Study Title: **Family Model of DSME in the Marshallese Community**

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Background and Rationale

The Marshallese population suffers from a significant and disproportionate burden of type 2 diabetes. The rate of type 2 diabetes among the Marshallese is one of the highest of any population group in the world—at least 400% higher than the general US population.[1-7] Our systematic review of local, national, and international data found estimates of diabetes in the Marshallese (populations living both in the US and Marshall Islands) ranging from 30% to 50% compared to 8.3% for the US population and 4% worldwide.[4-7] Causes for this disparity have not been completely unraveled and are partially embedded in the history of the Marshall Islands. Between 1946 and 1958, the US military tested nuclear weapons on several of the Marshall Islands. People who inhabited the bombed islands and atolls were relocated, but Marshallese living on nearby atolls that were not evacuated experienced nuclear fallout during and after nuclear tests. Because of the nuclear testing, the Atomic Energy Commission lists the Marshall Islands as one of the most contaminated places in the world, and several studies demonstrate ongoing health effects from the nuclear testing.[8] The nuclear contamination resulted in significant and long-term changes in diet and lifestyle of the Marshallese.[9-12] These changes in diet and lifestyle have contributed to an increased rate of type 2 diabetes.[2-5,16-19] The Compact of Free Association between the Republic of the Marshall Islands (RMI) and the US, signed in 1986, permits the US to conduct military activities in the Marshall Islands and also allows Marshallese individuals to come to the US without a visa. The Marshallese population living in the US tripled between 2000 and 2010, with Arkansas having the largest population of Marshallese living outside of the RMI.

Diabetes self-management education (DSME) is an evidence-based model that has been shown to improve glycemic control, reduce diabetic complications, and reduce the cost of managing diabetes. Traditional implementation approaches of DSME have not been effective in Marshallese populations, indicating that a unique approach tailored to this population is needed.[2-3] 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 needed.

Using a CBPR approach, we have conducted four focus groups and individual interviews with the Marshallese community to better understand how to best address the well-established need for diabetes education. Through interviews and focus groups, Marshallese participants pointed out that the delivery method and the concept of self-management as an individual experience are problematic components. DSME was designed with a very Western societal approach, which is highly individualistic. The Marshallese have a highly collectivist culture and the idea of self-management is counter to their cultural values. As stakeholders described, we eat together from one pot. For one person to refuse the food from that one pot is not just inconvenient, it is shameful. It shames the person and the person's family. It is not an acceptable option. We will not do it. The interviewees stated that any changes must be a family change. Incorporating

collectivist and family concepts into the delivery mechanism is imperative. Through the interviews and focus groups, the Marshallese community suggested that DSME be implemented within a family model with a family group receiving DSME so that the entire family can benefit and the patient can be supported in their effort to make lifestyle changes. Because ~30-50% of the Marshallese community have type 2 diabetes, this approach could be even more beneficial.

Hypothesis and/or Specific Aims or Objectives

We hypothesize that a culturally adapted DSME implemented in a family model will result in better diabetes management outcomes compared to traditional DSME for the Marshallese.

In the family delivery model, a participant is encouraged to invite his/her family members to the diabetes educational sessions. As outlined by stakeholders, the model has several potential benefits. First, patients are empowered to invite the people they define as family and as appropriate for taking part in the sessions with them. Second, the education will engage the patient-defined support unit. Third, given the high rate of diabetes within the community, it is highly probable that others within the group will have Type 2 diabetes or pre-diabetes and may benefit from the intervention as well.

Our aim is to test a Family Model of DSME using a mixed-methods approach. Marshallese participants with type 2 diabetes will be recruited. Those who are assigned to the family model will be asked to invite one to ten adult members of their families to participate in the DSME. Given that ~30-50% of adults in the Marshallese community have type 2 diabetes, and the Marshallese typically have large families, recruitment for this nontraditional model is plausible. Furthermore, the method was designed from input from our CBPR partnership with the Marshallese.

This research is highly translational. It will help bridge the gap between knowledge of an effective DSME intervention and actual implementation of the intervention among a Pacific Islander population with especially high rates of type 2 diabetes and significant health disparities.

