The Diabetes Nutrition Education Study Randomized Controlled Trial: a Comparative Effectiveness Study of Approaches to Nutrition in Diabetes Self-Management Education

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Abstract

Objective—To compare the effectiveness of different approaches to nutrition education in diabetes self-management education and support (DSME/S).

Methods—We randomized 150 adults with type 2 diabetes to either certified diabetes educator (CDE)-delivered DSME/S with carbohydrate gram counting or the modified plate method versus general health education. The primary outcome was change in HbA_{1C} over 6 months.

Results—At 6 months, HbA_{1C} improved within the plate method [−0.83% (−1.29, −0.33), $P<0.001$] and carbohydrate counting groups [−0.63% (−1.03, −0.18), $P=0.04$] but not the control group [$P = 0.34$]. Change in HbA_{1C} from baseline between the control and intervention groups

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was not significant at 6 months (carbohydrate counting, P=0.36; modified plate method, P=0.08). In a pre-specified subgroup analysis of patients with a baseline HbA$_{1C}$ 7–10%, change in HbA$_{1C}$ from baseline improved in the carbohydrate counting [−0.86% (−1.47, −0.26), P=0.006] and plate method groups [−0.76% (−1.33, −0.19), P=0.01] compared to controls.

Conclusion—CDE-delivered DSME/S focused on carbohydrate counting or the modified plate method improved glycemic control in patients with an initial HbA$_{1C}$ between 7–10%.

Practice Implications—Both carbohydrate counting and the modified plate method improve glycemic control as part of DSME/S.

Key terms

diabetes education; nutrition; numeracy; type 2 diabetes

1. Introduction

Successful diabetes management requires daily self-management activities [1–3]. Diabetes self-management education and support (DSME/S), which is the ongoing process of facilitating the knowledge, skill, and abilities necessary for diabetes self-care [2], provides the foundation upon which patients and providers build individualized, patient-centered diabetes care plans [4]. Because nearly all diabetes care is performed by patients outside of a healthcare setting [5], patient-centered approaches to diabetes care that empower and equip patients to take responsibility for managing their diabetes are critical [6].

Although DSME/S improves diabetes knowledge, self-care behaviors, quality of life, and glycemic control [7–11], approaches to DSME/S vary widely. Nutrition counseling is a critical component of DSME/S [12] and improves glycemic control similar to many glucose-lowering medications [13]. DSME/S allows for multiple approaches to carbohydrate monitoring, including gram counting, exchanges, and experience-based estimation [14]. However, the comparative effectiveness of these approaches and the characteristics of patients who benefit from each approach are unknown. Although carbohydrate gram counting may improve the accuracy of carbohydrate monitoring and allow dietary flexibility, it is computationally intensive and may intimidate some patients [15]. The modified plate method [16] – which divides serving plates into sections designated for specific food types and uses cups and bowls to assist with measurement – may be easier to learn and implement.

Individualization of DSME/S based on an individual's cultural preferences, health beliefs, psychosocial status, self-management skills, literacy, and numeracy skills is important to facilitating behavior change [2, 17]. Health literacy and numeracy are associated with diabetes knowledge, self-care, and glycemic control, and addressing literacy and numeracy can improve glycemic control [18, 19]. Individualizing nutrition education according to literacy and numeracy skills may be especially important because individuals with low health literacy and numeracy have difficulty understanding food labels and estimating portion sizes [20, 21].

This study was designed to evaluate the role of two approaches to nutrition education as part of DSME/S and evaluate the impact of certified diabetes educator (CDE)-delivered DSME/S

on glycemic control in patients with type 2 diabetes. We hypothesized that patients receiving CDE–delivered DSME/S including a nutrition focus on either carbohydrate counting or the modified plate method would have improved glycemic outcomes compared with those in an attention control group. Furthermore, we hypothesized that patients with lower diabetes numeracy would have greater improvements in glycated hemoglobin (HbA_{1C}) with the modified plate method approach than with carbohydrate counting.

2. Research Design and Methods

2.1 Design, Setting, and Participants

The Diabetes Nutrition Education Study (DINES) was a three-arm, randomized controlled trial designed to examine the impact of CDE-delivered DSME/S and the role of different approaches to nutrition education on glycemic control in patients with type 2 diabetes. We also examined the interaction between diabetes numeracy and nutrition education on glycemic control. Participants were recruited from the Vanderbilt Primary Care Clinics, the Vanderbilt Heart Institute, and the Nashville Veterans Affairs Medical Center via patient flyers and direct recruitment. Eligible patients were English speaking adults age 18–85 with type 2 diabetes, a most recent HbA_{1C} 7.0% (53 mmol/mol) indicating uncontrolled diabetes, and no formal diabetes or nutrition education in the past year. Patients actively counting carbohydrate grams or using a plate method were excluded. Additional exclusion criteria included: use of flexible dose insulin based on carbohydrate gram counting, poor visual acuity, dementia or psychosis, and life expectancy less than 1 year. All participants provided written informed consent, and study procedures were approved by the Vanderbilt Institutional Review Board. Participants received $50 as compensation.

One hundred fifty patients were enrolled and randomized using computer-generated random number assignment (*Stata 9.0;* StataCorp LP, College Station, TX) [22]. The allocation sequence was concealed from the research assistant responsible for recruitment and consent. Following randomization, group assignment was revealed to the patient and research team.

