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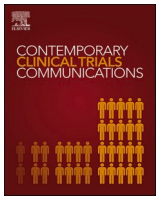

Study protocol for family model diabetes self-management education with Marshallese participants in faith-based organizations

Pearl A. McElfish [a,*], Sheldon Riklon [a], Rachel S. Purvis [a], Christopher R. Long [a], Holly C. Felix [b], Jonell S. Hudson [c], Derek Alik [a], Joseph Henske [d], Dinesh Edem [d], Gail O'Connor [e], Janine Boyers [e], Brett Rowland [e], James P. Selig [f]

[a] College of Medicine, University of Arkansas for Medical Sciences Northwest, 2708 S. 48th St., Springdale, AR, 72762, USA
[b] Fay W. Boozman College of Public Health, University of Arkansas for Medical Sciences, 4301 W. Markham St., Little Rock, AR, 72205, USA
[c] College of Pharmacy, University of Arkansas for Medical Sciences Northwest, 1125 N. College Ave., Fayetteville, AR, 72703, USA
[d] College of Medicine, University of Arkansas for Medical Sciences, 4301 W. Markham St., Little Rock, AR, 72205, USA
[e] Office of Community Health and Research, University of Arkansas for Medical Sciences Northwest, 2708 S. 48th St., Springdale, AR, 72762, USA
[f] Fay W. Boozman College of Public Health, University of Arkansas for Medical Sciences Northwest, 2708 S. 48th St., Springdale, AR, 72762, USA

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ABSTRACT

Background: Culturally-appropriate family models of diabetes self-management education and support (DSMES) using community health workers (CHWs) have been shown to help address barriers to improving type 2 diabetes mellitus (T2DM) self-management for racial/ethnic minority communities; however, there is limited DSMES research among Marshallese and other Pacific Islanders. Using a community-based participatory research approach, we engaged community stakeholders to co-design a study to implement a culturally adapted family model DSMES (F-DSMES) intervention in faith-based organizations (FBOs) (i.e., churches).

Methods: Using a cluster-randomized controlled trial design, we will assess the effectiveness of the F-DSMES intervention for Marshallese patients with T2DM in Arkansas and Oklahoma. Twenty-four FBOs (with 12 primary participants per FBO) will be randomized to one of two study arms: the intervention arm or the wait-list control arm. Primary participants must have at least one family member willing to attend education sessions and data collection events. The F-DSMES intervention consists of ten h of diabetes education delivered by CHWs over eight to ten weeks. Data will be collected from the intervention arm at pre-intervention (baseline), immediate post-intervention (12 weeks), and three months post-intervention. The wait-list control arm will complete a second pre-intervention data collection before receiving the intervention. The primary study outcome will be glycemic control, as measured by HbA1c. Secondary measures include glucose, weight, body mass index, blood pressure, diabetes self-management behaviors, and diabetes management self-efficacy.

Conclusion: The knowledge gained from this research will inform future DSMES and other health promotion interventions conducted with Marshallese and other Pacific Islander communities.

1. Introduction

The Pacific Islander population is rapidly increasing in the United States (US), with significant growth in rural southern and midwestern states [1]. Arkansas is home to the largest Marshallese community in the continental US with approximately 18,000 migrants residing in Arkansas [1,2]. Oklahoma also has a large Marshallese community with approximately 15,000 Marshallese residents [2].

While Pacific Islanders are underrepresented in health research and prior research has often grouped Pacific Islanders and Asians into a single racial category [3–6], the limited data available document significant health disparities between Pacific Islanders and other racial/ethnic populations in the US [7–13]. According to a Centers for Disease Control and Prevention report, 15.2% of Native Hawaiian and Pacific Islander adults reported a diagnosis of type 2 diabetes mellitus (T2DM), which was higher than the percentages among all U.S. (8.5%), white (7.9%), and Asian (7.9%) adults [14]. For the Marshallese community, estimates of T2DM range from 20% to 40% [15], and T2DM is the

* Corresponding author.
E-mail address: pamcelfish@uams.edu (P.A. McElfish).

