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Design of a randomized, controlled, comparative-effectiveness trial testing a Family Model of Diabetes Self-Management Education (DSME) vs. Standard DSME for Marshallese in the United States

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ABSTRACT

Background: Type 2 diabetes (T2D) is a significant public health problem, with U.S. Pacific Islander communities—such as the Marshallese—bearing a disproportionate burden. Using a community-based participatory approach (CBPR) that engages the strong family-based social infrastructure characteristic of Marshallese communities is a promising way to manage T2D.
Objectives: Led by a collaborative community-academic partnership, the Family Model of Diabetes Self-Management Education (DSME) aimed to change diabetes management behaviors to improve glycemic control in Marshallese adults with T2D by engaging the entire family.
Design: To test the Family Model of DSME, a randomized, controlled, comparative effectiveness trial with 240 primary participants was implemented. Half of the primary participants were randomly assigned to the Standard DSME and half were randomly assigned to the Family Model DSME. Both arms received ten hours of content comprised of 6–8 sessions delivered over a 6–8 week period.
Methods: The Family Model DSME was a cultural adaptation of DSME, whereby the intervention focused on engaging family support for the primary participant with T2D. The Standard DSME was delivered to the primary participant in a community-based group format. Primary participants and participating family members were assessed at baseline and immediate post-intervention, and will also be assessed at 6 and 12 months.
Summary: The Family Model of DSME aimed to improve glycemic control in Marshallese with T2D. The utilization of a CBPR approach that involves the local stakeholders and the engagement of the family-based social infrastructure of Marshallese communities increase potential for the intervention's success and sustainability.

1. Introduction

Pacific Islanders are one of the fastest growing populations in the United States (U.S.), with the most rapid growth in rural, Southern states such as Arkansas [1,2]. While advances in health sciences have extended the length and quality of life for the general U.S. population, U.S. Pacific Islanders have not shared equally in those benefits [3–7]. Available research indicates that health disparities between Pacific Islanders and other racial/ethnic populations in the U.S. are striking and include significant disparities in several chronic diseases, such as diabetes [7–12].

Despite bearing a disproportionate burden of disease compared to other populations, Pacific Islanders are underrepresented in all types of research, and much of the existing research combines Pacific Islanders and Asian Americans into one racial category, obscuring disparities and constraining health promotion [13–18].

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The disparities and inequities experienced by Pacific Islanders underscore the need to overcome these barriers to research in order to develop culturally appropriate and effective prevention interventions [3,6,7,19,20].

Prevalence of T2D in one growing community of Pacific Islanders in the U.S.—the Marshallese—is among the highest of any population group in the world [21–28]. Estimates of diabetes in the Marshallese population (both populations living in the U.S. and the Marshall Islands) range from 20% to 50% compared to 8.3% for the U.S. population and 4% worldwide [21–28]. The high rates of T2D is due in part to the U.S. Nuclear Testing Program that tested a payload equivalent to 7200 Hiroshima-sized bombs in the Republic of Marshall Islands (RMI) [29–34]. People who inhabited the bombed islands and atolls were relocated. However, Marshallese living on nearby atolls were not relocated and experienced nuclear fallout [35–44]. They subsequently consumed contaminated water, plants, and seafood [31,32,45,46]. The natural food supply on these atolls remains contaminated, and native food consumption throughout the Marshall Islands has been replaced with highly processed commodity foods [32,33]. Nuclear radiation may not have directly caused diabetes; however, the nuclear contamination did result in significant and lasting changes in the diet and lifestyle of Marshall Islanders, which have contributed to an increased rate of T2D [22–25,33,34,47,48].

DSME is a well-documented, evidence-based intervention that has improved the management of T2D [49–55]. Culturally appropriate implementations of DSME have improved diabetes management for some minority groups, including African-Americans and Hispanics [54,56]. However, no one has successfully implemented DSME within the Marshallese population [22,23]. Because of the disproportionate burden of diabetes and related complications experienced by this high-risk population, a novel adaptation of the evidence-based DSME model and subsequent testing in a community-based setting are imperative.