2.2 Intervention

All patients received usual diabetes care from their primary care provider throughout the study. Each patient also received three 30–60 minute face-to-face education visits over a 3 month period, with the focus of the education differing by study assignment. Patients randomized to the attention control group received general health education visits with a health educator focusing on fall prevention, vaccinations, osteoporosis, and oral hygiene. Patients randomized to the two intervention arms received individualized DSME/S based on current standards [8] from one of two clinic-based registered dietician-certified diabetes educators (RD-CDEs). One group focused on carbohydrate gram counting with instruction on reading food labels, correct serving sizes, using online carbohydrate-counting resources, and negotiated individualized carbohydrate gram goals. The other group focused on a modified plate method approach. The plate method [16, 23, 24] was originally developed in Sweden to teach meal planning to patients with diabetes and later modified to meet American Diabetes Association nutritional guidelines. The plate method provides patients with sized plates (9-inch) and bowls (4 and 8 ounces) and instructs them on how much of

different types of foods they can consume. For lunch and dinner, patients are typically instructed that they can use ½ the plate "free" foods such as low-carbohydrate, non-starchy vegetables, ¼ of the plate for their protein such as meat or eggs, and ¼ of the plate for carbohydrates. This approach allows patients to restrict their carbohydrate intake without calculating specific portions with measuring cups, food labels, or other devices. Since the traditional plate method [16, 23, 24] can vary widely in the amount of carbohydrate consumed, we provided patients with the carbohydrate content of common foods and appropriate portion sizes to improve the precision of carbohydrate intake. We also marked individualized portion-sizes of carbohydrates on plates (9-inch), bowls, and cups (4 ounce and 8 ounce) to assist in meal preparation. Portions of high carbohydrate and starch containing foods were negotiated with patients and individualized based on blood glucose readings. All DSME/S utilized literacy and numeracy sensitive educational materials from the Diabetes Literacy and Numeracy Education Toolkit (https://www.mc.vanderbilt.edu/root/vumc.php?site=CDTR&doc=37816) [19, 25].

2.3 Measures and Outcomes

Patient characteristics were collected at enrollment and follow-up visits by self-report and review of electronic medical records by trained research assistants. Health literacy and numeracy were assessed using the Rapid Estimation of Adult Literacy in Medicine (REALM) [26, 27] and the 15-item Diabetes Numeracy Test (DNT) [28]. HbA_{1C} was measured at enrollment, 3 and 6 months follow-up. At each time point, HbA_{1C} values collected during routine clinical care were accepted if available in the electronic medical record. If HbA_{1C} was not available, testing was obtained through the Vanderbilt University General Clinical Research Center. Additional outcomes included: weight, treatment satisfaction assessed with the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [29], and self-efficacy assessed with the Perceived Diabetes Self-Management Scale (PDSMS) [30]. The validated DTSQ includes 8 items, with 6 of the items scored for treatment satisfaction. Each item is scored on a 0–6 scale with a total score of 0–36. Previous studies that modified insulin regimens suggest that a 1–2 point improvement in DTSQ score may be clinically important [31]. The PDSMS scale includes 8 items that are each scored from 1–5, giving a total score of 8–40. Higher scores are correlated with improved glycemic control as measured by A1C (r=−0.30, p<0.001) [30]. In a previous intervention study, we found that a health literacy focused intervention increased self-efficacy by 5 points at 6 month follow-up, compared with a 2 point increase in an active control group [19].

2.4 Statistical Analyses

Baseline measures were reported as proportions for categorical variables and medians and interquartile ranges for continuous and ordinal variables. Baseline characteristics were compared using Wilcoxon rank-sum, Kruskal-Wallis, and Pearson Chi-square tests, as appropriate. All enrolled patients and data were analyzed using the intention to treat principle.

The primary outcome was change in HbA_{1C} at 6 months, which was 3 months after completion of the intervention, between the control group and each of the intervention groups (modified plate method or carbohydrate counting). To examine CDE-delivered care

overall, we also analyzed change in HbA_{1C} by combining the two intervention groups. Secondary outcomes included the change in patient weight, self-efficacy, and treatment satisfaction at 6 months between the control and intervention groups.

For unadjusted within-group comparisons, linear or proportional odds (PO) logistic regression was used depending on the normality of linear regression residuals. Although, we compared baseline to 3 months and baseline to 6 months separately, the analysis was performed from a single regression model that included observations from all 3 time points. For linear regression we reported model based change and 95% confidence intervals. For PO logistic regression, we report mean change and 95% bootstrapped confidence intervals.

Adjusted between-group comparisons were performed using linear regression models. All models adjusted for age, gender, race, income, duration of diabetes, baseline value of the corresponding outcome variable, and an interaction term of treatment arm and time (3 or 6 months). Age and duration of diabetes were modeled as non-linear terms using restricted cubic splines with three knots [32]. Multivariable regression analysis was performed with inclusion of cross product terms between treatment arms and time (both treated as categorical variables) with adjustment for the above listed covariates. For HbA_{1C}, analyses were performed with and without log transformations and results were similar, so we report analyses without transformation. Proportional odds logistic regression and linear regression were used to analyze self-efficacy and treatment satisfaction. Results were similar, so results of linear regression analyses are presented for ease of understanding. We also conducted a pre-specified subgroup analysis of patients with a baseline HbA_{1C} 7.0–10% (53–86 mmol/mol) to examine outcomes in patients most likely to benefit from education interventions [13].

