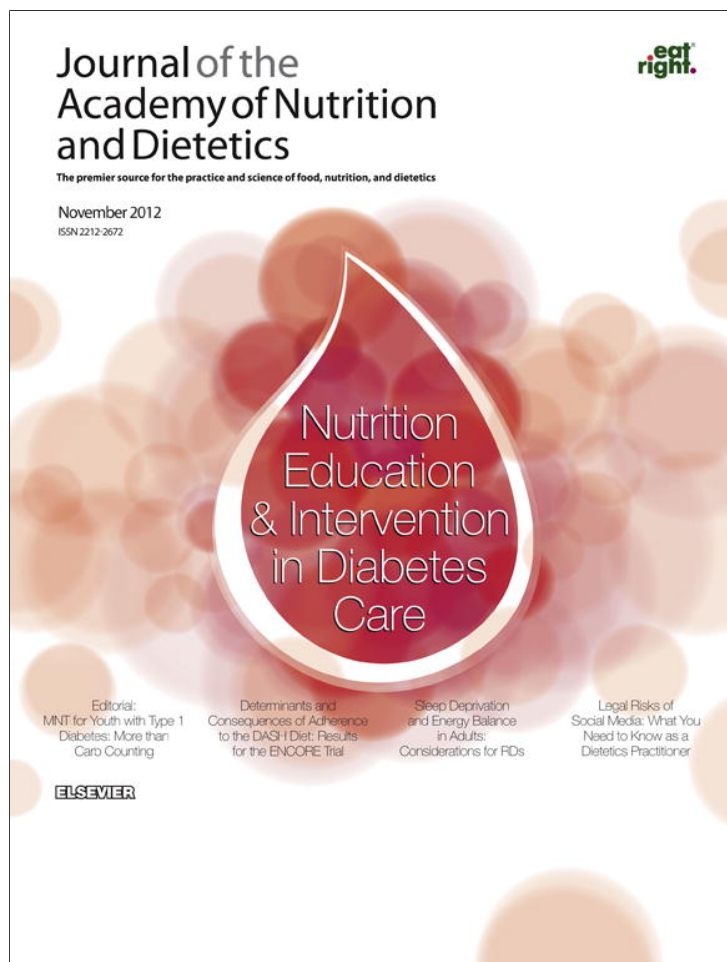


Provided for non-commercial research and education use.
Not for reproduction, distribution or commercial use.



This article appeared in a journal published by Elsevier. The attached copy is furnished to the author for internal non-commercial research and education use, including for instruction at the authors institution and sharing with colleagues.

Other uses, including reproduction and distribution, or selling or licensing copies, or posting to personal, institutional or third party websites are prohibited.

In most cases authors are permitted to post their version of the article (e.g. in Word or Tex form) to their personal website or institutional repository. Authors requiring further information regarding Elsevier's archiving and manuscript policies are encouraged to visit:

<http://www.elsevier.com/copyright>



Comparative Effectiveness of a Mindful Eating Intervention to a Diabetes Self-Management Intervention among Adults with Type 2 Diabetes: A Pilot Study

Carla K. Miller, PhD, RD; Jean L. Kristeller, PhD; Amy Headings, PhD, RD; Haikady Nagaraja, PhD; W. Fred Miser, MD, MA

ARTICLE INFORMATION

Article history:

Accepted 30 July 2012

Keywords:

Type 2 diabetes mellitus
Meditation
Patient education
Randomized controlled trial

Copyright © 2012 by the Academy of Nutrition and Dietetics.
2212-2672/\$36.00
doi: 10.1016/j.jand.2012.07.036

ABSTRACT

Mindful eating offers promise as an effective approach for weight management and glycemic control in people with diabetes. Diabetes self-management education (DSME) is an essential component of effective self-care. Yet, little research has compared the effect of mindful eating to DSME-based treatment. This study compared the impact of these two interventions in adults with type 2 diabetes mellitus. A prospective randomized controlled trial with two parallel interventions was used. Participants included adults age 35 to 65 years with type 2 diabetes mellitus for 1 year or more, body mass index (BMI) of 27 or more, and hemoglobin A1c (HbA1c) of 7% or more who were randomly assigned to a 3-month mindful eating (MB-EAT-D; n=27) or Smart Choices (SC) DSME-based (n=25) intervention. Follow-up occurred 3 months after intervention completion. Dietary intake, physical activity, weight, HbA1c and fasting plasma glucose, and fasting insulin were assessed using repeated measures analysis of variance with contrast analysis. There was no significant difference between groups in the change in weight or glycemia at study end. Significant difference occurred between groups in the change in dietary intake/1,000 kcal of *trans* fats, total fiber, and sugars (all $P<0.05$). Mean (\pm standard error) reduction in weight (-2.92 ± 0.54 kg for SC vs -1.53 ± 0.54 kg for MB-EAT-D) and HbA1c ($-0.67\pm 0.24\%$ for SC and $-0.83\pm 0.24\%$ for MB-EAT-D) were significant ($P<0.01$). Significant reduction in energy intake and glycemic load occurred (all $P<0.0001$) for both groups. Training in mindful eating and diabetes self-management facilitate improvement in dietary intake, modest weight loss, and glycemic control. The availability of effective treatments gives patients with diabetes choices in meeting their self-care needs.

J Acad Nutr Diet. 2012;112:1835-1842.