Study Design and Procedures

We will conduct a comparative effectiveness evaluation using a randomized control trial design of the adapted Family Model of DSME, and compare results of the Family Model of DSME with traditional DSME within the Marshallese population. The family model will cover the same concepts as the traditional format. However, the family model will incorporate culturally-adapted education and recommendations aimed at engaging family members in the management of the primary participant's diabetes, and family members will be invited to fully participate in the study. By contrast, the traditional model provides diabetes self- management education to the diabetic participant only, and the participant's family members do not participate in the classes or any other part of the

study. Biometric and survey data will be collected pre-intervention, post-intervention, 6 months post-intervention, and 12 months post-intervention. In the event missing data is identified, participants will be contacted to collect the missing data. A qualitative debriefing session will be held for each family between the final DSME session and the 6 month post-intervention to obtain qualitative data regarding the participant's perceptions of the intervention and implementation process. Participants will be offered a $20 gift card as compensation for their time for each biometric data collection event and the qualitative debriefing session.

Randomized participant assignment. Six cohorts will be recruited, approximately three months apart. Each cohort will be comprised of 75 participants with diabetes, with 50% being assigned to the Family Model arm and 50% being assigned to the traditional DSME control group. The study sample size will be the total of each cohort; thus a total of 300 diabetics and up to 2000 family members (only those in the family model arm will be inviting family members). We initially chose an unequal group design (70/30), but after assessing Cycle 1 attrition, we needed to adjust the ratio in order to have sufficient control group numbers for analysis. Discussion with stakeholders resulted in support for this modification. Each participant will be randomly assigned to a group after consent.

Randomization will occur at the family level rather than the individual level. Prior to randomization, consented participants will be grouped according to family unit to prevent two diabetics in the same family being randomly assigned to different groups, creating cross-contamination. Once an entire cohort is recruited and assigned a family identification number, each number (family) will be randomly assigned to a study arm. Randomization will be conducted utilizing the Excel random number generation function. Randomization will be conducted by an investigator who will have no interactions with potential participants and has no supervisory role with program staff responsible for recruitment consent, or intervention delivery. Designated study staff will send the investigator a list of consented participants prior to the start of each new DSME cycle. The investigator will deliver the study arm assignments to a designated study staff member at the project site. Participants will be notified of their group assignment at least one week prior to commencement of study activities.

Study arms description. The standard care group will receive traditional DSME in a group format. However, those in the standard group will attend classes with other un-related participants, unless two or more diabetics within the same family get assigned to the control group. The intervention group will receive the adapted Family Model of DSME in a family format, as described above. Participants in the Family Model will be encouraged to invite one to ten family members to participate in the DSME sessions as well as all other study events.

Intervention: Both the Family Model and the traditional DSME will include 10 hours of content comprised of 8 modules. The classes will be delivered over a 6-10 week period and each class will be approximately 75 minutes in length. To ensure fidelity, the DSME programs in both study groups will be facilitated by a Certified Diabetes Educator (CDE) or other licensed healthcare professional with expertise in the content areas. A translator/interpreter fluent in both English and Marshallese will be present for every

session. The family model intervention will be co-facilitated by a Certified Diabetes Educator or other licensed healthcare professional and a Marshallese staff person fluent in both English and Marshallese. The core elements of DSME intervention are: 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. These core elements will be maintained across both groups and are consistent with the American Association of Diabetes Educators' AADE seven self-care behaviors. Sessions will be provided at the Springdale AHEC clinic, the Jones Center, or at a location of the participant's choice.

Biometric Data

The primary study outcome will be glycemic control as measured by HbA1c. Secondary biometric measures include: fasting glucose, waist and hip circumference, weight, height, BMI, blood pressure, and fasting lipids: total cholesterol, LDL, HDL, and triglycerides. HbA1c, fasting glucose, and fasting lipids will be collected via finger prick, measured using portable equipment, and immediately discarded after results are recorded. The biometric collection will be completed by qualified, trained research staff. A translator/interpreter will be present for each biometric collection.

Survey Data

We have developed a survey instrument that includes modules from the Diabetes Care Profile (DCP), the Behavioral Risk Factor Surveillance Survey (BRFSS), and internally developed modules pertaining to diet and physical activity. We will also collect demographics, contact information, and a medication inventory using study specific forms. The documents will be translated into Marshallese and field tested by the study's Marshallese Community Advisory Board. These surveys/forms will be administered at the pre-intervention data collection events and all post- intervention data collection events. All surveys will be either self-administered or interviewer-administered, depending on the preference and/or literacy of the participant. A Marshallese translator/interpreter will be present for all DSME sessions and data collection events.

