias domain.

We created decision rules for consideration of blinding of participants, personnel, and outcome assessors (see Supplementary File). Examples which met the criteria for low risk of bias for these domains include: 1) for participants, when the comparator was an attention control, active control, or another behavioral program, if 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 risk of bias assessment was based on the responses to individual domains. If one or more individual domains had a high risk of bias, we rated the overall score as high risk of bias. We rated the overall risk of bias as low only if all components were assessed as having a low risk of bias. In all other situations, the overall risk of bias was rated as medium.

We assessed the risk of bias for prospective cohort studies and controlled before-after studies using the Newcastle-Ottawa Scale (see Supplementary File).<sup>68</sup> 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 risk of bias as low. We rated the overall risk as medium if the score was between five and seven. For scores below five, the overall risk of bias 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) 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, 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 from similar studies. 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 percent confidence intervals (95% CIs).

The focus of our analysis (and for determining which outcomes to grade for strength for evidence for KQ 1 [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<sub>1c</sub>, we used a difference of 0.4 units in percent HbA<sub>1c</sub> (e.g., 7.6% vs. 8.0% HbA<sub>1c</sub>), which is based on the value used by the U.S. Food and Drug Administration.<sup>66</sup> For quality of life measures and other subjective outcomes represented by continuous data, we used a difference of one-half standard deviation (0.50 SD) based on the data from the studies, which has been shown to represent a universal, conservative estimate of a meaningful difference.<sup>69, 70</sup>

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. 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 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. Care was taken to avoid counting time/contacts required solely for research purposes (e.g., consent, 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 there were very few studies evaluating these categories we collapsed all programs that were not DSME into a “lifestyle” category which largely contained programs focusing on diet and physical activity.

**Table 3. Categorization of program components and delivery factors**

<b>Program Factors</b>	<b>Categories and Description Variables</b>
Program Components*	DSME DSME + Support: DSME plus an added phase to extend program duration and support; often clinically focused but may be psychosocial, educational or behavioral 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 was used as a continuous variable for the regression analyses for KQs 3 and 6
Intensity* (contact hours; where contact hours could not be calculated, we used #contacts as a proxy)	≤10h 11 to 26h (e.g., weekly for up to 6m) ≥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 for T1DM
Method of communication†	In person only Mixture of in person and technology All technology with minimal interaction with providers
Method of delivery‡	Individual Mixed individual and group Group
Delivery personnel§	Delivered entirely by non-health professional (e.g., lay/community health worker, undergraduate students) after training and under some supervision One health professional for large majority (>75%) of delivery Provision by multidisciplinary team of health professionals
Degree of tailoring**	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) 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	Present, e.g., peer delivering program or peer support groups for support stage, use of community resources (infrastructure) for delivery or maintenance stages Absent, e.g., nothing reported or, at most, providing written information about community resources
Presence of support person††	Family or parent involved in >1 session No family or parent involvement in sessions

\*for network meta-analysis in KQ 5 and 6 only; † 2 and 3 were combined for analysis; ‡1 and 2 were combined for analysis; §2 and 3 were combined for KQ 5 and 6; \*\*used in summary tables and the analysis for T1DM; ††for T1DM only

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

## Synthesis for T1DM (KQs 1-4)

### KQ 1: Behavioral Programs and Behavioral, Clinical, and Health Outcomes; Diabetes-related Health Care Utilization; and Program Acceptability

For each comparison of interest, we conducted a pair-wise 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.<sup>71-73</sup> We calculated pooled MD, SMD, and risk ratios with corresponding 95% CIs, as appropriate. We analyzed outcomes at different postintervention timepoints using strata: end of active intervention- $\leq$ 1 month, 1- $\leq$ 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 [ $<70\%$ ] 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.<sup>74</sup> We explored between-study heterogeneity using subgroup and meta-regression analyses where there were at least 10 studies.<sup>75</sup> 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.<sup>76</sup>

## **KQ 2: Subgroups for Effectiveness in T1DM**

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 with the most data (i.e., HbA<sub>1c</sub>) based on age (children and adolescents [ $\leq 18$  years], young adults [19-30 years], adults [31-64 years], older adults  $\geq 65$  years]), race or ethnicity, socioeconomic status, time since diagnosis ( $\leq 1$  year vs.  $> 1$  year), and level of glycemic control (HbA<sub>1c</sub>  $< 7$  vs.  $\geq 7$  percent). We also considered the studies themselves as units for possible subgroup analysis, for example when the mean age of participants fell within one of the age categories, or the majority ( $\geq 75$  percent) of the participants were stated as racial/ethnic minorities (i.e., nonwhite).

## **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<sub>1c</sub>, 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 (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 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 5-6)**

Before synthesizing findings to answer KQs 5 and 6, we performed pair-wise 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**

To answer KQs 5 and 6 we performed network meta-analyses for key outcomes having enough data. Rather than providing a simple pair-wise 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. 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 (i.e., not all plausible nodes ended up containing data). Based on the number of comparisons studied in the trials for each key outcome and the diversity of variables within the behavioral programs, we used as many variables as possible when creating the nodes. The analysis was conducted for HbA<sub>1c</sub> 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.<sup>77, 78</sup> 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. Analysis was checked for consistency by contrasting direct and indirect estimates in each triangular loop using the methods described by Vernoiki.<sup>79</sup> 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 key outcomes with the most data (i.e., HbA<sub>1c</sub>). 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<sub>1c</sub> based on age (young adults [19-30 years], adults [31-64 years], older adults  $\geq 65$  years]), race or ethnicity, socioeconomic status, time since diagnosis ( $\leq 1$  year vs.  $> 1$  year), and level of glycemic control (HbA<sub>1c</sub>  $< 7$  vs.  $\geq 7$  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 pair-wise meta-analysis results for HbA<sub>1c</sub> 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<sub>1c</sub> for KQ 5, we then performed subgroup analysis of this network. This was possible for studies with baseline HbA<sub>1c</sub>  $\geq 7$  percent and with a mean participant age  $< 65$  years; the subgroups with baseline HbA<sub>1c</sub>  $< 7$  percent and age  $\geq 65$  years were too small for their own network analysis. For subgroups based on race/ethnicity ( $\geq 75$  vs.  $< 75$  percent nonwhite), the number of trials in either subgroup was not sufficient to perform a meaningful network meta-analysis, so we conducted a set of univariate meta-regressions within each subgroup using the variables in Table 3 and methods outlined for KQ 2.

## **Strength of the Body of Evidence**

We followed the Methods Guide<sup>57</sup> 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). 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, magnitude, and statistical significance of all 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. 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. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.<sup>57</sup>

We did not assess SOE for the other KQs. KQ 4 assesses harms, which was a minor focus of this review. The other KQs 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).<sup>57</sup> 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

[To be completed following peer review and public posting]

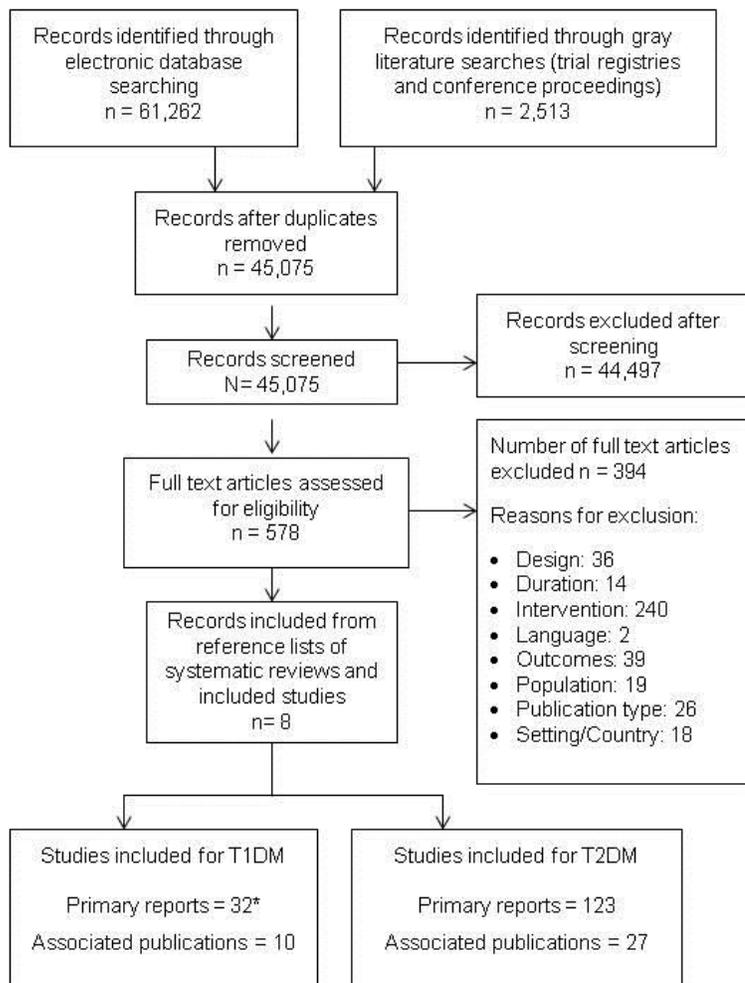
# Results

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

Searches of all sources identified a total of 45,075 citations. For T1DM, we included 32 studies described in 42 publications. For T2DM, we included 123 studies described in 151 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**



\* 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<sub>1c</sub>) 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) as figures with meta-analyses or in summary tables. Where statistical heterogeneity was considered substantial (>50 percent) we report the I<sup>2</sup> Statistic (I<sup>2</sup>%).

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<sub>1c</sub>. Other outcomes from the observational studies are documented in Appendix G. For KQ 1, we summarize the strength of evidence (SOE) assessments, which are provided in detail in Appendix H.

## Literature Search and Screening

For T1DM, we included 32 studies described in 42 publications (Figure 3). Primary reports were identified for 28 randomized controlled trials (RCT),<sup>80-107</sup> 1 non-RCT,<sup>108</sup> and 3 controlled before-after studies.<sup>109-111</sup> Ten additional publications contributed information related to the study methodology, outcomes, or descriptions of the interventions.<sup>112-121</sup> 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.<sup>105</sup>

## Characteristics of Included Studies

The majority of studies (28 trials, 2 observational studies) examined diabetes self-management education (DSME); two studies (1 RCT,<sup>103</sup> 1 observational study<sup>110</sup>) focused on lifestyle programs (see Appendix A for operational definitions). For DSME, most trials (n=21) were two-arm trials comparing DSME to usual care. Three two-arm RCTs compared DSME to an active control.<sup>85, 89, 90</sup> The active controls included telephone support<sup>85</sup> and basic education.<sup>89, 90</sup> Three RCTs were three-arm trials with one having two active control arms<sup>105</sup> and the other two each had a usual care and an active control arm.<sup>81, 106</sup> For one, the authors combined the usual care and active control arms.<sup>81</sup> For the other two, we analyzed the control arms separately.<sup>105, 106</sup> One RCT evaluated the comparative effectiveness of the same DSME program delivered in person compared with delivery by internet-based videoconferencing (Skype™).<sup>88</sup> Two observational studies compared DSME with usual care.<sup>109, 111</sup>

Both studies focusing on lifestyle programs compared them with usual care. One was a two-arm RCT<sup>103</sup> and the other was an observational study.<sup>110</sup>

## Youth

### Clinical Trials

Twenty-one RCTs<sup>81-88, 90, 91, 94-102, 104, 106</sup> and six associated publications<sup>113-115, 117, 118, 121</sup> examined the effectiveness of behavioral programs among youth. 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<sup>88</sup> and another compared delivery of DSME in person compared with a telephone support active control.<sup>85</sup> Two three-arm trials compared a DSME program with usual care and an active control (basic education program),<sup>81, 106</sup> although the authors of one combined the two control groups for their analyses.<sup>81</sup> Fifteen trials were conducted in the United States;<sup>81, 82, 84-86, 88, 90, 94-98, 101, 102, 106</sup> six were conducted in Europe.<sup>83, 87, 91, 99, 100, 104</sup>

The mean age of the youth participants ranged from 9.7–15.4 years (median=13.4). One study did not report age.<sup>95</sup> The percentage of males ranged from 5–63 percent (median=47). The proportion of nonwhite participants was between 2–82 percent (median=23.5); seven trials did not present information on race or ethnicity.<sup>88, 91, 96-99, 104</sup> For most trials, the mean HbA<sub>1c</sub> was >7 percent and ranged from 7.4–15.7 percent (median=9.5 percent). One trial did not report absolute baseline HbA<sub>1c</sub>.<sup>101</sup>

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.<sup>91</sup> Some studies reported additional components including: regular adherence assessments,<sup>81, 96</sup> in-clinic goal setting and a daily phone hour with education provided between visits,<sup>85, 86</sup> access to an emergency hotline,<sup>87</sup> and basic care coordination with clinic reminders and assistance with scheduling appointments.<sup>94, 102</sup> Three trials reported that usual care included more advanced education,<sup>85, 86, 106</sup> and one multicenter trial's exclusion criteria for study centers included the availability of a group education program.<sup>83</sup>

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.<sup>91, 99, 100</sup> 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.<sup>81, 90, 94, 96, 102</sup> One study combined in-clinic goal setting with automated weekly delivery of tailored education and support messages.<sup>87</sup> Two office-based programs had relatively high intensity with more than 10 contacts.<sup>91, 94</sup> The majority of office-based programs were delivered to the family, with a focus on family teamwork, conflict, and coping.<sup>81, 90, 94, 96, 99, 100, 102</sup> 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.<sup>82, 84, 95, 97, 98, 101, 104</sup> Some also offered a more therapeutic approach together with some degree of self-management training (i.e., behavioral family systems therapy,<sup>88, 97, 106</sup> motivational enhancement therapy combined with solution-focused therapy,<sup>83</sup> and multisystemic therapy<sup>85, 86</sup>). Many programs were targeted at adolescents,<sup>81, 82, 85-88, 90, 91, 95, 97,</sup>

100, 101, 104, 106 while others were tailored to children,<sup>98</sup> or offered to mixed age groups.<sup>83, 94, 96, 99, 102</sup> Below, we present a summary of implementation factors.

The total duration of the behavioral programs ranged from 1.5–25 months (median=6). The number of contact hours ranged from 2–48 hours (median=8). Four trials did not report enough information to calculate the number of contact hours.<sup>82, 87, 96, 101</sup>

Five trials delivered the programs to youth only;<sup>82, 84, 87, 101, 104</sup> 16 delivered the programs to both youth and their parents or family members.<sup>81, 83, 85, 86, 88, 90, 91, 94-100, 102, 106</sup> Three trials delivered the program in person to groups of youth only,<sup>82, 84, 104</sup> and two trials delivered the program to youth using a mix of in-person sessions supplemented by telephone calls<sup>101</sup> or text messaging.<sup>87</sup> Seven trials delivered the program in person to individual pairs of youth and family members.<sup>81, 85, 86, 88, 91, 96, 106</sup> Six trials delivered the program in person to groups of youth and family members.<sup>83, 95, 98-100, 104</sup> Three trials delivered the program to individual pairs of youth and family members using a mix of in-person sessions supplemented by telephone calls.<sup>90, 94, 102</sup> Two trials delivered the program to individuals using telehealth<sup>97</sup> and Skype.<sup>88</sup>

For six trials, the program was delivered by a single health care professional (e.g., nurse, psychologist, registered dietitian).<sup>82, 84-86, 88, 104</sup> Six trials engaged two or more health professionals,<sup>83, 87, 91, 99, 100, 106</sup> seven trials used non-health professionals (e.g., research assistants, health-related students or trainees),<sup>81, 90, 94, 96, 97, 101, 102</sup> and one trial used a combination of a health professional and a trainee.<sup>95</sup> One trial did not report this information.<sup>98</sup>

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.<sup>85, 86, 88, 90, 91, 94, 95, 97, 101, 102, 106</sup> Four interventions included some degree of community engagement.<sup>83, 85, 86, 88</sup>

## 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,<sup>111</sup> the other compared a lifestyle intervention with usual care.<sup>110</sup>

The study by Viner et al.<sup>111</sup> 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.<sup>110</sup> 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<sup>80, 89, 92, 93, 103, 105, 107</sup> with four associated publications,<sup>112, 116, 119, 120</sup> and one non-RCT<sup>108</sup> examined the effectiveness of behavioral programs among adults. Two RCTs included participants with T2DM. One RCT presented results for HbA<sub>1c</sub> separately for T1DM and T2DM and is included in both sections of this report.<sup>105</sup> 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.<sup>93</sup> Six trials focused on DSME compared with usual care,<sup>80, 92, 93, 103, 107, 108</sup> two examined DSME compared with one<sup>89</sup> or two<sup>105</sup> active controls, and one compared a lifestyle intervention with usual care.<sup>103</sup> Six of the trials were conducted in European countries,<sup>80, 89, 92, 93, 107, 108</sup> one was conducted in the United States,<sup>105</sup> and one was conducted in New Zealand.<sup>103</sup>

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;<sup>92, 105</sup> the other trials did not present information on race or ethnicity. For all trials, the mean HbA<sub>1c</sub> was >7 percent and ranged from 7.7–9.6 percent. The mean BMI ranged from 24.8–27.6 kg/m<sup>2</sup>; three trials did not report BMI.<sup>93, 107, 108</sup>

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.<sup>93</sup> who took a different approach by recruiting survey respondents, and may have been diverse in the trial of Perry et al.<sup>103</sup> 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.<sup>92, 103, 105, 108</sup> The usual care in one trial included provision of and training in a continuous glucose monitoring system.<sup>80</sup>

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,<sup>80, 92, 93, 105</sup> with one combining cognitive behavioral therapy with motivational enhancement therapy.<sup>92</sup> In one study authors described their program as taking an empowerment approach,<sup>89</sup> another incorporated guided self-determination group training,<sup>107</sup> and one offered self-management training using an ongoing self-help group style.<sup>108</sup> The program presented by Amsberg et al.<sup>80</sup> 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.<sup>80</sup> Five trials delivered the program in person to groups of participants,<sup>89, 93, 105, 107, 108</sup> two delivered the program in person to individuals,<sup>92, 103</sup> and one trial used a mix of individual and small group sessions that were delivered in person and by telephone.<sup>80</sup> For three of the trials, the program was delivered by a single health care professional (i.e., nurse, registered dietitian, physician).<sup>89, 92, 108</sup> Four trials engaged two or more health professionals,<sup>80, 103, 105, 107</sup> 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.<sup>80, 93, 107, 108</sup> One

trial incorporated community engagement through the use of a peer coleader;<sup>93</sup> 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 ( $\leq 65$  years) who were receiving intensive insulin therapy.<sup>109</sup> The study was conducted in Italy. Baseline HbA<sub>1c</sub> was  $\geq 7.5$  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.

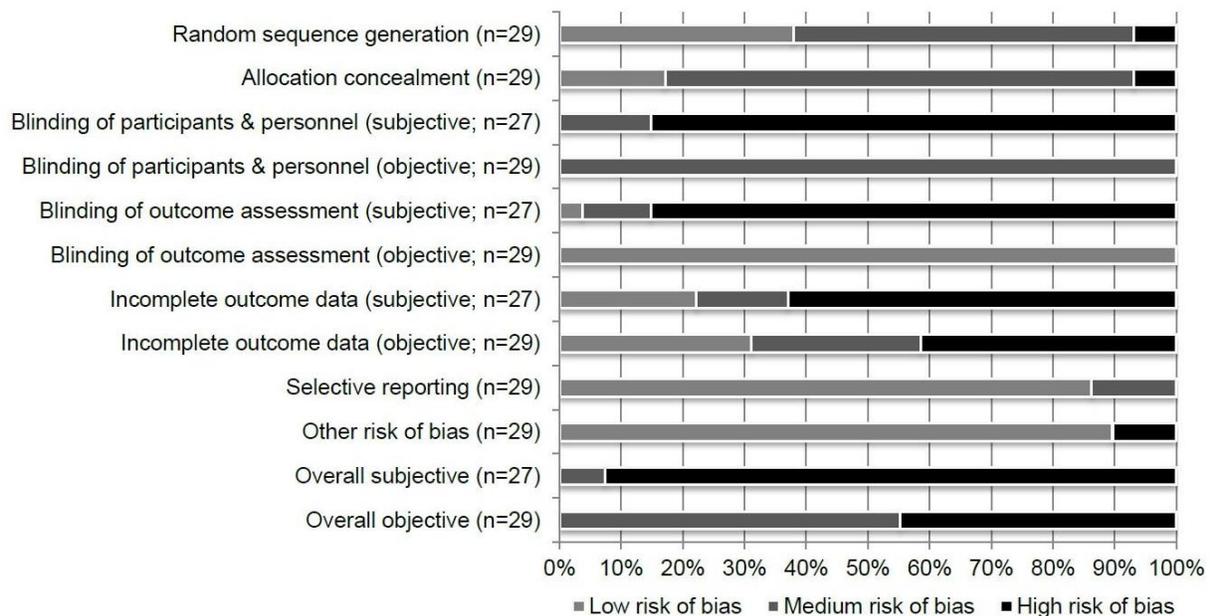
### **Risk of Bias of Individual Studies**

A summary of the ROB assessments for the 29 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 risk of bias. For objective outcomes (e.g., HbA<sub>1c</sub>, weight), 55 percent of trials had a medium risk of bias and 45 percent had a high risk. The assessment of high risk was largely driven by incomplete outcome data (i.e., loss to followup). For subjective outcomes (e.g., health-related quality of life [HRQL]), all but two trials had a high risk of bias (93 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.<sup>111</sup> was assessed as having medium risk of bias (seven stars out of a possible nine); the study by Forlani et al.<sup>109</sup> was assessed as medium (five stars); and the study by Thomas-Dobersen et al.<sup>110</sup> was assessed as low (eight stars). For all studies there was concern about the control of potential confounding variables. For Forlani et al. and Viner et al. there were concerns about the representativeness of the exposed cohort.

Five studies (16 percent) received funding from industry; 23 (84 percent) received funding from non-industry sources (e.g., government or foundations). Funding was not reported by three (10 percent) studies.

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



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

### **Key Points: HbA<sub>1c</sub>**

- There was no difference (low SOE) in changes in HbA<sub>1c</sub> at the end of intervention between behavioral programs and usual care.
- Behavioral programs compared with usual care reduced HbA<sub>1c</sub> (moderate SOE) at 6-month postintervention followup; the change did not meet our threshold for clinical importance.
- There was no significant difference in reduction of HbA<sub>1c</sub> 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 we cannot rule out benefit for behavioral programs.
- Behavioral programs compared with an active control reduced HbA<sub>1c</sub> 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<sub>1c</sub> at end of intervention and at 12-month followup. The SOE was low for both; risk of bias, 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 evidence 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.
- Evidence was insufficient to determine whether behavioral programs increased or decreased symptoms of depression, or 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 (low SOE).
- Few trials reported on generic HRQL at longer followup timepoints.
- Few trials reported on diabetes-specific quality of life.
- No trials reported on micro- and macrovascular complications or on all-cause mortality.

### **Key Points: Diabetes-Related Health Care Utilization**

- Few trials reported diabetes-related health care utilization.
- 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.

### **Key Points: Program Acceptability**

- There was a 17 percent increased risk of attrition for individuals receiving usual care compared with those receiving a behavioral program.

## **Detailed Synthesis**

### **HbA<sub>1c</sub>: Behavioral Programs Compared With Usual Care**

Figures 5-7 present our meta-analyses and forest plots of trials reporting HbA<sub>1c</sub> stratified by age (youth and adults). A negative MD represents a greater reduction in percent HbA<sub>1c</sub> 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.

