Comparative Effectiveness and Maintenance of Diabetes Self-Management Education Interventions for Marshallese Patients With Type 2 Diabetes: A Randomized Controlled Trial

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OBJECTIVE

Marshallese adults experience high rates of type 2 diabetes. Previous diabetes self-management education (DSME) interventions among Marshallese were unsuccessful. This study compared the extent to which two DSME interventions improved glycemic control, measured on the basis of change in glycated hemoglobin (HbA_{1c}).

RESEARCH DESIGN AND METHODS

A two-arm randomized controlled trial compared a standard-model DSME (standard DSME) with a culturally adapted family-model DSME (adapted DSME). Marshallese adults with type 2 diabetes (n = 221) received either standard DSME in a community setting (n = 111) or adapted DSME in a home setting (n = 110). Outcome measures were assessed at baseline, immediately after the intervention, and at 6 and 12 months after the intervention and were examined with adjusted linear mixed-effects regression models.

RESULTS

Participants in the adapted DSME arm showed significantly greater declines in mean HbA_{1c} immediately (−0.61% [95% CI −1.19, −0.03]; P = 0.038) and 12 months (−0.77% [95% CI −1.38, −0.17]; P = 0.013) after the intervention than those in the standard DSME arm. Within the adapted DSME arm, participants had significant reductions in mean HbA_{1c} from baseline to immediately after the intervention (−1.18% [95% CI −1.55, −0.81]), to 6 months (−0.67% [95% CI −1.06, −0.28]), and to 12 months (−0.87% [95% CI −1.28, −0.46]) (P < 0.001 for all). Participants in the standard DSME arm had significant reductions in mean HbA_{1c} from baseline to immediately after the intervention (−0.55% [95% CI −0.93, −0.17]; P = 0.005).

CONCLUSIONS

Participants receiving the adapted DSME showed significantly greater reductions in mean HbA_{1c} immediately after and 12 months after the intervention than the reductions among those receiving standard DSME. This study adds to the body of research that shows the potential effectiveness of culturally adapted DSME that includes participants' family members.

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Between 2000 and 2010, the Pacific Islander population grew 40% in the U.S. (1). In Arkansas, the Pacific Islander subpopulation of Marshallese grew 252% between 2000 and 2010 (1). Arkansas has the largest population of Marshallese in the continental U.S. (1), with ~10,000 residents as of 2016 (2). Marshallese experience significant health disparities, including extremely high rates of type 2 diabetes (3–5). Estimates of type 2 diabetes among Marshallese adults range from 20% to 40% (3–5), compared with ~12% among the U.S. adult population (6) and ~9% among the worldwide adult population (7). Pilot data from 401 Marshallese in Arkansas documented an extremely high incidence of type 2 diabetes (38.4%) and prediabetes (32.6%) (5).

Multiple studies have found diabetes self-management education (DSME) to be effective at improving patients' diabetes-related clinical outcomes, including glycated hemoglobin (HbA_{1c}), BMI, blood pressure, and lipids (8–11). However, positive outcomes are not documented equally across all racial/ethnic groups (12–14). Culturally appropriate DSME has been shown to improve diabetes self-management for minority and immigrant communities (12–16); an emerging body of literature shows that family models of DSME are effective (17,18). However, no prior DSME has been effective among Marshallese (19,20), and no culturally adapted or family models of DSME have been tested with Marshallese participants. Upon considering stakeholder input and the success of prior culturally adapted family models in other populations, the study team felt that a culturally adapted family-model DSME would work well in the Marshallese community.

Using a community-based participatory research approach, we worked with community stakeholders, including Marshallese community members with type 2 diabetes and leaders of Marshallese community organizations and Marshallese churches, to refine the research question, adapt a DSME curriculum, and design and implement the study (21). The primary aim of the study was to assess the effectiveness of a culturally adapted family-model DSME intervention (adapted DSME) compared with that of a standard DSME intervention among Marshallese with type 2 diabetes in Arkansas. The primary outcome, glycemic control, was measured by determining the change in mean HbA_{1c} from baseline to immediately after, 6 months after, and 12 months after the intervention. We hypothesized that the adapted DSME intervention would result in greater reductions of HbA_{1c} than would the standard DSME intervention.

RESEARCH DESIGN AND METHODS

The study was approved by the University of Arkansas for Medical Sciences Institutional Review Board (no. 203482) and is registered at ClinicalTrials.gov (identifier NCT02407132) and in the Health Services Research Projects in Progress database (project 20152031). The study design incorporated a community-based participatory research approach. A detailed protocol is published elsewhere (21–23).

