# Behavioral Programs for Type 1 Diabetes Mellitus: Current State of the Evidence

## **Focus of This Summary**

This is a summary of a systematic review evaluating the evidence about the effectiveness of behavioral programs for type 1 diabetes mellitus (T1DM). The systematic review included 34 studies of T1DM published between January 1,1993, and January 2015. The full report, listing all studies, is available at <a href="https://www.effectivehealthcare.ahrq.gov/diabetes-behavioral-programs">www.effectivehealthcare.ahrq.gov/diabetes-behavioral-programs</a>. This summary is provided to assist in informed clinical decisionmaking. However, reviews of evidence should not be construed to represent clinical recommendations or guidelines.

## **Background**

In 2012, 29.1 million Americans had diabetes mellitus, representing 9.3 percent of the entire U.S. population, 12.3 percent of adults aged 20 years or older, and 25.9 percent of adults aged 65 years or older. In the United States, type 2 diabetes mellitus (T2DM) accounts for 90 to 95 percent of diabetes cases, while T1DM accounts for 5 to 10 percent. T1DM is one of the most common chronic diseases in youth, and its prevalence in the United States has increased over the past 2 decades.

Management of T1DM and T2DM involves clinical care and enabling patients to adopt self-management behaviors. Because knowledge acquisition alone is insufficient for patients to achieve behavioral changes, the focus of many national and international guidelines for self-management education has shifted from traditional didactic educational services to more patient-centered methodologies that incorporate interaction and problem-solving.

Behavioral programs for diabetes may be defined as organized, multicomponent programs that consist of repeated interactions with one or more trained individuals for a duration of  $\geq 4$  weeks to improve disease control, patient health outcomes, or both. These programs consist of at least one of the following:

- a) diabetes self-management education, or DSME, which provides education on diabetes-related topics (including the disease process, treatment options, nutritional management, physical activity, safe medication use, glucose monitoring, prevention and detection of acute and chronic diabetic complications) and addresses psychosocial issues related to living with diabetes;
- b) a structured dietary intervention (related to weight loss, glycemic control, or reducing the 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; behavior change (including goal setting, problem-solving, motivational interviewing, coping skills training, and cognitive behavioral therapy); relaxation or stress reduction; blood glucose regulation; medication adherence; or selfmonitoring for diabetic complications (foot exam, eye exam, and renal tests).

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, [to foster] the maintenance of healthy diabetes-related behaviors, and to address psychological concerns."

Previous studies have shown that, in patients with T2DM, behavioral programs that focus on self-management and lifestyle interventions significantly improve short-term glycemic control. However, the effectiveness of behavioral programs in patients with T1DM is unclear. This systematic review sought to determine the effectiveness and harms of behavioral programs in the community health setting for patients with T1DM when compared with usual care or active comparators.

#### **Conclusions**

Participation in a behavioral program led to greater reductions in hemoglobin  $A_{\rm lc}$  (Hb $A_{\rm lc}$ ) levels at a 6-month postintervention followup when compared with usual care or a control intervention. More evidence is needed to determine if the reduction in Hb $A_{\rm lc}$  can be sustained at a 12-month or longer followup. More evidence is also required to determine the effects of behavioral programs on other outcomes, including lifestyle behaviors, body composition, diabetes-specific quality of life, diabetes distress, and diabetes-related complications.





<sup>&</sup>lt;sup>a</sup> Diabetes distress is a unique set of emotional issues experienced by patients with diabetes. These emotional issues are directly related to the burden of living with this chronic disease.

#### **Overview of Clinical Research Evidence**

#### Effectiveness of Behavioral Programs for Managing T1DM

- Overall, behavioral programs seemed to have some benefit in patients with T1DM for reducing HbA<sub>1c</sub> up to 6 months (*Table 1*).
  - Greater reductions in  $HbA_{1c}$  levels were observed in patients who participated in a behavioral program, when compared with those who received usual care or a control intervention, at a 6-month postintervention followup ( $\bullet \bullet \circ$ ).
  - The reduction in  $HbA_{1c}$  did not appear to be sustained at a 12-month or longer followup ( $\bullet \circ \circ$ ).
- Generic health-related quality of life was not significantly different between patients participating in behavioral programs and those receiving usual care (●●○).

- Adherence to diabetes self-management was not significantly different between patients participating in behavioral programs and those receiving usual care (●○○).
- Diabetes-related distress was not significantly different between patients participating in behavioral programs and those receiving usual care (●○○).
- The evidence for other behavioral, clinical, and health outcomes was too limited or insufficient to permit conclusions (○○○).
- No studies reported the associated harms (i.e., activityrelated injury) of behavioral programs in patients with T1DM.