CURRENT PROJECTIONS INDICATE THAT THE NUMBER of people with diabetes in the United States will more than double from 2005 to 2050.¹ Findings from the National Health and Nutrition Examination Survey 1999–2002 showed only 42.3% of adults had hemoglobin A1c (HbA1c) values less than 7%, a reasonable goal established by the American Diabetes Association; furthermore, only 55% of those with diabetes reported receiving diabetes education.² Diabetes self-management education (DSME) is an essential component of care for all people with diabetes and is necessary to improve patient outcomes and dietary quality.³ DSME is the process of facilitating the knowledge, skills, and abilities needed for diabetes self-care.⁴ Previous systematic reviews found that DSME improved dietary intake and glycemic control, and medical nutrition therapy (MNT) had the largest impact on weight loss.^{5,6} However, prior research found that “one size fits all” interventions may limit outcome improvements,⁷ and there is no one “best” educational approach.^{8,9} Thus, DSME is necessary and effective in improving diabetes

outcomes, but various approaches are likely needed to meet diverse patient needs.

An increasing body of evidence suggests intervention techniques that enhance mindful self-awareness improve well-being, including anxiety and depression,¹⁰ eating disorders,^{11–12} food cravings,¹³ and weight loss.¹⁴ Mindfulness-based interventions use systematic procedures for developing greater awareness of moment-to-moment experiences of physical sensations, affective states, and thoughts without judgment.¹⁵ Mindful eating, as taught in Mindfulness-Based Eating Awareness Training (MB-EAT),¹⁶ includes making conscious food choices, developing awareness of physical vs psychological hunger and satiety cues, and eating healthfully in response to those cues.

Psychological distress also is associated with impaired glycemic control in people with type 2 diabetes mellitus.^{17,18} Mindfulness-based interventions have been shown to improve HbA1c in people with diabetes¹⁹ and reduce episodes of binge-eating in obese individuals.^{12,20} Although mindfulness

RESEARCH

interventions offer promise as an effective approach for diabetes management, little research has compared the efficacy of DSME to a mindfulness-based approach in adults with type 2 diabetes mellitus. Therefore, the purpose of this study was to evaluate the impact of a DSME intervention compared to the MB-EAT program adapted for adults with type 2 diabetes mellitus. It was hypothesized the mindful eating intervention would facilitate greater weight loss than would the DSME approach.

METHODS

Research Design

A prospective randomized controlled trial with two parallel interventions was used. Participants were randomly assigned to treatment group, stratified by race. Randomization by computer occurred after the collection of baseline data. After randomization, participants proceeded through a 3-month intervention followed by a second round of data collection. Follow-up assessments occurred for both treatment groups at 1 and 3 months after the second data collection period.

Subjects

Eligibility criteria for study participation included being 35 to 65 years old with diagnosed type 2 diabetes mellitus for at least 1 year, body mass index (BMI) of 27 or more, HbA1c of 7% or more, and not requiring insulin therapy for glucose management. Individuals concurrently participating in a structured weight-loss program or women who were pregnant or lactating were ineligible. Participants were recruited through local medical practices, the university newswire, radio and Internet advertisements, and community flyers. All procedures were followed in accordance with the ethical standards of the Institutional Review Board at The Ohio State University; participants provided written, informed consent.

Measures

Anthropometric, metabolic, dietary, and physical activity measures were obtained at each assessment. Height was measured using a wall-mounted stadiometer (Seca). Weight was determined using an electronic scale (Tanita Corp), with participants wearing light clothing and not wearing shoes. BMI, which measures weight adjusted for height, was calculated. Waist circumference measurements were obtained using standardized procedures in the National Health and Nutrition Examination Survey.²¹

An overnight 12-hour fasting blood sample was drawn by venipuncture. Glucose was measured by standard enzymatic procedures (coefficient of variation of 2%), HbA1c was assessed by high performance liquid chromatography (coefficient of variation of 2.58%), and serum insulin was determined by immunoassay (coefficient of variation 5.9% to 8%) (The Ohio State University Medical Center, Columbus). Participants were asked to record the type, dose, and frequency of prescribed medications by means of an interview at the assessment visits to assess possible changes in glycemia due to medication changes.

The valid 110-item Block 2005 Food Frequency Questionnaire (NutritionQuest) was self-administered to assess usual intake in the previous year.^{22,23} Participants received a food-portion visual aide to assist with estimating portions; nine

response options regarding frequency were included. Nutrient intakes were quantified per 1,000 kcal to control for energy intake.

Change in physical activity was assessed using the Modifiable Physical Activity Questionnaire. This questionnaire assesses leisure-time physical activities during the past week and was previously shown to be reliable and associated with activity and physical fitness measures.²⁴ Activity levels are calculated as the product of the duration and frequency of each activity weighted by an estimate of the metabolic equivalent (MET) of that activity²⁵ and summed for all activities performed as MET hours per week.

Diabetes Interventions

Individuals in both treatment groups participated in a group-based, 3-month intervention. Each intervention included eight weekly and two biweekly 2.5-hour sessions led by facilitators trained in the intervention protocol. If participants missed a group session, they were encouraged to attend a make-up session. One- and 3-month follow-up sessions also were provided to facilitate maintenance of change. Intervention facilitators followed a written, standard protocol for each session.