Participant Inclusion Criteria and Recruitment

Marshallese adults (aged 18 years and older) who had received a diagnosis of type 2 diabetes from a health care provider were eligible to participate in the study. In the adapted DSME arm, participants were required to invite one or more adult (aged 18 years and older) family members to provide informed consent and join in study activities. Bilingual Marshallese staff recruited participants from among people attending community and church health screenings (5), community members who heard about the study and self-referred, and those people referred by local community health workers (CHWs), community partners, and local clinics serving Marshallese patients. Potential participants who met the inclusion criteria were provided information about the study and given the opportunity to discuss the study with bilingual Marshallese research staff. All recruitment and study information was available in English and Marshallese.

Randomization

A total of 240 participants with type 2 diabetes were recruited and provided consent. The participants' type 2 diabetes status was confirmed on the basis of HbA_{1c} measured during data collection at baseline, which occurred after enrollment but before implementation of the interventions. Participants not taking glucose-lowering medications and who did not have HbA_{1c} results indicative of diabetes (6.5% or above) when data were collected at baseline were unenrolled from the study. Participants were randomized to either the adapted DSME arm or the standard DSME arm. Randomization occurred at the family level. Before randomization, participants who had provided consent were grouped by family to prevent participants from the same family being assigned to different arms (i.e., to minimize cross-contamination). Randomization was conducted via a random number generation function that concealed the families' identities from the person making the assignment. The investigator who conducted randomization (C.R.L.) had no interactions with potential participants and no supervisory role with program staff who were responsible for recruiting or obtaining consent from participants or delivering the intervention.

Data Collection and Remuneration

Data were collected at baseline, immediately after the intervention (~9 weeks from the start of the interventions), and 6 and 12 months after the intervention. A $20 gift card was provided as remuneration at each of the four data collection events. Data were collected from all eligible participants at each data collection event, regardless of whether they had missed previous data collection events (e.g., a participant who missed the 6-month data collection event would be contacted to participate in the 12-month data collection event).

Study Setting

The study was conducted in Washington County and Benton County in northwest Arkansas. The adapted DSME was delivered in participants' homes. The standard DSME was delivered at a local nonprofit organization that was familiar to participants and was located near the Marshallese community. The study was conducted from May 2015 to May 2018.

Intervention Descriptions

The standard DSME included 10 h of content delivered over a 6-week period and covered eight core elements: healthy eating, being active, glucose monitoring, understanding blood glucose and taking medications, problem solving, reducing risks and healthy coping, mitigating complications of diabetes, and goal

setting. The core elements were consistent with the American Diabetes Association's and the American Association of Diabetes Educators' recommendations regarding self-care behaviors (24). A certified diabetes educator (CDE) delivered the standard DSME. An interpreter fluent in both English and Marshallese was present for every session to interpret the sessions. Family members of participants in the standard DSME arm were not invited to the education sessions.

The adapted DSME included 10 h of content delivered over an 8-week period and covered the same eight core elements of DSME. The curriculum was culturally adapted using a community-based participatory research approach. Changes to the curriculum included using culturally appropriate nature analogies, such as tidal changes to explain changes in glucose numbers; incorporating photos of Pacific Islanders; integrating culturally relevant food preferences, such as fish and fruit; discussing in depth the importance of medication adherence, with a focus on the natural, plant-based properties of metformin; and emphasizing engagement of participants' collectivistic, family orientation as a means of self-management. Specifically, the curriculum emphasized the importance of engaging the entire family in behavioral changes and incorporated family goal-setting and family motivational interviewing. A full description of the curriculum adaptation process has been published elsewhere (22). Through the community-based participatory research adaptation process, stakeholders encouraged the use of Marshallese CHWs when possible. Therefore, the adapted DSME was delivered in Marshallese by bilingual CHWs; a CDE was present at each session to provide support and answer any questions. CHWs completed 40 h of CHW training, plus more than 60 h of study-specific training (e.g., trainings focused on conducting clinical trials, research ethics, biospecimen handling, DSME curriculum and delivery, study protocol, and informed consent). Marshallese stakeholders also encouraged delivery in participants' homes as a way to engage family members and overcome transportation barriers. Participants were encouraged to include family members in intervention sessions, and the adapted DSME curriculum engaged family members in the educational sessions. Table 1 presents a summary of the differences in content and delivery between the adapted DSME and the standard DSME.