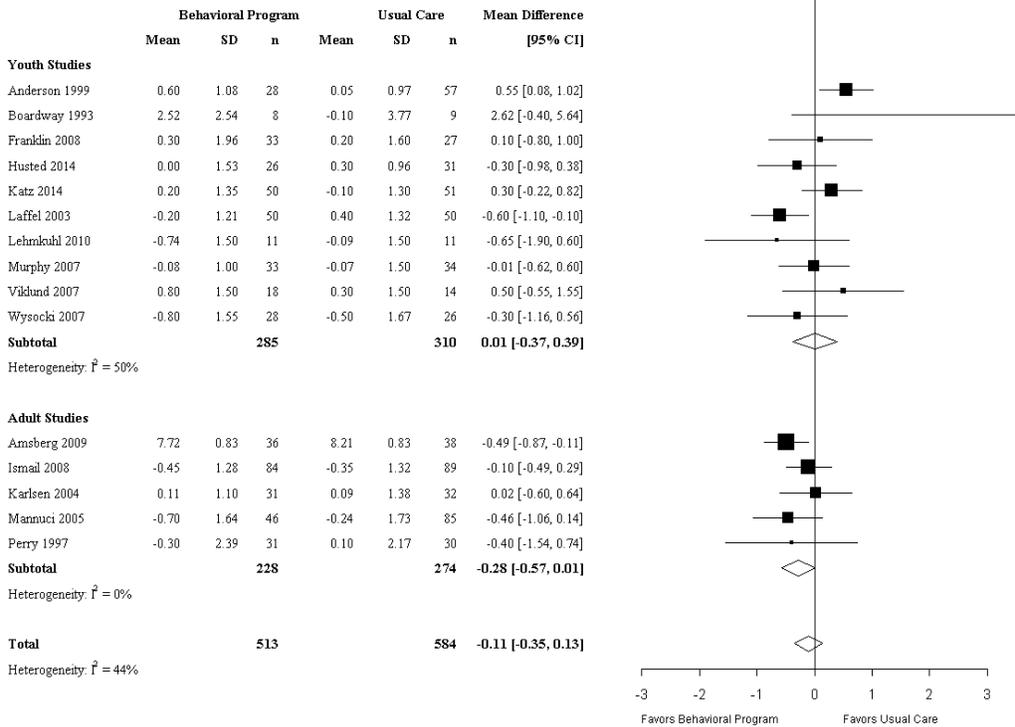
At the end of intervention for youth and adults combined, our meta-analysis (15 trials, 1,097 subjects) found no difference in HbA<sub>1c</sub> between individuals receiving a behavioral program and those receiving usual care (MD, -0.11 percent; 95% CI, -0.35 to 0.13).<sup>80-82, 87, 91-94, 96, 97, 99, 103, 104, 106, 108</sup> There was no difference between groups for youth (10 trials, 595 subjects)<sup>81, 82, 87, 91, 94, 96, 97, 99, 104, 106</sup> or for adults (5 trials, 502 subjects)<sup>80, 92, 93, 103, 108</sup>—MD = 0.01 percent (95% CI, -0.37 to 0.39) and MD = -0.28 percent (95% CI, -0.57 to 0.01), respectively.

At the end of 6-month postintervention followup for youth and adults combined, our meta-analysis (11 trials, 1,316 subjects) showed that HbA<sub>1c</sub> improved for persons who received a behavioral program compared with those receiving usual care (MD, -0.33 percent; 95% CI, -0.51 to -0.15).<sup>82, 84, 86, 91, 92, 98, 100-102, 106, 107</sup> The reduction in HbA<sub>1c</sub> was not clinically important. For youth (9 trials, 1,066 subjects),<sup>82, 84, 86, 91, 98, 100-102, 106</sup> the difference between groups was

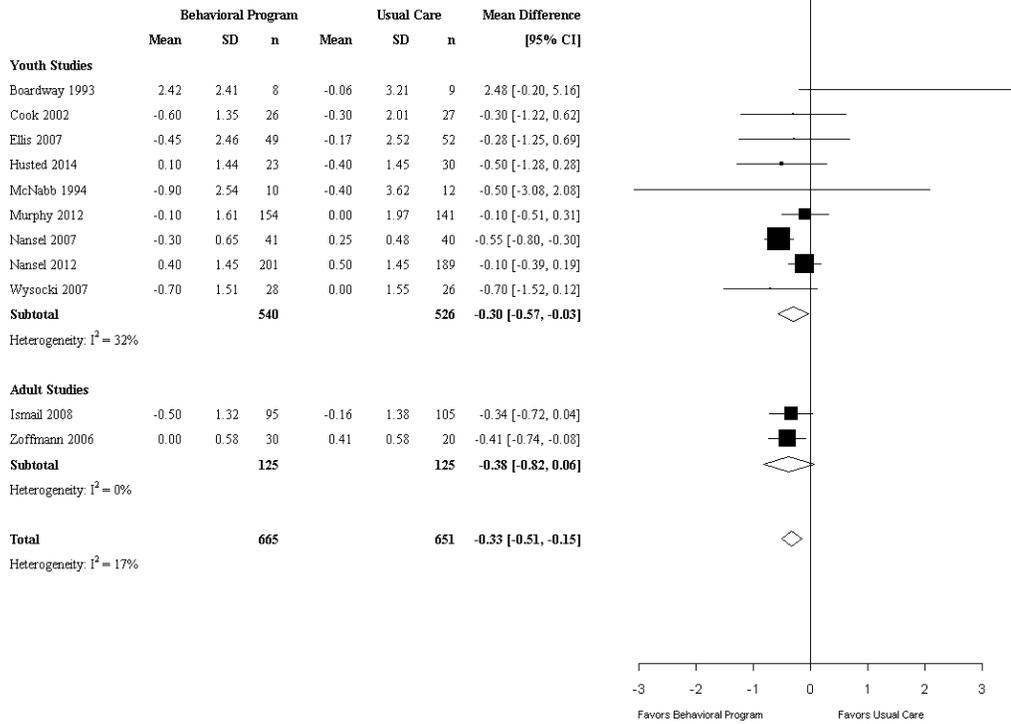
statistically significant, but it was not clinically important (MD, -0.30 percent; 95% CI, -0.57 to -0.03). For adults (2 trials, 250 subjects), there was no difference between groups.<sup>92, 107</sup>

At the end of 12-month postintervention followup for youth, our meta-analysis (6 trials, 1,186 youth) found no difference in HbA<sub>1c</sub> between individuals receiving a behavioral program and those receiving usual care (MD, -0.21 percent; 95% CI, -0.54 to 0.12).<sup>81, 83, 100-102, 106</sup>

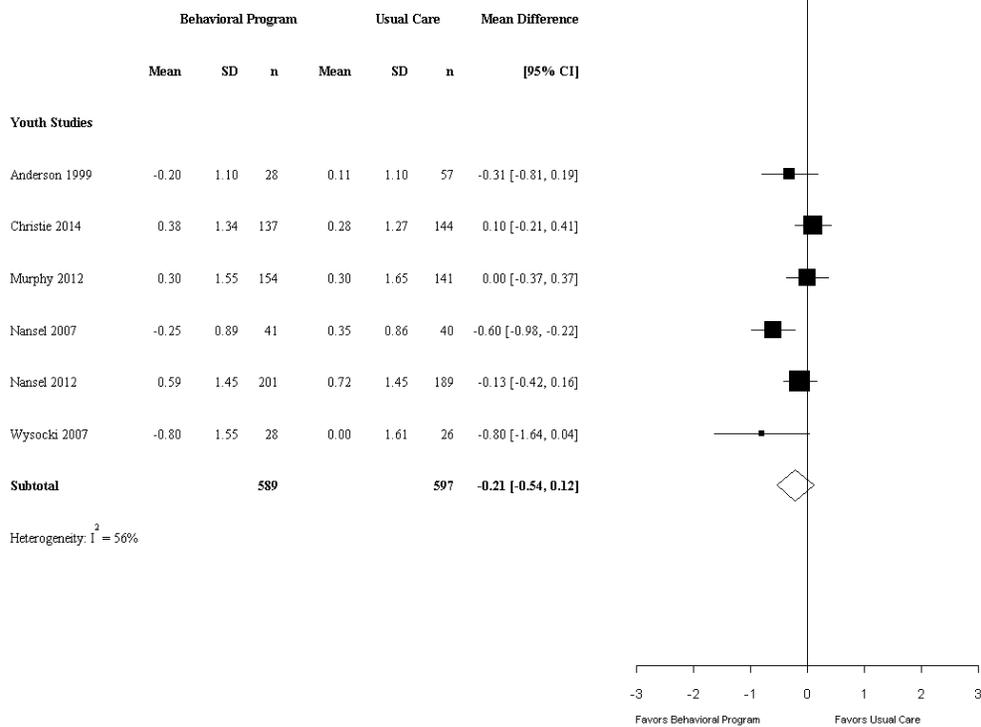
**Figure 5. Behavioral programs for diabetes compared with usual care: HbA<sub>1c</sub> at the end of intervention**



**Figure 6. Behavioral programs for diabetes compared with usual care: HbA<sub>1c</sub> at 6-month postintervention**



**Figure 7. Behavioral programs for diabetes compared with usual care: HbA<sub>1c</sub> at 12-month postintervention (youth only)**



Four studies provided data at longer followup timepoints (data not shown). Three RCTs (2 youth,<sup>101, 102</sup> 1 adult;<sup>92</sup> 671 subjects) reported data at more than 1 year, but less than 2 years; there was no difference in HbA<sub>1c</sub> between groups (MD, -0.40; 95% CI, -0.92 to 0.12). Two trials (1 youth,<sup>83</sup> 1 adult;<sup>92</sup> 467 subjects) reported outcomes at 24 months and found no difference in HbA<sub>1c</sub> (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.<sup>95</sup>

Three observational studies (2 youth,<sup>110, 111</sup> 1 adult;<sup>109</sup> 148 subjects) provided data on HbA<sub>1c</sub> at 12-month followup. One youth study (41 subjects) reported a statistically significant and clinically important improvement in HbA<sub>1c</sub> for the group receiving the behavioral program (MD, -1.2; 95% CI, -2.24 to -0.16).<sup>111</sup> The other youth study (17 subjects) found no difference between groups (MD, 0.67; 95% CI, -1.47 to 2.81).<sup>110</sup> The study that was conducted in adults (90 subjects) reported a statistically significant and clinically important improvement in HbA<sub>1c</sub> for the group receiving the behavioral program (MD, -0.70; 95% CI, -1.31 to -0.09).<sup>109</sup>

### **HbA<sub>1c</sub>: Behavioral Programs Compared With Active Control**

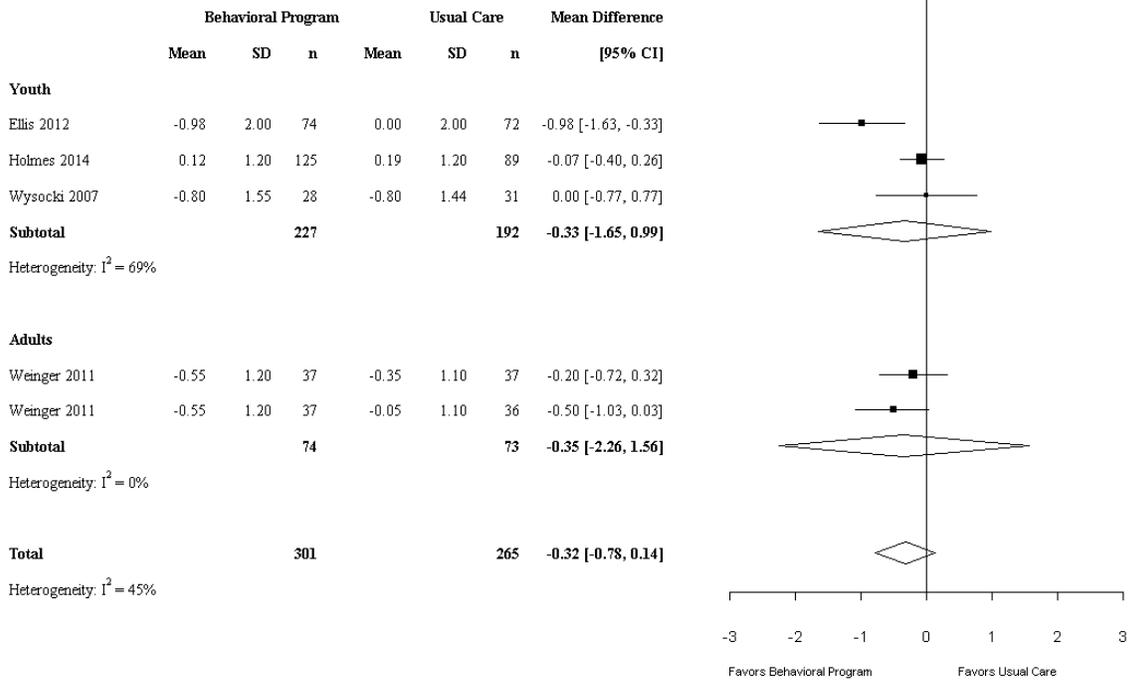
Figures 8-10 present our meta-analyses of trials reporting HbA<sub>1c</sub> for youth and adults. We present the results by followup timepoint (end of intervention, 6-month followup, 12-month followup) and age group. One trial in adults was a three-arm trial comparing a behavioral program to two different active controls (didactic education to either groups or individuals).<sup>105</sup>

At the end of intervention, our meta-analysis for youth and adults (5 comparisons, 419 youth<sup>85, 90, 106</sup> and 147 adults<sup>105</sup>) found no difference between behavioral programs and active controls for HbA<sub>1c</sub> (MD, -0.32; 95% CI, -0.78 to 0.14). When examining age subgroups, similar results were found for both youth (MD, -0.33; 95% CI, -1.65 to 0.99; I<sup>2</sup>=69%),<sup>85, 90, 106</sup> and adults (MD, -0.35; 95% CI, -2.26 to 1.56).<sup>105</sup>

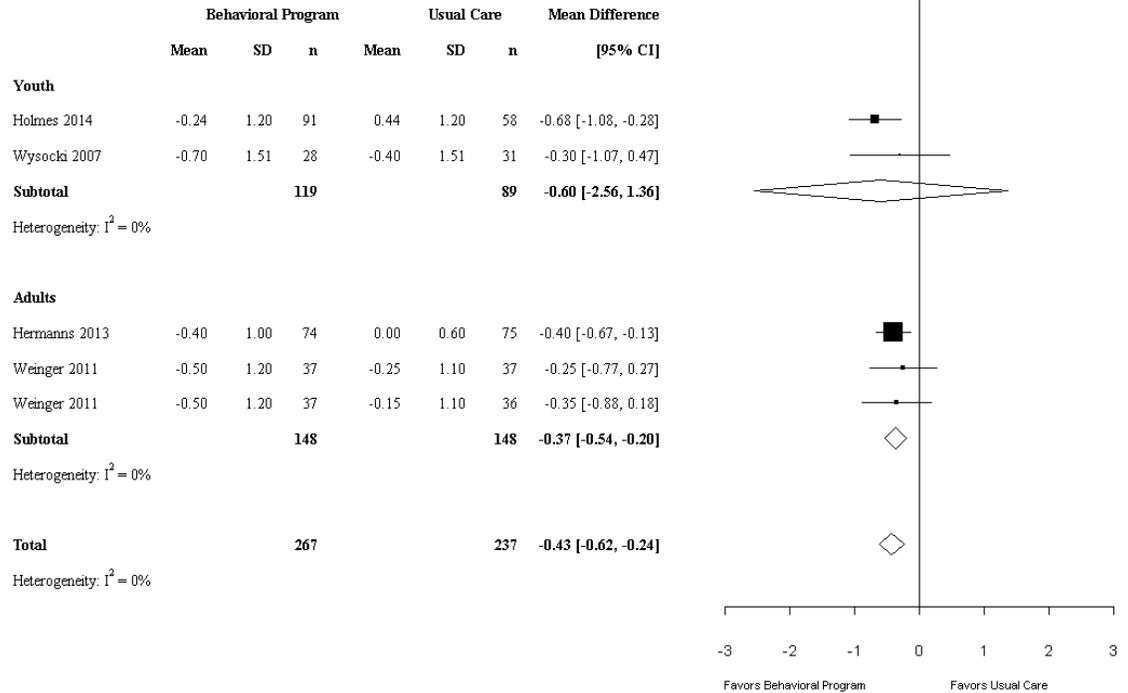
At the end of 6 months postintervention, our meta-analysis for youth and adults combined (4 trials [296 adults,<sup>89, 105</sup> 208 youth<sup>90, 106</sup>]) showed that HbA<sub>1c</sub> improved for those receiving a behavioral program compared with those receiving an active control (MD, -0.43; 95% CI, -0.62 to -0.24); this reduction in HbA<sub>1c</sub> is clinically important. For youth, the difference was not statistically significant (MD, -0.60; 95% CI, -2.56 to 1.36);<sup>90, 106</sup> for adults, the difference was statistically significant but not clinically important (MD, -0.37; 95% CI, -0.54 to -0.20).<sup>89, 105</sup>

At the end of 12-month followup, our meta-analysis for youth and adults combined (3 trials [147 adults,<sup>105</sup> 195 youth<sup>90, 106</sup>]) found no difference in HbA<sub>1c</sub> (MD, -0.34; 95% CI, -0.71 to 0.03). For youth, the difference was clinically important (MD, -0.52; 95% CI, -1.04 to 0.00); the two comparisons in adults by Weinger et al., failed to demonstrate any difference (MD, -0.14; 95% CI, -1.28 to 1.00).

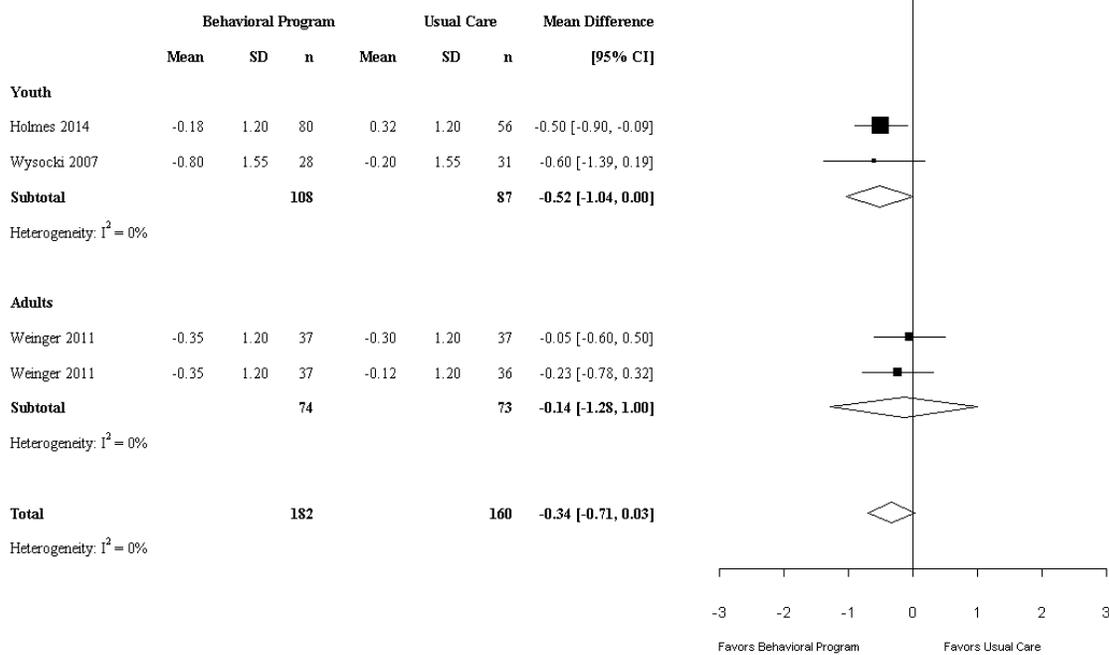
**Figure 8. Behavioral programs for diabetes compared with active control: HbA<sub>1c</sub> at end of intervention**



**Figure 9. Behavioral programs for diabetes compared with active control: HbA<sub>1c</sub> at 6-month postintervention**



**Figure 10. Behavioral programs for diabetes compared with active control: HbA<sub>1c</sub> at 12-month postintervention**



### HbA<sub>1c</sub>: Comparative Effectiveness of Two Behavioral Programs

One RCT (72 youth) examined the same DSME program delivered in person compared with delivery by Skype.<sup>88</sup> There was no difference in HbA<sub>1c</sub> 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).

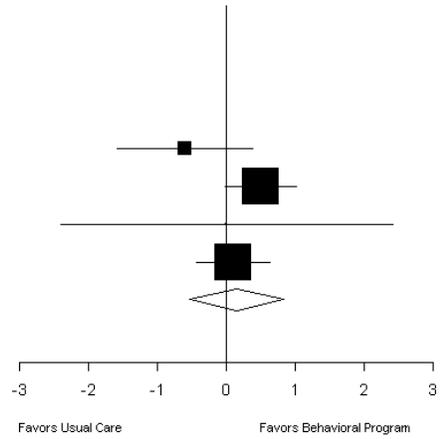
### Adherence to Diabetes Self-Management: Behavioral Programs Compared With Usual Care

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.<sup>82, 84, 86, 94, 102</sup> Two studies reported the frequency of testing over the past week;<sup>91, 107</sup> 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).<sup>82, 86, 91, 94</sup>

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

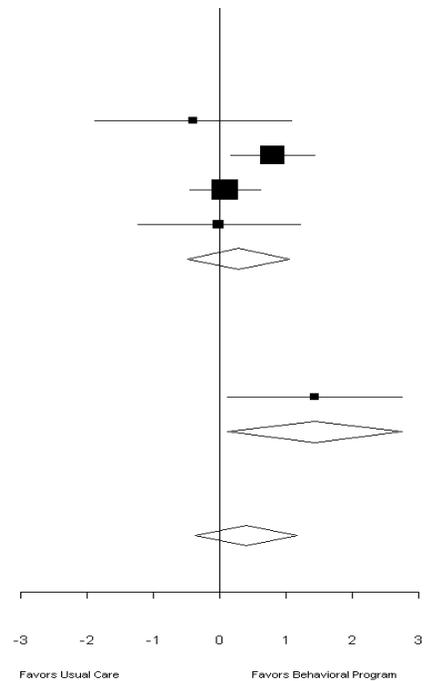
	Behavioral Program			Usual Care			Mean Difference
	Mean	SD	n	Mean	SD	n	[95% CI]
<b>Youth Studies</b>							
Boardway 1993	1.10	1.10	8	1.70	0.90	8	-0.60 [-1.58, 0.38]
Ellis 2007	2.62	1.30	57	2.12	1.44	51	0.50 [-0.02, 1.02]
Husted 2014	4.57	2.00	26	4.57	6.50	31	0.00 [-2.41, 2.41]
Katz 2014	3.90	1.30	50	3.80	1.40	51	0.10 [-0.43, 0.63]
<b>Subtotal</b>			<b>141</b>			<b>141</b>	<b>0.15 [-0.54, 0.84]</b>
Heterogeneity: $I^2 = 25\%$							



At the end of 6-month postintervention for youth and adults combined (Figure 12), our meta-analysis (5 trials [4 youth,<sup>82, 84, 86, 91</sup> 1 adult<sup>107</sup>], 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.<sup>107</sup> increased their frequency of SMBG (MD, 1.42; 95% CI, 0.11 to 2.75).

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

	Behavioral Program			Usual Care			Mean Difference
	Mean	SD	n	Mean	SD	n	[95% CI]
<b>Youth Studies</b>							
Boardway 1993	1.60	1.90	8	2.00	1.00	8	-0.40 [-1.89, 1.09]
Cook 2002	3.80	0.80	16	3.00	1.10	19	0.80 [0.17, 1.43]
Ellis 2007	2.09	1.44	47	2.01	1.30	51	0.08 [-0.46, 0.62]
Husted 2014	4.42	1.86	23	4.43	2.71	30	-0.01 [-1.24, 1.22]
<b>Subtotal</b>			<b>94</b>			<b>108</b>	<b>0.28 [-0.49, 1.05]</b>
Heterogeneity: $I^2 = 27\%$							
<b>Adult Studies</b>							
Zoffmann 2006	2.86	2.33	30	1.43	2.33	20	1.43 [0.11, 2.75]
<b>Subtotal</b>			<b>30</b>			<b>20</b>	<b>1.43 [0.11, 2.75]</b>
Heterogeneity: Not applicable							
<b>Total</b>			<b>124</b>			<b>128</b>	<b>0.40 [-0.36, 1.16]</b>
Heterogeneity: $I^2 = 41\%$							



One trial (390 youth) reported SMBG at 24-months postintervention.<sup>102</sup> 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.<sup>122</sup> 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.<sup>80</sup> At 6-month postintervention, one trial (244 adults) found no difference between groups (MD, -0.06; 95% CI, -0.60 to 0.48).<sup>92</sup>

Four trials in youth used the Diabetes Self-Management Profile (DSMP) to assess adherence to the diabetes regimen at different timepoints. At the end of intervention, Wysocki et al.<sup>106</sup> (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.<sup>102</sup> (390 youth) found no difference between groups (MD, 1.31; 95% CI, -1.12 to 3.74). In an earlier study, Nansel et al.<sup>101</sup> (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.<sup>97</sup>

Two trials reported 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.<sup>83</sup> 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 (DSCI; measuring adherence over the past month) 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).<sup>80</sup>

## **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).<sup>89</sup> 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).<sup>89</sup>

One trial (54 youth) used the DSMP to assess adherence to the diabetes regimen.<sup>106</sup> At the end of intervention and 12-month followup, Wysocki et al.<sup>106</sup> 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) used the Diabetes Behavior Rating Scale, which reflects the frequency of routine diabetes care behaviors.<sup>90</sup> 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 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.<sup>88</sup> 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 4 results were reported in single trials.

