Can a Cognitive Therapy Group Intervention Improve Glycemia in Patients with Poorly Controlled Diabetes?

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;171:1990–9.

Study Overview

Objective. To determine the efficacy of a cognitive behavioral intervention in lowering hemoglobin A1c levels in patients with poorly controlled diabetes.

Design. Single-center, 3-arm, randomized controlled trial.

Setting and participants. This study was conducted at the Joslin Diabetes Center in Boston between 2003 and 2008 and included male and female adults aged 18 to 70 years diagnosed with type 1 or type 2 diabetes for at least 2 years whose HbA1C level was higher than 7.5%. Participants also had to be taking insulin and/or medication for at least 1 year, be able to walk "briskly," and be able to read and speak English. Exclusion criteria included currently or planning to become pregnant, having a severe psychopathologic condition, unstable depression, elevated albumin-to-creatinine ratio, untreated retinopathy, unstable heart disease, blood pressure ≥160/90, severe neuropathy, recent substance dependence, initiation of insulin treatment within 1 year, and participation in diabetes education within 6 months.

Patients were randomized to 1 of 3 arms using computer-generated block assignment. Randomization occurred in 2 steps to minimize waiting time prior to intervention. Patients were first randomized to either an individual or group program, and individual arm participants began education immediately. Patients randomized to group programs were subsequently randomized to either the structured behavioral intervention or attention control arms.

Intervention. The structured behavioral intervention arm recevied a manual-based, highly structured group diabetes education program with behavioral support for self-care. In addition to providing core education on nutrition, medication management, exercise, and glucose management, this intervention used cognitive-behavior strategies including group review of glucose logs, educator-facilitated goal-setting around self-care goals, motivational interviewing, and problem solving. The intervention was delivered during 5 sessions over 6 weeks at a behavioral research laboratory outside of the Joslin Clinic. Certified diabetes educators (nurses or dieticians) who led the groups received 6 hours of

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group training in behavioral strategies. The attention control group also received a manual-based program delivered during 5 sessions over a 6-week period of time and had the same level of contact with health professionals and homework as the intervention arm, but instead of using cognitive behavioral techniques, teaching modalities included use of prepared slides and specific learning activities. Diabetes educators leading this arm received 3 hours of training, and groups were conducted at the Joslin Clinic. All group sessions were separated by diabetes type. The individual control arm received 6 months of unlimited individual diabetes education sessions but were not required to attend any appointments. These were taught 1:1 by certified diabetes educators at the Joslin Clinic, and the authors did not report any additional training. The educators in all control arms were provided access to clinic teaching and diabetes assessment guides.

Main outcome measures. The main outcome measure was HbA1c level measured at 3, 6, and 12 months post-intervention. Secondary outcome measures included LDL and HDL cholesterol levels, body mass index, number of daily glucometer checks, pedometer readings, frequency of diabetes self-care behaviors (5-point Likert scale), diabetes-related distress (Problem Areas in Diabetes) [1,2], depression and anxiety symptoms (Brief Symptom inventory-18) [3], and diabetes quality of life (Diabetes Quality of Life Questionnaire) [4,5]. Outcome assessors were blinded to treatment arm, and investigators used intention to treat analyses.

Main results. Researchers screened 2027 individuals via telephone, of which 464 were determined to be eligible for a screening visit. Subsequently, 222 patients were randomized; 110 patients had type 1 diabetes and 112 had type 2 diabetes. Seventy-four patients were randomized to the structured behavioral intervention, 75 to the attention control group intervention, and 73 to the individual control intervention. Six patients did not return for follow-up, and 1 randomized patient did not meet psychopathologic requirements and was excluded from the study. The mean age (SD) of the sample was 53 (12) years (range, 21.6–74.8 years). Half (50.4%) were female and 87.3% were non-Hispanic white. The mean duration of diabetes was 18 (12) years and the mean HbA1c concentration was 9.0% (1.1%). Patient groups did not differ significantly according to sociodemographic, behavioral, psychosocial characteristics, or treatment type. However, patients in the structured behavioral arm had more pedometer steps per day and higher levels of physical fitness at baseline. As expected, patients with type 1 and type 2 diabetes differed by baseline characteristics.

Linear mixed modeling showed improvement in HbA1c levels in all patients that participated in the study at 3 months. However, structured behavioral intervention participants showed greater improvement than the attention and individual control groups (3-month HbA1c concentration changes :−0.8% vs. −0.4% and −0.4%, $P = 0.04$ for group x time interaction). Type 2 diabetes patients showed greater improvement in HbA1c levels than patients with type 1 diabetes (3-month HbA1c concentration changes: −0.7% vs. −0.3%, $P = 0.04$ for type of diabetes × time interaction). These improvements were maintained at 12 months. After controlling for diabetes duration, age, and baseline pedometer steps, the association between intervention arm and HbA1c level remained significant but the association with type of diabetes did not remain significant ($P = 0.09$). Intervention type was not significantly associated with increased diabetes quality of life, number of daily glucometer checks, or frequency of self-care behaviors. Logistic regression was then used to identify characteristics associated with a clinically significant (−0.5%) decrease in HbA1c and demonstrated that a higher baseline HbA1c level was associated with a clinically significant decrease in HbA1c at 3 months.