Study Outcomes

Change in mean HbA_{1c} from baseline to immediately after, 6 months after, and 12 months after the intervention was the primary outcome of interest. HbA_{1c} was assessed by using blood collected from a finger prick in a rapid A1C test kit and a Siemens DCA Vantage Analyzer. Secondary outcome measures included fasting glucose, fasting lipids, and BMI. After collecting blood from a finger prick, point-of-care devices were used to test fasting glucose with a glucometer and fasting lipids with a commercial lipid panel kit and Cholestech LDX Analyzer. Participants (wearing light clothing and no shoes) had their weight measured to the nearest 0.5 lb (0.2 kg) by using a calibrated digital scale. Height (without shoes) was measured to the nearest 0.5 cm by using a stadiometer. Weight and height were used to compute a

Table 1—Description of the interventions*

	Standard DSME	Adapted DSME
Materials and approach	• Used individual motivational interviewing techniques and individual goal setting • Used food models showing the portion size of foods	• Adapted to be culturally sensitive on the basis of stakeholder input (e.g., culturally specific language, context, pictures of Pacific Islanders)† • Embraced the Marshallese spiritual belief system • Used "talk story" as a conversational, rhythmic, and culturally preferred way of sharing knowledge • Used collective motivational interviewing techniques and collective (family) goal setting • Used analogies and metaphors common in Pacific Islander culture and nature in the Pacific Islands (e.g., sea tide and fishing) • Applied culturally specific concepts and beliefs (e.g., importance of supporting family members and taking care of older adults) • Identified culturally specific nutritional strengths (e.g., fish) and weaknesses (e.g., rice and sweets) and conducted cooking demonstrations • Used anatomical models and picture-based posters showing parts of human anatomy and food models showing the portion size of foods
Mode of delivery	Delivered by a CDE with interpretation by a bilingual interpreter	Delivered in Marshallese by a bilingual CHW with support from a CDE
Dosage	10 h delivered in 100-min sessions over 6 weeks	10 h delivered in 75-min sessions over 8 weeks
Participants	Groups of participants with type 2 diabetes	Individual participants with type 2 diabetes and their family members
Settings	Delivered in a conveniently located community center	Delivered in participants' homes

Table adapted from Kim Yeary et al. (23). *Both interventions covered eight core topics: healthy eating, being active, glucose monitoring, understanding blood glucose and taking medications, problem solving, reducing risks and healthy coping, mitigating complications of diabetes, and goal setting. †Intervention adaptation process described in detail by Yeary et al. (22).

continuous measure of BMI (kilograms per square meter).

Analyses in this study controlled for the use of medication that lowers blood glucose. For this reason, at each data collection event, participants were asked to report all medications they were currently taking. Medications known to lower glucose levels were coded as such (yes/no).

Analytical and Statistical Approaches

Analysis Overview

The study design applied a randomized two-arm construct with four repeated-measure time points (baseline and three follow-ups). The target sample size of 240 achieved 80% power to detect an effect size of d = 0.3 in a design with four measurement time points and a compound symmetry covariance structure, assuming a correlation of 0.5 between measurements from the same subject and an α level of 0.05 (25,26). The hypothesized detectable effect was of a magnitude similar to that in studies that reported an ~0.5% (5.5 mmol/mol) change in HbA_{1c}, with an SD set conservatively at 1.5% (16.4 mmol/mol) in order to account for differences (or incomplete reporting) in the studies (27–29). A 0.5% (5.5 mmol/mol) change in HbA_{1c} is considered to be a clinically important difference (30–32). Power calculations accounted for model covariates by specifying the assumed R^2 between the main independent variable and preplanned adjustment variables. Power was calculated by using PASS 15 (NCSS, Kaysville, UT; www.ncss.com/software/pass).

The primary outcome was change in mean HbA_{1c} from baseline to immediately after, 6 months after, and 12 months after the intervention. For the primary analyses, we fit linear mixed-effects regression models for repeated measures over time in order to analyze the impact of the adapted DSME compared with that of the standard DSME (between-arm difference) on change in mean HbA_{1c}; fixed effects were arm assignment, time, and arm-by-time interaction. Models were adjusted for baseline data: sex, age, education, marital status, employment status, use of diabetes medication, and households containing multiple participants. To account for any familial correlation, we incorporated random effects in the models and assumed a compound symmetry as the underlying covariance structure. All analyses were conducted using SAS/STAT software version 14.2 (SAS Institute Inc., Cary, NC; www.sas.com). Statistical significance was set at the a priori α level of 0.05.