The MB-EAT for Diabetes (MB-EAT-D) intervention is a variation of the intervention developed for binge-eating disorder and obesity.¹⁶ The intervention incorporated training in mindful meditation, eating, and practice of physical activity and body awareness. Participants were encouraged to cultivate "inner wisdom" (ie, mindful awareness related to eating) and "outer wisdom" (ie, personal knowledge of food/diabetes needs). A primary component of the intervention was mindful meditation and its application to eating. Every session included guided meditations oriented toward the experiences and emotions associated with food intake. Other elements included cultivating awareness of the distinction between physical and emotional hunger cues, social pressures to eat, and preferences regarding food choices. Each participant received two CD-ROMs for home use to guide their meditation practice. Participants were encouraged to meditate with a CD-ROM 6 days/week and to practice mini-meditations before meals (ie, awareness of breath, hunger, and/or social pressures). MB-EAT-D also included basic information regarding MNT, including the relationship among energy, carbohydrate and fat intake, weight regulation, and glycemia. Participants were encouraged to engage in physical activity and mindful movement; however, no specific diet or activity goals were provided.

The Smart Choices (SC) intervention is a group DSME-based intervention. The self-management content addressed topics such as factors influencing the development of type 2 diabetes mellitus and glycemic control, common diabetes complications, incorporating physical activity, self-monitoring glucose, and sick-day management, which are topics frequently incorporated into DSME programs.²⁶ However, SC emphasized MNT more heavily than other DSME programs; MNT was addressed during every session. In-depth information regarding recommended energy, carbohydrate, and fat intakes and factors influencing weight and glycemia was provided. Estimated total energy needs were calculated by multiplying resting energy expenditure by an activity factor.²⁷ The participant's individual dietary goals represented energy

intake to promote weight maintenance and weight loss with a 500 kcal/day deficit from the weight-maintenance level for weight loss. Participants received carbohydrate (approximately 50% energy) and total fat (<30% energy) goals. The MNT addressed portion control, carbohydrate counting, guidelines for choosing low-fat/low-saturated fat foods, dining out guidelines, and the glycemic index. One session on physical activity was included,²⁸ and several sessions included a 15- to 20-minute walk. The study design intentionally de-emphasized changes in physical activity to better match MB-EAT-D so that diet effects on study outcomes would not be overshadowed by changes in physical activity. Participants set diet and/or activity goals at the end of each session. Progress in meeting goals was reviewed at the next group session and problem-solving regarding barriers to goal attainment was discussed. No information regarding mindful eating or meditation was presented during the SC group sessions.

The 90-minute 1- and 3-month follow-up sessions reviewed the key principles in each intervention, assessed participant progress in their change efforts, and addressed barriers to change. The MB-EAT-D intervention included meditation practice, whereas the SC intervention included time for walking during these sessions.

Statistical Methods

The Fisher exact test or two-sample *t* test compared between-group differences in participant characteristics at baseline. Repeated measures analysis of variance compared change in outcomes across time. The time-by-group interaction effect assessed group differences in outcome changes. Contrast analysis was used to evaluate between-group differences in outcome measures; corrections for multiple comparisons were made. Change in outcomes from baseline to immediate post-intervention and the change from baseline to the 3-month follow-up assessment are presented. Change in outcomes from baseline to the 1-month follow-up assessment is not presented because the results are similar to the 3-month follow-up results. Participants with at least two observed measures were included in the analyses. There were few missing values ($\leq 9\%$), and the statistical mixed effect models and the associated REML (restricted maximum likelihood) analysis did not use imputed data. Power analysis for the primary outcome weight change (power=0.80; 2-tailed $\alpha=.05$) based on a previous MNT intervention for type 2 diabetes mellitus indicated that 29 people per treatment group were needed to detect a 2.7-kg difference between groups.²⁹ All analyses were completed using the SAS statistical software package JMP version 9.0 (SAS Institute Inc).

RESULTS

A total of 450 people inquired about the study. Forty-four did not respond to repeated contact and 406 were assessed for eligibility. Of those, 245 did not meet inclusion criteria and 93 declined to participate. Thirty-two participants were randomly assigned to MB-EAT-D; 27 received the allocated intervention and completed data collection. Thirty-six people were randomly assigned to SC; 25 received the allocated intervention and completed data collection. There was no significant difference in rates of attrition between treatment groups ($P>0.05$). There were no differences in demographic characteristics, BMI, or

HbA1c between those who did and did not complete the study. On average, participants attended 7.0 and 6.5 of the 10 group sessions for MB-EAT-D and SC, respectively.

Table 1 reports the characteristics of participants in each treatment group. Randomization resulted in balanced groups at baseline (Tables 2 and 3). There was no significant difference between groups with regard to the change in weight, BMI, waist circumference, fasting glucose, HbA1c, or insulin at study end (Table 2). Mean (\pm standard error) reduction in weight for the SC group (-2.92 ± 0.54 kg) was greater than for the MB-EAT-D group (-1.53 ± 0.54 kg) at 3-month follow-up, but this was not statistically significant ($P=0.07$). Changes in weight and BMI from baseline to post-intervention and from baseline to study end were significant in both groups (all $P<0.01$). Both the SC and MB-EAT-D groups experienced a significant decline from baseline to study end in mean (\pm standard error) HbA1c values ($-0.67 \pm 0.24\%$ vs $-0.83 \pm 0.24\%$, respectively; $P<0.01$ for both groups). There was a significant decrease in fasting insulin for the SC group immediately after the intervention ($P<0.01$).

There was a significant difference between treatment groups in the change in intake of *trans* fat, total fiber, and total sugars (all $P<0.05$) at study end (Table 3). There was a significant reduction in energy intake, glycemic index, and glycemic load for the SC group immediately after the intervention and at study end (all $P<0.0125$). MB-EAT-D participants reported a significant decrease in energy intake immediately after the intervention and at 3-month follow-up and a significant decrease in glycemic load at study end (all $P<0.01$).

