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Family model diabetes self-management education and support in faith-based organizations in the republic of the Marshall Islands study protocol

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ABSTRACT

Background: Marshallese living in the Republic of the Marshall Islands (RMI) experience significant health disparities, with high rates of type 2 diabetes mellitus. In addition to health disparities, the RMI experienced nuclear testing that exposed inhabitants to nuclear fallout, unethical research practices, and contaminated natural food sources.

Objectives: This research uses a community-based participatory research (CBPR) approach to effectively engage community partners and honor their contributions in all stages of the research. A CBPR approach will leverage culturally situated knowledge and practices of the Marshallese community in the RMI to ensure the success of the research.

Methods: This manuscript describes the methods used to test the feasibility of delivering a culturally adapted family model of diabetes self-management education and support in faith-based organizations in the RMI.

Conclusions: This manuscript describes the protocol for creating working with community partners and implementing a feasibility study in the RMI.

1. Introduction

The Republic of the Marshall Islands (RMI) is an independent United States Affiliated Pacific Islands (USAPI) nation with a population of 77,917 [1]. The RMI signed a Compact of Free Association (COFA) agreement with the United States (US) in 1986 that allows Marshallese residents to live, work, and travel to the US without the need for visa or work certification, and it provides the US with an exclusive lease and control of a military base in a strategic Pacific location [2]. The Marshallese population in the RMI face significant health disparities with especially high prevalence rates of type 2 diabetes mellitus (T2DM) [3–8]. Diabetes among Marshallese adults in the RMI (33.8%) is significantly higher than global (9.3%) and US (13.3%) rates [9]. The International Diabetes Federation ranks the RMI as the country or territory with the highest age-adjusted comparative diabetes prevalence in adults (30.5%) for 2019 [9].

These health disparities are exacerbated by the historical trauma of nuclear testing conducted in the RMI by the US military between 1946 and 1958 [10]. The nuclear testing exposed many Marshallese to nuclear fallout, and impacted the natural environment [10,11]. American scientists studied the effects of nuclear fallout on humans in the RMI with Project 4.1; however, study materials were not translated into Marshallese and participants did not provide informed consent [10]. In addition, these nuclear weapons tests contaminated local food sources and significantly altered the traditional diet of Marshallese [10–12]. Commodity foods such as rice and canned meats replaced locally sourced fresh fish and fruits and vegetables [13,14]; and as a result,

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Marshallese transitioned to a diet high in simple carbohydrates and fat and low in fresh fruits and vegetables [12,13].

Diabetes self-management education and support (DSMES) is an evidence-based intervention that can improve risk factors, help patients effectively manage their condition, and is critical for persons with diabetes [15–19]. However, positive results are not shared equally across all racial/ethnic groups [20–22]. Culturally-appropriate family models of DSMES using community health workers (CHWs) have been shown to improve diabetes self-management for African-American, Hispanic/Latinx, and Native American communities [19–25]; however, there is limited DSMES research among Marshallese and other Pacific Islanders [26, 27]. There has been one published study of DSMES in the RMI, which was unable to document improvements in glycemic control or other diabetes-related outcomes [28]. Given the epidemic of T2DM in the RMI, it is critically important to determine an effective DSMES intervention and to broadly disseminate and implement the intervention.

The authors developed and tested a culturally adapted family model of DSMES (F-DSMES) with the Marshallese community in Arkansas [29,30]. The F-DSMES intervention was delivered to primary participants and at least one of their family members. The intervention was delivered in primary participants' homes by a bilingual CHW with a certified diabetes educator (CDE) present. The F-DSMES demonstrated effectiveness compared with standard DSMES delivered by CDEs in a group setting [31,32]; however, the methods used in this previous trial may not be directly transferable to the RMI. The RMI lacks the resources to deliver standard DSMES effectively due to a lack of CDEs in the RMI. Furthermore, the size of most homes in the RMI is not conducive to family education. As a result, the present study has several important differences from the prior F-DSMES trial conducted in Arkansas. First, the F-DSMES intervention will be delivered by trained CHWs without a CDE present. Second, the intervention will be delivered in faith-based organizations (FBOs) rather than in participants' homes. Finally, the study will take place in the RMI, not in the US.

This paper presents the study protocol for a pilot evaluation of the F-DSMES. All study procedures were approved by the University of Arkansas for Medical Sciences Institutional Review Board (IRB #239272).

2. Materials and methods

2.1. Study aims and design

This study will evaluate the preliminary feasibility, acceptability, and effectiveness of F-DSMES among primary participants and their family members when delivered by CHWs in the RMI. The pilot study will be a one-arm trial with outcomes measured at baseline (pre-intervention) and follow-up (immediate post-intervention, four months post-intervention, and 12 months post-intervention).