Analysis of Secondary Outcomes

We used analytic strategies similar to those we used to evaluate our primary outcome in order to examine the secondary measures. We examined study arm effects, time effects, and their interactions. For these analyses, we used linear mixed-effects regression models, accounting for familial correlation similar to how it was accounted for in the models we used for the primary outcome. Baseline demographic and socioeconomic factors were included for adjustment.

Handling Missing Data

Our primary outcome variable (differences in change in mean HbA_{1c} from baseline between arms) was analyzed in accordance with the intent-to-treat principle. That is, data from all randomized participants were analyzed regardless of their compliance with study protocol or their failure to complete the study.

Sensitivity analyses were conducted to examine the intervention effect from analyses based on multiple imputations of data relative to analyses based on only those who completed the study. First, we applied Markov chain Monte Carlo methods to impute missing values for an arbitrary missing data pattern so that each of the 25 imputed data sets had a monotone pattern of missing data. Next, we used regression-based imputation methods to create a complete data set for each imputation. In longitudinal regression analysis of the primary outcome, we analyzed each of the imputed data sets using the methods described above. Parameter estimates and their SE from each analysis were combined across imputations in order to generate valid statistical inferences.

RESULTS

Participant Flow

Figure 1 presents a CONSORT flow diagram for the study. Of the 240 participants who consented to be screened for eligibility, 221 were eligible to participate and were randomized to one of the two study arms.

Participant Characteristics

Supplementary Table 1 shows the baseline characteristics of participants by study arm. Among the 221 participants, the mean age was 52.2 years (SD 10.8 years; range 31–80 years), and 58.8% were female.

Missing Data

All participants provided data at baseline. Supplementary Tables 2–4 present comparisons of baseline characteristics of participants by missing outcome status at each follow-up time point. A smaller proportion of participants with missing data 12 months after the intervention were married ($P = 0.005$). We found no other differences between participants with missing data and those with complete data at any time point.

Changes in Primary Outcome

Table 2 presents the unadjusted means and 95% CIs for HbA_{1c} by study arm and time point. Detailed results of the analyses of the primary outcome are presented in Table 3. We used adjusted linear mixed-effects models to evaluate between-arm differences in change in mean HbA_{1c} from baseline at each time point. Significantly greater declines in mean HbA_{1c} occurred in participants in the adapted DSME arm than in participants in the standard DSME arm immediately after and 12 months after the intervention (between-arm differences, represented by arm-by-time interactions: $\beta_{A\times T} = -0.61$; $P = 0.038$, and $\beta_{A\times T} = -0.77$; $P = 0.013$, respectively). We found no between-arm difference in the change in mean HbA_{1c} 6 months after the intervention ($P = 0.139$).

Results based on multiple imputation of missing HbA_{1c} data are presented in Supplementary Tables 5 and 6. These results showed a pattern of findings similar to those presented above, with significantly greater declines among participants in the adapted DSME arm than those in the standard DSME arm both immediately after and 12 months after the intervention.

Within-arm changes in mean HbA_{1c} from baseline to each time point are presented in Supplementary Table 7. Participants in the adapted DSME arm showed statistically significant and clinically important reductions in mean HbA_{1c} from baseline to immediately after the intervention ($\beta_T = -1.18$; $P < 0.001$)