Physical activity and prescribed medications were similar between groups throughout the study and did not change significantly.

DISCUSSION

An urgent need exists for comparative-effectiveness research to evaluate novel interventions.^{30,31} This single-center randomized controlled trial is one of the first trials reported to compare the effect of group training in mindful eating to group self-management education in adults with type 2 diabetes mellitus. Outcomes comparing weight and glycemia were comparable between the two interventions and indicate modest reductions in body weight and HbA1c.

A meta-analysis evaluating the effect of nutrition counseling on weight loss found a change of -0.1 BMI unit per month during 3 to 12 months of treatment.³² Another meta-analysis reported a loss of 1.7 kg following a lifestyle intervention in adults with type 2 diabetes mellitus compared to usual care.³³ Both analyses found less weight loss among people with type 2 diabetes mellitus than among those without diabetes. Weight loss among participants in the SC group in the present study was greater than those observed in these prior reports. The Action for Health in Diabetes (Look AHEAD) trial also investigated the impact of an intensive lifestyle intervention in adults with type 2 diabetes mellitus. In Look AHEAD, participants in the intensive intervention lost 8.71 kg after 1 year of treatment.³⁴ The Look AHEAD intervention included a longer time period (12 months) than the current study (3 months), provided participants with meal replacements free of charge, and emphasized physical activity. Food was not provided to participants in the current study. Instead, participants purchased and prepared their own food and were encouraged to

RESEARCH

Table 1. Demographic and diabetes characteristics of participants in each treatment group at baseline in a study of the comparative effectiveness of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes

Characteristic	MB-EAT-D ^a (n=27)	Smart choices (n=25)	P value
	←—————%—————→		
Female	63.0	64.0	1.00
Race			0.52
White	81.5	72.0	
Black	18.5	24.0	
Asian	0	4.0	
Married	66.7	68.0	1.00
Bachelor's degree or higher	48.2	60.0	0.42
Employed full-time	77.8	84.0	0.73
Household income ≥\$60,000/y	51.9	63.6	0.56
Received previous diabetes education	65.4	80.0	0.20
Self-monitor blood glucose	69.2	76.0	0.76
Want more information about overall diabetes care	63.0	62.5	1.00
	←—————mean ± standard deviation—————→		
Age (y)	53.9 ± 8.2	54.0 ± 7.0	0.94
Diagnosed with diabetes (y)	6.9 ± 3.9	5.9 ± 3.4	0.31

^aMB-EAT-D=Mindfulness-Based Eating Awareness Training for Diabetes group.

modify intake based on awareness of hunger and satiety cues in MB-EAT-D or self-selected goals in SC. Both mindful awareness of hunger and goal-setting strategies were effective in helping participants reduce energy intake and lose weight.

Studies regarding the effect of changes in diet and/or physical activity on weight control found interventions that targeted both diet and physical activity rather than only one of these behaviors promoted a 2 to 3 kg greater weight change.^{32,35,36} Increasing physical activity was not the primary focus of either the MB-EAT-D or SC interventions. MB-EAT-D focused primarily on eating regulation; body awareness and physical activity were discussed, but MB-EAT-D did not emphasize activity at a level of intensity to promote weight loss. Therefore, SC also did not place as much emphasis on physical activity as on dietary change to enable a comparable evaluation of dietary change across intervention conditions; only one session in each intervention focused on physical activity. No significant increase in physical activity occurred in this study. Previous studies found greater weight loss when changes in both diet and physical activity were promoted.^{35,37} Thus, greater weight loss would likely be observed after the current interventions with more emphasis on physical activity; future research should evaluate the magnitude of weight loss with this added emphasis.

Significant reduction in energy intake occurred for both groups following the interventions. In addition, significant improvement in intake of *trans* fats, fiber, and glycemic load occurred. SC included five sessions on dietary fats, carbohydrates, and glycemic index combined and considerable time

was spent on strategies and skill-building for improving intakes. MB-EAT-D provided less detailed information on MNT because of the time spent in meditation practice during group sessions. Thus, the dietary changes observed are consistent with the focus of each intervention.

Participants in the current study had significant improvement in HbA1c, and the improvement in glycemia was similar to that observed previously. For Look AHEAD participants in the intensive intervention, HbA1c decreased by a mean of 0.643% at 1 year.³⁴ In a 6-week group-based intervention, which included diabetes education, cognitive behavioral approaches, goal-setting, and problem-solving regarding diabetes management, HbA1c decreased by a mean of 0.82% at 3 months.³⁸ Mean reduction in HbA1c was 0.27% after four 2-hour group-based DSME sessions in primary care patients.³⁹ A pilot study that involved implementation of an 8-week mindfulness intervention resulted in a mean reduction in HbA1c of 0.48% 1 month after the intervention.¹⁹ Thus, glycemia was improved in both DSME-based and mindfulness-based interventions in the current and previous studies. A reduction in HbA1c by 0.67% to 0.83% observed at 3-month follow-up in this study, if sustained over the long term, could result in substantial reduction in microvascular and cardiovascular endpoints.⁴⁰⁻⁴²

The identification of effective treatment approaches that improve diabetes outcomes is needed to meet the educational needs of the increasing population of people with diabetes. People with diabetes need the knowledge and skills to modify behavior and successfully self-manage the disease. Few random-

Table 2. Mean (\pm standard error) anthropometric and clinical outcomes at baseline and change in outcomes across time for the MB-EAT-D^a (n=27) and Smart Choices (n=25) treatment groups in a study of the comparative effectiveness of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes

Baseline values	Weight (kg)	Waist circumference (cm)	BMI (kg/m ²)	Hemoglobin A1c (%)	Glucose (mg/dL) ^b	Insulin (μ U/mL)
MB-EAT-D	106.04 (\pm 3.66)	115.06 (\pm 2.80)	36.19 (\pm 1.18)	8.49 (\pm 0.24)	181.89 (\pm 9.31)	13.32 (\pm 1.91)
Smart-Choices	103.38 (\pm 3.80)	112.53 (\pm 2.91)	36.08 (\pm 1.22)	8.33 (\pm 0.25)	163.80 (\pm 9.67)	17.07 (\pm 1.99)
<i>P</i> value ^c	0.6169	0.5326	0.9523	0.6587	0.1812	0.1775
Change Score at Immediate Post-intervention^d						
MB-EAT-D	-1.78 (\pm 0.54) <i>P</i> =0.0012	-1.59 (\pm 0.80) <i>P</i> =0.0493	-0.62 (\pm 0.19) <i>P</i> =0.0014	-0.77 (\pm 0.23) <i>P</i> =0.0015	-15.93 (\pm 8.38) <i>P</i> =0.0592	-0.95 (\pm 1.52) <i>P</i> =0.5339
Smart Choices	-3.25 (\pm 0.57) <i>P</i> <0.0001	-3.92 (\pm 0.85) <i>P</i> <0.0001	-1.13 (\pm 0.20) <i>P</i> <0.0001	-0.45 (\pm 0.25) <i>P</i> =0.0716	-12.24 (\pm 8.85) <i>P</i> =0.1690	-4.84 (\pm 1.61) <i>P</i> =0.0031
Change Score at 3-month Follow-up^d						
MB-EAT-D	-1.53 (\pm 0.54) <i>P</i> =0.005	-2.48 (\pm 0.80) <i>P</i> =0.0025	-0.53 (\pm 0.19) <i>P</i> =0.0058	-0.83 (\pm 0.24) <i>P</i> =0.0008	-5.43 (\pm 8.38) <i>P</i> =0.5186	-0.96 (\pm 1.52) <i>P</i> =0.5295
Smart Choices	-2.92 (\pm 0.54) <i>P</i> <0.0001	-4.71 (\pm 0.81) <i>P</i> <0.0001	-1.03 (\pm 0.19) <i>P</i> <0.0001	-0.67 (\pm 0.24) <i>P</i> =0.0077	-14.68 (\pm 8.60) <i>P</i> =0.0902	-3.58 (\pm 1.54) <i>P</i> =0.0214
<i>P</i> value ^e	<i>P</i> =0.0728	<i>P</i> =0.0523	<i>P</i> =0.0678	<i>P</i> =0.6222	<i>P</i> =0.4424	<i>P</i> =0.2277

^aMB-EAT-D=Mindfulness-Based Eating Awareness Training for Diabetes group.

^bTo convert mg/dL glucose to mmol/L, multiply mg/dL by 0.0555. To convert mmol/L glucose to mg/dL, multiply mmol/L by 18.0. Glucose of 6.0 mmol/L=108 mg/dL.

^cStudent's *t* test within an analysis of variance for between-group comparison at baseline; *P*<0.05 used for statistical significance.

^d*P*<0.0125 used for statistical significance to account for the Bonferroni correction of the four comparisons for the within-group changes from baseline to immediate post-intervention and from baseline to 3-month follow-up.

^eStudent's *t* test within an analysis of variance to compare the between-group change from baseline to 3-month follow-up; *P*<0.05 used for statistical significance.

ized trials have been done to compare alternative models for delivering patient education and MNT. DSME is widely endorsed through diabetes practice guidelines.⁴ However, little research has evaluated the impact of mindful eating on diabetes outcomes. Results from the current study indicate that training in mindful eating is feasible, well-accepted, and effective in promoting modest weight loss. Previous research found that behavioral lifestyle interventions (similar to the MB-EAT-D and SC interventions) that provided instruction, modeling, goal-setting, and problem-solving, also helped participants integrate diet and physical activity behaviors into their self-care and facilitated improvement in glycemic control.^{5,38}

The availability of multiple effective educational approaches to diabetes self-management will likely improve treatment adherence among patients and is a necessary first step in treatment evaluation. However, educators and clinicians need to know not only that a treatment works on average, but also which intervention works best for specific types of patients and the conditions under which each treatment is most effective. The answer to these questions was beyond the scope of this pilot study, and future research is needed to determine delivery of the right educational approach to the right patient at the right time.

Despite the comparative effectiveness findings, some limitations of the study should be noted. First, the sample had limited racial and ethnic diversity; replication of the study with more diverse populations would be desirable. Second, 24% of participants enrolled in the study withdrew before completing the in-

terventions, which prevented adequate testing of the hypotheses. The findings obtained from this study enable estimates of effect sizes for a future larger study. It should be noted that other studies experienced similar rates of attrition from group-based interventions.^{38,39} This study required a considerable time commitment with a predefined group schedule, and participants were randomly assigned to treatment group. Of the 16 participants who withdrew before completing their assigned intervention, seven withdrew due to scheduling conflicts and competing time demands. Whether greater retention would be achieved by allowing participants to self-select their intervention condition requires additional research. However, nonrandomized designs pose threats to validity. Finally, the long-term impact of the MB-EAT-D and SC interventions beyond 3 months is not known, and future research should evaluate the long-term impact on outcomes.