This paper describes the study development, purpose, and methods of a comparative effectiveness evaluation using a randomized control trial design to compare results of the Family Model of DSME with the Standard DSME. Currently the project has implemented the intervention arms but has not completed all of the assessment points, thus the subsequent description will reflect the study's current timeframe.

2. Methods

The Family Model of DSME study is funded by Patient-Centered Outcomes Research Institute (PCORI). The study is approved by the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (#203482) and registered in clinicaltrials.gov (NCT02407132).

2.1. Setting and population

The Compact of Free Association between the Republic of the Marshall Islands (RMI) and the U.S. permits the U.S. to conduct military activities in the RMI and allows Marshallese individuals to lawfully live, work, and study in the U.S. The Marshallese population in the U.S. tripled between 2000 and 2010, from an estimated 6700 to 22,400 [57]. It is expected that within a few decades, more Marshallese will live in the U.S. than in the Marshall Islands [58].

Over the past three decades, the Marshallese community in Arkansas has grown significantly. Arkansas has the largest population of Marshallese in the continental U.S., [59], with ~12,000 Marshallese living in Springdale, Arkansas [21–25,60]. Recent pilot data from 2014-2016 among 401 Arkansas-residing Marshallese showed an extremely high incidence of T2D (38.2%) and prediabetes (32.4%) [28].

2.2. Community-based participatory research partnership

Research points to the advantages of using community-based participatory research (CBPR) to: (1) mitigate barriers caused by historical trauma [61–65]; (2) adapt evidence-based interventions to incorporate Pacific Islanders' cultural values, worldviews, and social dynamics [66–75]; and (3) develop interventions that address both individual and contextual factors [71–75].

Our partnership began in 2012 when the University of Arkansas for Medical Sciences (UAMS) began working with the Marshallese community using a participatory process to understand community assets and needs. After two years of engagement, which included a broad-based mixed methods study and multiple focus groups to document the community's top priorities, the community chose T2D as their top health concern and recommended a family approach to address T2D [76]. Over the past three years, our partnership has conducted several pilot studies related to diabetes beliefs and behaviors [77–84]. Consistent with CBPR principles [85], development of the intervention, study design, and proposed evaluation and dissemination plans were conducted collaboratively between community and academic partners [76,83]. The application of the nine core CBPR principles delineated by Israel et al. [86] in our comparative effectiveness trial is outlined in Table 1.

2.3. Study aims and hypothesis

The primary aim of the study is to assess the comparative effectiveness of a Family Model of DSME intervention compared to a Standard DSME intervention, with the primary outcome of glycemic control (measured by HbA1c) and the secondary outcomes of fasting glucose, waist and hip circumference, body mass index (BMI), blood pressure, and fasting lipids: total cholesterol, LDL, HDL, and triglycerides. The Standard DSME group (standard care) received the Standard DSME in a group format consisting of participants only and delivered in local community settings. The Family Model DSME intervention group received the culturally-adapted DSME in a family group format delivered in the home. Primary participants in the Family Model of DSME group invited family members to join the study and take part in the DSME sessions. We hypothesize that a culturally adapted DSME implemented in a family model will result in better diabetes management outcomes compared to the Standard DSME for the Marshallese.

2.4. Theoretical framework

The project's overall conceptual framework was based on Social Cognitive Theory (SCT) [87]; and social support and network models [88], all of which focus on the dynamic interaction between individuals, their environment, and their behavior. Aspects of behavioral methods addressed the physical environment (e.g., stimulus control for physical activity) and increased social support for behavior change. The project further built on the social environmental components (family) of SCT, and the engagement of social relationships through engaging the family for behavioral diabetes management (e.g., dietary change and physical activity). Engaging and building upon current social networks through involving family members may facilitate changes in community or peer-group norms and promote sustained behavior change. Likewise, engaging family members targeted several components of SCT, including family members serving as models for observational

Table 1
Application of Community-Based Participatory Research (CBPR) Principles [86] in the Family Model of DSME.