**Table 4. Other clinical and behavioral outcomes**

Outcome	Timepoint	# Trials (# Subjects, Control Group)	Study Effect	Conclusion
Change in body composition (BMI)	EOI	1 (60 youth, UC) <sup>87</sup>	MD, 0.08; 95% CI, -0.35 to 0.51	No difference
Change in body composition (BMI)	6m followup	1 (227 adults, UC) <sup>92</sup>	MD, -0.21; 95% CI, -0.62 to 0.20	No difference
Change in body composition (kg)	EOI	1 (61 adults, UC) <sup>103</sup>	MD, -0.50; 95% CI, -5.69 to 4.69	No difference
Change in physical activity (fitness)	EOI	1 (43 adults, UC) <sup>103</sup>	MD, 0.59; 95% CI, 0.22 to 0.96	Improved with behavioral program
Change in physical activity (intensity/duration)	EOI	2 (17 youth, 73 adults, UC) <sup>80, 82</sup>	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) <sup>82, 92</sup>	SMD, -0.26; 95% CI, -1.00 to 0.49	No difference
Change in physical activity (fitness [VO <sub>2</sub> max])	EOI	1 (43 adults, UC) <sup>103</sup>	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) <sup>103</sup>	MD, -1.80; 95% CI, -3.53 to -0.07	Improved with behavioral program
Change in dietary or nutrient intake (caloric [kcal/day])	EOI	1 (61 adults, UC) <sup>103</sup>	MD, -247.10; 95% CI, -281.7 to -21	Improved with behavioral program
Severe hypoglycemia (# episodes needing 3 <sup>rd</sup> party assistance)	EOI	1 (60 youth, UC) <sup>87</sup>	MD, -1.02; 95% CI, -2.16 to 0.11	No difference
Severe hypoglycemia (# episodes needing 3 <sup>rd</sup> party assistance)	6m followup	1 (160 adults, AC) <sup>89</sup>	MD, -0.10; 95% CI, -0.48 to 0.28	No difference
Severe hypoglycemia (# episodes needing 3 <sup>rd</sup> party assistance)	6m followup	1 (227 adults, UC) <sup>92</sup>	MD, -0.62; 95% CI, -1.61 to 0.37	No difference
Severe hypoglycemia (# episodes needing 3 <sup>rd</sup> party assistance)	12m followup	1 (295 youth, UC) <sup>100</sup>	MD, -0.05; 95% CI, -0.22 to 0.12	No difference

Severe hypoglycemia (# episodes needing 3 <sup>rd</sup> party assistance)	>12m followup	1 (343 youth, UC) <sup>83</sup>	RR, 0.55; 95% CI, 0.10 to 2.97	No difference
Diabetic ketoacidosis (requiring treatment)	EOI	1 (61 youth, UC) <sup>87</sup>	MD, -0.38; 95% CI, -1.43 to 0.67	No difference
Diabetic ketoacidosis (requiring hospital admission)	12m followup	1 (295 youth, UC) <sup>100</sup>	MD, 0.01; 95% CI, -0.09 to 0.11	No difference
Diabetic ketoacidosis (requiring hospital admission)	>12m followup	1 (343 youth, UC) <sup>83</sup>	RR, 0.96; 95% CI, 0.72 to 1.27	No difference
HDL cholesterol	EOI	1 (61 adults, UC) <sup>103</sup>	MD, 0.10; 95% CI, -0.06 to 0.26	No difference
LDL cholesterol	EOI	1 (61 adults, UC) <sup>103</sup>	MD, -0.20; 95% CI, -0.67 to 0.27	No difference
Systolic blood pressure	EOI	1 (61 adults, UC) <sup>103</sup>	MD, -2.00; 95% CI, -11.25 to 7.25	No difference
Triglycerides	EOI	1 (61 adults, UC) <sup>103</sup>	MD, 0.00; 95% CI, -0.39 to 0.39	No difference

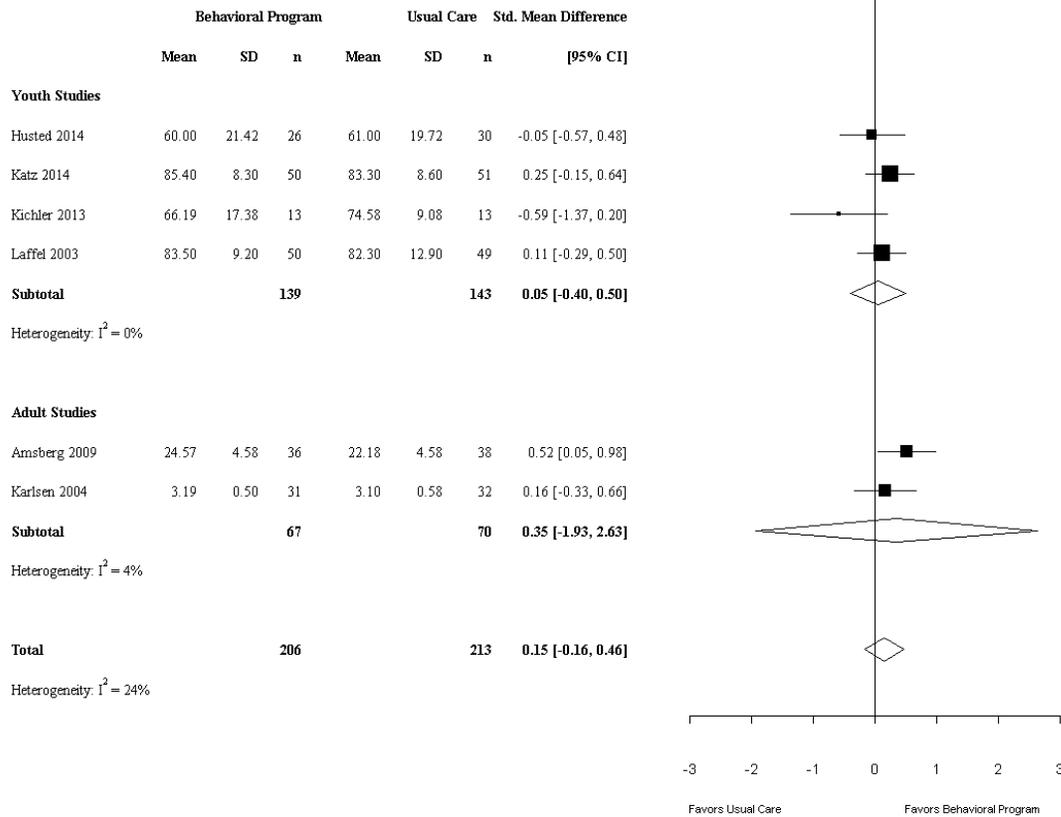
AC= active control; BMI = body mass index; CI= confidence interval; EOI = end of intervention; m = month; MD = mean difference; QOL = quality of life; SMD = standardized mean difference; UC= usual care

## 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; we report results separately for these two categories. Figure 13 presents our meta-analyses of trials, stratified by age (youth and adults), that reported generic HRQL at end of intervention. Generic HRQL was measured by a number of tools (e.g., World Health Organization Well-Being Index, Pediatric Quality of Life, Wellbeing Questionnaire), therefore we present the results as a SMD. We present a forest plot for end of intervention; for longer followup timepoints we summarize the results in Table 5.

At the end of intervention for youth and adults combined (Figure 13), our meta-analysis (6 trials [4 youth,<sup>91, 94-96</sup> 2 adult<sup>80, 93</sup>], 419 subjects) found no difference in HRQL between individuals receiving a behavioral program and those receiving usual care (SMD, 0.15; 95% CI, -0.16 to 0.46). The lack of difference remained for the subgroups of adults (2 trials, 137 subjects; MD, 0.35; 95% CI -1.93 to 2.63)<sup>80, 93</sup> and youth (4 trials, 282 subjects; MD, 0.05; 95% CI -0.4 to 0.5).<sup>91, 94-96</sup>

**Figure 13. Behavioral programs for diabetes compared with usual care: Health-related quality of life at end of intervention**



Three RCTs in youth reported HRQL for longer followup timepoints (Table 5).<sup>83, 91, 96</sup> There was no difference in HRQL between groups at any of the timepoints.

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

Timepoint	# Trials (#Subject)	Study Effect	Conclusion
6m followup	1 RCT (53) <sup>91</sup>	SMD, -0.29; 95% CI, -0.83 to 0.26	No difference
12m followup	2 RCTs (405) <sup>83, 96</sup>	SMD, 0.02; 95% CI, -0.11 to 0.15	No difference
24m followup	1 RCT (291) <sup>83</sup>	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

Two RCTs reported diabetes-specific quality of life at the end of intervention. Using the diabetes module of the Pediatric Quality of Life Inventory,<sup>123</sup> a trial in youth (26 subjects) found no difference between individuals receiving a behavioral program and those receiving usual care (SMD, -0.77; 95% CI -1.57 to 0.04).<sup>95</sup> A trial in adults (131 subjects) found a difference between groups using the Well-being Enquiry for Diabetes questionnaire;<sup>124</sup> however, the difference did not reach clinical importance (SMD, 0.44; 95% CI, 0.08 to 0.81).<sup>108</sup> 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).<sup>109</sup>

## 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).<sup>90</sup>

## 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.<sup>86</sup> The same trial also reported fewer admissions to the emergency department at the end of intervention. Another RCT in youth<sup>83</sup> and one in adults<sup>92</sup> 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.<sup>95</sup>

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

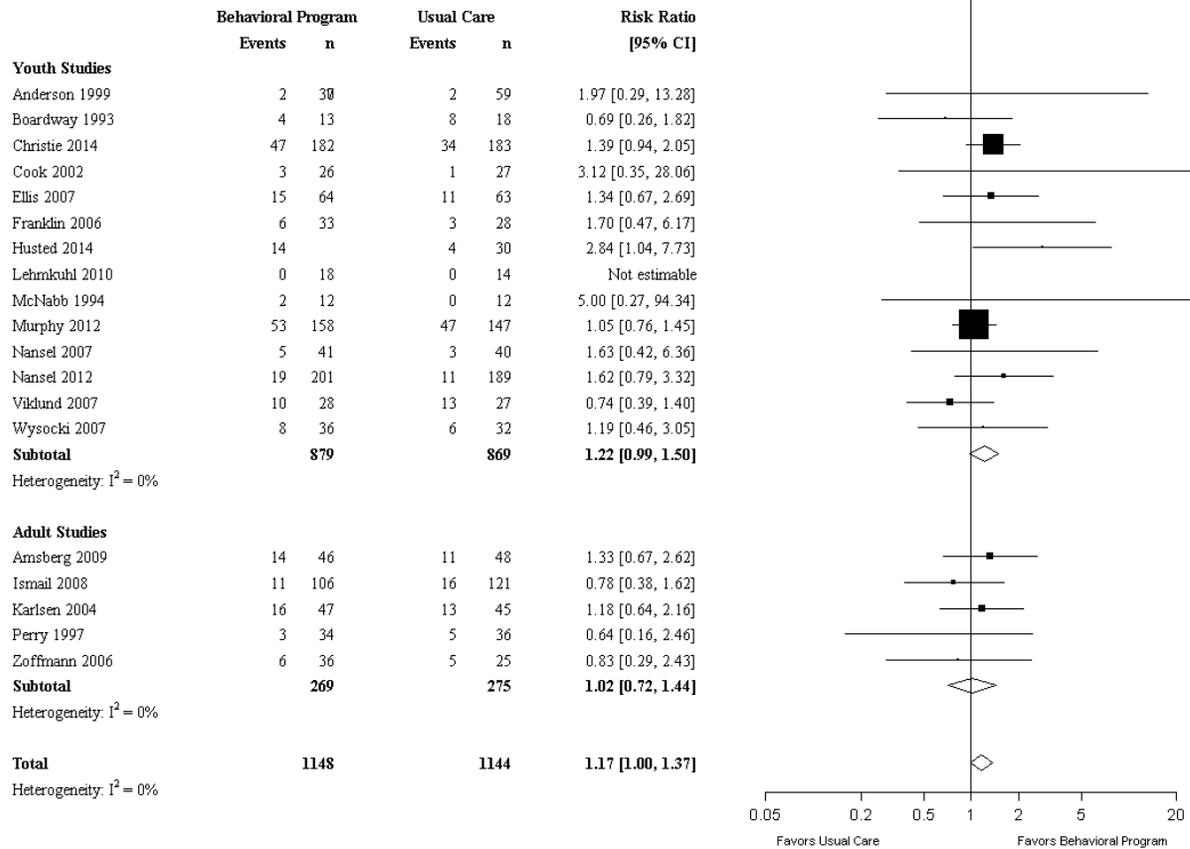
Outcome	Timepoint	# Trials (#Subjects)	Study Effect	Conclusion
Hospitalizations (# admissions)	EOI	1 (95 youth) <sup>86</sup>	RR, 0.28; 95% CI, 0.15 to 0.55	Lower risk of admissions for behavioral program
Hospitalizations (# admissions)	6m followup	1 (98 youth) <sup>86</sup>	RR, 0.41; 95% CI, 0.21 to 0.78	Lower risk of admissions for behavioral program
Hospitalizations (# admissions)	24m followup	1 (343 youth) <sup>83</sup>	RR, 0.78; 95% CI, 0.45 to 1.34	No difference
Hospitalizations (# admissions)	EOI	1 (159 adults) <sup>92</sup>	RR, 1.88; 95% CI, 0.49 to 7.25	No difference
Hospitalizations (# admissions)	6m followup	1 (198 adults) <sup>92</sup>	RR, 0.90; 95% CI, 0.35 to 2.32	No difference
Emergency Dept (# admissions)	EOI	1 (98 youth) <sup>86</sup>	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 14 presents our meta-analysis stratified by age (youth and adults) of trials that reported participant attrition at their longest followup timepoint. Our meta-analysis (19 trials, 2,292 subjects) found a 17 percent increased risk of attrition for individuals receiving usual care compared with those receiving the behavioral program (RR, 1.17; 95% CI, 1.0 to 1.37).

**Figure 14. Behavioral programs for diabetes compared with usual care: Participant attrition**



### Program Acceptability: Behavioral Programs Compared With Active Control

Three RCTs (218 youth<sup>85, 106</sup> and 160 adults<sup>89</sup>) 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.<sup>88</sup> 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<sub>1c</sub> at 6-month postintervention followup with greater reduction in HbA<sub>1c</sub> for individuals who were enrolled in behavioral programs compared with those receiving usual care (Table 7). For other timepoints, there was low SOE showing no difference in HbA<sub>1c</sub>. At long-term followup ( $\geq 12$  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. For generic HRQL, there was low SOE of no difference at the end of intervention. There was insufficient evidence for all other outcomes.

**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	Strength of Evidence
HbA <sub>1c</sub>	EOI	15 (1,097) <sup>80-82, 87, 91-94, 96, 97, 99, 103, 104, 106, 108</sup>	MD, -0.11; 95% CI, -0.35 to 0.13	Low for no difference
HbA <sub>1c</sub>	6m followup	11 (1,316) <sup>82, 84, 86, 91, 92, 98, 100-102, 106, 107</sup>	MD, -0.33; 95% CI, -0.51 to -0.15	Moderate for benefit
HbA <sub>1c</sub>	12m followup	6 (1,186) <sup>81, 83, 100-102, 106</sup>	MD, -0.21; 95% CI, -0.54 to 0.12	Low for no difference
HbA <sub>1c</sub>	≥12m followup	4 (1,138) <sup>83, 92, 101, 102</sup>	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 difference
Adherence to diabetes self-management	EOI	4(282); <sup>82, 86, 91, 94</sup> SMBG 1 (74); <sup>80</sup> SDSCA 1 (54); <sup>106</sup> DSMP 1 (74); <sup>80</sup> 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 difference
Adherence to diabetes self-management	6m followup	5 (252); <sup>82, 84, 86, 91, 107</sup> SMBG 1 (244); <sup>92</sup> SDSCA 2 (471); <sup>101, 102</sup> 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 difference
Adherence to diabetes self-management	12m followup	1 (54); <sup>106</sup> DSMP 1 (180); <sup>83</sup> 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 <sup>102</sup> 1 (190); <sup>83</sup> 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)	EOI	1 (60) <sup>87</sup>	MD, 0.08; 95% CI, -0.35 to 0.51	Insufficient
Change in body composition (BMI)	6m followup	1 (227) <sup>92</sup>	MD, -0.21; 95% CI, -0.62 to 0.20	Insufficient
Change in body composition (kg)	EOI	1 (61) <sup>103</sup>	MD, -0.50; 95% CI, -5.69 to 4.69	Insufficient
Change in physical activity (fitness – VO <sub>2</sub> max)	EOI	1 (43) <sup>103</sup>	MD, 0.59; 95% CI, 0.22 to 0.96	Insufficient
Change in physical activity (intensity/duration)	EOI	2 (91) <sup>80, 82</sup>	SMD, 0.16; 95% CI, -0.25 to 0.57	Insufficient
Change in physical activity (intensity/duration)	6m followup	2 (272) <sup>82, 92</sup>	SMD, -0.26; 95% CI, -1.00 to 0.49	Insufficient
Change in dietary or nutrient intake (kcal/day)	EOI	1 (61) <sup>103</sup>	MD, -247.10; 95% CI, -281.7 to -212.5	Insufficient
Change in dietary or nutrient intake (saturated fat)	EOI	1 (61) <sup>103</sup>	MD, -1.80; 95% CI, -3.53 to -0.07	Insufficient
Generic HRQL	EOI	6 (419) <sup>80, 91, 93-96</sup>	SMD, 0.15; 95% CI, -0.16 to 0.46	Low for no difference
Generic HRQL	6m followup	1 (53) <sup>91</sup>	SMD, -0.29; 95% CI, -0.83 to 0.26	Insufficient
Generic HRQL	12m followup	2 (405) <sup>83, 96</sup>	SMD, 0.02; 95% CI, -0.11 to 0.15	Insufficient
Generic HRQL	≥12m followup	1 (291) <sup>83</sup>	SMD, -0.04; 95% CI, -0.27 to 0.19	Insufficient
Diabetes-specific quality of life	EOI	1 (26) <sup>95</sup>	SMD, -0.77; 95% CI, -1.57 to 0.04	Insufficient

Outcome	Outcome Timing	# Trials (# Subjects); Tool if Applicable	Mean Difference or Standardized Mean Difference	Strength of Evidence
Diabetes-specific quality of life	EOI	1 (131) <sup>108</sup>	SMD, 0.44; 95% CI, 0.08 to 0.81	Insufficient

BMI = body mass index; CI = confidence interval; DSMP = Diabetes Self-Management Profile; EOI = end of intervention; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; 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

There was moderate SOE showing differences in HbA<sub>1c</sub> at 6-month postintervention followup with a clinically important reduction in HbA<sub>1c</sub> 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<sub>1c</sub>; because the 95% CI 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	Strength of Evidence
HbA <sub>1c</sub>	EOI	4 (566) <sup>85, 90, 105, 106</sup>	MD, -0.32; 95% CI, -0.78 to 0.14	Low for no difference
HbA <sub>1c</sub>	6m followup	4 (504) <sup>89, 90, 105, 106</sup>	MD, -0.43; 95% CI, -0.62 to -0.24	Moderate for benefit
HbA <sub>1c</sub>	12m followup	3 (342) <sup>90, 105, 106</sup>	MD, -0.34; 95% CI, -0.71 to 0.03	Low for no difference
Adherence to diabetes self-management	EOI	1 (54); <sup>106</sup> DSMP 1 (149); <sup>90</sup> 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); <sup>89</sup> SMBG 1 (149); <sup>90</sup> 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); <sup>90</sup> 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<sub>1c</sub> = hemoglobin A<sub>1c</sub>; m = month; MD = mean difference; SDSCA = Summary of Diabetes Self-Care Activities; SMBG = self-monitoring of blood glucose; SMD = standardized mean difference

## 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<sub>1c</sub> (the outcome with the greatest amount of data) based on age (children and adolescents [ $\leq 18$  years], young adults [19-30 years], adults [31-64 years], older adults  $\geq 65$  years]), race or ethnicity, socioeconomic status, time since diagnosis ( $\leq 1$  year vs.  $> 1$  year), and level of glycemic control (HbA<sub>1c</sub>  $< 7$  vs.  $\geq 7$  percent). We also compared subgroups at the study level, for example

when the mean age of participants fell within one of the age categories, or the majority ( $\geq 75$  percent) of the participants was stated as racial/ethnic minorities.

## Key Points

- The effectiveness of behavioral programs compared with usual care for HbA<sub>1c</sub> appeared higher for adults than for youth at end of intervention.
- The effectiveness of behavioral programs compared with active controls appeared higher for youth than for adults at 12-month followup; the effectiveness for youth was clinically important.
- One trial reported results separately for youth with baseline HbA<sub>1c</sub>  $\geq 8$  percent and found favorable results for this subgroup.
- No trials reported on HbA<sub>1c</sub> 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<sub>1c</sub> for adults than for youth at end of intervention when compared to usual care; the effect size in the meta-analysis for adults<sup>80, 92, 93, 103, 108</sup> was greater in absolute terms than for the youth<sup>81, 82, 87, 91, 94, 96, 97, 99, 104, 106</sup> (MD = -0.28 vs. 0.01, respectively), and the results for adults approached statistical significance. However, the effect size did not meet our threshold for clinical importance. At 6-month followup, the effect sizes between youth<sup>82, 84, 86, 91, 98, 100-102, 106</sup> and adults appeared similar (MD = -0.30 vs. MD = -0.38, respectively); both failed to reach statistical significance.

When compared with active controls, behavioral programs appeared to be more effective for youth at 12-month followup. At 6-month followup, the effect size was larger for the youth<sup>90, 106</sup> than for the adults<sup>89, 105</sup> (MD -0.60 vs. -0.37) but only the results for adults reached statistical significance. At 12-month followup, results for youth were statistically and clinically significant (2 trials, 195 subjects; MD, -0.52; 95% CI, -1.04 to 0.00); for adults there was no difference at 12-month followup in the two comparisons by Weinger et al.<sup>105</sup> (MD, -0.14; 95% CI, -1.28 to 1.00).

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<sub>1c</sub>  $\geq 8$  percent).<sup>94</sup> At the end of intervention, Katz et al.<sup>94</sup> found that those receiving the behavioral program had greater odds of maintaining or improving their HbA<sub>1c</sub> 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<sub>1c</sub>. Subgroup analysis at the study level was not conducted because the mean baseline HbA<sub>1c</sub> 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.

## 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. 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<sub>1c</sub>; other outcomes did not have sufficient studies ( $\geq 10$  studies) associated with them to support meaningful analyses. All but one study<sup>103</sup> fell under the category of DSME, therefore we did not conduct a regression analysis on program components.

### Key Points:

- None of the program factors (e.g., intensity, delivery personnel) was shown to significantly influence the effectiveness of behavioral programs compared with usual care on HbA<sub>1c</sub>.

### Detailed Synthesis

Table 9 summarizes the results of the univariate meta-regressions conducted with 23 studies.<sup>80-84, 86, 87, 91-94, 96-104, 106-108</sup> 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 9. 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<sup>80, 92, 93, 103, 107, 108</sup> were not included in this analysis.