In additional pre-specified analyses, we explored the effect modification of the patient's numeracy skill level on change in HbA_{1C}. In unadjusted analyses, we stratified numeracy into low [DNT score in the lowest quartile of the distribution (score <47%)] and high (DNT score 47%) [18] numeracy groups and examined the within-group change in HbA_{1C} between baseline and 6 months using paired t-tests. We used linear regression to adjust for baseline HbA_{1C}, treatment arm (plate method, carbohydrate counting, and control), study time point (3 months, and/or 6 months), numeracy score (as a continuous variable), and a three-way interaction term of treatment arm, time, and numeracy.

For all regression analyses, the Huber White robust sandwich variance-covariance estimator was used to account for repeated observations. Two-sided p-values of 0.05 or less were considered statistically significant for all findings. Statistical analyses were performed with R statistical software version 2.15 (http://www.r-project.org).

2.5 Sample Size Analysis

The study was designed with 80% power to detect a mean 1.0% difference in HbA_{1C} with standard deviation of 1.5% between each intervention group and control at 6 months. Power calculations were based on a sample size of 44 participants per arm completing the study with Bonferroni adjusted 2-sided significance level of 0.025.

3. Results

3.1. Participant Characteristics

A total of 293 patients were approached for enrollment between May 2008 and March 2010 of whom 230 met eligibility criteria. Eighty individuals declined participation (Figure 1). A total of 150 patients were enrolled and randomized; 135 participants had baseline and follow-up HbA$_{1C}$ data (at 3 and/or 6 months). The *a priori* subgroup analysis of participants with a baseline HbA$_{1c}$ 7.0–10.0% included 70% (n=105) of participants.

Table 1 summarizes patient characteristics, which were similar across study groups. Overall, patients were a median (interquartile range) of 55 (47, 62) years old with a BMI of 34 (30, 38) kg/m^2. Patients were 53% female, with 34% being non-white race. Twenty-five percent of patients had less than a high school education, and 11% had less than a 9th grade literacy level. The median score on the DNT-15 was 67% (47%, 87%). The median duration of diabetes was 8 (3, 11) years, 58% of patients had previously received diabetes education, and 26% reported prior knowledge of carbohydrate grams. At baseline, 35% of patients were using insulin, and the median HbA$_{1C}$ was 8.2% (7.5%, 9.9%) [63 mmol/mol (58–73)].

3.2 Glycemic control

The results of unadjusted within group comparisons are shown in Table 2. Immediately after completion of the intervention (3 months after enrollment), HbA$_{1C}$ decreased compared to baseline in all groups: carbohydrate counting: [−0.99% (−1.42, −0.56); −10.8 mmol/mol (−15.5, −6.1), $P < 0.001$]; modified plate method: [−1.04% (−1.52, −0.56); −11.4 mmol/mol (−16.6, −6.1), $P < 0.001$]; combined CDE: [−1.01% (−1.33, −0.69); −11.0 mmol/mol (−14.5, −7.5), $P < 0.001$]; and control: [−0.98% (−1.39, −0.57); −10.7 mmol/mol (−15.2, −6.2), $P < 0.001$]. At the 6 month follow-up, which was 3 months after completion of the intervention, the mean (95% CI) decrease in HbA$_{1C}$ compared to baseline remained significant in the carbohydrate [−0.45% (−0.88, −0.01); −4.9 mmol/mol (−9.6, −0.1), $P = 0.04$]), modified plate method [−1.13% (−1.65, −0.6); −12.4 mmol/mol (−18.0, −6.6), $P < 0.001$], and the combined CDE group [−0.79% (−1.13, −0.45); −8.6 mmol/mol (−12.4, −4.9), $P < 0.001$]. The decrease in the attention control group was no longer statistically significant [−0.25% (−0.78, 0.27); −2.7 mmol/mol (−8.5, 3.0), $P = 0.34$].

Table 3 summarizes the adjusted comparisons between the control and intervention groups. At 6 months, the change in HbA$_{1C}$ from baseline between the control and two nutrition education groups was not statistically significant in adjusted analyses (carbohydrate counting, $P = 0.36$; modified plate method, $P = 0.08$; combined CDE, $P = 0.12$). However, in the adjusted subgroup analysis of patients with a baseline HbA$_{1C}$ between 7–10% (53–86 mmol/mol), the decrease in HbA$_{1C}$ between baseline and 6 months was significant in the carbohydrate counting group [mean difference from control HbA$_{1C}$ −0.86% (95% CI −1.47, −0.26); −9.4 mmol/mol (−16.1, −2.8), $P = 0.006$], modified plate method group [−0.76% (95% CI −1.33, −0.19); −8.3 mmol/mol (−14.5, −2.1), $P = 0.01$] and the combined CDE group [−0.80% (95% CI −1.33, −0.27); −8.7 mmol/mol (−14.5, −3.0), $P = 0.004$] compared with the control group.

3.3 Weight, treatment satisfaction, and self-efficacy

In unadjusted within group comparison analyses (Table 2), no significant decrease in weight was observed at 3 months; however, at 6 months, patients in the modified plate method [−8.00 pounds (−13.90, −2.10), P = 0.008] and combined CDE groups [−5.14 pounds (−9.71, −0.58), P = 0.03] had modest, statistically significant weight loss compared to their own baseline.