CBPR Principle	Application of CBPR Principles in the Family Model of DSME
The community is the unit of identity	The Marshallese community in northwest Arkansas is the unit of identity and is engaged as a partner
The strengths and resources within the community are built upon	The family networks within the Marshallese community and particular cultural beliefs were engaged and built upon through training Marshallese community health workers (CHWs) to deliver the intervention, the incorporation of cultural beliefs in intervention materials, and Marshallese community organizations-led recruitment efforts
There are collaborative, equitable partnerships in all phases of the research	The issue of T2D was initially identified by the community through prior formative work; community investigators meet regularly with academic investigators for all project-related decisions
Co-learning and capacity building is promoted among all partners	Academic partners received formal training in CBPR; community partners received training in research methodology; regular team meetings facilitate co-learning of research principles and community values
The balance between research and action is integrated and achieved	The research question of whether a Family Model of DSME is more effective than a Standard DSME approach for diabetes management is balanced with the action to combat diabetes-related complications in the Marshallese community. The research is conducted in the larger context of our CBPR work that includes programs focused on healthy food access, cultural training for health care providers, and policy reform
An ecological model of health and local relevance of public health problems are emphasized	The issue of T2D was identified by the community as a relevant local public health problem in previous formative work and the research is part of larger policy, system, and environmental efforts that focus on ecological factors of diabetes
Systems development is involved through a cyclical and iterative process	Both academic and community partners underwent CBPR training to strengthen the partnership; regular team meetings where both community and academic partners participate to make project-related decisions facilitate systems development
Findings and knowledge gained are disseminated to all partners and all partners are involved in the data dissemination process	Outcome data will be disseminated through community forums, community information sheets, scientific manuscripts, and scientific conferences

Table 2
Description of Interventions. Consistent with the American Association of Diabetes Educators, both DSME evidence-based interventions covered the topics of 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.

	Family DSME	Standard DSME
Materials and Approach	■ Significant adaptation using Bernal's eight dimensions of culturally sensitive interventions: persons, metaphors, content, concepts, goals, methods, context, and language [91]. ■ Used "talk story" as a conversational, rhythmic, and culturally preferred way of sharing knowledge. ■ Evidence-based DSME curriculum adapted to include: • collective motivational interviewing and collective (family) goal setting • analogies common in Pacific Islander culture and nature in the Pacific Islands (i.e., sea tide and fishing) • culturally-specific concepts and beliefs • culturally-specific nutrition strengths (e.g. fish) and weaknesses (e.g. rice and sweets) and cooking demonstrations • extensive use of anatomical and food models, and hands-on cooking demonstrations	■ Used individual motivational interviewing techniques and individual goal setting. ■ Food models
Mode of Delivery	■ Delivered by a bilingual community health worker with support from a CDE	■ Delivered by a CDE with interpretation from a bilingual interpreter
Dosage	■ 10 h delivered in 75 min sessions over 8 weeks.	■ 10 h delivered in 100 min sessions over 6 weeks.
Participants	■ Primary participants with T2D and their family members	■ Primary participants with T2D

learning and the ability of family members to convey greater salience for behavior change to influence outcome expectations.

2.5. Study design and randomization

To assess the comparative effectiveness of the Family Model of DSME and Standard DSME on glycemic control, a randomized controlled design is being used. A total of 240 primary participants with T2D were recruited. Recruitment and randomization were conducted on a rolling basis in six cohorts.

2.6. Primary participant inclusion and exclusion criteria

Marshallese adults (aged 18 and older) who have a T2D diagnosis by a health care provider were eligible for the study. In the Family Model of DSME arm, primary participants invited an unlimited number of family members to join the study. Family members were 18 or older. Family members were provided the opportunity to consent after the primary participants invited them to take part in the study. The average number of family members who joined was two.