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leading cause of premature death and years of life lost in Marshallese patients in the Republic of the Marshall Islands (RMI) [16]. A local needs assessment with Marshallese participants in northwest Arkansas found an extremely high incidence of T2DM (38.4%) and prediabetes (32.6%) [15].

These health disparities are exacerbated by the historical trauma of extensive nuclear testing conducted in the RMI by the US military between 1946 and 1957 [17]. The nuclear testing exposed Marshallese residents on multiple atolls to significant levels of nuclear fallout [17,18]. US scientists studied the effects of the nuclear fallout on the exposed Marshallese individuals in a project called "Project 4.1"; however, study materials were not translated into Marshallese, and participants did not provide informed consent [17]. The nuclear tests also contaminated local fresh water and food sources, which significantly altered the traditional diet of Marshallese [17–19]. Commodity foods such as rice and canned meats provided as aid by the US gradually replaced fresh fish, fruits, and vegetables [20,21], and this became the diet of choice among Marshallese migrants to the US, contributing significantly to their high rates of T2DM [19,20].

Diabetes self-management education and support (DSMES) is an evidence-based intervention that has been shown to improve modifiable risk factors and help patients effectively manage their condition [22–26]. However, positive results are not shared equally across all racial/ethnic groups [27–29]. Marshallese migrants face many social ecological barriers to self-management of their T2DM. Culturally-appropriate family models of DSMES using community health workers (CHWs) have been shown to help address barriers to improving diabetes self-management for African-American, Hispanic, and Native American communities [26–32]; however, there is limited DSMES research among Marshallese and other Pacific Islanders [33,34]. The authors previously developed and tested a family model of DSMES (F-DSMES) with Marshallese participants in Arkansas [35,36]. While the previous study of F-DSMES demonstrated effectiveness with Marshallese in Arkansas when delivered in participants' homes with a Certified Diabetes Educator present, the intervention was very costly. The Marshallese community is highly collectivist, and more than 90% state they attend church regularly. Therefore, the researchers worked with community stakeholders to co-design a study to implement the culturally adapted F-DSMES in faith-based organizations (FBOs).

This paper presents the study protocol for a cluster-randomized controlled trial (cRCT) to evaluate the effectiveness of F-DSMES when delivered in a group setting by CHWs in FBOs with Marshallese T2DM patients in Arkansas and Oklahoma. The study was reviewed and approved by the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (IRB #229034).

2. Materials and methods

2.1. Study aim and design

This study will use a cRCT design to evaluate the effectiveness of F-DSMES among Marshallese and their family members when delivered in a group setting by CHWs in FBOs in Arkansas and Oklahoma. The primary aim of the study is to improve diabetes-related outcomes for Marshallese patients with T2DM.

2.2. Community-based participatory research partnership

The study uses a community-based participatory research (CBPR) approach. CBPR engages community stakeholders and incorporates their collaboration during every stage of the research [37–42]. CBPR makes the research more culturally acceptable and increases the likelihood of sustainability by ensuring that community knowledge informs the research process [43–45]. CBPR encourages research that is equitable and ethical. The CBPR approach will allow the team to utilize contextually- and culturally-situated knowledge, practices, and resources of the Marshallese community. The research team developed strong relationships with 41 Marshallese FBOs through our CBPR approach, which will allow us to facilitate the engagement of social support from the FBOs. Over half of the staff and investigators on the study are Marshallese. Our previous CBPR collaborations with the Marshallese community are published in several articles [35,46–52].

2.3. Sample size, population, and study setting

The cRCT will be conducted at 24 FBOs in Arkansas and Oklahoma. FBOs (i.e., churches) are central to Marshallese culture, and prior needs assessments show that 97% of Marshallese report regular attendance at a church [53]. FBOs in the Marshallese community represent the primary social and hierarchical institution of clan and atoll affiliation with pastors and madam pastors serving respected leadership roles more akin to a chief than strictly a religious leader [53]. Approximately 12 primary participants with T2DM and 12 family members will be recruited from each of the 24 FBOs, for a final sample of 288 primary participants with T2DM and 288 family member participants.