In adjusted analyses, the carbohydrate counting [mean (95% CI) difference −3.55 pounds (−7.05, −0.05), P = 0.05] and combined CDE [−3.59 pounds (−6.66, −0.52), P = 0.023] groups had significantly greater weight loss compared with the control group at 6 months (Table 3).

At 3 months and 6 months, diabetes treatment satisfaction improved significantly within all groups relative to their own baseline (Table 2). However, at 6 months, no statistically significant differences in treatment satisfaction were observed between the modified plate method [2.3 (−0.03, 4.6), P = 0.05], carbohydrate counting [−0.01 (−2.9, 2.9), P = 0.99], and combined CDE [1.2 (−1.0, 3.4), P = 0.29] groups relative to the control group (Table 3). In patients with baseline HbA_{1C} 7–10% (53–86 mmol/mol), statistically significant increases in diabetes treatment satisfaction at 6 months were observed in the modified plate method group [4.6 (1.7, 7.6), P = 0.002] and combined CDE group [3.9 (1.1, 6.7), P = 0.008] compared with the control group (Table 3).

Diabetes self-efficacy improved significantly from baseline in all groups at both 3 and 6 months (Table 2). However, no differential change was observed between the control and intervention groups at 6 months (Table 3).

3.4 Diabetes numeracy

In exploratory, unadjusted analyses stratified by numeracy status (Figure 2), no significant change in HbA_{1C} from baseline to 6 months was observed for low numeracy patients [n=14; −0.37% (−1.72, 0.97); −4.0 mmol/mol (−18.8, 10.6), P = 0.56] or for high numeracy patients [n=28; −0.21%, (−0.79, 0.36); −2.3 mmol/mol (−8.6, 3.9), P = 0.45] in the control arm. Among patients in the carbohydrate counting arm, those with low numeracy did not have a significant improvement in HbA_{1C} at 6 months [n=12; −0.33%, (−0.83, 0.18); −3.6 mmol/mol (−9.1, 2.0), P = 0.18] but patients with higher numeracy did have significant improvement [n=29; −0.76%, (−1.37, −0.15); −8.3 mmol/mol (−15.0, −1.6), P = 0.02]. In the plate method arm, patients with both low numeracy [n=13; −0.72%, (−1.50, 0.05); −7.9 mmol/mol (−16.4, 1.4), P = 0.06] and high numeracy [n= 30; −0.88%, (−1.54, −0.21); −9.6 (−16.8, −6.0), P = 0.01] had important improvements. However, sample size in each subgroup was small, and adjusted regression analyses did not reveal significant differences between subgroups (P = 0.37 for interaction effect).

4. Discussion and Conclusion

4.1 Discussion

Delivery of DSME/S by CDEs improved glycemic control in patients with type 2 diabetes compared with an attention control group receiving general health education. By including an attention control group to account for increased contact with the healthcare system resulting from study participation, our study addresses an important limitation in prior DSME/S studies. Although improvements in glycemic control were observed in both carbohydrate counting and modified plate method groups compared with the control group, these findings did not reach statistical significance overall. However, in patients with a baseline HbA_{1C} 7.0–10.0% (53–86 mmol/mol), the modified plate method, carbohydrate counting, and the combined CDE-delivered nutrition intervention significantly improved glycemic control compared with the attention control group. Patients in the modified plate method group also reported significantly higher diabetes treatment satisfaction compared to the control group. Our exploratory analyses suggest that all patients, regardless of numeracy skill level, may have significant improvements in HbA_{1C} using the modified plate method, but those patients with lower numeracy may not be as successful applying carbohydrate counting. All patients may benefit from simplified approaches to nutrition education.

Few studies have examined the effectiveness of different approaches to nutrition education in type 2 diabetes within the context of DSME/S. Ziemer et al [33] examined a quantitative, exchange-based meal plan versus a qualitative, healthy food choices plan and observed no differences in HbA_{1C} between the two groups. Our study expands upon this work by comparing carbohydrate gram counting, which is one of the most frequently taught nutrition approaches in DSME/S, with a less computationally intensive modified plate-based method. Even though glycemic improvement in the carbohydrate counting and modified plate method groups relative to control did not reach statistical significance, both groups demonstrated similar, significant improvements in glycemic control in the *a priori* subgroup analysis of patients with a HbA_{1C} between 7–10% (53–86 mmol/mol). Our findings suggest that selecting patients with moderately uncontrolled diabetes (HbA_{1C} between 7–10%) for DSME/S may allow improved targeting of DSME/S in settings with limited resources and a shortage of CDEs and nutritionists. Our inability to demonstrate improved HbA1c in the full analytic sample may be relate to difficulties improving glycemic control in patients that are poorly controlled (HbA_{1C} >10%, 86 mmol/mol), non-adherent to treatment plans, have socioeconomic barriers to optimal control, or other factors. Although the National Standards for DSME/S [2] do not endorse specific approaches to nutrition education, our findings suggest that both carbohydrate counting and the modified plate method are effective. Larger studies are needed to determine ways to make DSME/S more effective for patients with HbA_{1C} >10% (86 mmol/mol) and directly compare the effectiveness of carbohydrate counting and the modified plate method.

Although contact time is an important predictor of intervention effects in DSME/S [9], many previous studies examining the impact of DSME/S have failed to adequately control for increased contact with the healthcare system resulting from DSME/S participation. Improved study outcomes in control groups can be influenced by study participation,

attention, and the intensity of contact with the healthcare team [34, 35]. Thus, in previous studies, it is unclear if observed improvements are related to DSME/S or increased interactions. [7, 9]. Our study included a comparison group receiving general health education visits to control for increased attention resulting from participation in the study. During the first 3 months of the study, participants in the attention control group had significant improvements in HbA_{1c} that were similar to participants in the intervention groups. However, this effect diminished after intervention completion. Our findings suggest that DSME/S improves glycemic control independent of increased contact with the healthcare system.