2.7. Primary participant recruitment and retention

Bilingual and bicultural Marshallese staff recruited primary participants from community/church health screenings [28], self-referrals from members of the community who had heard about the study, and referrals from local community health workers, community partners, and local clinics serving Marshallese. Potential primary participants meeting the inclusion criteria were provided information about the study and given the opportunity to discuss the study with bilingual Marshallese research staff. All recruitment information was available in English and Marshallese.

A total of 240 primary participants with T2D were recruited and enrolled, and each primary participant in the Family Model of DSME group was asked to invite family members to join the study, attend the diabetes education sessions, and participate in study assessments. To ensure study retention, primary participants' alternate contact information was collected to be used in follow-up of enrolled primary participants. A $20 gift card was and will continue to be provided as an incentive for both primary participants and participating family members at each of the four data collection events.

2.8. Intervention arms (Table 2)

The Standard DSME consisted of eight core elements: healthy eating, being active, monitoring, understanding blood glucose and taking medication, problem solving, reducing risks and healthy coping, mitigating complications of diabetes, and goal setting. The eight core elements were consistent with the American Association of Diabetes Educators' (AADE) seven self-care behaviors. The Standard DSME included ten hours of content delivered in six sessions. The sessions were delivered over a 6-week period and each session was approximately 100 min in length. The Standard DSME was delivered by a Certified Diabetes Educator (CDE). In addition, a translator/interpreter fluent in both English and Marshallese was present for every session. Sessions were provided at a local non-profit organization that was familiar to participants and within easy reach of the target population. A total of 8–14 primary participants were assigned to each Standard DSME group session with the average standard group at 12 participants. Family members of the participant were not invited to the education sessions.

The Family Model of DSME shared the same number of content hours (10 content hours) and covered all of the AADE topics but delivered eight sessions over an 8-week period, with each session approximately 75 min in length. The Family Model of DSME was also delivered by a bilingual and bicultural community health worker with a CDE available for consultation to answer any questions. The Family Model of DSME predominately differed from the Standard DSME in delivery and content. Community partners collaborated with academic partners to adapt the DSME intervention to create a culturally adapted Family Model of DSME. The adaptations were based upon focus groups (n = 41) and pilot studies regarding Arkansas Marshallese's diabetes beliefs and behaviors [77–79,82], in addition to a broad literature review of previous health behavior interventions conducted with Pacific Islander groups [89]. Each lesson of the Family DSME included an educational module, a personal testimony about the topic from a community member, and goal setting. Specific cultural components were recommended for adapting the seven key components of the DSME curriculum. Cultural considerations included the dichotomous (vs. gradient) conceptualization of ideas, the importance of engaging the entire family, the use of nature analogies, the role of spirituality, the value of 'pacific natural' medicine, and a collectivistic orientation. The Extended Family Model DSME engaged family members to facilitate change in the primary participant; primary participants were allowed to include family members in intervention sessions. Details on the lessons and cultural adaptations are published in a separate manuscript [90]. In addition to the content, the Family Model of DSME differed from the Standard DSME in intervention delivery. The educational sessions were delivered by a bilingual and bicultural community health worker with a CDE available for consultation to answer any questions. The intervention was delivered in the home with the primary participant and their invited family. A total of 120 primary participants and 241 family participants were present for each group Family DSME session.

2.9. Measures

Data collection visits are scheduled at a time convenient for the participants and do not take place as part of the DSME sessions. Primary participants and participating, consented family members are asked to fast for 12 h prior to data collection. Biometric measures and survey instruments are collected by trained study staff. All measures have been assessed at baseline and immediate post-intervention follow-up 9 weeks, and will also be assessed at 6 months and 12 months.

Sociodemographic factors are assessed by self-report and include gender, age, education, marital status, employment status, income, and household size [92].

Change in HbA1c from baseline at post-intervention, 6 months, and 12 months is the primary endpoint. Through a finger prick blood collection, HbA1c is assessed using a Rapid A1c test kit and Siemens DCA Vantage Analyzer.