Table 1. Data Collection and Survey Instrument Description	
Biometric Measures	Biometric measures will include: HbA1c, fasting glucose, waist and hip circumference, weight, height, blood pressure, and fasting lipids: total cholesterol, LDL, HDL, triglycerides. Standardized protocols will be utilized for biometric measures. Waist and hip circumference will be measured to the nearest quarter inch utilizing a standard measuring tape. Waist to hip ratio will be calculated. Weight will be measured without shoes on a digital scale. Height will be measured without shoes to the nearest quarter inch. BMI will be calculated using weight and height measurements. Systolic and diastolic blood pressure will be measured with participant seated and arm elevated using a Sphygmomanometer and stethoscope or digital blood pressure monitor. Participants will be asked to fast for 8 hours prior to data collection. Point of Care tests will be used to test HbA1c, fasting glucose, and fasting lipids: total cholesterol, LDL, HDL, and triglycerides. Through a finger prick blood collection, we will test: 1) HbA1c using a Siemens DCA Vantage Analyzer. 2) Fasting glucose using the Cholestech LDX, 3) Fasting lipids using a commercial lipid panel kit and Cholestech LDX.
PCORI DSME Survey Instrument	A 43 item questionnaire that contains a total of seven modules: demographics, health status, health behavior, BRFSS diabetes, understanding, support, and health care access.
Participant Contact Form	This form is completed at consent to collect all relevant contact and address information as well as contact permissions, in order to schedule and administer study activities. Form will be updated as necessary.
Medication Inventory	A list of current diabetes medications will be collected at each data collection event so that we can control for variations in medications during the analytical phase and be better able to attribute changes in glycemic control to the DSME rather than confounding factors.

Estimated Study Calendar

Table 2: Milestones		
YEAR 1		
Milestones	Description	Approximate Dates
Recruitment and random assignment of participants	Recruitment and random assignment will begin during the second quarter of year one and continue throughout the year.	04/30/2015
Intervention sessions and data collection events completed	The intervention sessions will begin during the second half of year one, with approximately 53 participants from the intervention (plus family participants) and 22 control participants will complete the intervention and pre-post-data collection events.	04/30/2015
YEAR 2		
Recruitment and random assignment of participants.	Recruitment and random assignment will continue through the first half of year two.	10/31/2015
Intervention sessions and data collection events completed	The intervention sessions will continue throughout year two, approximately110 primary participants (plus family participants) and 50 control participants will complete the intervention and pre-post-data collection events. 6 and 12 month data collection events will be completed for year one participants.	04/30/2016
YEAR 3		
Data analysis	Collaborative analysis of data with stakeholders.	04/30/2017
Collaborative Dissemination	Collaborative dissemination of results back to the community.	04/30/2017

Study Population

Recruitment and Consent: There are ~11,000 Marshallese living in Springdale, Arkansas. Using conservative estimates, 3,000 of the Marshallese living in Springdale, Arkansas have type 2 diabetes, providing a sufficient participant pool for recruitment.[1-5,37] Participants will be recruited through the three primary clinics that care for the Marshallese—the Community Clinic (a Federally Qualified Health Center), the Springdale Family Medical Center, and the Dr. Bates Outreach Clinic in Springdale. In addition, participants will be recruited through local Marshallese churches, community leaders, and Yokwe.net, the primary social media site for the Marshallese community. A more detailed recruitment plan is outlined in the following section. Potential participants will be provided information about the study and given the opportunity to take a brief eligibility screener that determines and documents study eligibility. Up to 300 participants with diabetes (initial participants) will be recruited and enrolled, and each participant in the

treatment group will be asked to invite between one and ten family members to attend the diabetes education sessions and potentially join the study. All members of the research team will be trained and certified in participant consent procedures, the study protocol, human subjects protection, and HIPAA regulations. During the presentation/discussion of the study, potential participants will be screened for eligibility. Inclusion/exclusion criteria are as follows:

Initial Participant Inclusion Criteria

- 18 years and older
- Self-reported Marshallese ethnicity or descent
- Self-reported Diabetes Mellitus Type 2 diagnosis by a health care provider

Initial Participant Exclusion Criteria

- Younger than 18 years of age
- Not Marshallese ethnicity or descent
- No reported Diabetes Mellitus Type 2 diagnosis

Family Member Inclusion Criteria

- 18 years and older

Family Member Exclusion Criteria

- Younger than 18 years of age

Potential participants who are interested in joining the study will be provided the opportunity to ask questions, consent and enroll in the study. At enrollment, a participant contact information form will be completed and include participant contact information (phone numbers, address, e-mail), preferred method of contact (i.e. text, phone, mail, e-mail), and demographic information.

Recruitment Plan. Identified, recruited, and enrolled: Marshallese recruitment staff will be employed to conduct the study. Participants will be recruited through provider referrals from the three primary clinics that care for the Marshallese: Community Clinic (a Federally Qualified Health Center), the Springdale Family Medical Center, and the Dr. Bates Outreach Clinic in Springdale. In addition, participants will be recruited through local Marshallese churches, community leaders, our Community Advisory Board, community health events, and Yokwe.net.