2.4. Recruitment

Recruitment and enrollment of FBOs will be conducted in cycles of six to ten FBOs. FBOs will be recruited and enrolled in four cycles or until we reach our recruitment goal (N = 288 primary participants). Recruitment of FBOs will be conducted by bilingual study staff (Marshallese and English). Staff will contact FBO leadership to determine interest and work with leadership to coordinate informational sessions with FBO attendees. After a FBO agrees to partner, an informational session will be held at the FBO to discuss the study and begin recruiting participants. Eligibility screeners will be completed at informational sessions or any time prior to consent for individuals interested in joining the research study. Research staff will conduct the eligibility screening, which will include a finger stick to determine hemoglobin A1C (HbA1c). If the patient is determined to be eligible per eligibility criteria, the patient will be invited to consent and enroll. All recruitment information will be provided in both English and Marshallese and will use plain language. Both male and female adults are eligible to participate.

2.5. Randomization

Randomization will occur at the FBO-level (i.e., cluster-level) with 1:1 assignment of FBOs to each arm (intervention or waitlist control). FBOs will be enrolled and randomized in cycles as they are recruited and enrolled. Within each cycle, randomization of FBOs will be conducted utilizing a random number generation function. Except for the biostatistician co-investigator who will conduct the randomization, the allocation for each cycle will be concealed from study staff until after the cycle has been recruited and randomized. The biostatistician co-investigator will have no interactions with potential participants and will have no supervisory role over study staff responsible for recruitment or intervention delivery.

2.6. Participant inclusion and exclusion criteria

Marshallese adults (aged 18 or older) with T2DM (defined as having an HbA1c $\geq$ 6.5%) and at least one adult family member willing to participate in all educational sessions and data collection events will be considered eligible for the study as primary participants.

Exclusion criteria include persons who are not Marshallese, have received DSMES in the past five years, plan to move out of the geographic region, or have a condition that makes it unlikely that the participant will be able to follow the protocol. For the purposes of this study, a condition that makes it unlikely to participate in the protocol may also include an illness that would be contraindicative for participation in DSME (e.g., terminal illness, severe mental illness, severely

impaired vision or hearing) and conditions that present health risks for research staff or other participants in the group (e.g., tuberculosis, COVID-19).

For the purposes of this study, a "family member" is defined as someone that lives with or near the primary participant. Family members must be 18 years of age or older to consent and participate.

2.7. Consent

Consent materials will be available in English or Marshallese and presented in the participants' preferred language. Consent materials will use plain language to accommodate differences in literacy levels. The study will be explained using a video consent to ensure a standardized delivery of study information to each participant. If the consent video is unable to be viewed for any reason, bilingual staff will read the consent document with each participant. The consent will allow participants to choose if they consent to: linking their data to other UAMS studies they have participated in, using their de-identified data in future diabetes-related research, and agreeing to be contacted for future research opportunities. Participants will also be asked to consent to a HIPAA release for medical record data abstraction. After potential participants have watched the video of the consent material or read the consent, they will be able to ask bilingual staff members any questions about the study. Finally, they will be given the opportunity to provide consent. Written consent with the participant's signature will serve as documentation. Participants will be asked to invite family members to join the study. Family members who are willing to participate will complete the same consent process.

2.8. Theoretical framework

Integrated Acculturation Theory (IAT) and Social Cognitive Theory (SCT) inform the study's overall conceptual framework [54,55]. IAT conceptualizes the Marshallese migration experience as shaped by an array of barriers and facilitators. Both IAT and SCT emphasize the dynamic and reciprocal interaction between individuals, their environment, and their behavior [54,56]. F-DSMES is designed to increase social support as a mechanism for mitigating migrant-specific challenges and barriers that allow Marshallese migrants with T2DM to improve self-management behavior and ultimately improve health outcomes [54,56]. F-DSMES works to increase the support people receive from their family and increase self-efficacy for both people with T2DM and their family members. The F-DSMES teaches primary participants to recognize how supportive and non-supportive health behaviors affect their self-management, as well as factors in the families' physical environments that serve as facilitators and barriers to behavior change. In the F-DSMES, patients and family members learn, increase motivation, develop strategies, and set goals together. This collaborative learning experience is expected to improve family support and self-efficacy, which will improve self-management behavior and ultimately improve outcomes for the person with T2DM.