**Table 9. Results from univariate meta-regressions analyzing the association between different program factors and the effectiveness of behavioral programs in improving HbA<sub>1c</sub>**

Program Factors	# Studies	Coefficient and 95% CI	P value
Duration of intervention (continuous: months)	23	0.01; 95% CI, -0.01 to 0.03	0.352
Intensity (continuous: contact hours)	23	-0.01; 95% CI, -0.02 to 0.01	0.324
Frequency (continuous: hours/month)	23	-0.02; 95% CI, -0.08 to 0.03	0.396
Method of communication (dichotomous: in-person/ mix of in-person & technology)	23	-0.03; 95% CI, -0.34 to 0.28	0.851
Delivery method (dichotomous: individual/ group)	23	0.24; 95% CI, -0.04 to 0.51	0.084
Delivery personnel (3 categories)	23		

Program Factors	# Studies	Coefficient and 95% CI	P value
Non-health professionals only		-0.100; 95% CI, -0.520 to 0.320	0.624
One health professional		-0.031; 95% CI, -0.425 to 0.364	0.873
Multidisciplinary team		-0.189; 95% CI, -0.516 to 0.138	0.242
Community engagement (dichotomous: present/none or NR)	23	-0.33; 95% CI, -0.68 to 0.03	0.071
Support person present (dichotomous: yes/no)	17	-0.78; 95% CI, -0.58 to 0.42	0.745

CI = confidence interval; NR = not reported

## KQ4. Harms

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 risk of bias 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), 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 risk of bias 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<sub>1c</sub> in the subgroup analyses for KQ 6 are found in Appendix J. The Supplementary File includes figures (forest plots) of pair-wise 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 123 primary reports of RCTs,<sup>105, 125-246</sup> and 27 associated publications<sup>247-274</sup> (including one abstract)<sup>274</sup> providing information related to the study methodology, outcomes, or description of the interventions. One of the studies was also included in the section on T1DM because it provided data on HbA<sub>1c</sub> outcomes separately for T1DM and T2DM.<sup>105</sup>

## Characteristics of Included Studies

The majority of RCTs were two-arm trials with the following comparisons: 1) DSME with usual care (51 trials)<sup>125, 126, 128-133, 137, 139, 143, 145, 148, 152, 153, 161, 163, 166-169, 173, 177, 183-187, 193, 196, 201, 203, 205, 208-210, 213-216, 218, 219, 221, 223, 225, 228, 232, 235-237, 243</sup> or an active control (7 trials),<sup>136, 144, 171, 172, 188, 191, 192</sup> 2) DSME and support with usual care (8 trials)<sup>141, 179, 197, 198, 200, 206, 207, 212</sup> or with an active control (1 trial),<sup>154</sup> 3) lifestyle programs with usual care (15 trials)<sup>127, 133, 135, 147, 150, 157, 180, 195, 226, 229, 230, 239, 241, 244, 245</sup> or an active control (7 trials),<sup>146, 151, 155, 156, 159, 176, 242</sup> and, 4) between two behavioral programs (20 trials).<sup>134, 140, 142, 149, 160, 162, 170, 175, 178, 189, 194, 199, 202, 211, 222, 227, 233, 234, 238, 240, 246</sup> Twelve three-arm RCTs were included, with eight comparing behavioral programs with usual care,<sup>178, 190, 204, 224, 231</sup> or active control,<sup>158, 182, 220</sup> and four having one intervention arm compared with two controls.<sup>105, 164, 165, 174</sup> Three four-arm trials<sup>138, 181, 217</sup> examined 1) two lifestyle programs compared with two dietary interventions,<sup>138</sup> 2) one lifestyle program compared with two active controls (dietary and physical activity interventions) and a usual care arm,<sup>181</sup> and 3) the comparative effectiveness between DSME and three DSME and support programs delivered by different personnel.<sup>217</sup> 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,<sup>127, 130, 149, 155, 194, 203, 222, 235, 241</sup> and 57 (46 percent) were published since 2010.<sup>105, 125, 129, 136, 138, 142-145, 152, 154, 157, 158, 160-163, 165, 169, 171, 172, 181, 183, 184, 188, 189, 191, 192, 196-201, 204, 206-209, 211, 214, 217, 218, 223, 224, 226, 227, 230-232, 234, 237-239, 242, 243, 246</sup>

The mean age of the participants was between 45 and 72 years (median=58). Six studies did not report age.<sup>129, 150, 183, 214, 232, 235</sup> 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 ( $\geq 75$  percent) of participants in 43 trials reported nonwhite race/ethnicity,<sup>127, 128, 131, 133, 140-143, 149, 152, 154, 161, 169, 170, 172, 178, 179, 185, 187, 188, 190, 195-198, 200, 205-209, 212, 218-221, 223, 227, 230, 232, 233, 235-237</sup> and 9 trials included few (<10 percent) people of nonwhite race /ethnicity.<sup>139, 173-175, 202, 229, 239, 241, 246</sup> Baseline HbA<sub>1c</sub> was between 6.3 and 12.3 percent (median=8 percent); five trials did not report this information.<sup>128, 228, 232, 235, 241</sup> Median duration of diabetes was 8.1 years (range 1–18 years). The median percentage of participants prescribed treatment with insulin was 19.2 percent; one study assessed the effectiveness of a lifestyle program in a sample of patients who were all initiated on insulin therapy,<sup>135</sup> and another studied a DSME program in patients receiving ongoing intensive insulin treatment.<sup>171</sup> Body mass index ranged from 23.9–39.1 kg/m<sup>2</sup> (median=33.3 kg/m<sup>2</sup>).

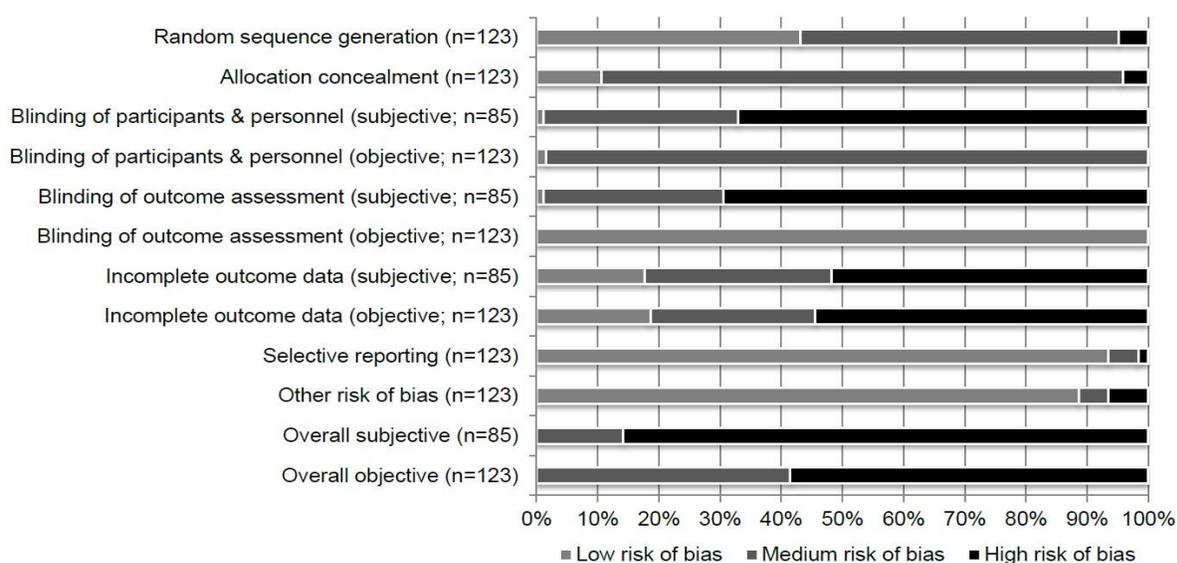
Table F3 in Appendix F includes details on each behavioral program studied. Several trials evaluated more than one behavioral program; there were 156 intervention arms in total. Overall, median program duration was 6 months (range 1–96) and median number of contact hours was 12 (range 1–208). Technology was the primary method of communication for 13 programs studied in 12 trials;<sup>128, 129, 137, 157, 161, 169, 175, 177, 184, 231, 237, 243</sup> based on our inclusion criteria, all programs were delivered with some form of communication with delivery personnel. Fifty-nine programs were delivered to individuals only, 54 to groups only, and 42 had some mixture of individual and group delivery (see Table F3 for details). A small majority (79 of 156; 51 percent) of programs were delivered by one health care professional, with (n=16) or without (n=63) the assistance of a non-health care professional; other programs were delivered by a multidisciplinary team (45 arms; 29 percent) or solely by non-health care professionals (29 arms; 19 percent) (see Table F3). Data on the delivery personnel could not be determined for two studies.<sup>177, 226</sup>

## Risk of Bias of Individual Studies

A summary of the ROB assessments for the 123 trials is presented in Figure 15; 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 risk of bias. For objective outcomes (e.g., HbA<sub>1c</sub>, 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). For subjective outcomes (e.g., HRQL, depression), 14 percent had a medium risk of bias; the remainder (86 percent) had a high risk of bias. This was primarily due to lack of blinding of participants, study personnel, and outcome assessors.

Twenty-four trials (19 percent) received funding from industry. Ninety-nine (80 percent) received funding from non-industry sources (e.g., government or foundations); of these, 15 (12 percent) received funding from both industry and non-industry sources. Funding was not reported by five (0.4 percent) studies.

**Figure 15. 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<sub>1c</sub> and Change in Body Composition

### HbA<sub>1c</sub>

Individuals receiving behavioral programs compared with usual control improved their glycemic control (i.e. reduced percent HbA<sub>1c</sub>) at end of intervention (59 comparisons; 7,867 subjects; MD, -0.34; 95% CI, -0.47 to -0.21; I<sup>2</sup>=73%),<sup>125, 127, 129, 131, 132, 135, 137, 141, 143, 145, 150, 152, 161, 163, 165-167, 169, 174, 178-181, 187, 193, 195-198, 200, 203-210, 212-216, 218, 219, 221, 223, 226, 229-231, 237, 239, 243-245</sup> and at 6-month followup (22 comparisons; 4,044 subjects; MD, -0.16; 95% CI, -0.3 to -0.02; I<sup>2</sup>=62%).<sup>126, 130, 133, 136, 153, 163, 168, 173, 183-186, 201, 205, 219, 224, 225, 231, 236, 239</sup> The results were of a smaller magnitude when behavioral programs were compared with active control groups; at end of intervention (24 comparisons; 7,439 subjects)<sup>105, 144, 151, 154-156, 158, 159, 164, 165, 174, 176, 181, 182, 188, 192, 220, 242</sup> the MD was -0.25 (95% CI, -0.42 to -0.08; I<sup>2</sup>=71%), and at 6-month followup (6 comparisons; 486 subjects)<sup>105, 146, 171, 172, 191</sup> it was -0.19 (95% CI, -0.37 to -0.01). Results at 12-month followup were nonsignificant. No result was clinically important based on our prespecified threshold of 0.4 unit change in percent HbA<sub>1c</sub>. The meta-analyses for HbA<sub>1c</sub> indicated high heterogeneity in effect between studies across timepoints (I<sup>2</sup> ranged from 62–98 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).<sup>182, 202, 275</sup> 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).<sup>234</sup> Several comparative effectiveness studies found no difference in HbA<sub>1c</sub> changes between groups. Some examples include the addition of an additional treatment (e.g., problem solving therapy,<sup>158</sup> music therapy<sup>189</sup>) or a support aspect to a DSME or lifestyle program;<sup>162, 217, 220</sup> others include comparisons between peer and health professional delivery of a program component (see Appendix I).<sup>134, 162, 217, 246</sup>

Six trials reported on HbA<sub>1c</sub> but did not provide data for inclusion in the meta-analysis. Five trials comparing a behavioral program with usual care did not find a significant difference between groups.<sup>139, 147, 157, 177, 190</sup> One trial comparing two behavioral interventions with different delivery methods also found no difference between groups.<sup>149</sup>

Visualization of funnel plots did not suggest publication bias, and using the Egger test<sup>76</sup> for our outcome with the most data (HbA<sub>1c</sub>) 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·m<sup>-2</sup>) at all three timepoints—end of intervention (32 comparisons; 4,001 subjects; MD, -0.47; 95% CI, -0.74 to -0.2),<sup>125, 127, 129, 135, 141, 143, 145, 152, 161, 165, 169, 174, 179, 180, 196, 198, 200, 204, 205, 214, 216, 223,</sup>

229-232, 236, 239, 241, 245 6-month followup (13 comparisons, 1,746 subjects; MD, -0.22; 95% CI, -0.34 to -0.1),<sup>126, 133, 136, 153, 173, 183, 201, 205, 231, 236, 239, 241</sup> and 12-month followup (5 comparisons; 867 subjects; MD, -0.92; 95% CI, -1.44 to -0.4).<sup>136, 147, 153, 183, 228</sup> 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 (30 comparisons; 3,206 subjects; MD, -1.88; 95% CI, -2.41 to -1.35),<sup>127, 131, 135, 137, 143, 150, 157, 166, 168, 174, 178, 180, 181, 190, 193, 195, 203, 204, 207, 212, 214-216, 229, 236, 239, 244</sup> or active control (14 comparisons; 6,145 subjects; MD, -1.42; 95% CI, -2.66 to -0.18;  $I^2=79\%$ ).<sup>138, 144, 155, 156, 159, 164, 174, 176, 181, 188, 192, 242</sup> 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).<sup>191</sup> Waist circumference (cm) was reduced at end of intervention (15 comparisons, 1,392 subjects),<sup>135, 143, 152, 157, 180, 193, 204, 205, 214, 216, 231, 244, 245</sup> in those comparisons with usual care—MD = -3.11 (95% CI, -4.46 to -1.76;  $I^2=66\%$ ). 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).<sup>146</sup> There was no difference found in two studies comparing behavioral programs to usual care at 12-month followup;<sup>147, 153</sup> no data was 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.<sup>160</sup> 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 (10 comparisons; 1,173 subjects; MD, -122.07; 95% CI, -211.04 to -33.1;  $I^2=53\%$ )<sup>125, 127, 145, 157, 178, 181, 205, 206, 235</sup> and 6-month followup (3 comparisons; 469 subjects; MD, -64.05; 95% CI, -96.44 to -31.66).<sup>153, 157, 205</sup> 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).<sup>153, 228</sup> These and several other trials<sup>128, 153, 174, 209, 216, 226, 228-230, 243</sup> 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).<sup>174</sup> There was no difference reported for objective measurements of exercise duration/intensity, or for measures of fitness in trials comparing behavioral programs to usual care or active controls.

Two comparative effectiveness trials found significant effects for changes in physical activity. Based on self-report of days per week of engaging in moderate-to-intense physical activity, Vadstrup et al.<sup>234</sup> 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.,<sup>199</sup> 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,<sup>128, 161</sup> the Hill-Bone Compliance Scale,<sup>158, 165</sup> and the Morisky Adherence Scale.<sup>243</sup> 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);<sup>228</sup> 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,<sup>145, 204, 212, 229</sup> or up to 6-months followup for comparisons with active controls.<sup>159, 171, 242</sup> There was no difference found for Quality of Life–Other in comparisons (n=7) with usual care up to 6-month followup,<sup>185, 186, 196, 216, 239, 243</sup> or in comparisons (n=7) with active controls up to 12-months followup.<sup>144, 182</sup> 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),<sup>132, 137, 201, 208, 215, 216, 218, 223</sup> but not at longer followup.<sup>136, 201, 224</sup> The result at end of intervention is not clinically important. One study (167 subjects) evaluating this outcome in a comparison to active controls found no difference at 6-month followup.<sup>171</sup> 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,<sup>136, 153, 165, 167, 179, 205, 243</sup> or at end of intervention for programs compared with active controls.<sup>144, 158, 165</sup>

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.<sup>217</sup> 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).<sup>274</sup> Results for the other outcomes failed to 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), diabetic nephropathy (RR, 0.68; 95% CI, 0.34 to 1.46), 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;<sup>242</sup> there was enough data in 22 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 (20 comparisons; 4,775 subjects; RR, 1.32; 95% CI, 0.82 to 2.12); mortality between behavioral programs and active control groups (4 comparisons, 5,949 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: HbA1c**

- 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 ( $\leq 10$  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 ( $\geq 5$  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<sub>1c</sub> and BMI. These outcomes represent two of our key outcomes and had the greatest amount of outcome data. Tables 10 (HbA<sub>1c</sub>) and 11 (BMI) provide descriptions of the nodes (no two containing the same combination of variables), and include the results including the MD and associated 95 percent credibility interval, the rank order of each node, and a percentage referring to the node's "probability of being best" (PB). We summarize our approach and the results for each outcome below. Figures 16 and 17 contain the plots showing the relative ranking of the different nodes; the studies within each node are cited in the accompanying tables.

### HbA<sub>1c</sub>

When choosing which variables to consider for creating the nodes, we used a hierarchical approach based on the categories in Table 3 (see Methods). 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 decided to use four additional variables (i.e. intensity, method of communication, delivery method, and delivery personnel) to create 24 potential nodes (16 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.

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 percent) for change in HbA<sub>1c</sub>. 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 ( $\geq 26$  contact hours), and two (nodes 17 [DSME and support] and 26 [lifestyle]) represent low-intensity programs ( $\leq 10$  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 (nodes 4–11) showed clinically important effects; all had greater impact on HbA<sub>1c</sub> than basic educational controls, but lower impact than a stand-alone dietary or physical activity intervention (node 3). Of the four nodes (13–16) representing DSME programs with MDs showing clinically important effect, three (14–16) 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. Nodes 15 and 32 had the highest PB (32 and 15.3 percent, respectively); behavioral programs in both nodes were delivered in person rather than by incorporating technology. Similar observations were noted for the other four nodes having PB  $\geq 5$  percent, of which three (14, 17, 24) were delivered in person and one was delivered using some form of technology (node 30). The two studies<sup>133, 150</sup> in node 30 provided supportive telephone calls between in-person sessions during lifestyle interventions tailored to minorities. All effective nodes representing some use of technology (13, 16, 30) were of moderate or high intensity.

Node 18 represented an outlier with an MD of 2.80 (95% CI 1.14 to 4.48). This study by Brown et al.<sup>142</sup> found greater HbA<sub>1c</sub> 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 25 nodes.

BMI at baseline was similar for programs classified as DSME (32.5 kg·m<sup>2</sup>), DSME and support (33.1 kg·m<sup>2</sup>), and lifestyle (32.9 kg·m<sup>2</sup>). The MDs for BMI from behavioral programs ranged between -1.75 kg·m<sup>2</sup> and 3.31 kg·m<sup>2</sup>. The node with the largest MD only represented one study<sup>147</sup> evaluating a low-intensity lifestyle program with multiple brief contacts over 6 months. Nodes with the next highest MDs (18 and 23) were both lifestyle programs of low and medium intensity, respectively. The node (8) having the most studies (n=10) 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 10. Network meta-analysis for HbA<sub>1c</sub>: Description of nodes and results**

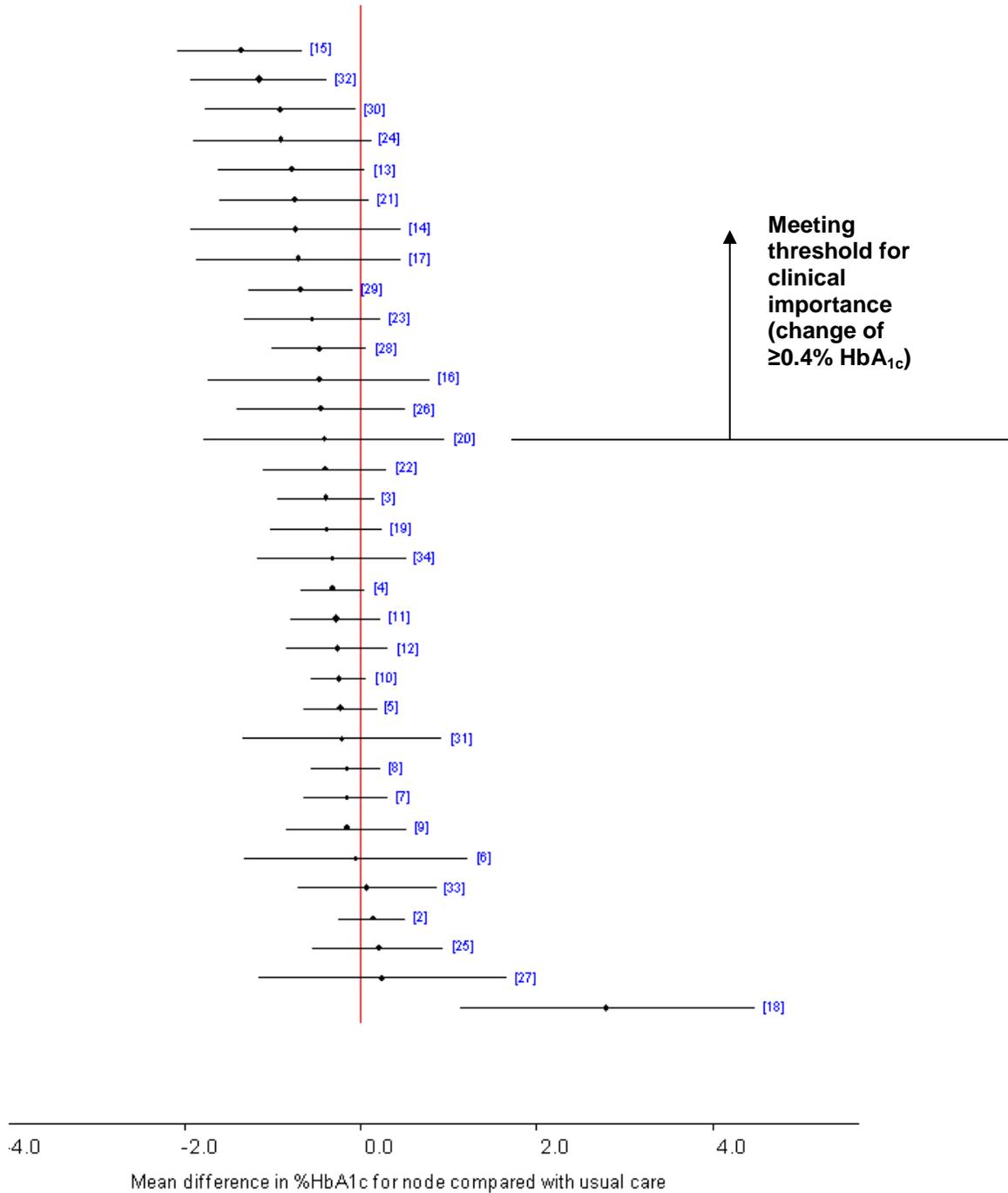
Arm Description	Network Node with Study References	Intensity	Method of Communication	Delivery Method	Delivery Personnel	Rank Order in NMA	MD, 95% Credibility Interval	Probability of Being Best
Usual care (reference category)	<b>1</b> <sup>125-127, 129-133, 135, 137, 141, 143, 145, 148, 150, 152, 153, 161, 163, 165-169, 173, 174, 178-181, 183-187, 193, 195-198, 200, 201, 203-210, 212-216, 218, 219, 221, 223-226, 228-231, 236, 237, 239, 243-245</sup>	NA	NA	NA	NA	NA	0 [NA, NA]	0.0%
Active comparator (non-DSME)	<b>2</b> <sup>105, 136, 144, 154, 158, 159, 165, 171, 172, 174, 182, 188, 191, 242</sup>	NA	NA	NA	NA	30	0.14 [-0.24, 0.52]	0.0%
Active comparator (other)	<b>3</b> <sup>146, 151, 155, 156, 164, 176, 181, 192, 220</sup>	NA	NA	NA	NA	16	-0.38 [-0.93, 0.16]	0.0%
DSME	<b>4</b> <sup>125, 143, 144, 168, 175, 202, 215, 221, 224, 228, 233, 234</sup>	≤10h	In person	Individual & mixed	HCP	19	-0.30 [-0.66, 0.06]	0.0%
	<b>5</b> <sup>105, 134, 136, 162, 163, 172, 189, 201, 202, 224</sup>	≤10h	In person	Group only	HCP	23	-0.22 [-0.63, 0.19]	0.0%
	<b>6</b> <sup>134</sup>	≤10h	In person	Group only	Non-HCP	28	-0.05 [-1.32, 1.23]	1.0%
	<b>7</b> <sup>161, 165, 169, 175, 193, 216, 231</sup>	≤10h	Some technology	Individual & mixed	HCP	26	-0.15 [-0.63, 0.31]	0.0%
	<b>8</b> <sup>158, 166, 167, 173, 184, 208-210, 237, 243</sup>	≤10h	Some technology	Individual & mixed	Non-HCP	25	-0.15 [-0.55, 0.23]	0.0%
	<b>9</b> <sup>182, 196, 203</sup>	11-26h	In person	Individual & mixed	HCP	27	-0.15 [-0.83, 0.53]	0.0%
	<b>10</b> <sup>126, 131, 145, 148, 153, 160, 171, 182, 183, 189, 213, 214, 225, 233</sup>	11-26h	In person	Group only	HCP	22	-0.24 [-0.55, 0.08]	0.0%
	<b>11</b> <sup>185, 186, 218, 219, 236</sup>	11-26h	In person	Group only	Non-HCP	20	-0.28 [-0.79, 0.24]	0.0%
	<b>12</b> <sup>129, 132, 137, 152</sup>	11-26h	Some technology	Individual & mixed	HCP	21	-0.25 [-0.82, 0.32]	0.0%
	<b>13</b> <sup>187, 223</sup>	11-26h	Some technology	Individual & mixed	Non-HCP	5	-0.78 [-1.61, 0.06]	3.9%
	<b>14</b> <sup>205</sup>	≥27h	In person	Individual & mixed	HCP	7	-0.73 [-1.92, 0.47]	8.4%
	<b>15</b> <sup>191, 192, 234</sup>	≥27h	In person	Group only	HCP	1	-1.35 [-2.07, -0.65]	32.0%

	<b>16</b> <sup>188</sup>	≥27h	Some technology	Individual & mixed	HCP	12	-0.46 [-1.71, 0.80]	3.8%
DSME + Support	<b>17</b> <sup>200</sup>	≤10h	In person	Individual & mixed	NA	8	-0.70 [-1.86, 0.46]	7.1%
	<b>18</b> <sup>142</sup>	≤10h	In person	Group only	NA	33	2.80 [1.14, 4.48]	0.0%
	<b>19</b> <sup>162, 197, 220</sup>	≤10h	Some technology	Individual & mixed	NA	17	-0.38 [-1.02, 0.26]	0.1%
	<b>20</b> <sup>154</sup>	11-26h	In person	Individual & mixed	NA	14	-0.40 [-1.77, 0.97]	4.4%
	<b>21</b> <sup>140, 198, 199</sup>	11-26h	In person	Group only	NA	6	-0.74 [-1.59, 0.10]	2.9%
	<b>22</b> <sup>142, 179, 199, 212</sup>	11-26h	Some technology	Individual & mixed	NA	15	-0.39 [-1.11, 0.31]	0.1%
	<b>23</b> <sup>206, 207</sup>	≥27h	In person	Individual & mixed	NA	10	-0.54 [-1.32, 0.24]	0.9%
	<b>24</b> <sup>140, 141</sup>	≥27h	In person	Group only	NA	4	-0.89 [-1.89, 0.12]	9.5%
Lifestyle	<b>25</b> <sup>135, 178, 239</sup>	≤10h	In person	Individual & mixed	NA	31	0.21 [-0.53, 0.96]	0.0%
	<b>26</b> <sup>146, 176</sup>	≤10h	In person	Group only	NA	13	-0.44 [-1.41, 0.52]	1.0%
	<b>27</b> <sup>178</sup>	≤10h	Some technology	Individual & mixed	NA	32	0.26 [-1.14, 1.66]	0.6%
	<b>28</b> <sup>155, 174, 180, 181, 222, 226</sup>	11-26h	In person	Individual & mixed	NA	11	-0.47 [-1.01, 0.08]	0.0%
	<b>29</b> <sup>159, 160, 195, 222, 245</sup>	11-26h	In person	Group only	NA	9	-0.67 [-1.27, -0.08]	0.5%
	<b>30</b> <sup>133, 150</sup>	11-26h	Some technology	Individual & mixed	NA	3	-0.90 [-1.75, -0.05]	7.3%
	<b>31</b> <sup>244</sup>	11-26h	Some technology	Group only	NA	24	-0.20 [-1.34, 0.93]	1.0%
	<b>32</b> <sup>127, 151, 164, 204</sup>	≥27h	In person	Individual & mixed	NA	2	-1.14 [-1.92, -0.38]	15.3%
	<b>33</b> <sup>229, 230</sup>	≥27h	In person	Group only	NA	29	0.08 [-0.71, 0.87]	0.0%
	<b>34</b> <sup>156, 242</sup>	≥27h	Some technology	Individual & mixed	NA	18	-0.31 [-1.16, 0.52]	0.2%

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

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

Figure 16. Plot of network meta-analysis results for HbA<sub>1c</sub>



This plot depicts the results from our network meta-analysis for the outcome of HbA<sub>1c</sub>. Each number in the plot represents a node containing the study arms cited in the Network Node column of Table 10. The black circles indicate the benefit (mean difference in %HbA<sub>1c</sub>) for the nodes when compared with a reference of usual care. All nodes at and above node 20 were found to have a mean difference at or above our threshold for clinical importance (greater than 0.40% HbA<sub>1c</sub> reduction compared with usual care).