2.2. Community-based participatory research

This study will utilize a community-based participatory research (CBPR). CBPR fosters research that is equitable and ethical [33–35]. A CBPR approach is especially important given the historical trauma experienced by the Marshallese people. This trauma comes from their experience with the nuclear weapons tests conducted in the RMI by the US military and the resulting unethical scientific research on those Marshallese who were exposed to the nuclear fallout [10]. CBPR engages community partners and honors their unique contributions at all stages of the research [36–43]. CBPR also ensures Marshallese cultural knowledge will inform the research, so that it is culturally acceptable and, as a result, increases the likelihood of implementation and sustainability [33,34,44]. Grounding the study in CBPR methods will allow the team to integrate and leverage the contextually- and culturally-situated knowledge, practices, and resources of the Marshallese community in the RMI.

2.3. Community partners

Community partners in the RMI include the RMI Ministry of Health and Human Services (MHHS), the Marshallese Educational Initiative (MEI), and Kora In Jiban Lolorjake Ejmour (KIJLE) (roughly translated to "Women for Health"). The RMI Constitution designated the MHHS as the state health agency to help researchers appropriately implement research activities in the RMI [45]. MEI is a non-profit organization headquartered in Springdale, Arkansas, that promotes cultural, intellectual, and historical awareness of the Marshallese people. A CHW contracted by MEI and living in the RMI will help teach F-DSMES classes and will be an important factor in community and participant engagement. KIJLE is a nonprofit women's group that collaborates with the MHHS to engage the community in public health initiatives. KIJLE's members will function as CHWs for the study, reminding participants about classes and doctors' appointments, as well as coordinating participants' transportation to data collection events. CHWs participate in 20 h of research training and 40 h of F-DSMES training over 10 weeks. KIJLE is important to maintaining cultural congruence during implementation as they represent the matriarchal leadership of the RMI. The research team will establish two local offices in the RMI: one in the MHHS and a second with KIJLE.

2.4. Sample size

The pilot study will be conducted with 72 primary participants (defined as patients with T2DM) and up to 144 family members (1–2 family members per primary participant). Approximately 12 primary participants will be enrolled at each of the six FBO settings.

2.5. Study setting

Group educational classes for primary participants and family members will be held at the six FBO settings in the RMI. In this study, all of the faith-based organizations will be churches. Churches play an important role in Marshallese culture and prior needs assessments have shown that 96.5% of Marshallese report regular church attendance [46].

2.6. Theoretical framework

The study's overall conceptual framework is based on Social Cognitive Theory (SCT), which recognizes the dynamic and reciprocal interaction between individuals, their environment, and their behaviors [47,48]. SCT recognizes that human health is often a social matter, not just an individual endeavor [48]. This is particularly important for the successful implementation of a DSMES intervention in the RMI. Poor self-management, while frequently attributed to the patient, is often the product of her/his social and environmental context [24,25,49–60]. Marshallese collectivist culture situates family at the center of decision-making [61]. Through their communications, habits, and attitudes, family members can greatly influence primary participants' decisions to follow recommended treatment and self-care regimens [13,25,53–55,57,58,60–64]. In the F-DSMES intervention, primary participants and family members learn, increase motivation, develop strategies, and set goals together. The F-DSMES is designed to increase social support (family support) as a mechanism for changing behavior and ultimately improving health outcomes [47,48]. F-DSMES works to increase the support primary participants' receive from their family and to increase self-efficacy for managing T2DM. The F-DSMES teaches participants and family members to recognize supportive and non-supportive health behaviors that affect self-management, as well as fac-

tors in the families' physical environment that serve as facilitators and barriers to change.

2.7. Intervention

Primary participants and family members will participate in 10 h of diabetes education over an 8 week period, followed by a 2 week window for makeup classes. Group educational classes for primary participants and family members will be held at the participating church. The F-DSMES culturally adapted and translated curriculum includes eight core elements that are consistent with the American Association of Diabetes Educators' (AADE) seven self-care behaviors: 1) healthy eating; 2) being active; 3) understanding blood glucose and following doctor prescribed medications; 4) problem-solving; 5) reducing risks and healthy coping; 6) mitigating complications of diabetes; and 7) goal setting [65]. F-DSMES is based on a collectivist approach and uses familiar contexts and analogies such as the role of spirituality, nature analogies, the value of traditional Pacific medicine, and "talk story." [66] F-DSMES includes family members as secondary participants and focuses on family motivational interviewing, setting goals as a family, and family behavioral change [29,66]. The curriculum is designed to provide participants with education on supportive and non-supportive family behaviors [29,66]. The curriculum is asset-based and works to overcome barriers facing Marshallese participants by leveraging culturally specific facilitators of healthy behavioral change. The intervention is specifically designed for low literacy and low health literacy. All materials are provided in both English and Marshallese.