Individualized DSME/S strategies that are sensitive to patient preferences, willingness to change, beliefs, knowledge, literacy, and numeracy skills are an important part of patient-centered diabetes care [17]. Low numeracy, which is the ability to use numbers in daily life [36], is associated with worse diabetes knowledge [37], poorer diabetes self-management skills [18], difficulty reading food labels [20] and quantifying dietary intake [21], and glycemic control [18]. Although our exploratory analyses suggest the plate method, but not carbohydrate counting, may improve HbA_{1C} in patients with both high and low numeracy, numeracy did not significantly moderate the response to nutrition education in adjusted analyses. Additional, sufficiently powered studies are needed to further evaluate numeracy as an effect modifier of the response to diabetes nutrition education. It is possible that the modified plate method may be easier for participants of all skill levels to understand and execute because it relies on visual cues and assessments to guide dietary choices. In contrast, carbohydrate gram counting requires more advanced numeracy skills that may be difficult for a wide range of patients to integrate into daily self-care. Patients randomized to the modified plate method also reported statistically significant increases in patient satisfaction and diabetes self-efficacy supporting prior research findings that the modified plate method is highly accessible, easy to understand, and facilitates individual meal planning in the home, supermarket, and restaurant settings [38].

Patients participating in DSME/S interventions achieve modest weight loss that can contribute to improvements in glycemic control and long term sustainability of glycemic improvements. However, participants in behavioral and educational interventions for type 2 diabetes can improve glycemic control without significant weight loss [39]. Although weight loss is a desired outcome of nutrition interventions, improved glycemic control can decrease rates of macrovascular and microvascular diabetes complications without weight loss or in the presence of weight gain [40]. The magnitude of weight loss observed in our study is similar to that reported in a meta-analysis of DSME/S interventions [39]. Although patients randomized to the plate method achieved greater weight loss at 6 months, no difference in weight loss was observed relative to the control group. However, patients in the carbohydrate counting group achieved statistically significant weight loss at 6 months relative to the control group. Because carbohydrate counting teaches patients to quantitatively track carbohydrate intake at each meal, patients skilled in carbohydrate counting may be more successful in meeting defined dietary targets to promote weight loss.

There are several limitations to this study. First, this study was conducted in an academic setting with English speaking patients, and may not generalize to other settings or

populations. Second, because only two CDEs were available for this study, each CDE provided instruction on both the carbohydrate counting and modified plate methods during the study, which may contaminate the intervention arms. Although CDEs were not blinded to group assignment, they were trained to deliver only the assigned approach to limit potential bias. Additionally, we utilized highly experienced CDEs and our findings may not generalize to all CDEs. Third, since the duration of the study was only 6 months, we were unable to assess the long term impact and sustainability of the interventions on glycemic outcomes. Fourth, our study was not designed to evaluate the role of weight loss and other mechanisms by which DSME/S interventions improve glycemic control. Finally, while our exploration of the role of numeracy was pre-specified, this study was not adequately powered to examine differences in intervention effectiveness by diabetes numeracy.

4.2 Conclusion

Our study suggests that CDE-delivered DSME/S utilizing carbohydrate counting or the modified plate method of nutrition can significantly improve glycemic control independent of increased healthcare interactions for individuals with HbA$_{1Cs}$ between 7–10% (53–86 mmol/mol). Consistent with national DSME/S guidelines, our study also suggests that approaches to diabetes education may need to be customized to specific patient characteristics – including numeracy level.

4.3 Practice Implications

DSME/S has an important role in improving glycemic control in patients with type 2 diabetes, especially those with a HbA$_{1C}$ between 7–10% (53–86 mmol/mol). Increased awareness and understanding of patient characteristics may be important for tailoring approaches to nutrition education. Additional studies are needed to identify the key attributes of DSME/S programs that are most effective in improving outcomes for patients with type 2 diabetes.

Acknowledgments

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Highlights

- HbA_{1c} improved with both carbohydrate counting and plate method of nutrition.

- HbA_{1C} improved independently of increased contact time from diabetes education.

- In those with a HbA_{1C} 7–10%, both nutrition methods improved diabetes control.