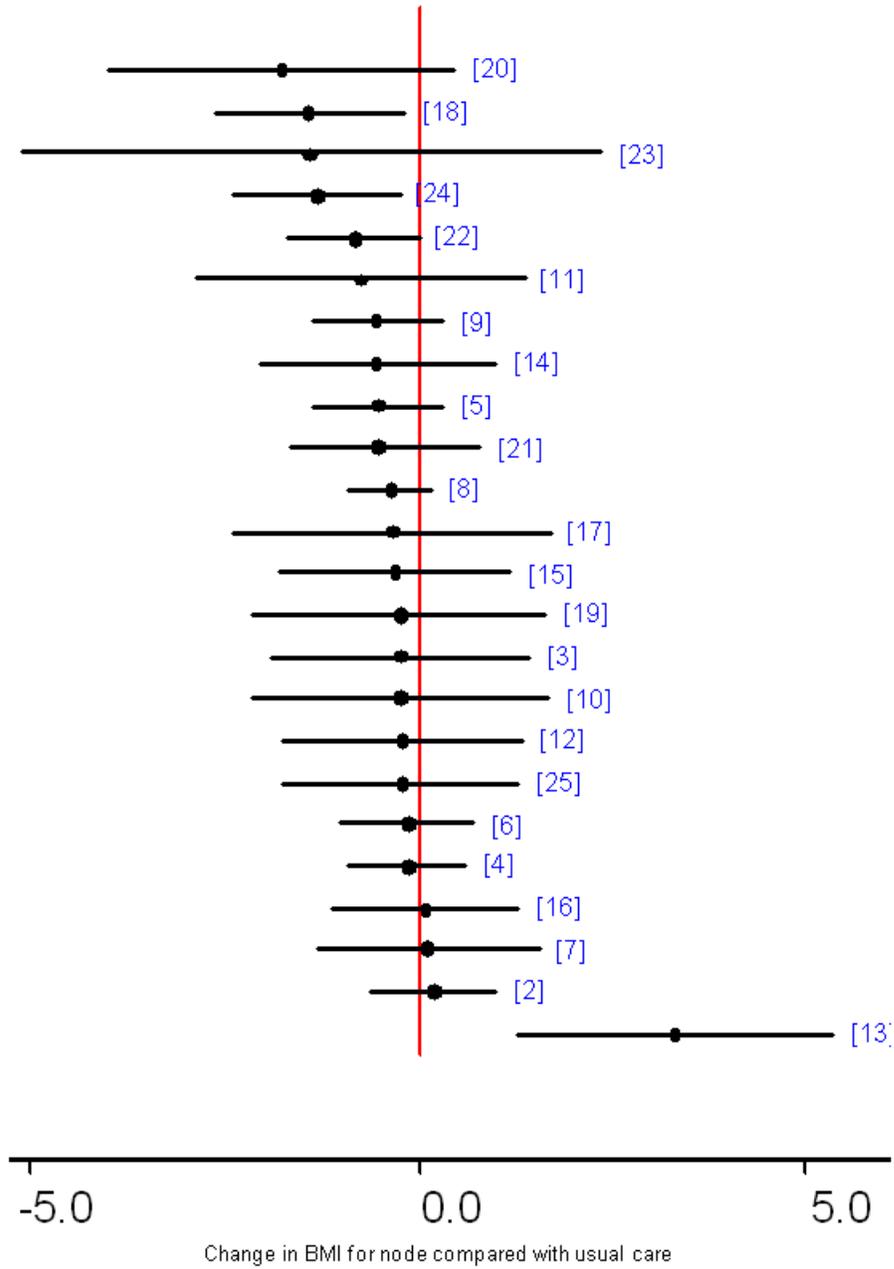
**Table 11. Network meta-analysis for body mass index: Description of nodes and results**

Arm Description	Network Node	Intensity	Method of Communication	Delivery Method	Rank Order in NMA	MD (kg·m <sup>-2</sup> ), 95% Credibility Interval	Probability of Being Best
Usual care (reference category)	<b>1</b> <sup>125-127, 129, 131, 133, 135, 141, 143, 145, 147, 152, 153, 161, 163, 165, 169, 173, 174, 179, 180, 183, 196, 198, 200, 201, 204, 205, 214, 216, 223, 228-232, 236, 239, 241, 245</sup>	NA	NA	NA	NA	0 [NA, NA]	0.0%
Active comparator (non-DSME)	<b>2</b> <sup>136, 144, 159, 165, 174, 182</sup>	NA	NA	NA	23	0.20 [-0.61, 1.00]	0.0%
Active comparator (other)	<b>3</b> <sup>146, 164, 176, 192</sup>	NA	NA	NA	15	-0.24 [-1.90, 1.43]	0.1%
DSME	<b>4</b> <sup>125, 143, 144, 202, 228</sup>	≤10h	In person	Individual & mixed	20	-0.13 [-0.89, 0.60]	0.0%
	<b>5</b> <sup>136, 162, 163, 189, 201, 202</sup>	≤10h	In person	Group only	9	-0.53 [-1.35, 0.32]	0.1%
	<b>6</b> <sup>161, 165, 169, 173, 216, 231</sup>	≤10h	Some technology	Individual & mixed	19	-0.14 [-0.98, 0.70]	0.0%
	<b>7</b> <sup>182, 196</sup>	11-26h	In person	Individual & mixed	22	0.14 [-1.28, 1.56]	0.2%
	<b>8</b> <sup>126, 131, 145, 153, 160, 182, 183, 189, 214, 236</sup>	11-26h	In person	Group only	11	-0.34 [-0.89, 0.19]	0.0%
	<b>9</b> <sup>152, 223, 232</sup>	11-26h	Some technology	Individual & mixed	7	-0.53 [-1.32, 0.31]	0.1%
	<b>10</b> <sup>129, 205</sup>	≥27h	In person	Group only	16	-0.21 [-2.10, 1.68]	1.9%
	<b>11</b> <sup>192</sup>	≥27h	In person	Individual & mixed	6	-0.74 [-2.84, 1.37]	6.2%
DSME + Support	<b>12</b> <sup>200</sup>	≤10h	In person	Individual & mixed	17	-0.20 [-1.75, 1.35]	0.9%
	<b>13</b> <sup>142</sup>	≤10h	In person	Group only	24	3.31 [1.29, 5.32]	0.0%
	<b>14</b> <sup>162</sup>	≤10h	Some technology	Individual & mixed	8	-0.53 [-2.03, 0.98]	1.8%
	<b>15</b> <sup>198, 199</sup>	11-26h	In person	Group only	13	-0.29 [-1.76, 1.21]	0.8%
	<b>16</b> <sup>142, 179, 199</sup>	11-26h	Some technology	Individual & mixed	21	0.10 [-1.07, 1.29]	0.0%
	<b>17</b> <sup>141</sup>	≥27h	In person	Group only	12	-0.32 [-2.34, 1.71]	3.2%

Arm Description	Network Node	Intensity	Method of Communication	Delivery Method	Rank Order in NMA	MD (kg·m <sup>-2</sup> ), 95% Credibility Interval	Probability of Being Best
Lifestyle	<b>18</b> <sup>135, 239</sup>	≤10h	In person	Individual & mixed	2	-1.41 [-2.62, -0.16]	11.8%
	<b>19</b> <sup>146, 176, 241</sup>	≤10h	In person	Group only	14	-0.24 [-2.14, 1.62]	1.0%
	<b>20</b> <sup>147</sup>	≤10h	Some technology	Individual & mixed	1	-1.75 [-3.97, 0.45]	32.5%
	<b>21</b> <sup>174, 180</sup>	11-26h	In person	Individual & mixed	10	-0.49 [-1.61, 0.81]	0.6%
	<b>22</b> <sup>159, 160, 245</sup>	11-26h	In person	Group only	5	-0.80 [-1.69, 0.01]	0.7%
	<b>23</b> <sup>133</sup>	11-26h	Some technology	Individual & mixed	3	-1.37 [-5.08, 2.36]	31.6%
	<b>24</b> <sup>127, 164, 204</sup>	≥27h	In person	Individual & mixed	4	-1.28 [-2.35, -0.24]	5.7%
	<b>25</b> <sup>229, 230</sup>	≥27h	In person	Group only	18	-0.20 [-1.71, 1.31]	0.8%

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

Figure 17. Plot of network meta-analysis results for body mass index



This plot depicts the results from our network meta-analysis for the outcome of body mass index (BMI). Each number in the plot represents a node containing the study arms cited in the Network Node column of Table 11. The black circles indicate the benefit (mean difference BMI) for the nodes when compared with a reference of usual care.

## KQ 6. Subgroups for Factors Moderating Effectiveness in T2DM

### Key Points

#### Glycemic Control

- In terms of overall effectiveness at longest followup for HbA<sub>1c</sub>, participants with suboptimal glycemic control ( $\geq 7$  percent HbA<sub>1c</sub>) 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.

#### Age

- Older adults ( $\geq 65$  years) did not benefit at longest followup in terms of reduction in HbA<sub>1c</sub> 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 ( $\geq 75$  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<sub>1c</sub>. Results for the variable of program intensity approached statistical significance.

### Detailed Synthesis

#### Glycemic Control

Initially, we conducted a subgroup analysis on the outcome of HbA<sub>1c</sub> by baseline glycemic control (HbA<sub>1c</sub>  $< 7$  vs.  $\geq 7$  percent) using the pair-wise meta-analysis results for HbA<sub>1c</sub> at longest followup timepoint (data not shown). For behavioral programs compared with usual care, our meta-analysis showed no difference (MD, -0.09; 95% CI, -0.20 to 0.01;  $I^2=0\%$ ) in change in HbA<sub>1c</sub> for participants with a baseline HbA<sub>1c</sub>  $< 7$  percent (5 trials, 1151 subjects);<sup>184, 186, 213, 236, 239</sup> the analysis showed benefit (although not clinically important) for participants with a baseline HbA<sub>1c</sub>  $\geq 7$  percent (70 trials; subjects; MD, -0.32; 95% CI, -0.43 to -0.21;  $I^2=71\%$ ). There was no difference in change in HbA<sub>1c</sub> for persons with baseline HbA<sub>1c</sub>  $< 7$  percent receiving a behavioral program compared with an active control (3 trials, 169 participants; MD, -1.43; 95% CI, -3.57 to 0.71;  $I^2=99\%$ );<sup>164, 176, 191</sup> persons with HbA<sub>1c</sub>  $\geq 7$  percent at baseline had greater reduction in

HbA<sub>1c</sub> after receiving behavioral programs compared with an active comparator (MD, -0.19; 95% CI -0.31 to -0.06; I<sup>2</sup>=41%), 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<sub>1c</sub> was <7 percent (n=8)<sup>164, 176, 184, 186, 191, 213, 236, 239</sup> and repeated the analysis for a subgroup with baseline HbA<sub>1c</sub> ≥7 percent; there were an insufficient number of studies with baseline HbA<sub>1c</sub> <7 percent to run the analysis using these studies, or to perform meta-regression analysis. The results are presented in Table J1 and Figure 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 15 and 26 shifted towards usual care (MDs 0.10 from -1.35 and -0.13 from -0.44, respectively), and 2) the active (dietary or physical activity) control became less effective (MD -0.13 vs. -0.38) for participants having ≥7 percent HbA<sub>1c</sub>.

## 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<sub>1c</sub> had a mean age ≥65 years.<sup>137, 145, 156, 186, 193, 208, 211, 213, 220, 226</sup> We first performed subgroup analyses by age group (≥65 years vs. <65 years) using the pair-wise meta-analyses results for HbA<sub>1c</sub> 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<sub>1c</sub> reduced to a statistically significant extent at longest followup (70 comparisons; 10,768 subjects; MD, -0.31; 95% CI, -0.41 to -0.20; I<sup>2</sup>=71%); for older adults the results indicated no difference (7 comparisons; 734 subjects; MD, -0.24; 95% CI, -0.50 to 0.03; I<sup>2</sup>=55%). For comparisons with active controls for participants <65 years, the benefit of behavioral programs was statistically and clinically significant (25 comparisons; 7,591 subjects; MD, -0.43; 95% CI -0.73 to -0.13; I<sup>2</sup>=93%). For older adults, behavioral programs compared with an active control (3 comparisons, 206 subjects) failed to reduce HbA<sub>1c</sub> (MD, -0.23; 95% CI, -0.60 to 0.14; I<sup>2</sup>=0%).

Subsequently, we performed a subgroup analysis for populations <65 years by removing the data from the nine studies (as above) having mean age ≥65 from our network meta-analysis described in the section for KQ5. The results are presented in Table J2 and Figure J2 in Appendix J. The categorization of all nodes remained the same in relation to the variables of interest. The notable changes in this subgroup analysis include: (1) the effect size for programs represented by node 34 favored usual care instead of behavioral programs, and (2) the effect size for node 3 (active control with dietary or physical activity intervention) became clinically important (MD, -0.55) although the PB remained at 0 percent.

## 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<sub>1c</sub> at longest followup for behavioral programs compared to usual care and active controls (data not shown). Using the pair-wise meta-analysis for HbA<sub>1c</sub> when comparing behavioral programs to usual care, there was a clinically important effect for minority participants (31 comparisons; 4,601 participants; MD, -0.43; 95% CI -0.59 to -0.28; I<sup>2</sup>=57%)<sup>127, 131, 133, 141, 143, 152, 161, 169, 178, 179, 185, 187, 195-198, 200, 205-209, 212, 218, 219, 221, 223, 230, 236, 237</sup> which was greater than that seen for the comparisons with <75 percent minorities (22 comparisons; 4,639 participants; MD, -0.17, 95% CI -0.33 to

0.00;  $I^2=76\%$ ).<sup>129, 132, 137, 150, 165-167, 173, 174, 184, 186, 204, 210, 214, 224, 225, 229, 239, 243, 244</sup> For comparisons between behavioral programs and active control groups, there was no statistically significant reduction in HbA<sub>1c</sub> among minorities (5 comparisons, 400 participants; MD, -0.32; 95% CI -0.67 to 0.04;  $I^2=0\%$ );<sup>154, 163, 172, 188, 220</sup> 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;  $I^2=99\%$ ).<sup>105, 158, 159, 165, 174, 191, 192, 242</sup> It is noteworthy that glycemic control at baseline appeared to be worse for the minority (8.80 percent HbA<sub>1c</sub>) compared with the majority/white (7.60 percent HbA<sub>1c</sub>) subgroup.

We also conducted univariate meta-regressions for each race/ethnicity subgroup. For this analysis, we used outcome data for changes in HbA<sub>1c</sub> at longest followup in comparisons between behavioral programs and usual care. Table 12 shows the results for each variable examined. No statistically significant finding was generated. The subgroup of minorities appeared to benefit more with increasing intensity (contact hours), but the result did not reach statistical significance.

**Table 12. 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<sub>1c</sub>**

Program Factors	# studies	Coefficient and 95% CI	P value
Duration of intervention (continuous: months)	<75% nonwhite (22)	-0.016; 95% CI, -0.05 to 0.02	0.38
	≥75% nonwhite (31)	0.012; 95% CI, -0.015 to 0.038	0.37
Intensity (continuous: contact hours)	<75% nonwhite (22)	-0.003; 95% CI, -0.011 to 0.004	0.36
	≥75% nonwhite (31)	0.0037; 95% CI, -0.0005 to 0.008	0.082
Frequency (continuous: hours/month)	<75% nonwhite (22)	-0.006; 95% CI, -0.05 to 0.05	0.78
	≥75% nonwhite (31)	0.013; 95% CI, -0.04 to 0.065	0.63
Method of communication (dichotomous: in-person/ some use of technology)	<75% nonwhite (22)	-0.17; 95% CI, -0.57 to 0.22	0.37
	≥75% nonwhite (31)	0.049; 95% CI, -0.30 to 0.39	0.75
Delivery method (dichotomous: individual & mixed/ group only)	<75% nonwhite (22)	0.12; 95% CI, -0.30 to 0.54	0.56
	≥75% nonwhite (31)	0.18; 95% CI, -0.18 to 0.53	0.32
Delivery personnel (dichotomous: non-health professionals only/health professional(s))	<75% nonwhite (22)	0.001; 95% CI, -0.40 to 0.42	0.96
	≥75% nonwhite (31)	-0.13; 95% CI, -0.47 to 0.20	0.43
Community engagement (dichotomous: present/none or NR)	<75% nonwhite (22)	0.038; 95% CI, -0.40 to 0.48	0.86
	≥75% nonwhite (31)	0.070; 95% CI, -0.43 to 0.56	0.78

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). Our terminology for KQ 1—in terms of low or moderate evidence—represents the results of our strength of evidence 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 and Behavioral, Clinical, and Health Outcomes; Diabetes-Related Health Care Utilization; and Program Acceptability**

There was moderate SOE showing reduction in hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) at 6-month postintervention followup with percent HbA<sub>1c</sub> reduced by 0.33 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<sub>1c</sub>; 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<sub>1c</sub> of 0.43 percent at 6-month postintervention followup. There was no difference in HbA<sub>1c</sub> 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 any followup timepoint. For generic health-related quality of life, there was low SOE of no difference at the end of intervention. There was insufficient evidence for all other outcomes. The SOE grading was highly influenced by the moderate-high risk of bias 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 17 percent increased risk of attrition usual care compared with behavioral programs.

### **KQ 2. Subgroups for Effectiveness in T1DM**

Behavioral programs compared with usual care for HbA<sub>1c</sub> appeared more effective for adults than for youth at end of intervention. The effectiveness of behavioral programs compared with active controls appeared higher for youth than for adults at 12-month followup, but few studies were included in the pooled results for these subgroups. One trial reported results separately for youth with baseline HbA<sub>1c</sub> ≥ 8 percent and found favorable results for this subgroup; no other within-study subgroup analysis was conducted because the majority of trials enrolled participants

with poor control (HbA<sub>1c</sub> >8.5 percent). No trials reported on HbA<sub>1c</sub> by race or ethnicity, socioeconomic status, or time since diagnosis.

### **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. None of the factors were shown to significantly influence the effectiveness of behavioral programs for HbA<sub>1c</sub>. 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<sub>1c</sub>.

### **KQ4. Harms**

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<sub>1c</sub>, when followup extends beyond the immediate postintervention period up to 6 months. The delay in benefit likely in part reflects the time required for this marker of glycemic control, indicating control over the past 2-3 months, to demonstrate change. 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<sub>1c</sub> 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 (17%) 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.<sup>276</sup>

Our finding of a statistically significant and clinically important reduction by 0.43 percent HbA<sub>1c</sub> 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  $\geq 4$  weeks with the inclusion of behavior change techniques; because of this, traditional, didactic educational<sup>89, 90, 105, 106</sup> or support interventions<sup>85</sup> 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<sub>1c</sub> 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.<sup>277-280</sup> For these reasons, many of the studies included in this review aimed to prevent deterioration of glycemic control rather than to improve it. The clinically important reductions in HbA<sub>1c</sub> at 6- and 12-month followup (0.60 and 0.54 percent, respectively) when behavioral programs were compared with active controls in youth lend substantial support for these programs.

Most studies for T1DM were undertaken in populations with baseline glycemic control  $\geq 8.5$  percent HbA<sub>1c</sub>. 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)<sup>19</sup> found that these individuals receive the greatest benefit from HbA<sub>1c</sub> reduction.

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. Our review did not identify enough studies of lifestyle programs to make any conclusions with respect to their benefits. 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. Although some behavioral programs were of fairly long duration with highly intense contact with patients,<sup>86</sup> only one explicitly incorporated a support component.<sup>80</sup>

Our pair-wise meta-analyses use the Hartung-Knapp-Sidik-Jonkman random effects model<sup>71-73</sup> that typically provides a more conservative estimate of the 95% CI around pooled effect sizes than the common DerSimonian and Laird approach; this holds especially when pooling a small number of studies. The effect of this is that some results are found statistically nonsignificant when another approach may find significance. For example, our reported 95% CI 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 less conservative calculation 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, 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, in the short-term (up to 6 months) for glycemic control; however, results at 12-month followup were not statistically significant and none of the results were considered to be clinically important based on our threshold of a 0.4 percent change in HbA<sub>1c</sub>. There was substantial statistical heterogeneity in these pair-wise 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 (0.2-0.9 kg/m<sup>2</sup> to 12-month followup), weight (1.4-1.9 kg; short term) and waist circumference (3cm; short term), and daily energy intake (120 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% 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.<sup>274</sup> Mortality between behavioral programs and active control groups (4 RCTs; 5,949 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 (20 RCTs, 4,775 participants; RR, 1.32; 95% CI, 0.82 to 2.21).

## **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<sub>1c</sub> at or above our threshold for clinical importance (i.e., 0.4 percent 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**

In terms of overall effectiveness at longest followup for HbA<sub>1c</sub>, participants with suboptimal or poor glycemic control ( $\geq 7$  percent HbA<sub>1c</sub>) 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 ( $\geq 65$  years) did not benefit at longest followup in terms of reduction in HbA<sub>1c</sub> 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<sub>1c</sub>—removing the studies of participants with a mean age  $\geq 65$ —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<sub>1c</sub>). 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 ( $\geq 75$  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<sub>1c</sub>). 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<sub>1c</sub>. Results for the variable of program intensity approached statistical significance ( $p=0.082$ ).