2.9. Intervention

Primary participants and family members will participate in ten h of education delivered in eight sessions over a period of ten weeks, with extra time allowed to accommodate for church cancellations, holidays, and make-up sessions. Each session will provide between one and two h of education and will include time after each session dedicated to goalsetting. Group educational classes led by trained Marshallese CHWs will be held at the participating FBOs. The CHWs will utilize an adapted version of the standard DSMES curriculum, which covers all of the Association of Diabetes Care and Education Specialists' seven self-care behaviors: being active, healthy eating, understanding blood glucose and following doctor prescribed medications, reducing risks and healthy coping, problem solving, mitigating complications of diabetes, and goal setting [57].

The cultural adaptation of the standard DSMES curriculum was guided by Bernal's eight dimensions of culturally sensitive interventions to put specific focus on leveraging cultural strengths to overcome migrant-specific barriers to effective self-management [58,59]. Many in the Marshallese community face significant social, economic, and environmental barriers to self-management, including low income, unstable housing, food insecurity, access to healthcare, language, and transportation [53,60–64]. The curriculum is based on a collectivist approach, is conducted exclusively in Marshallese, and uses familiar contexts and analogies such as the role of spirituality, nature analogies, the value of traditional Pacific medicine, and "talk story." [47] The F-DSMES includes family members as secondary participants and focuses on family motivational interviewing, setting goals as a family, and family behavioral change [35,47]. Family members can hinder or aid in a person's diabetes self-management through their attitudes, behaviors, communication, and habits [65–67]. The curriculum is specifically designed to provide participants with education on supportive and non-supportive family behaviors [35,47]. The curriculum aims to increase supportive family member behaviors such as developing a healthy family meal plan, exercising together, and assisting in management activities such as blood sugar checks and taking medications. The curriculum aims to reduce non-supportive family member behaviors such as criticizing and arguing about the person's behaviors, buying and cooking unhealthy foods, and making the person feel that they must manage their diabetes alone. The curriculum is asset-based and works to overcome barriers facing Marshallese participants by leveraging culturally specific facilitators of healthy behavioral change.

2.10. Data collection

Data will be collected from both the primary participants with T2DM and the family member participants. For the intervention arm, data will be collected at pre-intervention (baseline), immediate post-intervention (12 weeks), and three months post-intervention. For the wait-list control arm, data will be collected during the same pre-intervention data collection window as the intervention arm. Instead of receiving the intervention immediately, the control arm will wait 12 weeks and will then participate in an additional pre-intervention data collection event before receiving the intervention. This second pre-intervention data collection will correspond with the post-intervention data collection event for the intervention arm and serve as the post-intervention control data. The control arm will then receive the intervention, and data will be collected at post-intervention and three months post-intervention (Fig. 1).

Data collection events will take place in the FBOs, and all data will be collected by trained bilingual staff. All data collection staff will have prior experience collecting both biometric and survey data. A HIPAA release will be obtained during consent to allow medical record abstraction for UAMS patients at 12, 18, and 24-months post-intervention. Research Electronic Data Capture (REDCap) will be utilized to capture, store, and manage study data [68]. To prevent/minimize missing data, REDCap includes a missing data report in the Quality Assurance tool [68]. This allows convenient quality assurance validation and monitoring as well as prompt collection of missing data.

2.11. Biometric data

The primary study outcome will be glycemic control, as measured by HbA1c. Secondary biometric measures include glucose, weight, height, body mass index (BMI), and blood pressure. Point of Care tests will be used to test HbA1c. Staff will use a Siemens DCA Vantage Analyzer to collect HbA1c via finger prick blood collection [69]. Participants' weight (without shoes) will be measured to the nearest 0.5 lb (0.2 kg) using a calibrated scale. Height (without shoes) will be measured to the