- The plate method may improve control for both higher and lower numeracy patients.
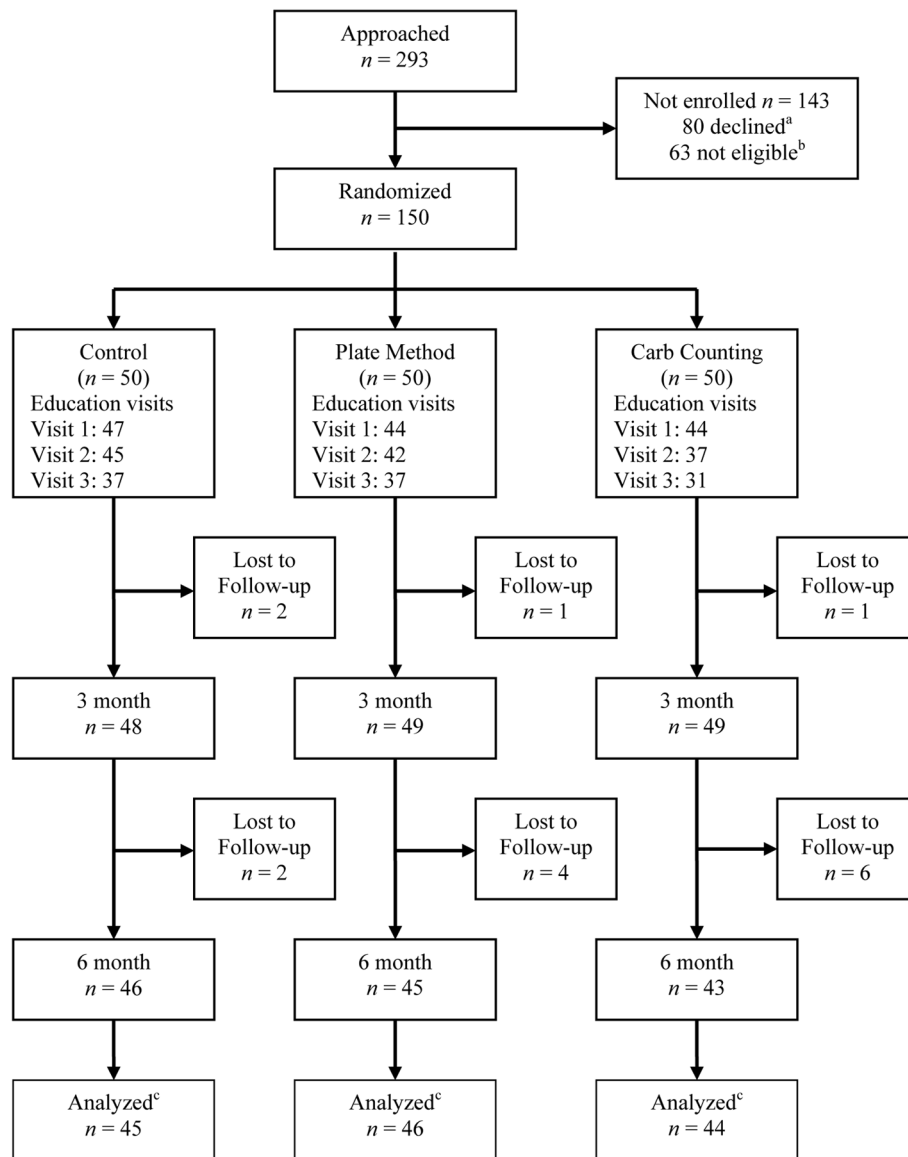
Figure 1. Study flow diagram

[a]Reasons for declining participation included time constraints ($n = 33$), lack of interest ($n = 29$), transportation ($n = 12$), and deferred participation ($n = 9$). Some individuals reported more than one reason for not participating.

[b]Reasons for not meeting eligibility criteria ($n = 63$) included pre-enrollment $HbA_{1C} < 7.0\%$ (53 mmol/mol) ($n = 47$), cognitive or visual impairment ($n = 7$), adjusting insulin for carbohydrate intake ($n = 3$), not established patients ($n = 3$), enrolled in diabetes education program ($n = 2$), type 1 diabetes ($n = 1$).

[c]Patients were included in analysis if they had a baseline and either 3 or 6 month HbA_{1C} available
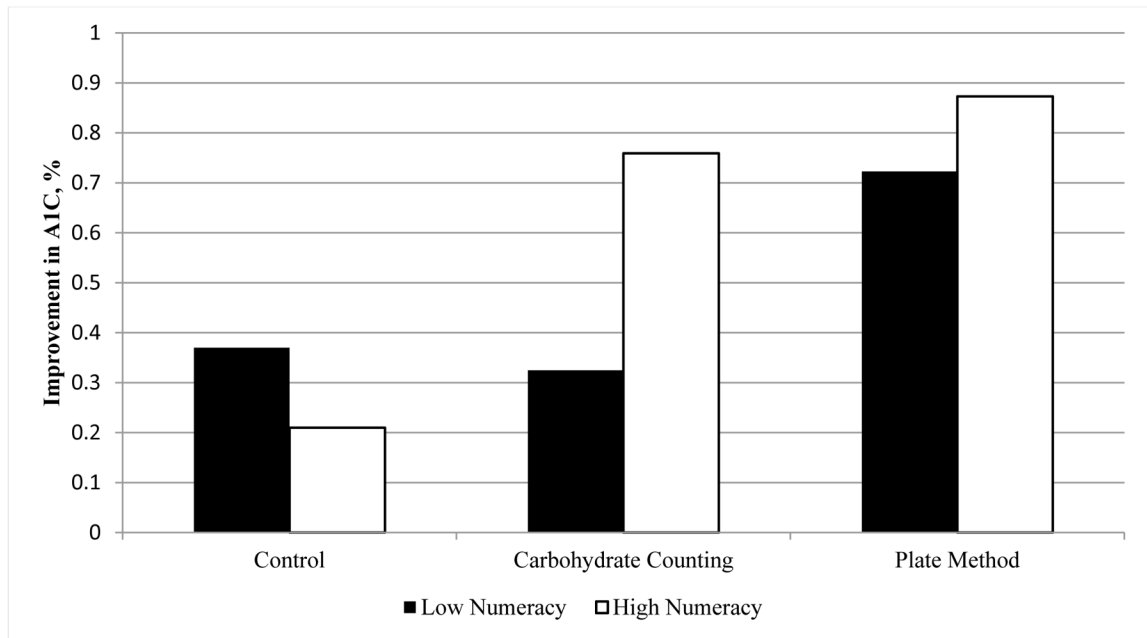
Figure 2. Within group Percent Change in HbA$_{1C}$ from Baseline by Numeracy Status
Numeracy assessed using the Diabetes Numeracy Test (DNT). Low numeracy: DNT score in the lowest quartile of the distribution (score <47%); High numeracy (DNT score 47%). SI conversion factors: mmol/mol = [10.93* Hb$_{A1c}$ (%)] − 23.50