## **Discussion of Key Findings for T2DM**

Our systematic review built upon several previous reviews examining factors influencing effectiveness of interventions for T2DM. 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 ( $\geq 11$  hours contact time) programs appear to be necessary to provide individuals with clinically important effects on HbA<sub>1c</sub>; 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<sub>1c</sub> 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<sub>1c</sub>, that both individual and group delivery can be beneficial; this agrees with other work in this area<sup>281</sup> (also see below section on Findings in Relation to What is Already Known). In contrast, our pair-wise meta-analysis of three RCTs<sup>182, 202, 224</sup> (701 subjects) comparing group to individual program delivery favored group therapy (MD, -0.36 percent HbA<sub>1c</sub>; 95% CI, -0.63 to -0.08). Our network meta-analysis suggests that other factors (or combination of factors) may influence outcomes; 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,<sup>140, 142, 198</sup> 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 health 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)<sup>134, 162, 217, 246</sup> 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).<sup>217</sup> 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<sup>222, 240</sup> but not by diabetes educators.<sup>238</sup> 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<sub>1c</sub>), 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.<sup>281</sup>). 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  $\geq 65$  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 KQ 5 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<sub>1c</sub>=8.80 percent) compared with the majority/white (HbA<sub>1c</sub>=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. There is some evidence that ethnicity may be an independent predictor. 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. Ethnic minority groups have also been shown to have higher HbA<sub>1c</sub> 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.<sup>282</sup> Moreover, a systematic review by Nam et al.<sup>283</sup> which found benefit for culturally tailored diabetes education, found that lower baseline HbA<sub>1c</sub> levels better predicted positive responses to the programs. 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<sup>242</sup> should be highlighted. Reduction in retinopathy by 14% in those participating in a long-duration, intensive lifestyle program cannot be ignored.<sup>274</sup> Additionally, our findings from pairwise meta-analysis of 14% reduced mortality between those receiving behavioral programs and active control groups 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 built upon the limited number of previous reviews to determine the effectiveness of behavioral programs for multiple outcomes and all age groups. Few systematic reviews have been conducted over the past decade,<sup>3,5,6</sup> 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.<sup>3,4,6,7</sup> 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.<sup>4,5</sup> [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<sub>1c</sub>, as used in this review. Our results of 0.33 (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].<sup>284</sup> 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.<sup>6</sup> called for larger, multicenter trials 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,<sup>100</sup> and DSME with motivational interviewing and solution-focused brief therapy<sup>83</sup>) to standard care and enrolling patients with poor glycemic control (baseline HbA<sub>1c</sub>  $\geq$ 9 percent in both trials).<sup>83,100</sup> Neither study found benefit in terms of HbA<sub>1c</sub>. 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.<sup>6</sup> 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.<sup>4</sup> 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<sub>1c</sub> 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.<sup>50</sup> 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<sub>1c</sub> 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<sub>1c</sub> 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<sub>1c</sub>. 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 ( $\geq$ 1 h) 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<sub>1c</sub> than do behavioral programs meeting our operational definition.

Another group led by Norris<sup>32</sup> 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<sup>32, 50</sup> 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.<sup>285, 286</sup> This may explain in part why our effect sizes for HbA<sub>1c</sub> at end of intervention are smaller than that (0.76 percent) found by Norris et al.<sup>50</sup>

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<sub>1c</sub> results assessed immediately after 28 interventions, Ellis et al.<sup>53</sup> 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<sub>1c</sub>. 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.<sup>45</sup> 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<sub>1c</sub>, 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.<sup>287, 288</sup> In a qualitative examination of 11 interventions showing beneficial effects for socially disadvantaged populations, Glazier et al.<sup>54</sup> 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<sup>47</sup> 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<sub>1c</sub> level; however, for all studies the mean HbA<sub>1c</sub> was over 7 percent. For most (70 percent), the mean HbA<sub>1c</sub> was over

8.5 percent. The results of this report may only be applicable to individuals with 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);<sup>98</sup> 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 ( $\geq 65$  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  $\geq 1$  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 to 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 (73 percent) were conducted in the United States; the remaining studies were conducted in Europe. 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<sub>1c</sub> 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.  $\geq 7$  percent HbA<sub>1c</sub>) 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=8 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<sub>1c</sub> levels  $\geq 7$  percent.

The range of mean ages in the included studies was 45-72 years (median=58), therefore the results of the pair-wise 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.  $\geq 65$  years) provided some data on the relative effectiveness for these age groups, but similar to that for baseline HbA<sub>1c</sub>, 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 ( $\leq 1$  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 regimes (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 (21 comparisons for <75 percent minorities vs. 31 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<sup>60</sup> 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<sup>246</sup> or without data on our outcomes of interest);<sup>88</sup> (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<sup>76</sup> for our outcome with the most data (HbA<sub>1c</sub>) 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.<sup>289</sup> 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 125 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 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 were not able to incorporate all factors into our network meta-analyses and may have missed some meaning. The diversity in programs and other contextual factors was apparent when considering the high heterogeneity in results from the pair-wise meta-analysis for HbA<sub>1c</sub> and some other outcomes in T2DM; this finding served to further support the analyses in KQs 5 and 6 related to factors influencing the effectiveness of behavioral programs.

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 was 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<sub>1c</sub> and generic quality of life. 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<sub>1c</sub> 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. 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<sub>1c</sub> and BMI to enable meaningful groupings into nodes to examine multiple factors simultaneously. 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 risk of bias. Blinding of participants and personnel are arguably difficult for trials of behavioral programs. According to our guidelines for assessing risk of bias, a low risk of bias for participant and personnel blinding was granted if the authors stated some means to blind the study hypothesis from participants, or if there was a structured training and protocol followed for the personnel. The former 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 co-intervention; 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 risk of bias being assigned for most trials for their subjective outcomes. 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. only reporting on results for completers) and/or from high participant attrition. Some studies had small sample sizes and accordingly failed to achieve baseline comparability in their samples; although we analyzed change from baseline scores when able, the differential effect of behavioral programs based on these baseline imbalances (e.g., HbA<sub>1c</sub>, age)—as suggested by our subgroup analyses—cannot be ruled out.

## Research Gaps

Table 13 highlights some potential research needs based on our KQs.

**Table 13. Potential research needs, by Key Question**

KQ	Potential Research Needs
1	There was 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	There was insufficient evidence to demonstrate whether lifestyle programs 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	The effectiveness of a support component added 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	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	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.

<b>KQ</b>	<b>Potential Research Needs</b>
<b>3 &amp; 5</b>	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.
<b>5</b>	The correct mix of providers (e.g., physician, nurse, dietitian, pharmacists, social workers, psychologist, and trained lay individuals) for implementation of behavioral programs for T2DM deserves further evaluation.
<b>5</b>	The impact of training level for health care professionals—apart from clinical psychologists—on outcomes from behavioral programs employing advanced behavioral approaches needs further investigation.
<b>5</b>	Few trials directly compared interactive programs delivered in person to those delivered via technology. Because a technology-based approach may lessen resource burden and help to reach patients living in rural areas, its effectiveness needs further evaluation.
<b>6</b>	Trials including populations of diverse ethnic backgrounds should perform subgroup analysis based on age and ethnicity 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.
<b>All</b>	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.
<b>All</b>	Study attrition rates affected the overall risk of bias substantially; more research on methods for maintaining study participation is required.
<b>All</b>	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 requires some mechanism to blind participants from the study hypothesis. Blinding of outcome assessors should always be attempted for subjective outcomes.
<b>All</b>	There exists the need to gain consensus in the field on what constitutes clinically important differences for behavioral programs, such that outcomes can be interpreted in meaningful ways for clinicians and patients.

## Conclusions

This systematic review found that behavioral programs (essentially DSME) for T1DM have some benefit on glycemic control when followup extends to 6 months after the program, but that more, good quality evidence is required to draw conclusions about long-term effects. There appears to be no difference in generic quality of life at end of intervention, or for self-management behaviors at up to 6-month followup, although we have limited confidence in these findings. Data was insufficient to draw conclusions for other outcomes including diabetes-specific quality of life, change in body composition or lifestyle behaviors, micro- and macrovascular complications, and mortality. Based on current evidence, it is unclear whether encouraging patients with T1DM to participate in behavioral programs will yield important benefits for most outcomes.

For T2DM, our analyses showed limited benefit in glycemic control from DSME programs offering  $\leq 10$  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 good control. Tailoring programs to ethnic minorities—such as 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 generic quality of life measures would be beneficial.

Efforts at integrating behavioral programs into care settings that incorporate the latest treatment 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.

## References

1. Renders CM, Valk GD, Griffin SJ, et al. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev.* 2000(4). PMID: 11279717.
2. Landon BE, Hicks LS, O'Malley AJ, et al. Improving the management of chronic disease at community health centers. *N Engl J Med.* 2007 Mar 1;356(9):921-34. PMID: 17329699.
3. Couch R, Jetha M, Dryden DM, et al. Diabetes education for children with type 1 diabetes mellitus and their families. Evidence report no. 166. (Prepared by the University of Alberta Evidence-based Practice Center under contract no. 290-02-0023.) AHRQ publication no. 08-e011. Rockville, MD: Agency for Healthcare Research and Quality, April 2008.
4. Hampson SE, Skinner TC, Hart J, et al. Behavioral interventions for adolescents with type 1 diabetes: how effective are they? *Diabetes Care.* 2000 Sep;23(9):1416-22. PMID: 10977043.
5. Hood KK, Rohan JM, Peterson CM, et al. Interventions with adherence-promoting components in pediatric type 1 diabetes: meta-analysis of their impact on glycemic control. *Diabetes Care.* 2010 Jul;33(7):1658-64. PMID: 20587726.
6. Murphy HR, Rayman G, Skinner TC. Psycho-educational interventions for children and young people with type 1 diabetes. *Diabet Med.* 2006 Sep;23(9):935-43. PMID: 16922699.
7. Urban AD, Berry D, Grey M. Optimizing outcomes in adolescents with type 1 diabetes and their families. *Journal of Clinical Outcomes Management.* 2004;11(5):299-306. PMID: Not available.
8. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care.* 2014 Jan;37 Suppl 1:S81-90. PMID: 24357215.
9. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2014. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2014 [cited 2014 Nov. 27]; <http://www.cdc.gov/diabetes/data/statistics/2014statisticsreport.html>.
10. Search for Diabetes in Youth Study Group. The burden of diabetes mellitus among us youth: prevalence estimates from the search for diabetes in youth study. *Pediatrics.* 2006 Oct;118(4):1510-8. PMID: 17015542.
11. Agency for Healthcare Research and Quality. 2012 National Healthcare Disparities Report: Chapter 2. Effectiveness (continued). Rockville, MD: Agency for Healthcare Research and Quality; 2012 [cited 2013 Nov. 15]; <http://www.ahrq.gov/research/findings/nhqrdr/nhdr12/chap2a>.
12. Gallegos-Macias AR, Macias SR, Kaufman E, et al. Relationship between glycemic control, ethnicity and socioeconomic status in Hispanic and white non-Hispanic youths with type 1 diabetes mellitus. *Pediatr Diabetes.* 2003 Mar;4(1):19-23. PMID: 14655519.
13. Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. *JAMA.* 2002 Jul 24-31;288(4):475-82. PMID: 12132978.
14. Valenzuela JM, Seid M, Waitzfelder B, et al. Prevalence of and disparities in barriers to care experienced by youth with type 1 diabetes. *J Pediatr.* 2014 Feb 25. PMID: 24582008.
15. Dall TM, Zhang Y, Chen YJ, et al. The economic burden of diabetes. *Health Affairs.* 2010 Feb;29(2):297-303. PMID: 20075080.
16. Centers for Disease Control and Prevention. Diabetes Report Card 2012. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2012 [cited 2013 Nov 15]; <http://www.cdc.gov/diabetes/pubs/pdf/diabetesreportcard.pdf>.
17. Bystritsky A, Danial J, Kronemyer D. Interaction between diabetes and anxiety

- and depression: implications for treatment. *Endocrinol Metab Clin N Am*. 2014;43(1):269-83. PMID: 24582102.
18. American Diabetes Association. Standards of medical care in diabetes--2014. *Diabetes Care*. 2014 Jan;37 Suppl 1:S14-80. PMID: 24357209.
  19. Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993 Sep 30;329(14):977-86. PMID: 8366922.
  20. Nathan DM. The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study at 30 years: overview. *Diabetes Care*. 2014 Jan;37(1):9-16. PMID: 24356592.
  21. Orchard TJ, Nathan DM, Zinman B, et al. Association between 7 years of intensive treatment of type 1 diabetes and long-term mortality. *Jama*. 2015 Jan 6;313(1):45-53. PMID: 25562265.
  22. Fullerton B, Jeitler K, Seitz M, et al. Intensive glucose control versus conventional glucose control for type 1 diabetes mellitus. *Cochrane Database Syst Rev*. 2014;2:CD009122. PMID: 24526393.
  23. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998 Sep 12;352(9131):837-53. PMID: 9742976.
  24. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet*. 1998 Sep 12;352(9131):854-65. PMID: 9742977.
  25. Hemmingsen B, Lund SS, Gluud C, et al. Targeting intensive glycaemic control versus targeting conventional glycaemic control for type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2013;11:CD008143. PMID: 24214280.
  26. Colhoun HM, Betteridge DJ, Durrington PN, et al. Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the collaborative atorvastatin diabetes study (CARDS): multicentre randomised placebo-controlled trial. *Lancet*. 2004 Aug 21-27;364(9435):685-96. PMID: 15325833.
  27. Heart Protection Study Collaborative Group. MRC/BHF heart protection study of cholesterol-lowering with simvastatin in 5963 people with diabetes: a randomised placebo-controlled trial. *Lancet*. 2003 Jun 14;361(9374):2005-16. PMID: 12814710.
  28. UK Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. *BMJ*. 1998;317(7160):703-13. PMID: Not available.
  29. Lv J, Neal B, Ehteshami P, et al. Effects of intensive blood pressure lowering on cardiovascular and renal outcomes: a systematic review and meta-analysis. *PLoS Med*. 2012;9(8):e1001293. PMID: 22927798.
  30. Griffin S. Diabetes care in general practice: meta-analysis of randomised control trials. *Bmj*. 1998 Aug 8;317(7155):390-6. PMID: 9694757.
  31. Tomky D, Cypress M, Dang D, et al. AADE7 self-care behaviors. *Diabetes Educ*. 2008 May-Jun;34(3):445-9. PMID: 18535317.
  32. Norris SL, Zhang X, Avenell A, et al. Long-term effectiveness of lifestyle and behavioral weight loss interventions in adults with type 2 diabetes: a meta-analysis. *Am J Med*. 2004 Nov 15;117(10):762-74. PMID: 15541326.
  33. Schellenberg ES, Dryden DM, Vandermeer B, et al. Lifestyle interventions for patients with and at risk for type 2 diabetes: a systematic review and meta-analysis. *Ann Intern Med*. 2013 Oct 15;159(8):543-51. PMID: 24126648.
  34. Thomas DE, Elliott EJ, Naughton GA. Exercise for type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2006(3):CD002968. PMID: 16855995.
  35. Watts NB, Spanheimer RG, Digirolamo M, et al. Prediction of glucose response to weight loss in patients with non-insulin-dependent diabetes mellitus. *Arch Intern Med*. 1990 Apr;150(4):803-6. PMID: 2327840.

36. Funnell M. Beyond the data: moving towards a new dawn in diabetes. *Diabet Med.* 2013 Jul;30(7):765-6. PMID: 23710971.
37. International Diabetes Federation. Position Statement: Self-management Education. Brussels, Belgium: International Diabetes Federation; 2011 [cited 2013 Nov. 15]; <http://www.idf.org/education/self-management-education>.
38. Knight KM, Dornan T, Bundy C. The diabetes educator: trying hard, but must concentrate more on behaviour. *Diabet Med.* 2006;23(5):485-501. PMID: 16681557.
39. Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care.* 2001 Mar;24(3):561-87. PMID: 11289485.
40. Haas L, Maryniuk M, Beck J, et al. National standards for diabetes self-management education and support. *Diabetes Care.* 2013;36(Suppl. 1):S100-S8. PMID: 23264420.
41. Jones H, Berard LD, Macneill G, et al. Clinical practice guidelines: Self-management education. *Can J Diabetes.* 2013;37(Suppl. 1):S26-S30. PMID: 24070958.
42. National Institute for Health and Clinical Excellence. The management of type 2 diabetes. London: National Collaborating Centre for Chronic Conditions, Centre for Clinical Practice; 2010. <http://www.nice.org.uk/guidance/cg87>
43. Hoerger TJ, Segel JE, Gregg EW, et al. Is glycemic control improving in U.S. Adults? *Diabetes Care.* 2008 Jan;31(1):81-6. PMID: 17934153.
44. Funnell MM. The Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Clinical Diabetes.* 2006;24(4):154-5. PMID: Not available.
45. Chodosh J, Morton SC, Mojica W, et al. Meta-analysis: chronic disease self-management programs for older adults. *Ann Intern Med.* 2005 Sep 20;143(6):427-38. PMID: 16172441.
46. Deakin T, Mcshane CE, Cade JE, et al. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev.* 2005(2):CD003417. PMID: 15846663.
47. Fan L, Sidani S. Effectiveness of diabetes self-management education intervention elements: a meta-analysis. *Can J Diabetes.* 2009;33(1):18-26. PMID: Not available.
48. Gary TL, Genkinger JM, Guallar E, et al. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educ.* 2003 May-Jun;29(3):488-501. PMID: 12854339.
49. Minet L, Moller S, Vach W, et al. Mediating the effect of self-care management intervention in type 2 diabetes: a meta-analysis of 47 randomised controlled trials. *Patient Educ Couns.* 2010 Jul;80(1):29-41. PMID: 19906503.
50. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care.* 2002 Jul;25(7):1159-71. PMID: 12087014.
51. Warsi A, Wang PS, Lavalley MP, et al. Self-management education programs in chronic disease: a systematic review and methodological critique of the literature. *Arch Intern Med.* 2004;164(15):1641-9. PMID: 15302634.
52. Medical Advisory Secretariat. Behavioural interventions for type 2 diabetes: an evidence-based analysis. *Ont Health Technol Assess Ser.* 2009;9(21):1-45. PMID: 23074526.
53. Ellis SE, Speroff T, Dittus RS, et al. Diabetes patient education: a meta-analysis and meta-regression. *Patient Educ Couns.* 2004 Jan;52(1):97-105. PMID: 14729296.
54. Glazier RH, Bajcar J, Kennie NR, et al. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care.* 2006 Jul;29(7):1675-88. PMID: 16801602.
55. Public Health Agency of Canada. Glossary of terms. Public Health Agency of Canada; 2010 [cited 2013 Nov. 15]; <http://www.phac-aspc.gc.ca/php-ppsp/ccph-cesp/glos-eng.php>.
56. Piette JD. Interactive behavior change technology to support diabetes self-management: where do we stand? *Diabetes*

- Care. 2007 Oct;30(10):2425-32. PMID: 17586735.
57. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ publication no. 10(14)-ehc063-ef. Agency of Healthcare Research and Quality; 2014. <http://effectivehealthcare.ahrq.gov/ehc/products/60/318/CER-Methods-Guide-140109.pdf>. Last accessed March 4, 2014.
  58. University of Alberta Evidence-Based Practice Center. Behavioral programs for diabetes mellitus (protocol). Rockville, MD: Agency for Healthcare Research and Quality, Jun 2014. [www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)
  59. Higgins JP, Green S. Section 6.4.11.1. Search filters. The Cochrane Collaboration; 2011. <http://handbook.cochrane.org>. Accessed March 4, 2014.
  60. Malik K, Human Development Report 2013 Team. Human development report 2013. The rise of the south: human progress in a diverse world. N.Y., New York. : United Nations Development Programme, 2013.
  61. Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract.* 1995 May;28(2):103-17. PMID: 7587918.
  62. Hartling L, Bond K, Santaguida PL, et al. Testing a tool for the classification of study designs in systematic reviews of interventions and exposures showed moderate reliability and low accuracy. *J Clin Epidemiol.* 2011;64(8):861-71. PMID: 21531537.
  63. Higgins JPT, Green S. *Cochrane Handbook for Systematic Reviews of Interventions.* The Cochrane Collaboration; 2009. [www.cochrane-handbook.org/](http://www.cochrane-handbook.org/). Accessed January 5, 2015.
  64. Pimouguet C, Le Goff M, Thiebaut R, et al. Effectiveness of disease-management programs for improving diabetes care: a meta-analysis. *CMAJ.* 2011 Feb 8;183(2):E115-27. PMID: 21149524.
  65. Tricco AC, Ivers NM, Grimshaw JM, et al. Effectiveness of quality improvement strategies on the management of diabetes: a systematic review and meta-analysis. *Lancet.* 2012 Jun 16;379(9833):2252-61. PMID: 22683130.
  66. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. Guidance for industry diabetes mellitus: developing drugs and therapeutic biologics for treatment and prevention. 2008: <http://www.fda.gov/downloads/Drugs/Guidances/ucm071624.pdf>. Accessed May 27, 2014.
  67. Higgins JP, Green S. Section 8. Assessing risk of bias in included studies. In: *Cochrane Handbook for Systematic Reviews of Interventions.* The Cochrane Collaboration; 2011. <http://handbook.cochrane.org> Last accessed March 4, 2014.
  68. Wells GA, Shea B, O'connell D, et al. The Newcastle-Ottawa scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. 2000. [http://www.ohri.ca/programs/clinical\\_epidemiology/oxford.asp](http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp) Accessed Jan 20, 2015
  69. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Med Care.* 2003 May;41(5):582-92. PMID: 12719681.
  70. Revicki D, Hays RD, Cella D, et al. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *J Clin Epidemiol.* 2008 Feb;61(2):102-9. PMID: 18177782.
  71. Sidik K, Jonkman JN. A simple confidence interval for meta-analysis. *Stat Med.* 2002 Nov 15;21(21):3153-9. PMID: 12375296.
  72. Inthout J, Ioannidis JP, Borm GF. The Hartung-Knapp-Sidik-Jonkman method for random effects meta-analysis is straightforward and considerably outperforms the standard dersimonian-laird method. *BMC Med Res Methodol.* 2014;14:25. PMID: 24548571.
  73. Cornell JE, Mulrow CD, Localio R, et al. Random-effects meta-analysis of inconsistent effects: a time for change. *Ann Intern Med.* 2014 Feb 18;160(4). PMID: 24727843.
  74. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med.*

- 2002 Jun 15;21(11):1539-58. PMID: 12111919.
75. Deeks JJ, Higgins JPT, Altman DG. Analysing data and undertaking meta-analysis. In: Higgins JPT, Green, S. (eds). *Cochrane Handbook for Systematic Reviews of Interventions*. Chicester, U.K.: John Wiley & Sons; 2008.
  76. Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. *BMJ*. 1997 Sep 13;315(7109):629-34. PMID: 9310563.
  77. Lu G, Ades AE. Combination of direct and indirect evidence in mixed treatment comparisons. *Stat Med*. 2004 Oct 30;23(20):3105-24. PMID: 15449338.
  78. Salanti G. Indirect and mixed-treatment comparison, network, or multiple-treatments meta-analysis: many names, many benefits, many concerns for the next generation evidence synthesis tool. *Res Synth Methods*. 2012;3:80-97. PMID:
  79. Veroniki AA, Vasiliadis HS, Higgins JP, et al. Evaluation of inconsistency in networks of interventions. *Int J Epidemiol*. 2013 Feb;42(1):332-45. PMID: 23508418.
  80. Amsberg S, Anderbro T, Wredling R, et al. A cognitive behavior therapy-based intervention among poorly controlled adult type 1 diabetes patients--a randomized controlled trial. *Patient Educ Couns*. 2009 Oct;77(1):72-80. PMID: 19297117.
  81. Anderson BJ, Brackett J, Ho J, et al. An office-based intervention to maintain parent-adolescent teamwork in diabetes management. Impact on parent involvement, family conflict, and subsequent glycemic control. *Diabetes Care*. 1999 May;22(5):713-21. PMID: 10332671.
  82. Boardway RH, Delamater AM, Tomakowsky J, et al. Stress management training for adolescents with diabetes. *J Pediatr Psychol*. 1993 Feb;18(1):29-45. PMID: 8463932.
  83. Christie D, Thompson R, Sawtell M, et al. Structured, intensive education maximising engagement, motivation and long-term change for children and young people with diabetes: a cluster randomised controlled trial with integral process and economic evaluation - the cascade study. *Health Technol Assess*. 2014 Mar;18(20):1-202. PMID: 24690402.
  84. Cook S, Herold K, Edidin DV, et al. Increasing problem solving in adolescents with type 1 diabetes: the Choices Diabetes Program. *Diabetes Educ*. 2002 Jan-Feb;28(1):115-24. PMID: 11852741.
  85. Ellis DA, Naar-King S, Chen X, et al. Multisystemic therapy compared to telephone support for youth with poorly controlled diabetes: findings from a randomized controlled trial. *Ann Behav Med*. 2012 Oct;44(2):207-15. PMID: 22644587.
  86. Ellis DA, Templin T, Naar-King S, et al. Multisystemic therapy for adolescents with poorly controlled type 1 diabetes: stability of treatment effects in a randomized controlled trial. *J Consult Clin Psychol*. 2007 Feb;75(1):168-74. PMID: 17295576.
  87. Franklin VL, Waller A, Pagliari C, et al. A randomized controlled trial of Sweet Talk, a text-messaging system to support young people with diabetes. *Diabet Med*. 2006 Dec;23(12):1332-8. PMID: 17116184.
  88. Freeman KA, Duke DC, Harris MA. Behavioral health care for adolescents with poorly controlled diabetes via skype: does working alliance remain intact? *J Diabetes Sci Technol*. 2013 May;7(3):727-35. PMID: 23759406.
  89. Hermanns N, Kulzer B, Ehrmann D, et al. The effect of a diabetes education programme (PRIMAS) for people with type 1 diabetes: Results of a randomized trial. *Diabetes Res Clin Pract*. 2013 Dec;102(3):149-57. PMID: 24210673.
  90. Holmes CS, Chen R, Mackey E, et al. Randomized clinical trial of clinic-integrated, low-intensity treatment to prevent deterioration of disease care in adolescents with type 1 diabetes. *Diabetes Care*. 2014 Jun;37(6):1535-43. PMID: 24623027.
  91. Husted GR, Thorsteinsson B, Esbensen BA, et al. Effect of guided self-determination youth intervention integrated into outpatient visits versus treatment as usual on glycemic control and life skills: a randomized clinical trial in adolescents with type 1 diabetes. *Trials*. 2014 Aug 12;15(1):321. PMID: 25118146.