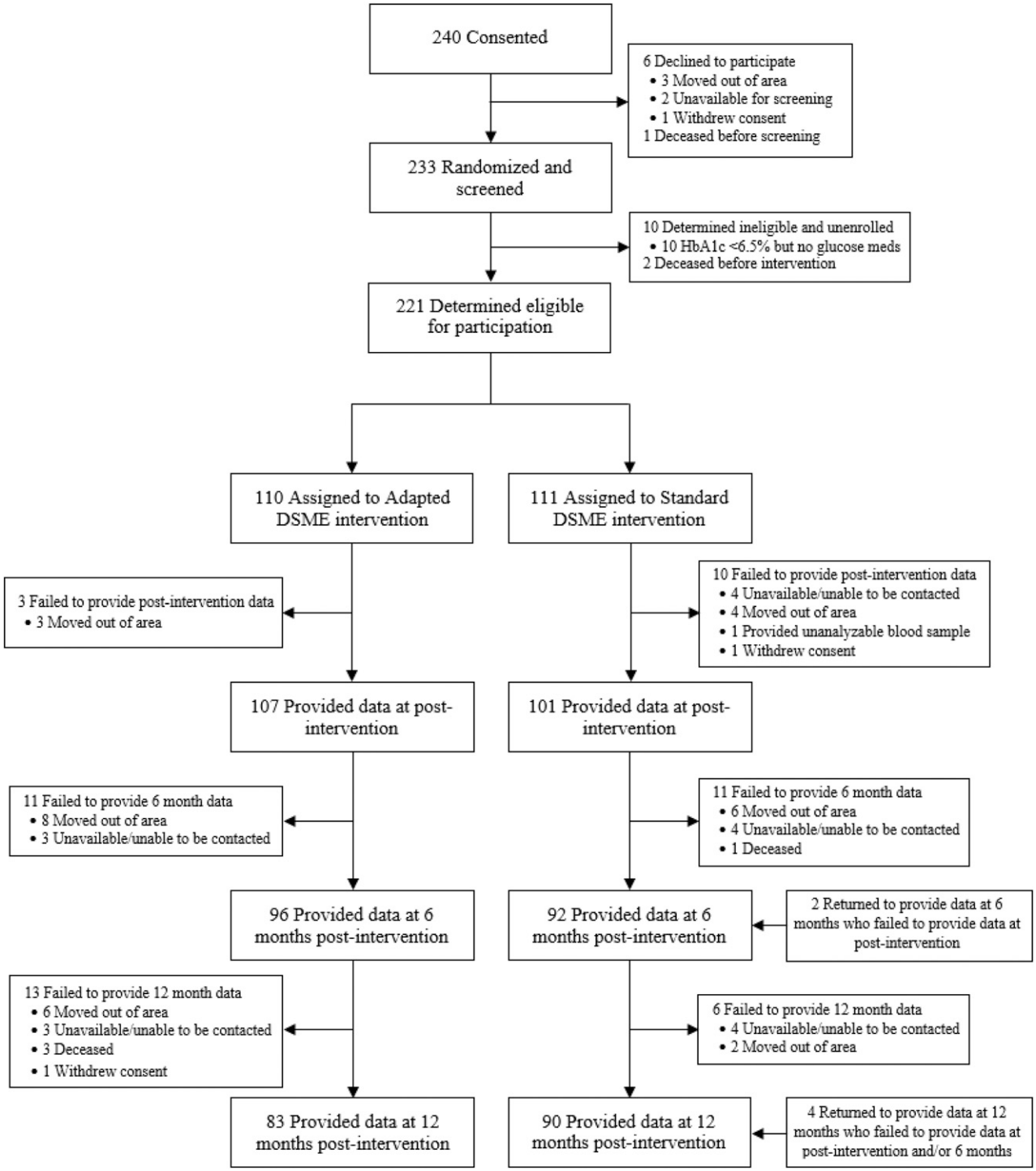

Figure 1—Enrollment, randomization, and retention of study participants.

and at 6 months ($\beta_T = -0.67$; $P < 0.001$) and 12 months ($\beta_T = -0.87$; $P < 0.001$) after the intervention. Participants in the standard DSME arm showed a statistically significant and clinically important reduction in mean HbA_{1c} from baseline to immediately after the intervention ($\beta_T = -0.55$; $P = 0.005$), but they showed no significant reductions in mean HbA_{1c} from baseline at 6 or 12 months after the intervention.

Changes in Secondary Outcomes

Many participants reported that they had not adhered to instructions to fast before data were collected. For this reason, we do not present analyses for fasting glucose, LDL, or triglycerides. Unadjusted means and 95% CIs by study arm and time point for BMI, total cholesterol, and HDL are presented in Table 2.

Results from linear mixed-effects models for BMI, total cholesterol, and HDL are presented in Table 3. Comparing the between-arm change in mean BMI from baseline to any time point for either arm, we found no differences by study

Table 2—Primary and secondary outcomes: unadjusted means and 95% CIs by study arm and time