In summary, the present results suggest that adults with type 2 diabetes mellitus can modify their dietary intake to achieve weight loss and improve glycemia regardless of whether they receive training in mindful eating or MNT for diabetes self-management. Maintenance of weight loss and optimal glycemia are associated with reductions in the morbidity associated with diabetes. Future research should examine preferences for treatment focus (ie, MNT only vs mindful eating only vs combined treatment) and whether the magnitude of change is greater when patients select one approach over another. Alternatively, some patients with diabetes may prefer to complete a DSME-based program first to learn the fundamentals of MNT and self-management followed by a

RESEARCH

Table 3. Mean (\pm standard error) energy, nutrient intakes, and metabolic equivalent (MET) hours/week of physical activity at baseline and change in outcomes across time for the MB-EAT-D^a (n=26) and Smart Choices (n=25) treatment groups in a study of the comparative effectiveness of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes

Baseline values	Energy (kcal)	Total fat (% energy)	Saturated fat (g/1,000 kcal)	Monounsaturated fat (g/1,000 kcal)	Polyunsaturated fat (g/1,000 kcal)	Trans fat (g/1,000 kcal)	Cholesterol (mg/1,000 kcal) ^b
MB-EAT-D	1,851 (\pm 129)	41.16 (\pm 1.15)	14.53 (\pm 0.47)	18.14 (\pm 0.62)	9.64 (\pm 0.44)	1.48 (\pm 0.10)	147 (\pm 12.68)
Smart Choices	2,019 (\pm 131)	40.53 (\pm 1.17)	13.38 (\pm 0.48)	18.01 (\pm 0.63)	10.20 (\pm 0.45)	1.60 (\pm 0.10)	152 (\pm 12.93)
P value ^c	0.3628	0.7056	0.0937	0.8816	0.3715	0.4232	0.9738
Change Score at Immediate Post-intervention^d							
MB-EAT-D	-298 (\pm 109) P=0.0068	-0.62 (\pm 1.03) P=0.551	-0.65 (\pm 0.41) P=0.1147	-0.02 (\pm 0.59) P=0.9721	0.15 (\pm 0.44) P=0.7255	0.00 (\pm 0.10) P=0.9838	5.59 (\pm 11.94) P=0.6505
Smart Choices	-574 (\pm 114) P<0.0001	-1.46 (\pm 1.09) P=0.1813	-0.79 (\pm 0.43) P=0.0698	-0.84 (\pm 0.62) P=0.1734	0.18 (\pm 0.46) P=0.6898	-0.30 (\pm 0.10) P=0.0030	-14.37 (\pm 12.76) P=0.3189
Change Score at 3-month Follow-up^d							
MB-EAT-D	-490 (\pm 109) P<0.0001	-0.19 (\pm 1.04) P=0.8517	0.12 (\pm 0.41) P=0.7724	0.10 (\pm 0.59) P=0.8644	0.46 (\pm 0.44) P=0.2962	0.05 (\pm 0.10) P=0.6361	-4.01 (\pm 11.95) P=0.9734
Smart Choices	-682 (\pm 111) P<0.0001	-1.26 (\pm 1.06) P=0.2364	-1.04 (\pm 0.42) P=0.0151	0.64 (\pm 0.60) P=0.2868	0.42 (\pm 0.44) P=0.3442	-0.23 (\pm 0.10) P=0.0219	-4.58 (\pm 12.19) P=0.4615
P value ^e	P=0.2198	P=0.3286	P=0.1221	P=0.5206	P=0.9553	P=0.0489	P=0.5827

Baseline values	Carbohydrate (% energy)	Total fiber (g/1,000 kcal) ^f	Total sugars (g/1,000 kcal)	Glycemic index	Glycemic load	Protein (% energy)	MET hr/wk ^g
MB-EAT-D	43.57 (\pm 1.35)	10.48 (\pm 0.82)	42.52 (\pm 2.78)	51.59 (\pm 0.82)	101.35 (\pm 5.48)	16.76 (\pm 0.49)	9.56 (\pm 2.41)
Smart Choices	44.38 (\pm 1.38)	10.18 (\pm 0.84)	45.53 (\pm 2.83)	52.04 (\pm 0.83)	106.40 (\pm 7.83)	16.56 (\pm 0.50)	10.00 (\pm 2.50)
P value ^c	0.6738	0.9928	0.4494	0.7014	0.3603	0.7754	0.3307
Change Score at Immediate Post-intervention^d							
MB-EAT-D	0.37 (\pm 1.23) P=0.7629	0.77 (\pm 0.70) P=0.0887	1.02 (\pm 2.95) P=0.7307	-0.77 (\pm 0.70) P=0.2705	-16.25 (\pm 6.61) P=0.0151	0.41 (\pm 0.49) P=0.4075	0.62 (\pm 0.28) P=0.0277
Smart Choices	1.25 (\pm 1.30) P=0.3370	2.97 (\pm 0.74) P<0.001	4.80 (\pm 3.09) P=0.1229	-2.32 (\pm 0.73) P=0.0019	-34.12 (\pm 6.94) P<0.0001	0.92 (\pm 0.52) P=0.0784	0.38 (\pm 0.29) P=0.1970
Change Score at 3-month Follow-up^d							
MB-EAT-D	1.38 (\pm 1.23) P=0.2641	0.86 (\pm 0.70) P=0.0656	-1.50 (\pm 2.95) P=0.6127	-1.53 (\pm 0.70) P=0.0301	-30.13 (\pm 6.61) P<0.0001	1.27 (\pm 0.49) P=0.0107	0.49 (\pm 0.28) P=0.0809
Smart Choices	1.87 (\pm 1.26) P=0.1394	3.46 (\pm 0.72) P<0.001	7.03 (\pm 3.01) P=0.0209	-2.87 (\pm 0.71) P=0.0001	-38.80 (\pm 6.74) P<0.0001	0.40 (\pm 0.50) P=0.4277	0.30 (\pm 0.28) P=0.2926
P value ^e	0.0670	0.0221	0.0449	0.1793	0.3603	0.2156	0.6325

^aMindfulness-Based Eating Awareness Training for Diabetes (MB-EAT-D) group.