Table 1

Baseline characteristics of DINES participants

	Control	Carbohydrate Counting	Modified Plate Method	Combined CDE[a]	All Patients	Subgroup with HbA1C 7–10%
N	50	50	50	100	150	105
Age, median (IQR), years	57 (48, 62)	54 (47, 68)	55 (45, 60)	54 (47, 62)	55 (47, 62)	58 (48, 66)
Female (%)	52	62	46	54	53	51
Non-white race (%)	34	42	27	34	34	30
Income <$20,000/year (%)	22	22	26	24	23	20
Education <12 years (%)	22	18	36	27	25	23
Private insurance (%)	62	64	64	64	63	62
REALM[c] score<9th grade level (%)	10	8	14	11	11	9
DNT-15[d], median (IQR), (% correct)	67 (47, 80)	73 (40, 93)	67 (40, 85)	70 (40, 87)	67 (47, 87)	67 (47, 87)
Weight, median (IQR), pounds	216 (180, 243)	218 (190, 252)	224 (189, 259)	220 (189, 258)	220 (188, 251)	212 (183, 240)
BMI, median (IQR), (kg/m^2)	34 (30, 39)	34 (30, 37)	34 (30, 39)	34 (30, 38)	34 (30, 38)	33 (29, 38)
Prior diabetes education (%)	68	52	54	53	58	59
Prior carb count education (%)	24	22	32	27	26	29
Current insulin use (%)	34	28	42	35	35	30
>1 insulin shot/day (%)[b]	47	57	77	79	62	56
Diabetes duration, median (IQR), years	8 (3, 13)	8 (4, 10)	7 (3, 10)	8 (3, 11)	8 (3, 11)	8 (4, 12)
HbA1C, median (IQR), %	8.0 (7.5, 9.7)	8.4 (7.6, 9.7)	8.3 (7.5, 10.4)	8.3 (7.6, 9.9)	8.2 (7.5, 9.9)	7.9 (7.5, 8.8)
Treatment satisfaction (DTSQ)[e], median (IQR)	26 (19, 31)	24 (17, 30)	22 (17, 29)	23 (17, 29)	24 (18, 30)	24 (18, 30)
Self-efficacy (PDSMS)[f], median (IQR)	24 (21, 29)	24 (18, 29)	24 (21, 27)	24 (20, 28)	24 (20, 29)	24 (21, 28)

SI conversion factors: mmol/mol = [10.93* HbA1c (%)] − 23.50

p>0.05 for all comparisons in the control, carbohydrate counting, and modified plate method groups

[a]CDE, certified diabetes educator. Combined CDE group represents combined carbohydrate counting and modified plate method groups.

[b]Restricted to patients prescribed insulin (*n* = 53)

[c]REALM, Rapid Estimation Adult Literacy in Medicine

[d] DNT-15, Diabetes Numeracy Test-15

[e] DTSQ, Diabetes Treatment Satisfaction Questionnaire (DTSQ), scoring range 0–36

[f] PDSMS, Perceived Diabetes Self-Management Scale (PDSMS), scoring range 8–40

Table 2

Within-group change in HbA$_{1C}$, weight, treatment satisfaction, and self-efficacy