	Baseline		Immediately after the intervention		6 Months after the intervention		12 Months after the intervention	
	Participants (*n*)	Mean (95% CI)	Participants (*n*)	Mean (95% CI)	Participants (*n*)	Mean (95% CI)	Participants (*n*)	Mean (95% CI)
Primary outcome								
HbA_{1c} (%)								
Standard DSME	111	10.41 (10.00, 10.83)	101	9.79 (9.40, 10.18)	92	10.14 (9.66, 10.62)	90	10.36 (9.87, 10.85)
Adapted DSME	110	10.51 (10.06, 10.96)	107	9.36 (9.00, 9.71)	96	9.89 (9.45, 10.34)	83	9.64 (9.18, 10.10)
HbA_{1c} (mmol/mol)								
Standard DSME	111	90.3 (85.8, 94.9)	101	83.5 (79.2, 87.8)	92	87.3 (82.1, 92.6)	90	89.7 (84.4, 95.1)
Adapted DSME	110	91.4 (86.5, 96.3)	107	78.8 (74.9, 82.6)	96	84.6 (79.8, 89.5)	83	81.9 (76.8, 86.9)
Secondary outcomes								
BMI (kg/m^2)								
Standard DSME	110	31.46 (30.52, 32.41)	102	31.46 (30.48, 32.44)	89	31.31 (30.31, 32.30)	90	31.46 (30.43, 32.49)
Adapted DSME	108	30.50 (29.37, 31.64)	105	30.68 (29.60, 31.78)	92	31.26 (30.05, 32.48)	91	30.84 (29.54, 32.14)
Total cholesterol (mg/dL)								
Standard DSME	111	189.68 (182.47, 196.90)	102	181.64 (174.07, 189.20)	91	173.81 (165.75, 181.88)	90	179.42 (170.81, 188.03)
Adapted DSME	110	181.23 (174.10, 188.36)	106	169.50 (163.30, 175.70)	96	177.66 (169.31, 186.01)	83	168.22 (160.24, 176.19)
HDL (mg/dL)								
Standard DSME	106	37.81 (35.73, 39.89)	96	36.49 (34.65, 38.32)	90	36.32 (34.30, 38.34)	87	36.31 (34.27, 38.35)
Adapted DSME	105	35.99 (34.02, 37.96)	103	37.01 (34.65, 39.36)	93	38.32 (36.01, 40.63)	79	36.16 (33.75, 38.58)

arm over time. Analyses of change in adjusted means within the study arms showed no clinically important changes in BMI from baseline to any time point for either arm (Supplementary Table 7).

With respect to total cholesterol, a significantly greater decline occurred immediately after the intervention ($\beta_{A\times T} = -12.50$; $P = 0.019$) for participants in the adapted DSME arm than for those in the standard DSME arm. No between-arm difference was found in the reduction of mean total cholesterol from baseline at 6 months or 12 months after the intervention.

Among participants in the adapted DSME arm, mean total cholesterol decreased significantly from baseline immediately after the intervention ($\beta_T = -11.24$; $P = 0.001$) and 12 months after the intervention ($\beta_T = -10.51$; $P = 0.004$). We found no change from baseline at the 6-month follow-up. Among participants in the standard DSME arm, mean total cholesterol decreased significantly from baseline at 6 months ($\beta_T = -13.24$; $P < 0.001$) and 12 months ($\beta_T = -8.29$; $P = 0.018$) after the intervention but not immediately.

With respect to HDL, the only between-arm difference was a significant increase in mean HDL 6 months after the intervention for the participants in the adapted DSME arm compared with those in the standard DSME arm at the same time point ($\beta_{A\times T} = 3.85$; $P = 0.009$). Within the adapted DSME arm, participants' mean HDL increased significantly from baseline to 6 months after the intervention ($\beta_T = 2.91$; $P = 0.001$), but not at any other time point. Within the standard DSME arm, participants' mean HDL did not change from baseline to any follow-up time point.

CONCLUSIONS

Participants receiving the adapted DSME showed significantly greater reductions in mean HbA_{1c} than did those receiving the standard DSME immediately after and 12 months after the intervention. An adjusted between-arm difference of −0.77% (−8.4 mmol/mol) sustained 12 months after the intervention is likely to have positive clinical implications for participants in the adapted DSME arm compared with those in the standard DSME arm, including reduced risks of heart attack, microvascular complications, and death from diabetes (33).

This finding supports the hypothesis that adapted DSME would produce greater reductions in mean HbA_{1c} than occur with standard DSME.

Participants in both the adapted and the standard DSME arms experienced a reduction in mean HbA_{1c} immediately after the intervention that was statistically significant and clinically important. However, at 6 months and 12 months after the intervention, only those in the adapted DSME arm showed a significant reduction. Somewhat surprisingly, neither intervention produced significant changes in secondary biometric outcomes (BMI, total cholesterol, HDL). Comparison of baseline data between participants who provided follow-up data and those who did not suggests that missing data would not explain these findings. The findings remained robust after multiple imputation for incomplete data.