92. Ismail K, Thomas SM, Maissi E, et al. Motivational enhancement therapy with and without cognitive behavior therapy to treat type 1 diabetes: a randomized trial. *Ann Intern Med.* 2008 Nov 18;149(10):708-19. PMID: 19017589.
93. Karlsen B, Idsoe T, Dirdal I, et al. Effects of a group-based counselling programme on diabetes-related stress, coping, psychological well-being and metabolic control in adults with type 1 or type 2 diabetes. *Patient Educ Couns.* 2004 Jun;53(3):299-308. PMID: 15186867.
94. Katz ML, Volkening LK, Butler DA, et al. Family-based psychoeducation and care ambassador intervention to improve glycemic control in youth with type 1 diabetes: a randomized trial. *Pediatr Diabetes.* 2014 March;15(2):142-50. PMID: 23914987.
95. Kichler JC, Kaugars AS, Marik P, et al. Effectiveness of groups for adolescents with type 1 diabetes mellitus and their parents. *Fam Syst Health.* 2013 Sep;31(3):280-93. PMID: 23957874.
96. Laffel LM, Vangsness L, Connell A, et al. Impact of ambulatory, family-focused teamwork intervention on glycemic control in youth with type 1 diabetes. *J Pediatr.* 2003 Apr;142(4):409-16. PMID: 12712059.
97. Lehmkuhl HD, Storch EA, Cammarata C, et al. Telehealth behavior therapy for the management of type 1 diabetes in adolescents. *J Diabetes Sci Technol.* 2010 Jan;4(1):199-208. PMID: 20167185.
98. Mcnabb WL, Quinn MT, Murphy DM, et al. Increasing children's responsibility for diabetes self-care: the In Control study. *Diabetes Educ.* 1994 Mar-Apr;20(2):121-4. PMID: 7851224.
99. Murphy HR, Wadham C, Rayman G, et al. Approaches to integrating paediatric diabetes care and structured education: experiences from the families, adolescents, and children's teamwork study (FACTS). *Diabet Med.* 2007 Nov;24(11):1261-8. PMID: 17894831.
100. Murphy HR, Wadham C, Hassler-Hurst J, et al. Randomized trial of a diabetes self-management education and family teamwork intervention in adolescents with type 1 diabetes. *Diabet Med.* 2012 Aug;29(8):e249-54. PMID: 22507080.
101. Nansel TR, Iannotti RJ, Simons-Morton BG, et al. Diabetes personal trainer outcomes: short-term and 1-year outcomes of a diabetes personal trainer intervention among youth with type 1 diabetes. *Diabetes Care.* 2007 Oct;30(10):2471-7. PMID: 17620445.
102. Nansel TR, Iannotti RJ, Liu A. Clinic-integrated behavioral intervention for families of youth with type 1 diabetes: randomized clinical trial. *Pediatrics.* 2012 Apr;129(4):e866-73. PMID: 22392172.
103. Perry TL, Mann JI, Lewis-Barned NJ, et al. Lifestyle intervention in people with insulin-dependent diabetes mellitus (IDDM). *Eur J Clin Nutr.* 1997 Nov;51(11):757-63. PMID: 9368810.
104. Viklund G, Ortqvist E, Wikblad K. Assessment of an empowerment education programme. A randomized study in teenagers with diabetes. *Diabet Med.* 2007 May;24(5):550-6. PMID: 17367306.
105. Weinger K, Beverly EA, Lee Y, et al. The effect of a structured behavioral intervention on poorly controlled diabetes: a randomized controlled trial. *Arch Intern Med.* 2011 Dec 12;171(22):1990-9. PMID: 21986346.
106. Wysocki T, Harris MA, Buckloh LM, et al. Randomized trial of behavioral family systems therapy for diabetes: maintenance of effects on diabetes outcomes in adolescents. *Diabetes Care.* 2007 Mar;30(3):555-60. PMID: 17327320.
107. Zoffmann V, Lauritzen T. Guided self-determination improves life skills with type 1 diabetes and A1c in randomized controlled trial. *Patient Educ Couns.* 2006 Dec;64(1-3):78-86. PMID: 16720089.
108. Mannucci E, Pala L, Rotella CM. Long-term interactive group education for type 1 diabetic patients. *Acta Diabetol.* 2005 Mar;42(1):1-6. PMID: 15868107.
109. Forlani G, Zannoni C, Tarrini G, et al. An empowerment-based educational program improves psychological well-being and health-related quality of life in type 1 diabetes. *J Endocrinol Invest.* 2006 May;29(5):405-12. PMID: 16794363.
110. Thomas-Dobersen DA, Butler-Simon N, Fleshner M. Evaluation of a weight

- management intervention program in adolescents with insulin-dependent diabetes mellitus. *J Am Diet Assoc.* 1993 May;93(5):535-40. PMID: 8315162.
111. Viner RM, Christie D, Taylor V, et al. Motivational/solution-focused intervention improves HbA1c in adolescents with type 1 diabetes: a pilot study. *Diabet Med.* 2003 Sep;20(9):739-42. PMID: 12925054.
112. Amsberg S, Anderbro T, Wredling R, et al. Experience from a behavioural medicine intervention among poorly controlled adult type 1 diabetes patients. *Diabetes Res Clin Pract.* 2009 Apr;84(1):76-83. PMID: 19181414.
113. Ellis DA, Frey MA, Naar-King S, et al. Use of multisystemic therapy to improve regimen adherence among adolescents with type 1 diabetes in chronic poor metabolic control: a randomized controlled trial. *Diabetes Care.* 2005 Jul;28(7):1604-10. PMID: 15983308.
114. Ellis DA, Naar-King S, Frey M, et al. Use of multisystemic therapy to improve regimen adherence among adolescents with type 1 diabetes in poor metabolic control: a pilot investigation. *J Clin Psychol Med Settings.* 2004 December;11(4):315-24. PMID: 15983308.
115. Ellis DA, Naar-King S, Frey M, et al. Multisystemic treatment of poorly controlled type 1 diabetes: effects on medical resource utilization. *J Pediatr Psychol.* 2005 Dec;30(8):656-66. PMID: 16260435.
116. Ismail K, Maissi E, Thomas S, et al. A randomised controlled trial of cognitive behaviour therapy and motivational interviewing for people with type 1 diabetes mellitus with persistent sub-optimal glycaemic control: a diabetes and psychological therapies (ADAPT) study. *Health Technol Assess.* 2010 May;14(22):1-101, iii-iv. PMID: 20483060.
117. Nansel TR, Anderson BJ, Laffel LMB, et al. A multisite trial of a clinic-integrated intervention for promoting family management of pediatric type 1 diabetes: feasibility and design. *Pediatr Diabetes.* 2009 Apr;10(2):105-15. PMID: 18721167.
118. Nansel TR, Iannotti RJ, Simons-Morton BG, et al. Long-term maintenance of treatment outcomes: diabetes personal trainer intervention for youth with type 1 diabetes. *Diabetes Care.* 2009 May;32(5):807-9. PMID: 19208916.
119. Patel A, Maissi E, Chang HC, et al. Motivational enhancement therapy with and without cognitive behaviour therapy for type 1 diabetes: economic evaluation from a randomized controlled trial. *Diabet Med.* 2011 Apr;28(4):470-9. PMID: 21392068.
120. Ridge K, Bartlett J, Cheah Y, et al. Do the effects of psychological treatments on improving glycemic control in type 1 diabetes persist over time? A long-term follow-up of a randomized controlled trial. *Psychosom Med.* 2012 Apr;74(3):319-23. PMID: 22434919.
121. Wysocki T, Harris MA, Buckloh LM, et al. Effects of behavioral family systems therapy for diabetes on adolescents' family relationships, treatment adherence, and metabolic control. *J Pediatr Psychol.* 2006 Oct;31(9):928-38. PMID: 16401678.
122. Toobert DJ, Hampson SE, Glasgow RE. The Summary of Diabetes Self-Care Activities measure: results from 7 studies and a revised scale. *Diabetes Care.* 2000 Jul;23(7):943-50. PMID: 10895844.
123. Varni JW, Burwinkle TM, Jacobs JR, et al. The PedsQL in type 1 and type 2 diabetes: reliability and validity of the pediatric quality of life inventory generic core scales and type 1 diabetes module. *Diabetes Care.* 2003 Mar;26(3):631-7. PMID: 12610013.
124. Mannucci E, Ricca V, Bardini G, et al. Well-being enquiry for diabetics: a new measure of diabetes-related quality of life. *Diabetes Nutr Metab.* 1996;9:89-102. PMID:
125. Adachi M, Yamaoka K, Watanabe M, et al. Effects of lifestyle education program for type 2 diabetes patients in clinics: A cluster randomized controlled trial. *BMC Public Health.* 2013;13:467. PMID: 23672733.
126. Adolfsson ET, Walker-Engstrom ML, Smide B, et al. Patient education in type 2 diabetes: a randomized controlled 1-year follow-up study. *Diabetes Res Clin Pract.* 2007 Jun;76(3):341-50. PMID: 17069923.
127. Agurs-Collins TD, Kumanyika SK, Ten Have TR, et al. A randomized controlled trial of weight reduction and exercise for diabetes management in older African-

- American subjects. *Diabetes Care*. 1997 Oct;20(10):1503-11. PMID: 9314625.
128. Amoako E, Skelly AH, Rossen EK. Outcomes of an intervention to reduce uncertainty among African American women with diabetes. *West J Nurs Res*. 2008 Dec;30(8):928-42. PMID: 18596303.
129. Anderson DR, Christison-Lagay J, Villagra V, et al. Managing the space between visits: a randomized trial of disease management for diabetes in a community health center. *J Gen Intern Med*. 2010 Oct;25(10):1116-22. PMID: 20556536.
130. Anderson RM, Funnell MM, Butler PM, et al. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care*. 1995 Jul;18(7):943-9. PMID: 7555554.
131. Anderson RM, Funnell MM, Nwankwo R, et al. Evaluating a problem-based empowerment program for African Americans with diabetes: results of a randomized controlled trial. *Ethn Dis*. 2005 Autumn;15(4):671-8. PMID: 16259492.
132. Anderson RM, Funnell MM, Aikens JE, et al. Evaluating the efficacy of an empowerment-based self-management consultant intervention: results of a two-year randomized controlled trial. *Therapeutic Patient Education*. 2009;1(1):3-11. PMID: 20076768.
133. Anderson-Loftin W, Barnett S, Bunn P, et al. Soul food light: culturally competent diabetes education. *Diabetes Educ*. 2005 Jul-Aug;31(4):555-63. PMID: 16100331.
134. Baksi AK, Al-Mrayat M, Hogan D, et al. Peer advisers compared with specialist health professionals in delivering a training programme on self-management to people with diabetes: a randomized controlled trial. *Diabet Med*. 2008 Sep;25(9):1076-82. PMID: 18937675.
135. Barratt R, Frost G, Millward DJ, et al. A randomised controlled trial investigating the effect of an intensive lifestyle intervention v. standard care in adults with type 2 diabetes immediately after initiating insulin therapy. *Br J Nutr*. 2008 May;99(5):1025-31. PMID: 18197995.
136. Beverly EA, Fitzgerald SM, Brooks KM, et al. Impact of reinforcement of diabetes self-care on poorly controlled diabetes: a randomized controlled trial. *Diabetes Educ*. 2013 Jul-Aug;39(4):504-14. PMID: 23640303.
137. Bond GE, Burr R, Wolf FM, et al. The effects of a web-based intervention on the physical outcomes associated with diabetes among adults age 60 and older: a randomized trial. *Diabetes Technol Ther*. 2007 Feb;9(1):52-9. PMID: 17316098.
138. Bozzetto L, Annuzzi G, Costabile G, et al. A CHO/fibre diet reduces and a MUFA diet increases postprandial lipaemia in type 2 diabetes: no supplementary effects of low-volume physical training. *Acta Diabetol*. 2014 Jun;51(3):385-93. PMID: 24132660.
139. Bradshaw BG, Richardson GE, Kumpfer K, et al. Determining the efficacy of a resiliency training approach in adults with type 2 diabetes. *Diabetes Educ*. 2007 Jul-Aug;33(4):650-9. PMID: 17684166.
140. Brown SA, Blozis SA, Kouzekanani K, et al. Dosage effects of diabetes self-management education for mexican americans: the Starr County Border Health Initiative. *Diabetes Care*. 2005 Mar;28(3):527-32. PMID: 15735182.
141. Brown SA, Garcia AA, Kouzekanani K, et al. Culturally competent diabetes self-management education for Mexican Americans: the Starr County Border Health Initiative. *Diabetes Care*. 2002 Feb;25(2):259-68. PMID: 11815493.
142. Brown SA, Garcia AA, Winter M, et al. Integrating education, group support, and case management for diabetic hispanics. *Ethn Dis*. 2011;21(1):20-6. PMID: 21462725.
143. Castejon AM, Calderon JL, Perez A, et al. A community-based pilot study of a diabetes pharmacist intervention in Latinos: impact on weight and hemoglobin a1c. *J Health Care Poor Underserved*. 2013 Nov;24(4 Suppl):48-60. PMID: 24241260.
144. Chan JC, Sui Y, Oldenburg B, et al. Effects of telephone-based peer support in patients with type 2 diabetes mellitus receiving integrated care: a randomized clinical trial. *JAMA Intern Med*. 2014 Apr 28. PMID: 24781960.

145. Chan LS. Chronic disease self-management in Hong Kong Chinese older adults living in the community. Dissertation Abstracts International: Section B: The Sciences and Engineering. 2012;74(4-B E). PMID: Not available.
146. Cheong SH, Mccargar LJ, Paty BW, et al. The First Step First Bite program: guidance to increase physical activity and daily intake of low-glycemic index foods. *J Am Diet Assoc.* 2009 Aug;109(8):1411-6. PMID: 19631048.
147. Clark M, Hampson SE, Avery L, et al. Effects of a tailored lifestyle self-management intervention in patients with type 2 diabetes. *Br J Health Psychol.* 2004 Sep;9(Pt 3):365-79. PMID: 15296683.
148. Cooper H, Booth K, Gill G. A trial of empowerment-based education in type 2 diabetes--global rather than glycaemic benefits. *Diabetes Res Clin Pract.* 2008 Nov;82(2):165-71. PMID: 18804887.
149. Corkery E, Palmer C, Foley ME, et al. Effect of a bicultural community health worker on completion of diabetes education in a hispanic population. *Diabetes Care.* 1997 Mar;20(3):254-7. PMID: 9051367.
150. Cramer JS, Sibley RF, Bartlett DP, et al. An adaptation of the diabetes prevention program for use with high-risk, minority patients with type 2 diabetes. *Diabetes Educ.* 2007 May-Jun;33(3):503-8. PMID: 17570881.
151. Dasgupta K, Grover SA, Da Costa D, et al. Impact of modified glucose target and exercise interventions on vascular risk factors. *Diabetes Res Clin Pract.* 2006 Apr;72(1):53-60. PMID: 16256242.
152. Davis RM, Hitch AD, Salaam MM, et al. Telehealth improves diabetes self-management in an underserved community: Diabetes Telecare. *Diabetes Care.* 2010 Aug;33(8):1712-7. PMID: 20484125.
153. Deakin TA, Cade JE, Williams R, et al. Structured patient education: the diabetes X-PERT programme makes a difference. *Diabet Med.* 2006 Sep;23(9):944-54. PMID: 16922700.
154. D'eramo Melkus G, Chyun D, Vorderstrasse A, et al. The effect of a diabetes education, coping skills training, and care intervention on physiological and psychosocial outcomes in black women with type 2 diabetes. *Biol Res Nurs.* 2010 Jul;12(1):7-19. PMID: 20484058.
155. Dunstan DW, Mori TA, Puddey IB, et al. The independent and combined effects of aerobic exercise and dietary fish intake on serum lipids and glycemic control in NIDDM. A randomized controlled study. *Diabetes Care.* 1997 Jun;20(6):913-21. PMID: 9167099.
156. Dunstan DW, Daly RM, Owen N, et al. Home-based resistance training is not sufficient to maintain improved glycemic control following supervised training in older individuals with type 2 diabetes. *Diabetes Care.* 2005 Jan;28(1):3-9. PMID: 15616225.
157. Eakin EG, Winkler EA, Dunstan DW, et al. Living Well with Diabetes: 24-month outcomes from a randomized trial of telephone-delivered weight loss and physical activity intervention to improve glycemic control. *Diabetes Care.* 2014 Mar 21. PMID: 24658390.
158. Fisher L, Hessler D, Glasgow RE, et al. REDEEM: a pragmatic trial to reduce diabetes distress. *Diabetes Care.* 2013 Sep;36(9):2551-8. PMID: 23735726.
159. Foster GD, Borradaile KE, Vander Veur SS, et al. The effects of a commercially available weight loss program among obese patients with type 2 diabetes: a randomized study. *Postgrad Med.* 2009 Sep;121(5):113-8. PMID: 19820280.
160. Foster GD, Wadden TA, Lagrotte CA, et al. A randomized comparison of a commercially available portion-controlled weight-loss intervention with a diabetes self-management education program. *Nutr Diabetes.* 2013;3:e63. PMID: 23507967.
161. Frosch DL, Uy V, Ochoa S, et al. Evaluation of a behavior support intervention for patients with poorly controlled diabetes. *Arch Intern Med.* 2011 Dec 12;171(22):2011-7. PMID: 21986347.
162. Gagliardino JJ, Arrechea V, Assad D, et al. Type 2 diabetes patients educated by other patients perform at least as well as patients trained by professionals. *Diabetes Metab Res Rev.* 2013a Feb;29(2):152-60. PMID: 23166062.

163. Gagliardino JJ, Lapertosa S, Pfirter G, et al. Clinical, metabolic and psychological outcomes and treatment costs of a prospective randomized trial based on different educational strategies to improve diabetes care (PRODIACOR). *Diabet Med*. 2013b Sep;30(9):1102-11. PMID: 23668772.
164. Giannopoulou I, Fernhall B, Carhart R, et al. Effects of diet and/or exercise on the adipocytokine and inflammatory cytokine levels of postmenopausal women with type 2 diabetes. *Metabolism*. 2005 Jul;54(7):866-75. PMID: 15988694.
165. Glasgow RE, Kurz D, King D, et al. Twelve-month outcomes of an internet-based diabetes self-management support program. *Patient Educ Couns*. 2012 Apr;87(1):81-92. PMID: 21924576.
166. Glasgow RE, Strycker LA, King DK, et al. Robustness of a computer-assisted diabetes self-management intervention across patient characteristics, healthcare settings, and intervention staff. *Am J Manag Care*. 2006b Mar;12(3):137-45. PMID: 16524346.
167. Glasgow RE, Nutting PA, Toobert DJ, et al. Effects of a brief computer-assisted diabetes self-management intervention on dietary, biological and quality-of-life outcomes. *Chronic Illn*. 2006a Mar;2(1):27-38. PMID: 17175680.
168. Goudswaard AN, Stolk RP, Zuithoff NP, et al. Long-term effects of self-management education for patients with type 2 diabetes taking maximal oral hypoglycaemic therapy: a randomized trial in primary care. *Diabet Med*. 2004 May;21(5):491-6. PMID: 15089797.
169. Hawkins SY. Improving glycemic control in older adults using a videophone motivational diabetes self-management intervention. *Res Theory Nurs Pract*. 2010;24(4):217-32. PMID: 21197917.
170. Hendricks LE, Hendricks RT. The effect of diabetes self-management education with frequent follow-up on the health outcomes of African American men. *Diabetes Educ*. 2000 Nov-Dec;26(6):995-1002. PMID: 11912812.
171. Hermanns N, Kulzer B, Maier B, et al. The effect of an education programme (MEDIEAS 2 ICT) involving intensive insulin treatment for people with type 2 diabetes. *Patient Educ Couns*. 2012 Feb;86(2):226-32. PMID: 21715124.
172. Hill-Briggs F, Lazo M, Peyrot M, et al. Effect of problem-solving-based diabetes self-management training on diabetes control in a low income patient sample. *J Gen Intern Med*. 2011 Sep;26(9):972-8. PMID: 21445680.
173. Holtrop JS, Hickner J, Dosh S, et al. "Sticking to it—diabetes mellitus": a pilot study of an innovative behavior change program for women with type 2 diabetes. *Am J Health Educ*. 2002 2002/06/01;33(3):161-6. PMID: Not available.
174. Huisman S, De Gucht V, Maes S, et al. Self-regulation and weight reduction in patients with type 2 diabetes: a pilot intervention study. *Patient Educ Couns*. 2009 Apr;75(1):84-90. PMID: 19097740.
175. Izquierdo RE, Knudson PE, Meyer S, et al. A comparison of diabetes education administered through telemedicine versus in person. *Diabetes Care*. 2003 Apr;26(4):1002-7. PMID: 12663564.
176. Johnson ST, Bell GJ, Mccargar LJ, et al. Improved cardiovascular health following a progressive walking and dietary intervention for type 2 diabetes. *Diabetes Obes Metab*. 2009 Sep;11(9):836-43. PMID: 19614943.
177. Jones H, Edwards L, Vallis TM, et al. Changes in diabetes self-care behaviors make a difference in glycemic control: the Diabetes Stages of Change (DISC) study. *Diabetes Care*. 2003 Mar;26(3):732-7. PMID: 12610030.
178. Keyserling TC, Samuel-Hodge CD, Ammerman AS, et al. A randomized trial of an intervention to improve self-care behaviors of African-American women with type 2 diabetes: impact on physical activity. *Diabetes Care*. 2002 Sep;25(9):1576-83. PMID: 12196430.
179. Kim MT, Han HR, Song HJ, et al. A community-based, culturally tailored behavioral intervention for Korean Americans with type 2 diabetes. *Diabetes Educ*. 2009 Nov-Dec;35(6):986-94. PMID: 19934458.
180. Kim SH, Lee SJ, Kang ES, et al. Effects of lifestyle modification on metabolic