Table 1: Summary of Key Findings and Strength of Evidence for Behavioral Programs for T1DM

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Comparison	Outcome	Outcome Timing	No. Trials	No. Subjects	Summary of Key Findings	Mean Difference in HbA <sub>1c</sub> (95% CI)*	SOE
Behavioral program vs. usual care	HbA <sub>1c</sub>	End of intervention†	16	1155	$\leftrightarrow$	-0.11 (-0.33 to 0.11)	•00
		6-month followup	12	1463	<b>J</b>	−0.31 (−0.47 to −0.15) <sup>††</sup>	••0
		12-month followup	7	1333	$\leftrightarrow$	-0.22 (-0.49 to 0.05)	•00
		>12-month followup	4	1138	$\leftrightarrow$	-0.40 (-0.92 to 0.12) (>12 months to <24 months)	•00
Behavioral program vs. active control <sup>§</sup>	HbA <sub>1c</sub>	End of intervention	4	566	$\leftrightarrow$	-0.32 (-0.78 to 0.14)	•00
		6-month followup	4	504	<b>J</b>	-0.43 (-0.62 to -0.24)	••0
		12-month followup	3	342	$\leftrightarrow$	-0.34 (-0.71 to 0.03)	•00

 $<sup>\</sup>Leftrightarrow$  = no significant difference between the two interventions;  $\downarrow$  = statistically significant reduction related to the behavioral program; 95% CI = 95-percent confidence interval; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; SOE = strength of evidence

#### Strength of Evidence Scale\*\*

High: ••• High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.

Moderate: ••• Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.

Low: •OO Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.

Insufficient: OOO Evidence either is unavailable or does not permit a conclusion.

<sup>\*</sup> Negative values for mean differences are favorable for the outcome measure.

<sup>&</sup>lt;sup>†</sup> Outcomes were measured at ≤1 month after the intervention; the duration of the interventions ranged between 1.5 to 25.0 months.

<sup>&</sup>lt;sup>††</sup> This point estimate did not meet the prespecified threshold for clinical significance (≥0.4 unit change in percent HbA<sub>1c</sub>), although the 95-percent confidence interval included a clinically important difference.

<sup>§</sup> The active control included telephone support or basic education.

<sup>\*\*</sup> The overall evidence grade was assessed based on the ratings for the following domains: study limitations, directness, consistency, precision, and reporting bias. Other domains that were considered, as appropriate, included dose-response association, plausible confounding, and strength of association (i.e., magnitude of effect). For additional details on the methodology used to assess strength of evidence, please refer to: Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—Agency for Healthcare Research and Quality and the Effective Health-Care Program. J Clin Epidemiol. 2010 May;63(5):513-23. PMID: 19595577.

### **Overview of Clinical Research Evidence (Continued)**

#### Factors Contributing to the Effectiveness of Behavioral Programs for T1DM

- Older adults (aged 31–64 years) appeared to have greater benefit for glycemic control (-0.28 [95% CI, -0.57 to 0.01]) than did younger adults (aged 19–30 years; 0.00 [95% CI, -0.33 to 0.33]) at program end.
- Program intensity (duration, contact hours, contact frequency) does not appear to influence effectiveness.
- Incorporating some individual (vs. solely group) delivery appeared to be beneficial.
- Behavioral programs appeared to be acceptable to patients with T1DM; there was a 21-percent higher risk of attrition for individuals receiving usual care when compared with those enrolled in behavioral programs.

# Gaps in Knowledge and Limitations of the Evidence Base

- Data to determine the effectiveness of behavioral programs for T1DM at durations of followup beyond 6 months were limited.
- It is not known if adding a clinical, behavioral, psychosocial, or educational support phase to behavioral programs for T1DM improves outcomes. These additions may be useful for prolonging the effects of behavioral programs and for addressing some of the psychosocial aspects of the disease (particularly in adolescents) to a greater extent.
- Only one T1DM study compared behavioral programs delivered in person with those delivered via some form of technology that allowed interaction between the provider and patient.
- The use of behavior change techniques within the programs assessed in this review was highly variable.
- Evaluation of outcomes important to patients and decisionmakers (e.g., quality of life, microvascular and macrovascular complications, health care utilization) was inconsistent across studies.
- Consensus is needed on what constitutes clinically important differences in outcomes for behavioral programs.

# What To Discuss With Your Patients and Their Caregivers

Clinicians might consider encouraging appropriate patients to engage in behavioral support programs to improve the risk factors of diabetes mellitus. Points to be discussed with patients and their caregivers include:

- That some types of behavioral programs for diabetes may be effective, particularly for improving glycemic control, and what evidence there is for their effectiveness
- Which programs are covered by the patient's insurance
- The importance of adherence to the behavioral programs and the need for following up with their clinician after program completion to assess progress

#### **Companion Resource for Patients**



Behavioral Programs To Help Manage Type 1 Diabetes: A Review of the Research for Children, Teens, and Adults is a free companion to this clinician research summary. It can help patients with diabetes and their caregivers talk with their health care professionals about the various behavioral programs that might help manage diabetes.

# **Ordering Information**

For electronic copies of this clinician research summary, the companion patient resource, and the full systematic review, visit www.effectivehealthcare.ahrq.gov/diabetes-behavioral-programs. To order free print copies of the patient resource, call the AHRQ Publications Clearinghouse at 800-358-9295.

#### Source

The information in this summary is based on *Behavioral Programs for Diabetes Mellitus*, Evidence Report/
Technology Assessment No. 221, prepared by the University of Alberta Evidence-based Practice Center under Contract No. 290-2012-00013-I for the Agency for Healthcare Research and Quality, September 2015. Available at <a href="https://www.effectivehealthcare.ahrq.gov/diabetes-behavioral-programs">www.effectivehealthcare.ahrq.gov/diabetes-behavioral-programs</a>. This summary was prepared by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, TX.