This study fills several important gaps in the literature. Pacific Islanders are a rapidly growing population that experiences significant health disparities, but they have been underrepresented in research (34–36). Marshallese are a Pacific Islander subpopulation with rates of diabetes documented at 20–40% (3–5). While DSME has been effective in improving diabetes-related glycemic outcomes in other populations, prior studies of DSME in Marshallese populations were unable to document improvements in glycemic control (19,20). To our knowledge, this study is the first randomized controlled trial (RCT) in a Marshallese community and the first implementation of DSME with Marshallese participants to show significant improvements in HbA_{1c}. The significant changes in mean HbA_{1c} for participants in the adapted DSME arm are consistent with changes found in other studies that have shown the effectiveness of incorporating community and family connectedness as a means of delivering behavioral health interventions to Pacific Islanders (37–39). As such, the family approach may be particularly important for the family-centered, collectivist nature of the Pacific Islander culture (40).

This study is among the largest RCTs of a family model of DSME, and the findings add to those from a growing body of literature that suggests family-centered DSME can be effective at improving glycemic control (17,18). An

Table 3—Longitudinal analysis: estimated means, regression coefficients, and 95% CIs for study outcomes by study arm and time*

Outcome variables by study arm	Estimate mean (95% CI)				Between-arm difference† (arm × time interaction)							
	Baseline	Immediately after	6 Months	12 Months	Baseline	*P* value	Immediately after	*P* value	6 Months	*P* value	12 Months	*P* value
Primary outcome												
HbA_{1c} (%)												
Standard DSME	10.46 (10.07, 10.86)	9.91 (9.50, 10.32)	10.26 (9.84, 10.68)	10.38 (9.96, 10.81)	0.02 (−0.55, 0.58)	0.955	−0.61 (−1.19, −0.03)	**0.038**	−0.45 (−1.04, 0.15)	0.139	−0.77 (−1.38, −0.17)	**0.013**
Adapted DSME	10.48 (10.08, 10.89)	9.30 (8.90, 9.70)	9.81 (9.40, 10.23)	9.61 (9.17, 10.04)								
HbA_{1c} (mmol/mol)												
Standard DSME	90.8 (86.6, 95.2)	84.8 (80.3, 89.3)	88.6 (84.1, 93.2)	90.0 (85.4, 94.7)	0.2 (−6.0, 6.3)	0.955	−6.7 (−13.0, −0.3)	**0.038**	−4.9 (−11.4, 1.6)	0.139	−8.4 (−15.1, −1.9)	**0.013**
Adapted DSME	91.1 (86.7, 95.5)	78.2 (73.8, 82.5)	83.7 (79.2, 88.3)	81.5 (76.7, 86.2)								
Secondary outcomes												
BMI (kg/m^2)												
Standard DSME	31.46 (30.50, 32.42)	31.49 (30.53, 32.46)	31.39 (30.42, 32.36)	31.32 (30.35, 32.29)	−0.88 (−2.26, 0.49)	0.205	−0.84 (−2.22, 0.54)	0.234	−0.42 (−1.81, 0.97)	0.552	−0.54 (−1.93, 0.85)	0.447
Adapted DSME	30.58 (29.60, 31.55)	30.66 (29.68, 31.63)	30.97 (29.99, 31.95)	30.78 (29.80, 31.77)								
Total cholesterol (mg/dL)												
Standard DSME	189.08 (181.97, 196.19)	182.64 (175.35, 189.94)	175.84 (168.30, 183.37)	180.79 (173.24, 188.34)	−7.69 (−17.81, 2.43)	0.136	−12.50 (−22.82, −2.18)	**0.019**	2.85 (−7.77, 13.48)	0.598	−9.91 (−20.76, 0.94)	0.073
Adapted DSME	181.39 (174.25, 188.52)	170.15 (162.92, 177.37)	178.69 (171.27, 186.12)	170.88 (163.15, 178.61)								
HDL (mg/dL)												
Standard DSME	36.99 (35.04, 38.93)	35.63 (33.63, 37.63)	35.49 (33.46, 37.52)	35.58 (33.53, 37.62)	−0.56 (−3.33, 2.21)	0.691	1.90 (−0.92, 4.72)	0.186	3.85 (0.97, 6.72)	**0.009**	1.92 (−1.02, 4.87)	0.201
Adapted DSME	36.43 (34.47, 38.39)	37.53 (35.56, 39.50)	39.34 (37.31, 41.36)	37.50 (35.39, 39.60)								