	Control	Carbohydrate Counting	Modified Plate Method	Combined CDE[f]
Change in HbA$_{1C}$, %				
Baseline to 3 months	−0.98 (−1.39, −0.57)[a]	−0.99 (−1.42, −0.56)[a]	−1.04 (−1.52, −0.56)[a]	−1.01 (−1.33, −0.69)[a]
Baseline to 6 months	−0.25 (−0.78, 0.27)	−0.45 (−0.88, −0.01)[b]	−1.13 (−1.65, −0.6)[a]	−0.79 (−1.13, −0.45)[a]
Change in Weight, pounds				
Baseline to 3 months	1.09 (−3.75, 5.93)	0.9 (−7.76, 9.55)	−3.92 (−9.53, 1.69)	−1.60 (−6.68, 3.48)
Baseline to 6 months	0.66 (−4.66, 5.98)	−2.07 (−9.34, 5.20)	− 8.00 (−13.90, −2.10)[b]	−5.14 (−9.71, −0.58)[b]
Change in Treatment Satisfaction (DTSQ)[d]				
Baseline to 3 months	2.93 (0.8, 5.04)[b]	5.21 (2.82, 7.61)[a]	6.88 (4.38, 9.21)[a]	6.09 (4.36, 7.85)[a]
Baseline to 6 months	3.86 (0.98, 6.16)[b]	4.49 (1.98, 7.15)[b]	7.33 (5.07, 9.91)[a]	5.98 (4.12, 7.81)[a]
Change in Self-efficacy (PDSMS)[e]				
Baseline to 3 months	2.87 (0.82, 5.13)[b]	3.79 (2.03, 5.55)[a]	4.17 (2.19, 5.98)[a]	3.99 (2.67, 5.36)[a]
Baseline to 6 months	3.16 (1.61, 4.89)[a]	4.44 (2.15, 6.54)[a]	4.49 (2.36, 6.53)[a]	4.47 (2.99, 5.93)[a]
Subgroup Analysis[c]: Baseline HbA$_{1C}$ 7–10% (53–86 mmol/mol)				
Change in HbA$_{1C}$, %				
Baseline to 3 months	−0.65 (−0.95, −0.36)[a]	−0.89 (−1.23, −0.56)[a]	−0.62 (−0.94, −0.29)[a]	−0.76 (−1.0, −0.53)[a]
Baseline to 6 months	0.20 (−0.35, 0.75)	−0.51 (−0.92, −0.10)[b]	−0.48 (−0.78, −0.17)[b]	−0.51 (−0.77, −0.26)[a]
Change in Weight, pounds				
Baseline to 3 months	2.77 (− 3.0, 8.53)	1.24 (−5.26, 7.75)	− 1.05 (−5.75, 3.64)	0.04 (−3.91, 3.98)
Baseline to 6 months	0.73 (−5.85, 7.31)	−2.81 (−12.64, 7.03)	−6.25 (−11.77, −0.74)[b]	− 4.95 (−10.39, −0.49)
Change in Treatment Satisfaction (DTSQ)[d]				
Baseline to 3 months	1.69 (−0.66, 4.17)	5.17 (2.57, 7.53)[a]	6.55 (3.14, 9.69)[a]	5.85 (3.80, 8.10)[a]
Baseline to 6 months	2.67 (−0.48, 5.74)	5.07 (1.79, 8.07)[b]	8.25 (5.31, 11.28)[a]	6.74 (4.56, 8.93)[a]
Change in Self-efficacy (PDSMS)[e]				

	Control	Carbohydrate Counting	Modified Plate Method	Combined CDE[f]
Baseline to 3 months	3.17 (−0.10, 6.17)[b]	2.83 (0.83, 4.73)[b]	3.76 (1.55, 6.07)[b]	3.29 (1.85, 4.78)[*]
Baseline to 6 months	3.59 (1.11, 6.00) [b]	3.72 (1.38, 5.79)[b]	5.16 (2.88, 7.44)[a]	4.48 (2.93, 6.00)[a]

Data presented as mean change from baseline (95% bootstrap confidence intervals). P-values computed using contrasts in unadjusted model.

SI conversion factors: mmol/mol = [10.93* HbA1c (%)] − 23.50

[a] $P < 0.001$

[b] $P < 0.05$

[c] $n = 105$

[d] Diabetes Treatment Satisfaction Questionnaire (DTSQ), scoring range 0–36

[e] Perceived Diabetes Self-management Scale (PDSMS), scoring range 8–40

[f] CDE, certified diabetes educator. Combined CDE group represents combined carbohydrate counting and modified plate method groups.

Table 3

Adjusted change in HbA1C, weight, treatment satisfaction, and self-efficacy at 6 months

	Carbohydrate Counting vs. Control	Modified Plate Method vs. Control	Combined CDE[c] vs. Control
Primary Outcome, Mean (95% CI) Change in HbA1C			
Baseline to 6 months, %	−0.28 (−0.87, 0.31)	−0.52 (−1.10, 0.06)	−0.41 (−0.91, 0.10)
Secondary Outcomes, Mean (95% CI) Change in Weight, Satisfaction, Self-efficacy			
Change in weight, pounds			
Baseline to 6 months	−3.55 (−7.05, −0.05)[a]	−3.65 (−7.47, 0.17)	−3.59 (−6.66, −0.52)[a]
Change in Treatment Satisfaction (DTSQ)			
Baseline to 6 months	−0.01(−2.90, 2.89)	2.27 (−0.028, 4.57)	1.20 (−1.03, 3.43)
Change in Self-efficacy (PDSMS)			
Baseline to 6 months	0.88 (−1.37, 3.11)	1.36 (−0.73, 3.45)	1.14 (−0.68, 2.96)
Subgroup Analysis [b]: Baseline HbA1C 7–10%			
Primary Outcome, Mean (95% CI) Change in HbA1C			
Baseline to 6 months, %	−0.86 (−1.47, −0.26)[a]	−0.76 (−1.33, −0.19)[a]	−0.80 (−1.33, −0.27)[a]
Secondary Outcomes, Mean (95% CI) Change in Weight, Satisfaction, Self-efficacy			
Change in weight, pounds			
Baseline to 6 months	−3.54 (−8.05, 0.97)	−3.58 (−8.10, 0.93)	−3.52 (−7.30, 0.25)
Change in Treatment Satisfaction (DTSQ)			
Baseline to 6 months	2.93 (−0.59, 6.44)	4.64 (1.72, 7.56)[a]	3.87 (1.06, 6.68)[a]
Change in Self-efficacy (PDSMS)			
Baseline to 6 months	1.45 (−1.13, 4.02)	2.12 (−0.17, 4.41)	1.82 (−0.26, 3.90)

SI conversion factors: mmol/mol = [10.93* HbA1c (%)] − 23.50

[a]$P < 0.05$

[b]$n = 105$

[c]CDE, certified diabetes educator. Combined CDE group represents combined carbohydrate counting and modified plate method groups