^bDietary cholesterol intakes were not normally distributed and were log-transformed; the P values were based on the comparison of means of the log-transformed data using the transform log(x).

^cStudent's t test within an analysis of variance for between-group comparison at baseline; P value <0.05 used for statistical significance.

^dP value <0.0125 used for statistical significance to account for the Bonferroni correction of the four comparisons for the within-group changes from baseline to immediate post-intervention and from baseline to 3-month follow-up.

^eStudent's t test within an analysis of variance to compare the between-group change from baseline to 3-month follow-up; P value <0.05 used for statistical significance.

^fDietary fiber intakes were not normally distributed and were log-transformed; the P values were based on the comparison of means of the log-transformed data using the transform log(x).

^gSex, employment, current age, age at time of diabetes diagnosis, and diabetes duration were significant covariates for MET hours/week and were incorporated into the repeated measures model. The data were not normally distributed and were log-transformed; the p-values were based on the comparison of means of the log-transformed data using the transform log(1+x).

mindful-eating intervention to facilitate maintenance of change. Eating in response to body awareness and hunger cues offers the opportunity to develop self-management skills for weight maintenance. The availability of several effective treatments allows patients greater choice in meeting their self-care needs and enables clinicians to tailor diabetes programs.

References

- Narayan KMV, Boyle JP, Geiss LK, Saaddine JB, Thompson TJ. Impact of recent increase in incidence on future diabetes burden: U.S., 2005-2050. *Diabetes Care*. 2006;29(9):2114-2116.
- Saaddine JB, Cadwell B, Gregg EW, et al. Improvements in diabetes processes of care and intermediate outcomes: United States, 1988-2002. *Ann Intern Med*. 2006;144(7):465-474.
- Franz MJ, Powers MA, Leontos C, et al. The evidence for medical nutrition therapy for type 1 and type 2 diabetes in adults. *J Am Diet Assoc*. 2010;110(12):1852-1889.
- Funnell MM, Brown TL, Childs BP, et al. National standards for diabetes self-management education. *Diabetes Care*. 2012;35(Suppl 1):S101-S108.
- Norris SL, Engelgau MM, Narayan KMV. Effectiveness of self-management training in type 2 diabetes: A systematic review of randomized controlled trials. *Diabetes Care*. 2001;24(3):561-587.
- Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: A meta-analysis of the effect on glycemic control. *Diabetes Care*. 2002;25(7):1159-1171.
- TRIAD Study Group. Health systems, patients factors, and quality of care for diabetes: A synthesis of findings from the TRIAD study. *Diabetes Care*. 2010;33(4):940-947.
- Roter DL, Hall JA, Merisca R, Nordstrom B, Cretin D, Svarstad B. Effectiveness of interventions to improve patient compliance: A meta-analysis. *Med Care*. 1998;36(8):1138-1161.
- Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: A review. *Patient Educ Couns*. 2002;48(2):177-187.
- Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. *J Consult Clin Psychol*. 2010;78(2):169-183.
- Wanden-Berghe RG, Sanz-Valero J, Wanden-Berghe C. The application of mindfulness to eating disorders treatment: A systematic review. *Eat Disord*. 2011;19(1):34-48.
- Kristeller JL, Hallett CB. An exploratory study of a meditation-based intervention for binge eating disorder. *J Health Psychol*. 1999;4(3):357-363.
- Alberts JH, Mulkens S, Smeets M, Thewissen R. Coping with food cravings: Investigating the potential of a mindfulness-based intervention. *Appetite*. 2010;55(1):160-163.
- Dalen J, Smith BW, Shelley BM, Sloan AL, Leahigh L, Begay D. Pilot study: Mindful Eating and Living (MEAL): Weight, eating behavior, and psychological outcomes associated with a mindfulness-based intervention for people with obesity. *Complement Ther Med*. 2010;18(6):260-264.
- Grossman P, Niemann L, Schmidt S, Walach H. Mindfulness-based stress reduction and health benefits: A meta-analysis. *J Psychosom Res*. 2004;57(1):35-43.
- Kristeller JL, Wolever RQ. Mindfulness-based eating awareness training for treating binge eating disorder: The conceptual foundation. *Eat Disord*. 2011;19(1):49-61.
- Peyrot M, McMurry JF, Kruger DF. A biopsychosocial model of glycemic control in diabetes: Stress, coping and regimen adherence. *J Health Soc Behav*. 1999;40(2):141-158.
- Surwit RS, van Tilburg MAL, Zucker N, et al. Stress management improves long-term glycemic control in type 2 diabetes. *Diabetes Care*. 2002;25(1):30-34.
- Rosenzweig S, Reibel DK, Greeson JM, et al. Mindfulness-based stress reduction is associated with improved glycemic control in type 2 diabetes mellitus: A pilot study. *Altern Ther Health Med*. 2007;13(5):36-38.
- Smith BW, Shelley BM, Leahigh L, Vanleit B. A preliminary study of the effects of a modified mindfulness intervention on binge eating. *Complement Health Practice Rev*. 2006;11(3):133-143.