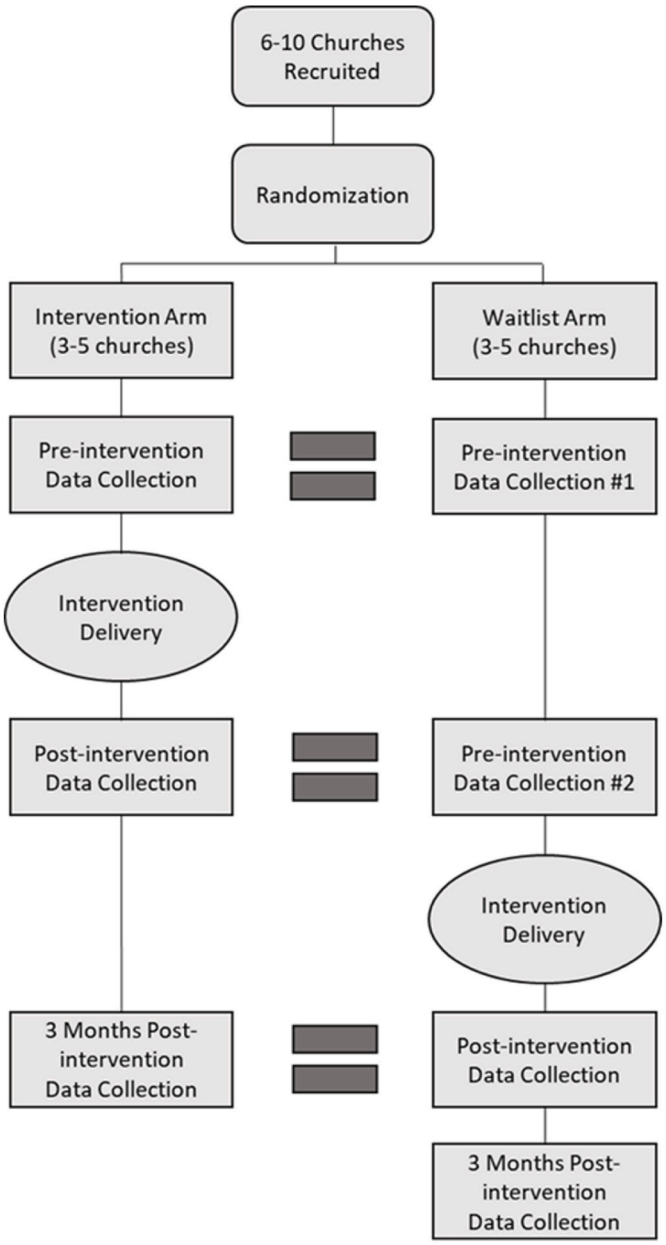

Fig. 1. Illustration of study cycle recruitment, randomization, and alignment of data collection intervals.

nearest 0.25 inch using a stadiometer. Weight and height will be used to compute a continuous measure of BMI (kg/m^2). Blood pressure will be measured using a digital blood pressure device, with the participant seated and arm supported and elevated to place the cuff at approximately heart height. Blood pressure readings will be taken after allowing participants to rest (i.e., seated for at least five min or standing still for one to three min). At least two measurements will be taken, waiting at least 60 s between readings. The average of those two measurements will be recorded as the participant's blood pressure reading. If there is > 5 mmHg difference between the first and second readings, an additional two readings will be obtained, and the average of these four readings will be used [70,71]. Trained study staff will collect biometric data from both primary participants and family members. By collecting biometric data from family members, it will allow us to explore the effects of the intervention on their biometric outcomes as well. If a participants' biometric reading is out of normal/healthy range, study staff will provide referrals to local clinics.

2.12. Survey data

A survey instrument has been developed with input from Marshallese stakeholders that includes internally developed items and scales, as well as items and scales adapted from the Diabetes Care Profile [72] and the Behavioral Risk Factor Surveillance System [73]. Participants will answer different questions in the survey instrument depending on their qualification as 1) a primary participant with T2DM, 2) family member participant with T2DM, or 3) family member participant without T2DM (Table 1). All survey instruments will be translated into Marshallese and presented in both Marshallese and English. The surveys will be administered at the pre-intervention and post-intervention data collection events but not at three months post-intervention. Surveys will either be self-administered or interviewer-administered, depending on the preference and/or literacy of the participant. Bilingual research staff will be present at all data collection events.