2.8. Study team

The study team includes a principal investigator and co-investigators who have prior experience conducting randomized controlled trials and other research studies with Marshallese participants in the US. The project manager for the study has 15 years of community health and research experience, and is a native of the RMI. The project manager relocated to the RMI and will manage all local CHWs and research staff. The local CHWs and research staff have completed CITI, HIPAA, blood borne pathogen, biometric data collection, and study-specific trainings. The CHWs will also complete Arkansas Faith-Academic Initiatives for Transforming Health Network training, which focuses on delivering health programs and education to faith communities.

2.9. Participant recruitment

Recruitment will be conducted by bilingual staff (Marshallese and English) who have extensive CBPR research training and experience. Staff will contact church leadership to determine interest and work with leadership to coordinate informational sessions with church attendees. An informational session will be held at the church to discuss the study and begin recruiting participants. All recruitment information will be provided in both English and Marshallese and will use plain language summaries of the study. Both male and female adults will be eligible to participate and will be targeted for equal representation. Recruitment began in March 2019 and will continue until recruitment goals are met.

2.10. Eligibility determination

Study staff and the data safety monitoring team will review the eligibility-screening instrument to determine enrollment in the study. The data safety monitoring team includes a Marshallese family practice doctor and a health researcher. To determine eligibility, the instrument will ask potential participants to verify: they are Marshallese; have been diagnosed with T2DM by a health care professional; have a family member willing to participate in the study with them; have participated in a DSMES program in the past five years, or have any medical conditions that would exclude them from participation. The data safety monitoring team will review the eligibility screening instrument to determine if persons have clinically significant medical conditions that will exclude them from participating in the study.

2.11. Participant inclusion criteria

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

2.12. Participant exclusion criteria

Persons who are not Marshallese, have received DSMES in the past five years, have plans to move out of the geographic region, or have a condition that makes it unlikely that they will be able to follow the protocol will not be eligible to participate in the study.

2.13. Family member inclusion criteria

For the purposes of this study, a family member is defined as a relative living in the same household as the primary participant. Family members must be 18 years of age or older to consent and participate.

2.14. Informed consent

Consent materials will be in English or Marshallese and will use plain language study summaries. Bilingual staff will explain the study to participants and provide sufficient time for questions and answers. After participants have read the consent forms fully and had time to ask questions, they will be given the opportunity to provide consent. Written consent with the participant's signature will serve as documentation. Family members who are willing to participate will also complete the same consent process.

2.15. Data collection

Data will be collected pre-intervention, immediately post-intervention, four months post-intervention, and 12 months post-intervention. In the event missing data is identified, participants will be contacted to collect the missing data. All data collection staff will have prior experience collecting biometric and survey data. REDCap will be utilized to manage study data [67]. To prevent/minimize missing data, REDCap includes a missing data report in the Quality Assurance tool [67]. This will allow for convenient quality assurance validation and monitoring, as well as prompt collection of missing data. Instruments will be chosen collaboratively with Marshallese stakeholders, and they will be translated into Marshallese. Data collection events will take place in the FBO or a location of the participants' choice, and will take about 1 h per data collection event.

2.16. Biometric data

The primary study outcome will be glycemic control as measured by change in HbA1c. Secondary biometric measures include: glucose, weight, height, BMI, blood pressure, and fasting lipids (total cholesterol, LDL, HDL, and triglycerides). Participants' weight (without shoes) will be measured to the nearest 0.5 pound using a calibrated digital scale. Height (without shoes) will be measured to the nearest 0.25 inch using a stadiometer. Weight and height will be used to compute a continuous measure of BMI (weight in pounds/[height in inches] [2]). Systolic and diastolic blood pressure will be measured using a digital

blood pressure device with the participant seated and arm elevated. Point of care tests will be used to collect HbA1c, fasting glucose, and fasting lipids. Staff will be using a Siemens DCA Vantage Analyzer to collect HbA1c, Cholestech LDX to collect fasting glucose, and a commercial lipid panel kit and Cholestech LDX to collect fasting lipids via a finger prick blood collection [68].

2.17. Survey data

The survey instrument for the study was developed with input from Marshallese stakeholders and utilizes adapted modules from the Diabetes Care Profile (DCP) [69] and the Behavioral Risk Factor Surveillance System (BRFFS) [70]. The survey instruments will be translated into Marshallese. Surveys will be administered at the pre-intervention data collection events and all post-intervention data collection events. All surveys will be collected on paper and then entered into a REDCap database with double data entry. The survey can be either interviewer-administered or self-administered, depending on the preference and/or literacy of the participant.