In the clinical setting, potential participants who meet the enrollment criteria will be identified by their healthcare provider. All potential participants meeting the inclusion criteria will be systematically provided information about the study and given the opportunity to discuss the study with a Marshallese research staff member. To reduce selection bias and ensure we reach persons who may not have a primary care provider

(there is a low rate of insurance and medical homes among the target population), we will also recruit from local Marshallese churches.

For recruitment in the churches, we will distribute recruitment information, which will include the purpose of the study, the PI, sponsor, and inclusion criteria. Study information will be distributed in both English and Marshallese. Marshallese recruitment staff will also give a presentation about the study at churches after religious services. While this method of recruitment may seem unconventional, we have successfully used it to engage the Marshallese community, and our CBPR group believes it is the most culturally appropriate way to recruit.

At targeted community and health events, we will set up a booth and provide informational materials as well as be available to discuss the study in more detail. If potential participants are interested in enrolling in the study, they will complete a form that captures contact information and a meeting will be set up so that the consent process can take place in private.

We will also provide a dedicated e-mail address and phone lines for any interested community members who hear about this study through community leaders, Marshallese Community Advisory Board members, and Yokwe.net to learn about and participate in the study.

Participants and family member measures. As discussed above, the participants assigned to the treatment group will be asked to invite between one and ten family members to join them for the education sessions. Family members may or may not have Type 2 diabetes. Family members will be provided the opportunity to consent after the initial participants have invited them to take part in the study. Primary analysis will be based on the participants with diabetes. In addition, we will collect and analyze the outcomes of the family participants who have consented and report any value added by including outcomes of family members. We will collect biometric and survey instrument data on family members who consent and participate. If family members are found to have elevated HbA1c during the data collection but have not previously been diagnosed with diabetes, we will refer them to a health care provider.

Primary participant's diabetes status will be confirmed by their HbA1c at the time of initial data collection. Primary participants who do not have HbA1c results indicative of diabetes, 6.5 or above, will be unenrolled from the study as primary participants. If they were randomized into the family arm of the study and another family member does have HbA1c results indicative of diabetes, participation of the entire family unit (including with an HbA1c less than 6.5) will continue.

Risks and Benefits

Potential risks to study participants are minimal and no greater than usual care or standard health screenings. There is a potential risk for loss of confidentiality. Measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section below.

The DSME has the potential to benefit participants by fostering better disease management activities and improving health and quality of life. In addition, knowledge gained from the study could impact future delivery of DSME to minorities and underserved populations.

Data Capture

The study team will utilize an electronic database to capture study data. Survey instrument responses will be captured with paper and pencil instruments (PAPI). All surveys will be available in English or Marshallese and then entered into the database. A translator/interpreter will be available to assist participants. Biometric data will be collected and recorded in the database. Upon entry into the study, each participant will be assigned a participant identification number and registered to the study.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject material will be assigned a unique identifying code or number. Only study investigators and analytical and quality assurance staff will have access to the code and information that identifies the subject in this study. All hard copies of study materials will be kept in a locked file and the key to the participant codes and any electronic data will be stored on a secure, encrypted server.

Data Analysis

Sample size and power considerations
All of the power and sample size calculations and estimations were performed using PASS 2008 (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, which can be expanded into a general linear regression model, with main covariates being group assignment, time, their interaction, and adjustment for other covariates. The sample sizes will achieve 80% power to detect a medium effect of 0.3 in a design with 4 repeated measurements having a 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.[38-39] 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%.

Statistical Analysis
All of the analyses are going to be conducted using SAS v9.3 (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.

Comparison 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. Additional statistical analyses and considerations follow.

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 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.

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.

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.[40-41] 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.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. All subjects for this study will be provided a consent form describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their participation in this study. A translator/interpreter will be available for the consent process. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a private setting (e.g. participant's home, the UAMS office at the JTL Shops in Springdale, or the UAMS offices in Fayetteville) of the participant's choice and subjects may take as much time as needed to make a decision about their participation. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject and the individual obtaining the consent. A copy of the consent will be given to the participant, and the informed consent process will be documented in each subject's research record.

Dissemination of Data

The data gained from the proposed research will help providers offer effective diabetes self-management programs, and care plans for the Marshallese and further research on diabetes among the Marshallese. Our first priority will be to disseminate results back to participants. Through our CBPR collaborative, we will also provide a summary of the results back to the Marshallese community, ensuring that participant confidentiality is maintained. Additionally, results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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