Table 1
Study measures for surveys designed for Primary Participants (PP), Family Members without Diabetes (FM), and Family Members with Diabetes (FMD).

Constructs	Participant	Measure/Item Descriptions
Demographic, Socioeconomic, & Household Characteristics	PP, FM, FMD	Age, sex, primary language spoken at home, English speaking ability, marital status, education level, employment status, household size, household income, length of residence in the US, household food security status [74]
Health Status	PP, FM, FMD	Self-reported general health status and prior diagnosed chronic health conditions including hypertension and diabetes
Access to Care	PP, FM, FMD	Health insurance status, having a primary care physician, barriers to primary care, barriers to medication adherence
	PP, FMD	Barriers to diabetic testing supplies
Diabetes-Related Treatments	PP, FMD	Currently taking insulin, currently using a continuous glucose monitor
Diabetes Self-Efficacy	PP, FMD	Diabetes Management Self-Efficacy Scale [75] will capture participants' confidence in performing important self-care behaviors including following a diet plan, engaging in regular exercise, and knowing what to do when blood sugar levels get out of range
Diabetes Self-Care Behaviors/Health Behaviors	PP, FMD	Summary of Diabetes Self-Care Activities (SDSCA) scale [76] and items from the Behavioral Risk Factor Surveillance System's (BRFSS) self-management module and sugar-sweetened beverage module will assess participants' level of engagement in self-care behaviors
Health Behaviors	FM	Subscales of the SDSCA focused on diet and exercise, BRFSS sugar-sweetened beverage module
Diabetes Understanding	PP, FMD	Diabetes Care Profile's Understanding module [72] will capture how well participants understand important concepts including how to cope with stress and the role of exercise in diabetes care
Support for Diabetes Self-Management	PP, FMD	Family and Friend Involvement in Adults' Diabetes (FIAD) scale [77] will capture perceived helpful and harmful friend/family involvement in diabetes self-management
	FM	Family member version of the FIAD will capture family member's assessment of their own helpful and harmful involvement in the PP's diabetes self-management [77]

2.13. Medication data

A list of current medications will be collected at each data collection event to provide consideration of variations in medications during the analytical phase, and changes in glycemic control will be appropriately attributed to the DSME rather than confounding factors.

2.14. Fidelity data

Fidelity will be determined by evaluating 1) fidelity of intervention delivery by the CHW educator, 2) recruitment and retention rates for data collections, and 3) attendance at F-DSMES sessions. Trained study staff will observe intervention sessions using a fidelity checklist to ensure fidelity and adherence to the curriculum. Primary participant and family member enrollment will be tracked and reported weekly as FBOs are being recruited and enrolled. Primary participant and family member retention will be tracked and reported at each data collection event. Attendance of primary participants and family members for each F-DSMES session will be recorded and reported weekly.

2.15. Remuneration

Remuneration will be provided to both primary participants and family member participants. Participants will receive $30 gift cards for data collection events that include collection of both survey and biometric data. For data collection events that do not include the survey (i.e., biometric-only), participants will receive $20 gift cards. Participants will only receive gift cards for the data collection events they attend. Participants included in the intervention arm of the study will be eligible to collect two $30 gift cards and one $20 gift card for a total of $80 for those who participate in all three data collection events. Participants in the wait-list control arm will have one additional data collection event (second pre-intervention) and will, therefore, be eligible to collect two $20 cards and three $30 gift cards for a total of $110 for those who participate in all four data collection events. An additional $20 gift card will be provided to those who attend all of the educational sessions. Participants in the intervention arm attending all data collection events and educational sessions will receive a total of $100 in gift cards. Participants in the control arm attending all data collection events and educational sessions will receive a total of $130 in gift cards.