- Centers for Disease Control and Prevention (2007) *National Health and Nutrition Examination Survey (NHANES) Anthropometry Procedures Manual*. Atlanta, GA: CDC. http://cdc.gov/nchs/data/nhanes/nhanes_07_08/manual_an.pdf. Accessed November 27, 2009.
- Mares-Perlman JA, Klein BEK, Klein R, Ritter LL, Fisher MR, Freudenheim JL. A diet history questionnaire ranks nutrient intakes in middle-aged and older men and women similarly to multiple food records. *J Nutr*. 1993;123(3):489-501.
- Block G, Woods M, Potosky A, Clifford C. Validation of a self-administered diet history questionnaire using multiple diet records. *J Clin Epidemiol*. 1990;43(12):1327-1335.
- Gabriel KP, McClain JJ, Lee CD, et al. Evaluation of physical activity measures used in middle-aged women. *Med Sci Sports Exerc*. 2009;41(7):1403-1412.
- Ainsworth BE, Haskell WL, Whitt MC, et al. Compendium of physical activities: An update of activity codes and MET intensities. *Med Sci Sports Exerc*. 2000;32(9 suppl):S498-S516.
- American Association of Diabetes Educators. *Library of Patient Handouts for Diabetes Education: Basic Skills for Self-Care*. Timonium, MD: Milner-Fenwick, Inc; 2003.
- Mifflin MD, St Jeor ST, Hill LA, Scott BJ, Daugherty SA, Koh YO. A new predictive equation for resting energy expenditure in healthy individuals. *Am J Clin Nutr*. 1990;51(2):241-247.
- US Department of Health and Human Services. 2008 Physical Activity Guidelines for Americans. U.S. Department of Health and Human Services, Washington, DC. ODPHP Publication No. U0036, October 2008. <http://www.health.gov/paguidelines>. Accessed October 1, 2009.
- Gutschall MD, Miller CK, Mitchell DC, Lawrence FR. A randomized behavioural trial targeting glycaemic index improves dietary, weight and metabolic outcomes in patients with type 2 diabetes. *Public Health Nutr*. 2009;12(10):1846-1854.
- Sullivan P, Goldmann D. The promise of comparative effectiveness research. *JAMA*. 2011;305(4):400-401.
- Iglehart JK. Prioritizing comparative-effectiveness research: IOM recommendations. *N Engl J Med*. 2009;361(4):325-328.
- Dansinger ML, Tatsioni A, Wong JB, Chung M, Balk EM. Meta-analysis: The effect of dietary counseling for weight loss. *Ann Intern Med*. 2007;147(1):41-50.
- 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;117(10):762-774.
- Unick JL, Beavers D, Jakicic JM, et al. for the Look AHEAD Research Group. Effectiveness of lifestyle interventions for individuals with severe obesity and type 2 diabetes: Results from the Look AHEAD trial. *Diabetes Care*. 2011;34(10):2152-2157.
- Greaves CJ, Sheppard KE, Abraham C, et al. for the IMAGE Study Group. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health*. 2011;11:119.
- Franz MJ, VanWormer JJ, Crajin L, et al. Weight-loss outcomes: A systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. *J Am Diet Assoc*. 2007;107(10):1755-1767.
- Goodpaster BH, DeLany JP, Otto AD, et al. Effects of diet and physical activity interventions on weight loss and cardiometabolic risk factors in severely obese adults: A randomized trial. *JAMA*. 2010;304(16):1795-1802.
- Weinger K, Beverly EA, Lee Y, Sitnikov L, Ganda OP, Caballero E. The effect of a structured behavioral intervention on poorly controlled diabetes: A randomized controlled trial. *Arch Intern Med*. 2011;171(22):1990-1999.
- 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;171(22):2001-2010.
- 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;352(9131):837-853.
- Selvin E, Marinopoulos S, Berkenblit G, et al. Meta-analysis: Glycosylated hemoglobin and cardiovascular disease in diabetes mellitus. *Ann Intern Med*. 2004;141(6):421-431.
- The ADVANCE Collaborative Group. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. *N Engl J Med*. 2008;358(24):2560-2572.

RESEARCH**AUTHOR INFORMATION**

C. K. Miller is an associate professor, Department of Human Nutrition, H. Nagaraja is a professor, College of Public Health, Division of Biostatistics, and W. F. Miser is a professor, College of Medicine, Department of Family Medicine, all at The Ohio State University, Columbus. J. L. Kristeller is professor emeritus and senior research scientist, Department of Psychology, Indiana State University, Terre Haute. A. Headings is with the Mid-Ohio Food Bank, Grove City; at the time of the study, she was with the Department of Human Nutrition, The Ohio State University, Columbus.

Address correspondence to: Carla K. Miller, PhD, RD, Department of Human Nutrition, The Ohio State University, 350 Campbell Hall, 1787 Neil Ave, Columbus, OH 43210. E-mail: CMiller@ehe.osu.edu

STATEMENT OF POTENTIAL CONFLICT OF INTEREST

No potential conflict of interest was reported by the authors.

FUNDING/SUPPORT

The project described was supported by Award Number R21DK084330 from the National Institute of Diabetes and Digestive and Kidney Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases or the National Institutes of Health.

ACKNOWLEDGEMENTS

The project described was supported by Award Number R21DK084330 from the National Institute of Diabetes and Digestive and Kidney Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases or the National Institutes of Health.