2.18. Feasibility data

Feasibility will be determined by evaluating: 1) fidelity of intervention delivery by CHWs; 2) recruitment and retention rates; and 3) attendance/dosage rates. The study manager will also observe intervention sessions to ensure fidelity and adherence to the curriculum. Intervention delivery will be monitored for fidelity using the F-DSMES fidelity checklist (developed with our prior study). Participant enrollment will be tracked and reported weekly. Participant retention will be tracked and reported at each data collection event. Attendance of primary participants and family members for each intervention session will be recorded and reported weekly by CHWs.

2.19. Qualitative data

Up to 20 participants will be asked to take part in qualitative interviews that will be used to gain patient feedback regarding their experiences and the cultural acceptability of the intervention. A semi-structured interview guide will be used to allow participants to speak in-depth about their experiences and ensure that all interviews cover the same topics. Interviews will take approximately 30 min to complete.

2.20. Remuneration

Remuneration will be provided to both primary participants and family members for their participation. Participants will be given $20 cash as compensation for their time for each data collection event they complete. Each participant will be eligible to collect four $20 incentives, for a total of $80 for those who participate in all four data collection events. Those who participate in the qualitative interviews will receive an additional $20.

2.21. Data analysis

2.21.1. Quantitative data analysis

Analyses will be performed with SAS/STATv14.1 [71]. The proposed research will be pilot study with the primary goal of testing feasibility and acceptability. Therefore, the study will not be powered to test specific hypotheses. In addressing the question of preliminary effectiveness, pilot study data will be used to estimate parameters and effect sizes needed to plan a larger study. Using pilot data, we will estimate the mean difference in measures at pre-intervention and post-intervention (immediate post-intervention, four months post-intervention, and 12 months post-intervention), the standard deviations, and the standard effect size. We will focus on point estimates and confidence intervals rather than *p*-values. Judgement of the preliminary effectiveness of the intervention will be based on the estimated mean differences in outcomes and the range of plausible values for that parameter from confidence intervals. For people with T2DM, a reduction of ~1% can have significant improvements clinical outcomes. For each 1% reduction in HbA1c patients see a 14% decrease in risk for heart attack, a 12% decrease in risk for stroke, a 37% decrease in risk for microvascular complications, and a 21% decrease in risk for death related to diabetes [72]. We will be looking to see if the effect is in the right direction (consistent with the intervention being effective) and whether the estimate would be clinically meaningful.

2.21.2. Feasibility analysis

The feasibility of the study will be determined through analysis of the fidelity of the intervention delivered by the CHWs, recruitment and retention rates, and attendance/dosage rates. For the study to be considered feasible, the intervention will be delivered with fidelity of at least 90% using the F-DSMES fidelity checklist. Recruitment rates of at least 75%, a retention rate of 75% for all four data collection events, and at least 75% of participants receiving a minimum of 50% of the intervention will further demonstrate feasibility.

2.21.3. Qualitative analysis

Qualitative interviews will be used to evaluate participants' experiences and perceptions of the intervention and its acceptability. All interviews will be audio recorded, transcribed verbatim, and translated from Marshallese to English. Data will be imported into MAXQDA qualitative software [73] and analyzed using content analysis and thematic coding related to the acceptability of the intervention. A sample set of transcripts will first be coded independently by two researchers with extensive qualitative research experience. A codebook will be developed that includes both *a priori* and emergent themes and will be refined at least two times through discussions with the study team during data analysis. A third confirmation coder will review all coded transcripts and any discrepancies will be discussed and decided by consensus of the study team.

2.21.4. Dissemination plan

Through an existing CBPR collaborative, study staff will also provide a summary of the results back to the Marshallese community, ensuring that participant confidentiality is maintained. Through previous research, the study team has found that individual in-person meetings, church meetings, town hall meetings, using infographics, and plain language summaries are the culturally preferred methods for dissemination of study results [74]. Individual participant results will be shared with participants after each data collection event. Following data collection events, aggregated de-identified results will be shared with the entire congregation at participating churches and at community-wide town halls. Town hall meetings will be announced through Facebook, newspaper, and radio. CBPR partners will co-host town hall dissemination events. Culturally and linguistically appropriate infographics and plain language summaries will be created and used as flyers and posters to be distributed at community events and in-person meetings and posted on Facebook. A summary of the results will be provided in a formal report and presentation to the RMI MHHS. Additionally, results of this study will be used for academic presentations, posters, or publications.

3. Summary

This study will be based on a CBPR approach, which engages Marshallese community members and allows UAMS researchers to build trust among Marshallese in the RMI and overcome barriers created by the historical trauma of nuclear testing. This study will build upon a

growing body of literature on family models of DSMES. The Marshallese collectivist culture puts family at the center of communication, decision-making, and behaviors [24,25,75]. Family members greatly influence primary participants' decisions to engage in self-care. This study will provide new and innovative information about the effects of F-DSMES in a low-resource country with a collectivist, family-centered culture. The results will be important for future research in other parts of the USAPI, other collectivist cultures, and other low- and middle-income countries.

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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