3. Statistical analysis

3.1. Sample size calculations

All power calculations were conducted with PASS12. Sample size estimates are based on our previous RCT data obtained on the main outcome measure, HbA1c, in the Marshallese population from this region [36]. The previously tested F-DSMES intervention resulted in an HbA1c reduction of 1.09% (NGSP units) (effect size = 0.87) relative to baseline. Assuming a cluster-randomized design, intracluster correlation of 0.01, and significance level $\alpha = 0.05$, sample sizes of 144 primary participants in each treatment arm (12 FBOs x 12 primary participants, accounting for an estimated 20% attrition rate) will achieve greater than 90% power to reject the null hypothesis of equal mean change in HbA1c between groups. We will analytically maximize the use of all collected data by implementing multiple imputation methods that produce valid statistical inferences [78]. For both primary participant and family member outcomes, we have sufficient sample size and power to detect small to medium effects within the proposed design.

3.2. Outcome analyses

Outcomes will be analyzed using all available data from all randomized participants, using either multiple imputed data sets or full-information maximum likelihood (FIML) estimation. We will use Markov Chain Monte Carlo monotone regression-based multiple random imputation of the outcomes by treatment arm using SAS PROC MI, and we will assume that data are missing at random. The analysis will be carried out in multiple data sets, and results will be combined using standard methods (SAS PROC MIANALYZE) to produce summary effect and standard error estimates that incorporate the imputation error. As a sensitivity check, we will also carry out a secondary analysis without imputation or FIML estimation, to compare results from a complete cases analysis.

3.3. Analysis of primary outcome

The primary outcome is change in HbA1c between pre-intervention and post-intervention. We will also evaluate change in HbA1c at three months, 12 months, 18 months, and 24 months post-intervention. Our primary analytic approach will use general linear models (GLM) such as mixed linear regression analysis for continuous repeated measures to model the mean outcome differences and covariance structures between the treatment arms while accounting for cluster-randomized design with repeated measures. Using these models, treatment, time, and interaction effects will be estimated and tested by comparing group-specific means at post-intervention, three months, 12 months, 18 months, and 24 months post-intervention, while conservatively adjusting for additional covariates. The criterion for statistical significance will be $\alpha = 0.05$.

3.4. Analysis of secondary outcomes

Analytic strategies similar to those used to evaluate our primary outcome will be employed to examine the proposed secondary measures. We will examine treatment effects, time effects, and the interaction between them on other measures (blood pressure, fasting glucose, BMI, and survey instrument data) using mixed and general/generalized linear mixed models, depending on the measurement scale of the outcome. Additional analyses will expand the existing multivariate models to include several covariates (e.g., demographics and socioeconomic factors) for adjustments and to examine their associations with the outcomes. Finally, we will examine the association between treatment adherence, such as program participation, and the outcome measures in order to determine the magnitude of impact each additional intervention session has on the change in the outcome (e.g., how much of the reduction in HbA1c is attributed to each additional unit of program participation).

3.5. Mediation analysis

An innovative aspect of the study is the examination of changes in perceived social (family) support as a potential mediator of the effect of F-DSMES on participants' outcomes. Meditation will be assessed by examining the appropriate 95% confidence interval for the indirect effect of F-DSMES on participant outcomes as mediated by perceived social support. Mediation analyses will be conducted using Mplus software [79], and inferences will be made based on a bootstrapped 95% confidence interval.

3.6. Dissemination plan

The data gained from the research will help healthcare providers offer effective DSMES for Marshallese, as well as other Pacific Islander communities. The first priority will be to disseminate results back to participants and their family members. Through an existing CBPR collaborative, the research team will also provide a summary of the results back to the broader Marshallese community, ensuring that primary participant and family member confidentiality is maintained. Study reports will be disseminated to health care providers serving the Marshallese and other Pacific Islander communities. The study reports disseminated to health care providers will also be distributed to national

Pacific Islander advocacy groups and health organizations. Additionally, study results will be used for academic presentations, posters, and publications. These materials will not contain any identifiable information that could be linked to a primary participant or family member.

4. Summary

This study is grounded in a CBPR approach, which engages Marshallese community members in the research process and builds on the relationship that the study team has cultivated with the Marshallese communities in Arkansas and Oklahoma. This study will add to a growing body of literature on family models of DSMES [65,66,80]. This study will provide new and innovative information on the effectiveness of F-DSMES delivered by CHWs in an FBO setting with Marshallese patients with T2DM. The knowledge gained from this research will inform development and implementation of DSMES interventions conducted with Marshallese and other Pacific Islander communities.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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