Biometric measures and other diabetes-specific outcomes are secondary endpoints. Participants are asked to fast for 12 h prior to data collection. Through a finger prick blood collection, point of care tests are used to test: Fasting glucose using glucometer and fasting lipids using a commercial lipid panel kit and Cholestech LDX. Participants are measured in light clothing to the nearest 0.5 lb (0.2 kg) using a calibrated digital scale. Height (without shoes) is measured to the nearest 0.5 cm using a stadiometer. Weight and height are used to compute a continuous measure of BMI (kg/m^2) [93]. Waist and hip circumference are measured to the nearest quarter inch utilizing an electronic measuring tape. Waist to hip ratio is calculated. Systolic and diastolic blood pressure is measured with the participant seated and arm elevated using a sphygomometer and stethoscope.

Health status is assessed through a 10-item measure with questions selected and adapted from the SF-36 and BRFSS [92,94], whereby participants were asked their self-reported health status, to generally rate their health, health professional diagnoses of up to 13 health conditions, self-reported fatigue, and activities limited by health. Light, moderate, and vigorous physical activity is assessed by a 7-item measure [95]. Intake of healthy and unhealthy foods is assessed through a 16-item measure [96]. Health-care access is assessed by a 13-item adapted version of the BRFSS healthcare module [92]. Diabetes care is assessed through the 9-item BRFSS Diabetes Care Module [92]. Understanding of diabetes and support for diabetes management are assessed by an adapted version of the support scales of the Diabetes Care Profile (DCP), which assesses the social and psychological factors related to diabetes and its treatment [97–99].

2.10. Evaluation

2.10.1. Sample size calculations

All of the power and sample size calculations and estimations were performed using PASS12 (NCSS, LLC. Kaysville, Utah. www.ncss.com). Our study design is a randomized two-group construct with 4 repeated time points (baseline, post intervention, 6 months, and 12 months). So at its core, the study is a two-factor design with repeated measures over time, which can be expanded into a general linear regression model, with main covariates being group assignment, time, and their interaction, with adjustment for other covariates. The sample size of 240 with 120 in each arm will achieve 80% power to detect a small to medium effect of 0.3 in a design with 4 repeated measurements having an assumed compound symmetry covariance structure. The correlation between observations on the same subject is assumed to be of moderate magnitude at 0.5, and the alpha level is 0.05. This hypothesized detectable effect is of the same magnitude as a study that reported approximately 0.5%

change in HbA1c with the standard deviation of the change being 1.5% [100].

2.10.2. Outcome analyses

All of the analyses are going to be conducted using SAS/STATv14.1 (SAS Institute Inc. Cary, NC. www.sas.com). Preliminary analyses will include the generation of descriptive statistics and assessment of group differences at baseline, as well as examination of distributions, treatment drop-out, and missing data patterns' impact on treatment effects. Univariate comparisons of baseline characteristics between the two groups are going to be performed using two sample techniques such as a two-sample *t*-test and chi-square test; however, if the distributional or other assumptions have been violated we are going to use non-parametric alternatives, like Wilcoxon Rank Sum test, and/or Fishers exact test.

2.11. Analysis of primary outcome

The primary outcome is change in HbA1c between baseline, post intervention, 6 months post-intervention, and 12 months post-intervention. Repeated measures of these outcomes will be obtained at four visits as described. Our primary analytic approach will use general linear models (GLM) and mixed models for continuous repeated measures to model the mean outcome differences and covariance structures between the treatment groups. Using these models, group effects will be estimated and tested by comparing group-specific means at post intervention, 6 months, and 12 months, while conservatively adjusting for the baseline differences in ANCOVA-like mixed regression models.

2.12. 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 group effects, time effects, and the interaction between them on other measures (fasting glucose, % weight loss, BMI, waist-hip ratio, lipids, and survey instrument data) using mixed and general/generalized linear ANCOVA like mixed models or general estimating equations (GEE), depending on the measurement scale of the outcome. Additional analyses would expand the existing multivariate models to include several other covariates for adjustments as well as to examine their associations with the outcomes. Demographics and socioeconomic factors will be included for conservative adjustment if not comparable between conditions.