- parameters and carotid intima-media thickness in patients with type 2 diabetes mellitus. *Metabolism*. 2006 Aug;55(8):1053-9. PMID: 16839841.
181. Koo BK, Han KA, Ahn HJ, et al. The effects of total energy expenditure from all levels of physical activity vs. physical activity energy expenditure from moderate-to-vigorous activity on visceral fat and insulin sensitivity in obese type 2 diabetic women. *Diabet Med*. 2010 September;27(9):1088-92. PMID: 20722686.
182. Kulzer B, Hermanns N, Reinecker H, et al. Effects of self-management training in type 2 diabetes: a randomized, prospective trial. *Diabet Med*. 2007 Apr;24(4):415-23. PMID: 17298590.
183. Lee A, Siu CF, Leung KT, et al. General practice and social service partnership for better clinical outcomes, patient self efficacy and lifestyle behaviours of diabetic care: randomised control trial of a chronic care model. *Postgrad Med J*. 2011 Oct;87(1032):688-93. PMID: 21693570.
184. Lorig K, Ritter PL, Laurent DD, et al. Online diabetes self-management program: a randomized study. *Diabetes Care*. 2010 Jun;33(6):1275-81. PMID: 20299481.
185. Lorig K, Ritter PL, Villa F, et al. Spanish diabetes self-management with and without automated telephone reinforcement: two randomized trials. *Diabetes Care*. 2008 Mar;31(3):408-14. PMID: 18096810.
186. Lorig K, Ritter PL, Villa FJ, et al. Community-based peer-led diabetes self-management: a randomized trial. *Diabetes Educ*. 2009 Jul-Aug;35(4):641-51. PMID: 19407333.
187. Lujan J, Ostwald SK, Ortiz M. Promotora diabetes intervention for Mexican Americans. *Diabetes Educ*. 2007 Jul-Aug;33(4):660-70. PMID: 17684167.
188. Lynch EB, Liebman R, Ventrelle J, et al. A self-management intervention for African Americans with comorbid diabetes and hypertension: a pilot randomized controlled trial. *Prev Chronic Dis*. 2014;11:E90. PMID: 24874782.
189. Mandel SE, Davis BA, Secic M. Effects of music therapy and music-assisted relaxation and imagery on health-related outcomes in diabetes education: a feasibility study. *Diabetes Educ*. 2013 Jul-Aug;39(4):568-81. PMID: 23771840.
190. Mayer-Davis EJ, D'antonio AM, Smith SM, et al. Pounds off with empowerment (POWER): a clinical trial of weight management strategies for Black and White adults with diabetes who live in medically underserved rural communities. *Am J Public Health*. 2004 Oct;94(10):1736-42. PMID: 15451743.
191. McGowan P. The efficacy of diabetes patient education and self-management education in type 2 diabetes. *Can J Diabetes*. 2011;35(1):46-53. PMID: Not available.
192. Miller CK, Kristeller JL, Headings A, et al. Comparison of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes: a randomized controlled trial. *Health Educ Behav*. 2014 Apr;41(2):145-54. PMID: 23855018.
193. Moriyama M, Nakano M, Kuroe Y, et al. Efficacy of a self-management education program for people with type 2 diabetes: results of a 12 month trial. *Jpn J Nurs Sci*. 2009 Jun;6(1):51-63. PMID: 19566639.
194. Muchmore DB, Springer J, Miller M. Self-monitoring of blood glucose in overweight type 2 diabetic patients. *Acta Diabetol*. 1994 Dec;31(4):215-9. PMID: 7888692.
195. Murrock CJ, Higgins PA, Killion C. Dance and peer support to improve diabetes outcomes in African American women. *Diabetes Educ*. 2009 Nov-Dec;35(6):995-1003. PMID: 19776334.
196. Nishita C, Cardazone G, Uehara DL, et al. Empowered diabetes management: life coaching and pharmacist counseling for employed adults with diabetes. *Health Educ Behav*. 2013 Oct;40(5):581-91. PMID: 23174629.
197. Palmas W, Findley SE, Mejia M, et al. Results of the Northern Manhattan Diabetes Community Outreach Project: a randomized trial studying a community health worker intervention to improve diabetes care in Hispanic adults. *Diabetes Care*. 2014 April;37(4):963-9. PMID: 24496805.
198. Philis-Tsimikas A, Fortmann A, Lleva-Ocana L, et al. Peer-led diabetes education programs in high-risk Mexican Americans improve glycemic control compared with

- standard approaches: a Project Dulce promotora randomized trial. *Diabetes Care*. 2011 Sep;34(9):1926-31. PMID: 21775748.
199. Plotnikoff RC, Pickering MA, Glenn N, et al. The effects of a supplemental, theory-based physical activity counseling intervention for adults with type 2 diabetes. *J Phys Act Health*. 2011 Sep;8(7):944-54. PMID: 21885885.
200. Prezio EA, Cheng D, Balasubramanian BA, et al. Community diabetes education (CODE) for uninsured Mexican Americans: a randomized controlled trial of a culturally tailored diabetes education and management program led by a community health worker. *Diabetes Res Clin Pract*. 2013 Apr;100(1):19-28. PMID: 23453178.
201. Reaney M, Zorzo EG, Golay A, et al. Impact of Conversation Map education tools versus regular care on diabetes-related knowledge of people with type 2 diabetes: a randomized, controlled study. *Diabetes Spectrum*. 2013 November;26(4):236-45. PMID: Not available.
202. Rickheim PL, Weaver TW, Flader JL, et al. Assessment of group versus individual diabetes education: a randomized study. *Diabetes Care*. 2002 Feb;25(2):269-74. PMID: 11815494.
203. Ridgeway NA, Harvill DR, Harvill LM, et al. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *South Med J*. 1999 Jul;92(7):667-72. PMID: 10414474.
204. Rock CL, Flatt SW, Pakiz B, et al. Weight loss, glycemic control, and cardiovascular disease risk factors in response to differential diet composition in a weight loss program in type 2 diabetes: a randomized controlled trial. *Diabetes Care*. 2014 Jun;37(6):1573-80. PMID: 24760261.
205. Rosal MC, Olendzki B, Reed GW, et al. Diabetes self-management among low-income Spanish-speaking patients: a pilot study. *Ann Behav Med*. 2005 Jun;29(3):225-35. PMID: 15946117.
206. Rosal MC, Ockene IS, Restrepo A, et al. Randomized trial of a literacy-sensitive, culturally tailored diabetes self-management intervention for low-income latinos: Latinos en Control. *Diabetes Care*. 2011 Apr;34(4):838-44. PMID: 21378213.
207. Rothschild SK, Martin MA, Swider SM, et al. Mexican American trial of community health workers: a randomized controlled trial of a community health worker intervention for Mexican Americans with type 2 diabetes mellitus. *Am J Public Health*. 2014 Aug;104(8):1540-8. PMID: 23947316.
208. Ruggiero L, Moadsiri A, Butler P, et al. Supporting diabetes self-care in underserved populations: a randomized pilot study using medical assistant coaches. *Diabetes Educ*. 2010 Jan-Feb;36(1):127-31. PMID: 20185612.
209. Ruggiero L, Riley BB, Hernandez R, et al. Medical assistant coaching to support diabetes self-care among low-income racial/ethnic minority populations: randomized controlled trial. *West J Nurs Res*. 2014 Feb 25. PMID: 24569698.
210. Sacco WP, Malone JI, Morrison AD, et al. Effect of a brief, regular telephone intervention by paraprofessionals for type 2 diabetes. *J Behav Med*. 2009 Aug;32(4):349-59. PMID: 19365719.
211. Salinero-Fort MA, Carrillo-De Santa Pau E, Arrieta-Blanco FJ, et al. Effectiveness of precede model for health education on changes and level of control of HbA1c, blood pressure, lipids, and body mass index in patients with type 2 diabetes mellitus. *BMC Public Health*. 2011;11:267. PMID: 21524316.
212. Samuel-Hodge CD, Keyserling TC, Park S, et al. A randomized trial of a church-based diabetes self-management program for African Americans with type 2 diabetes. *Diabetes Educ*. 2009 May-Jun;35(3):439-54. PMID: 19383882.
213. Sarkadi A, Rosenqvist U. Experience-based group education in type 2 diabetes: a randomised controlled trial. *Patient Educ Couns*. 2004 Jun;53(3):291-8. PMID: 15186866.
214. Sevick MA, Korytkowski M, Stone RA, et al. Biophysiologic outcomes of the enhancing adherence in type 2 diabetes (Enhance) trial. *J Acad Nutr Diet*. 2012 Aug;112(8):1147-57. PMID: 22818724.

215. Shibayama T, Kobayashi K, Takano A, et al. Effectiveness of lifestyle counseling by certified expert nurse of Japan for non-insulin-treated diabetic outpatients: a 1-year randomized controlled trial. *Diabetes Res Clin Pract.* 2007 May;76(2):265-8. PMID: 17049662.
216. Sigurdardottir AK, Benediktsson R, Jonsdottir H. Instruments to tailor care of people with type 2 diabetes. *J Adv Nurs.* 2009 Oct;65(10):2118-30. PMID: 19674176.
217. Siminerio L, Ruppert KM, Gabbay RA. Who can provide diabetes self-management support in primary care? Findings from a randomized controlled trial. *Diabetes Educ.* 2013 Sep-Oct;39(5):705-13. PMID: 23782622.
218. Sinclair KA, Makahi EK, Shea-Solatorio C, et al. Outcomes from a diabetes self-management intervention for native hawaiians and pacific people: Partners in Care. *Ann Behav Med.* 2013 Feb;45(1):24-32. PMID: 23086589.
219. Sixta CS, Ostwald S. Texas-mexico border intervention by promotores for patients with type 2 diabetes. *Diabetes Educ.* 2008 Mar-Apr;34(2):299-309. PMID: 18375779.
220. Skelly AH, Carlson J, Leeman J, et al. Controlled trial of nursing interventions to improve health outcomes of older African American women with type 2 diabetes. *Nurs Res.* 2009 Nov-Dec;58(6):410-8. PMID: 19851122.
221. Skelly AH, Carlson JR, Leeman J, et al. Symptom-focused management for African American women with type 2 diabetes: a pilot study. *Appl Nurs Res.* 2005 Nov;18(4):213-20. PMID: 16298697.
222. Smith DE, Heckemeyer CM, Kratt PP, et al. Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM. A pilot study. *Diabetes Care.* 1997 Jan;20(1):52-4. PMID: 9028693.
223. Spencer MS, Rosland AM, Kieffer EC, et al. Effectiveness of a community health worker intervention among African American and Latino adults with type 2 diabetes: a randomized controlled trial. *Am J Public Health.* 2011 Dec;101(12):2253-60. PMID: 21680932.
224. Sperl-Hillen J, Beaton S, Fernandes O, et al. Are benefits from diabetes self-management education sustained? *Am J Manag Care.* 2013 Feb;19(2):104-12. PMID: 23448107.
225. Steed L, Lankester J, Barnard M, et al. Evaluation of the ucl diabetes self-management programme (UCL-DSMP): a randomized controlled trial. *J Health Psychol.* 2005 Mar;10(2):261-76. PMID: 15723895.
226. Sung K, Bae S. Effects of a regular walking exercise program on behavioral and biochemical aspects in elderly people with type 2 diabetes. *Nurs Health Sci.* 2012 Dec;14(4):438-45. PMID: 22676205.
227. Tang TS, Funnell M, Sinco B, et al. Comparative effectiveness of peer leaders and community health workers in diabetes self-management support: results of a randomized controlled trial. *Diabetes Care.* 2014 Jun;37(6):1525-34. PMID: 24722495.
228. Thoolen B, De Ridder D, Bensing J, et al. Effectiveness of a self-management intervention in patients with screen-detected type 2 diabetes. *Diabetes Care.* 2007 Nov;30(11):2832-7. PMID: 17666461.
229. Toobert DJ, Glasgow RE, Strycker LA, et al. Biologic and quality-of-life outcomes from the mediterranean lifestyle program: a randomized clinical trial. *Diabetes Care.* 2003 Aug;26(8):2288-93. PMID: 12882850.
230. Toobert DJ, Strycker LA, King DK, et al. Long-term outcomes from a multiple-risk-factor diabetes trial for Latinas: Viva bien! *Transl Behav Med.* 2011 September;1(3):416-26. PMID: 22022345.
231. Trief P, Sandberg JG, Ploutz-Snyder R, et al. Promoting couples collaboration in type 2 diabetes: the diabetes support project pilot data. *Fam Syst Health.* 2011 Sep;29(3):253-61. PMID: 21744962.
232. Tucker CM, Lopez MT, Campbell K, et al. The effects of a culturally sensitive, empowerment-focused, community-based health promotion program on health outcomes of adults with type 2 diabetes. *J Health Care Poor Underserved.* 2014 Feb;25(1):292-307. PMID: 24509027.
233. Utz SW, Williams IC, Jones R, et al. Culturally tailored intervention for rural African Americans with type 2 diabetes.

- Diabetes Educ. 2008 Sep-Oct;34(5):854-65. PMID: 18832290.
234. Vadstrup ES, Frolich A, Perrild H, et al. Effect of a group-based rehabilitation programme on glycaemic control and cardiovascular risk factors in type 2 diabetes patients: the Copenhagen Type 2 Diabetes Rehabilitation Project. *Patient Educ Couns*. 2011 Aug;84(2):185-90. PMID: 20702058.
235. Vazquez IM, Millen B, Bissett L, et al. Buena Alimentacion, Buena Salud: a preventive nutrition intervention in Caribbean Latinos with type 2 diabetes. *Am J Health Promot*. 1998 Nov-Dec;13(2):116-9. PMID: 10346658.
236. Vincent D, Pasvogel A, Barrera L. A feasibility study of a culturally tailored diabetes intervention for Mexican Americans. *Biol Res Nurs*. 2007 Oct;9(2):130-41. PMID: 17909165.
237. Walker EA, Shmukler C, Ullman R, et al. Results of a successful telephonic intervention to improve diabetes control in urban adults: a randomized trial. *Diabetes Care*. 2011 Jan;34(1):2-7. PMID: 21193619.
238. Welch G, Zagarins SE, Feinberg RG, et al. Motivational interviewing delivered by diabetes educators: does it improve blood glucose control among poorly controlled type 2 diabetes patients? *Diabetes Res Clin Pract*. 2011 Jan;91(1):54-60. PMID: 21074887.
239. Welschen LMC, Van Oppen P, Bot SDM, et al. Effects of a cognitive behavioural treatment in patients with type 2 diabetes when added to managed care: a randomised controlled trial. *J Behav Med*. 2013 Dec;36(6):556-66. PMID: 23054175.
240. West DS, Dilillo V, Bursac Z, et al. Motivational interviewing improves weight loss in women with type 2 diabetes. *Diabetes Care*. 2007 May;30(5):1081-7. PMID: 17337504.
241. Wierenga ME. Life-style modification for weight control to improve diabetes health status. *Patient Educ Couns*. 1994 Apr;23(1):33-40. PMID: 7971538.
242. Wing RR, Bolin P, Brancati FL, et al. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. *N Engl J Med*. 2013 Jul 11;369(2):145-54. PMID: 23796131.
243. Wolever RQ, Dreusicke M, Fikkan J, et al. Integrative health coaching for patients with type 2 diabetes: a randomized clinical trial. *Diabetes Educ*. 2010 Jul-Aug;36(4):629-39. PMID: 20534872.
244. Wolf AM, Conaway MR, Crowther JQ, et al. Translating lifestyle intervention to practice in obese patients with type 2 diabetes: improving control with activity and nutrition (ICAN) study. *Diabetes Care*. 2004 Jul;27(7):1570-6. PMID: 15220230.
245. Yoo JS, Lee SJ, Lee HC, et al. The effect of a comprehensive lifestyle modification program on glycemic control and body composition in patients with type 2 diabetes. *Asian Nursing Research*. 2007;1(2):106-15. PMID: 25030747.
246. Zgibor J, Piatt G. Project SEED: support, education and evaluation in diabetes. [Report to funding agency; International Diabetes Federation]. In press, 2014.
247. Amoako EP. Managing uncertainty in diabetes: an intervention for older African-American women: University of North Carolina at Chapel Hill; 2004.
248. Bond GE, Burr RL, Wolf FM, et al. The effects of a web-based intervention on psychosocial well-being among adults aged 60 and older with diabetes: a randomized trial. *Diabetes Educ*. 2010 May-Jun;36(3):446-56. PMID: 20375351.
249. Brown SA, Hanis CL. Culturally competent diabetes education for Mexican Americans: The Starr County Study. *Diabetes Educ*. 1999 Mar-Apr;25(2):226-36. PMID: 10531848.
250. Cooper H, Booth K, Gill G. Using combined research methods for exploring diabetes patient education. *Patient Educ Couns*. 2003 Sep;51(1):45-52. PMID: 12915279.
251. Daly RM, Dunstan DW, Owen N, et al. Does high-intensity resistance training maintain bone mass during moderate weight loss in older overweight adults with type 2 diabetes? *Osteoporos Int*. 2005 Dec;16(12):1703-12. PMID: 15937634.
252. Davis RM, Hitch AD, Nichols M, et al. A collaborative approach to the recruitment and retention of minority patients with diabetes in rural community health centers. *Contemp Clin Trials*. 2009 Jan;30(1):63-70. PMID: 18824135.

253. Dunstan DW, Daly RM, Owen N, et al. High-intensity resistance training improves glycemic control in older patients with type 2 diabetes. *Diabetes Care*. 2002 Oct;25(10):1729-36. PMID: 12351469.
254. Glasgow RE, Kurz D, King D, et al. Outcomes of minimal and moderate support versions of an internet-based diabetes self-management support program. *J Gen Intern Med*. 2010 Dec;25(12):1315-22. PMID: 20714820.
255. Gurka MJ, Wolf AM, Conaway MR, et al. Lifestyle intervention in obese patients with type 2 diabetes: impact of the patient's educational background. *Obesity (Silver Spring)*. 2006 Jun;14(6):1085-92. PMID: 16861614.
256. King DK, Estabrooks PA, Strycker LA, et al. Outcomes of a multifaceted physical activity regimen as part of a diabetes self-management intervention. *Ann Behav Med*. 2006 Apr;31(2):128-37. PMID: 16542127.
257. LookAHEAD Research Group. Impact of intensive lifestyle intervention on depression and health-related quality of life in type 2 diabetes: The Look AHEAD trial. *Diabetes Care*. 2014 Jun;37(6):1544-53. PMID: 24855155.
258. LookAHEAD Research Group Eight-year weight losses with an intensive lifestyle intervention: The Look AHEAD study. *Obesity (Silver Spring)*. 2014 Jan;22(1):5-13. PMID: 24307184.
259. LookAHEAD Research Group. Effect of a long-term behavioural weight loss intervention on nephropathy in overweight or obese adults with type 2 diabetes: a secondary analysis of the Look AHEAD randomised clinical trial. *Lancet Diabetes Endocrinol*. 2014 Oct;2(10):801-9. PMID: 25127483.
260. Lujan J. The effectiveness of a promotora-led intervention for Mexican Americans with type 2 diabetes. University of Texas School of Nursing at Houston; 2006.
261. Miller CK, Kristeller JL, Headings A, et al. Comparative effectiveness of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes: a pilot study. *J Acad Nutr Diet*. 2012 Nov;112(11):1835-42. PMID: 23102183.
262. Samuel-Hodge CD, Keyserling TC, France R, et al. A church-based diabetes self-management education program for African Americans with type 2 diabetes. *Prev Chronic Dis*. 2006 Jul;3(3):A93. PMID: 16776894.
263. Sevick MA, Stone RA, Zickmund S, et al. Factors associated with probability of personal digital assistant-based dietary self-monitoring in those with type 2 diabetes. *J Behav Med*. 2010 Aug;33(4):315-25. PMID: 20232131.
264. Shreck E, Gonzalez JS, Cohen HW, et al. Risk perception and self-management in urban, diverse adults with type 2 diabetes: The improving diabetes outcomes study. *Int J Behav Med*. 2014 Feb;21(1):88-98. PMID: 23385488.
265. Sixta CS. Border intervention by promotores for type 2 diabetes. University of Texas School of Nursing at Houston; 2007.
266. Spencer MS, Hawkins J, Espitia NR, et al. Influence of a community health worker intervention on mental health outcomes among low-income Latino and African American adults with type 2 diabetes. *Race and Social Problems*. 2013;5(2):137-46. PMID: Not available.
267. Thoolen BJ, De Ridder D, Bensing J, et al. Beyond Good Intentions: the role of proactive coping in achieving sustained behavioural change in the context of diabetes management. *Psychol Health*. 2009 Mar;24(3):237-54. PMID: 20204991.
268. Toobert DJ, Glasgow RE, Strycker LA, et al. Long-term effects of the mediterranean lifestyle program: a randomized clinical trial for postmenopausal women with type 2 diabetes. *Int J Behav Nutr Phys Act*. 2007;4:1. PMID: 17229325.
269. Toobert DJ, Strycker LA, Barrera MJ, et al. Outcomes from a multiple risk factor diabetes self-management trial for Latinas: viva bien! *Ann Behav Med*. 2011 Jun;41(3):310-23. PMID: 21213091.
270. Toobert DJ, Strycker LA, Glasgow RE, et al. Effects of the mediterranean lifestyle program on multiple risk behaviors and psychosocial outcomes among women at risk for heart disease. *Ann Behav Med*. 2005 Apr;29(2):128-37. PMID: 15823786.

271. Vadstrup ES, Frolich A, Perrild H, et al. Health-related quality of life and self-related health in patients with type 2 diabetes: effects of group-based rehabilitation versus individual counselling. *Health Qual Life Outcomes*. 2011;9:110. PMID: 22152107.
272. Wang ML, Lemon SC, Whited MC, et al. Who benefits from diabetes self-management interventions? The influence of depression in the Latinos en Control trial. *Ann Behav Med*. 2014 Mar 25. PMID: 24664615.
273. Wolf AM, Siadaty M, Yaeger B, et al. Effects of lifestyle intervention on health care costs: improving control with activity and nutrition (ican). *J Am Diet Assoc*. 2007 Aug;107(8):1365-73. PMID: 17659904.
274. Knowler WC. Impact of a lifestyle intervention on diabetes control and microvascular complications American Diabetes Association 73rd Scientific Sessions; 2013 June; Chicago, IL.
275. Sperl-Hillen J, Beaton S, Fernandes O, et al. Comparative effectiveness of patient education methods for type 2 diabetes: a randomized controlled trial. *Arch Intern Med*. 2011 Dec 12;171(22):2001-10. PMID: 21986350.
276. Ayling K, Brierley S, Johnson B, et al. How standard is standard care? Exploring control group outcomes in behaviour change interventions for young people with type 1 diabetes. *Psychol Health*. 2015 Jan;30(1):85-103. PMID: 25118842.
277. Court JM, Cameron FJ, Berg-Kelly K, et al. Diabetes in adolescence. *Pediatr Diabetes*. 2009 Sep;10 Suppl 12:185-94. PMID: 19754629.
278. Ingerski LM, Anderson BJ, Dolan LM, et al. Blood glucose monitoring and glycemic control in adolescence: contribution of diabetes-specific responsibility and family conflict. *J Adolesc Health*. 2010 Aug;47(2):191-7. PMID: 20638012.
279. Schilling LS, Knafl KA, Grey M. Changing patterns of self-management in youth with type 1 diabetes. *J Pediatr Nurs*. 2006 Dec;21(6):412-24. PMID: 17101399.
280. Peters A, Laffel L. Diabetes care for emerging adults: Recommendations for transition from pediatric to adult diabetes care systems: a position statement of the American Diabetes Association, with representation by the American College of Osteopathic Family Physicians, the American Academy of Pediatrics, the American Association of Clinical Endocrinologists, the American Osteopathic Association, the Centers for Disease Control and Prevention, Children with Diabetes, the Endocrine Society, the International Society for Pediatric and Adolescent Diabetes, Juvenile Diabetes Research Foundation International, the National Diabetes Education Program, and the Pediatric Endocrine Society (formerly Lawson Wilkins Pediatric Endocrine Society). *Diabetes Care*. 2011 Nov;34(11):2477-85. PMID: 22025785.
281. Duke SAS, Colagiuri S, Colagiuri R. Individual patient education for people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2009(1):CD005268. PMID: 19160249.
282. Herman WH, Dungan KM, Wolffenbuttel BH, et al. Racial and ethnic differences in mean plasma glucose, hemoglobin A1c, and 1,5-anhydroglucitol in over 2000 patients with type 2 diabetes. *J Clin Endocrinol Metab*. 2009 May;94(5):1689-94. PMID: 19276235.
283. Nam S, Janson SL, Stotts NA, et al. Effect of culturally tailored diabetes education in ethnic minorities with type 2 diabetes: a meta-analysis. *J Cardiovasc Nurs*. 2012 Nov-Dec;27(6):505-18. PMID: 21747287.
284. Cohen J. A power primer. *Psychol Bull*. 1992 Jul;112(1):155-9. PMID: 19565683.
285. Sone H, Tanaka S, Iimuro S, et al. Long-term lifestyle intervention lowers the incidence of stroke in Japanese patients with type 2 diabetes: a nationwide multicentre randomised controlled trial (the Japan Diabetes Complications Study). *Diabetologia*. 2010 Mar;53(3):419-28. PMID: 20054522.
286. Trento M, Passera P, Bajardi M, et al. Lifestyle intervention by group care prevents deterioration of type II diabetes: a 4-year randomized controlled clinical trial. *Diabetologia*. 2002 Sep;45(9):1231-9. PMID: 12242455.
287. Jaber LA, Halapy H, Fernet M, et al. Evaluation of a pharmaceutical care model on diabetes management. *Ann*

- Pharmacother. 1996 Mar;30(3):238-43.  
PMID: 8833557.
288. Kim HS, Oh JA. Adherence to diabetes control recommendations: impact of nurse telephone calls. *J Adv Nurs*. 2003 Nov;44(3):256-61. PMID: 14641395.
289. Moher D, Pham B, Klassen TP, et al. What contributions do languages other than English make on the results of meta-analyses? *J Clin Epidemiol*. 2000 Sep;53(9):964-72. PMID: 11004423.

## 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 <sub>1c</sub>	hemoglobin A <sub>1c</sub>
HRQL	health-related quality of life
I <sup>2</sup>	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 <sub>2</sub> max	maximal oxygen uptake
yr	year