Conclusion. A 5-session, group-based, cognitive-behavioral program given by trained, certified diabetes educators is more efficacious at lowering HbA1c than either the attention control group or individual control interventions in patients with poorly controlled diabetes.

Commentary

Long-term glycemic control is associated with lower mortality [6], and tight glycemic control can prevent diabetic complications [7]. Despite this, NHANES data from 2003–2004 showed that greater than 40% of diabetic patients did not achieve glycemic control (HbA1c < 7.0%) [8], and more than 10% had HbA1c levels greater 9.0% [8]. Poor glycemic control in diabetic patients can persist due to various patient, provider, and treatment barriers including poor medication adherence and lack of counseling from provid-

ers. Thus, more intensive intervention for patients not meeting treatment goals is warranted, but the best way to overcome glycemic control barriers in this population is not well known.

This 3-arm, randomized controlled trial demonstrated that a structured, group-based, cognitive behavioral intervention delivered by highly-trained, certified diabetic educators was superior to 2 control interventions in lowering HbA1c levels in type 1 and type 2 diabetic patients with poor glycemic control. This study was a well-designed trial; it randomized group assignment and achieved limited loss of follow-up. Further, outcome assessment was blinded to treatment arm, and they used intention to treat analyses.

There are 2 main limitations to this study. The first limitation is that the mechanisms by which the structured behavioral intervention achieved better outcomes are not entirely clear. The use of cognitive behavioral techniques such as goal-setting may have been one reason for the improvement. Group-based cognitive behavioral therapy has been used to prevent and/or manage several conditions including low back pain [9], depression in women with breast cancer [10], and as secondary prevention of myocardial infarction [11]. Further, there was an emphasis on goal-setting, an effective technique used to promote behavior change in primary care settings [12]. Thus, use of superior patient education strategies may be the reason that the structured behavioral intervention was more efficacious than the other treatment arms. However, an alternative explanation may have to do with differences in the levels of training that the diabetes educators received in each group. The structured behavioral intervention educators received 6 hours of additional training; the attention group control educators received 3 hours of additional training; the individual control educators received no extra training. Provider training may improve behavior change counseling skills [13], and thus may be one of the reasons for the differences in outcomes between the 3 groups.

In a multi-center, 3-arm randomized controlled trial of 623 type 2 diabetic subjects with poor glycemic control by Sperl-Hillen et al (published in the same issue of the journal) patients randomized to individual education actually had greater decrease in HbA1c (−0.51%) than either group-based education (−0.27%) or usual care (−0.24%) [14]. Educators in this trial all received the same level of training regardless of intervention, and the groups did not use cognitive behavioral strategies. It is thus unclear whether this difference in outcomes between the 2 trials is due to differences in curricular components of the groups, training differences between the educators, or other differences (eg, population differences), and this needs to be explored further.

Another limitation of this study is that the findings may not be generalizable to other populations. This was a single-center study, and the majority of patients identified themselves as white, non-Hispanic race/ethnicity. Patients with several comorbidities were excluded, and only a relatively small number of individuals screened were found to be eligible for the study. In contrast, the study conducted by Sperl-Hillen et al had fewer exclusions and a more diverse patient sample with 22.1% Hispanic and 65.2% white non-Hispanic patients. Thus, studies of the structured behavioral intervention need to be replicated in other patient populations.

While both studies showed decreased HbA1c in all groups, the changes were modest. This may be due to the fact that the patients had longstanding, poorly controlled diabetes and may have already been exposed to various forms of diabetes education over the years. Further, these patients may have other barriers not measured by the researchers such as access to healthy food and inadequate public resources [15]. Despite the modest results, the authors point out that, based on the United Kingdom Prospective Diabetes Study [7], the reduction in HbA1c if sustained should result in a 20% reduction in microvascular endpoints and a 10% reduction in cardiovascular endpoints. Future studies should determine the cost-effectiveness of the intervention and explore longer-term outcomes.

Applications for Clinical Practice

A 5-week, structured cognitive behavioral group intervention decreased HbA1c levels in patients and was superior to 2 control interventions in a sample of mostly white patients with poorly controlled type 1 and type 2 diabetes. Further investigation is needed to determine if this study can be replicated in diverse populations and to determine the cost-effectiveness of the intervention.

—Review by Stella M. Savarimuthu, BA, and Melanie Jay, MD, MS

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