2.13. Missing data

Analyses of our primary outcome variable (mean differences in HbA1c between groups) will be done in accordance with the intent-to-treat principle. That is, data from all randomized participants will be analyzed regardless of compliance with study protocol or failure to complete the study. For this reason, we propose to impute the missing data using SAS PROC MI and its inbuilt MCMC algorithm, which is the most appropriate imputation method for the arbitrary missing data mechanism. If the data are missing according to non-ignorable mechanism, alternative imputation mechanisms will be considered. Imputed data will be combined and analyzed using SAS PROC MIANALYZE in order to generate appropriate estimates and their standard errors.

2.14. Data dissemination plan

Dissemination and implementation are crucial to achieving research impact. In addition, there is a social responsibility to disseminate and implement findings in participatory partnerships. The findings (including results, best practices, and challenges) will be disseminated to appropriate stakeholder groups and target adopters. The first priority of a dissemination and implementation plan is returning results to study participants. Research participants will be given a written report of their individual results as well as the study's aggregated results, using easy-to-understand language. Research participants will also be invited to oral presentations employing visual aids to communicate research findings and asked to provide feedback on research findings.

We will also disseminate information to the target adopters: health clinics and healthcare providers to the Marshallese and other Pacific Islanders who may want to offer DSME to these communities. The findings are important to these healthcare providers because they will provide new information on effectively implementing DSME for the Marshallese. The information will also be informative to other Pacific Islanders. Given that diabetes rates for the Marshallese and other Pacific Islanders are among the highest in the world [21], and that more Marshallese are entering the U.S. every year, healthcare providers and diabetes educators across the U.S. will view these new findings as relevant and timely for improving their work. Healthcare providers and diabetes educators to the Marshallese have been involved in the research plan from early on and will guide dissemination and implementation so that it is accessible and relevant to target adopters.

We will also share the results of our study with trusted individuals and organizations within the Marshallese and Pacific Islander communities. Locally, this includes Marshallese pastors, Marshallese Task Force, and Arkansas Coalition of Marshallese. Nationally this will include the Pacific Islander Health Partnership, National Coalition for Asian Pacific American Community Development (NCAPACD), and other advocacy and health organizations. The Marshallese prefer word-of-mouth ("talk story") and social media, particularly Facebook, for sharing information [60,101]. We will capitalize on these preferred communication tools to share research findings and engage in dialogue on how to best translate findings into practice.

3. Summary

The Family Model of DSME is the culmination of a four-year collaborative partnership between community and academic partners, whereby the community identified the issue of T2D, co-led the pilot studies upon which the Family Model of DSME was built, and co-created the design of the current large-scale trial. The trial builds upon the well-documented DSME, which has improved T2D management in majority and minority groups [49–55,102]. However, to the authors' knowledge, DSME has not been successfully implemented in a U.S. Marshallese community.

Reddy et al.'s DSME study with Marshallese reported 100% attrition and closed their DSME sessions in Oahu early due to lack of participation [103]. A later study conducted by the same research team with Marshallese living on the island of Ebeye were unable to document significant improvements in glycemic control [104]. Neither of these studies built on the strong family networks within Marshallese communities to address the disproportionate rate of T2D in this understudied population. This study builds on a growing body of literature supporting family-based, culturally-adapted diabetes interventions for positive effects on a range of diabetes outcomes [105–112].

This study also builds upon an emerging body of literature on family-based DSME [113–115], whereby family members are included to improve a range of diabetes outcomes for both primary participants and their family members [113,114]. This study is significant because it will be generalizable to a reasonably

large segment of at-risk individuals living in the U.S [21–27]. Furthermore, the results are likely to be applicable to other U.S. Pacific Islander communities, one of the fastest growing U.S. populations [2].

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