Statistically significant *P* values are in boldface type. *Estimates from linear mixed-effects regression models are adjusted for baseline data: sex, age, education, marital status, employment status, use of diabetes medication, and households containing multiple participants. †The estimated arm contrast of the changes from baseline corresponds to the estimates of the arm-by-time interaction.

important finding of this study was the sustained significant improvements in HbA_{1c} among study participants in the adapted DMSE arm at 12 months after the intervention. According to Stratton et al. (33), a 1% (10.9 mmol/mol) reduction in HbA_{1c} is associated with reductions in risk for a range of macrovascular and microvascular complications. Given the unadjusted change in mean HbA_{1c} of −0.87% (9.5 mmol/mol) at 12 months, participants in the adapted DSME arm are likely to experience clinically meaningful improvements in their overall health.

Few DSME studies targeting racial/ethnic minority populations include follow-up data from 12 months after the intervention or later; thus, knowledge of long-term maintenance of outcomes is limited (14). Furthermore, few studies of family-model DSME interventions have examined outcomes at 12 months. A review of 19 family-model DMSE interventions found only 4 studies that measured HbA_{1c} at least 12 months after the intervention, and only 1 of those showed sustained improvements in HbA_{1c} at 12 months (18). One major difference between that family-model DSME intervention and the intervention tested in this study was the duration of the intervention. The previously studied family DMSE with sustained results 12 months after the intervention included an active intervention that lasted 12 weeks and was followed by 6 months of biweekly support group sessions (18); our study used 8 weeks for the intervention. Because most adults experience heavy demands on their time, our relatively brief adapted DMSE intervention might be particularly attractive to patients.

This RCT was implemented among Marshallese adults living in Arkansas, which limits the generalizability of the results to other populations or to Marshallese living outside of Arkansas. However, Arkansas is home to the largest population of Marshallese in the continental U.S. (1). This study contributes substantially to the sparse existing literature addressing the significant type 2 diabetes disparities among this understudied population, which faces significant health disparities (4,5). The Marshallese population is also culturally and genetically homogeneous; therefore, this research may inform interventions for other Marshallese populations in the U.S. and the U.S.-affiliated Pacific Islands. Based on input from Marshallese stakeholders regarding the design of the intervention (21–23), the adapted DSME intervention had notable differences from the standard DSME intervention (e.g., cultural adaptation of the curriculum, delivery by a CHW vs. delivery in English by a CDE, inclusion of family members, and delivery to individual participants in their home vs. delivery in group settings in the community). Therefore, the unique effects of each cultural adaptation element on the outcome variables cannot be separated. Future studies could examine the unique contributions of the culturally adapted curriculum, delivery by a CHW, delivery in the home, and inclusion of family members. Further analyses are also needed to explore whether participants in the adapted DSME arm showed improvements in self-management behaviors (e.g., regularly checking blood glucose, being physically active). Performing self-care behaviors is an integral component of successfully managing type 2 diabetes; for this reason, any between-arm differences in improvements for these behaviors may help explain the significant reductions in mean HbA_{1c} observed among participants in the adapted DSME arm. In addition, future studies should also collect and examine cost-effectiveness data to understand whether there are additional costs in implementing the adapted DSME relative to the standard DSME and whether there are spillover benefits to family members who participate.

This study has several promising implications for patient decision-making and clinical practice. This study presents evidence for Marshallese patients, their families, and the health care professionals who work with them to consider choosing (or providing) culturally adapted, family-focused DSME. Moreover, given the findings from this study and others about the effectiveness of culturally adapted family DSME, patients and other health care decision makers from other populations may wish to consider choosing (or providing) adapted DSME as an alternative to standard DSME. More generally, this study points to the potential effectiveness of mobilizing family members and cultural context in education about chronic disease self-management.

The primary outcome analyses suggest that the adapted DSME was more effective than the standard DSME in reducing mean HbA_{1c}, both immediately after and 12 months after the intervention in this sample of Marshallese with type 2 diabetes. This study fills an important gap in the current literature on DSME in several ways. To our knowledge, this study is the first RCT in a Marshallese community, the first study of DSME within a Marshallese community to show significant improvements in glycemic control, the largest RCT of a DSME intervention with any Pacific Islander population, one of the largest RCTs of a family model of DSME, and one of the few RCTs of a family model of DSME to include a 12-month follow-up time point. This study adds to a growing body of literature that has found that culturally adapted DSME that engages family members can achieve statistically significant and clinically important improvements in glycemic control (17,18).

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