



Research paper

Study protocol for a multilevel diabetes prevention program for Marshallese Pacific Islanders in faith-based organizations

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1. Introduction

The Marshallese are a Pacific Islander population experiencing significant health disparities, with very high rates of obesity and type 2 diabetes mellitus (T2DM) [1–7]. Local, national, and international estimates of T2DM in the Marshallese population range from 20% to 50%, compared to 9% for the United States (US) population and 4% worldwide [2–5]. Arkansas has the largest population of Marshallese outside the Republic of the Marshall Islands with approximately 14,000 Marshallese [8,9]. Pilot study data ($n = 401$) documented high incidence of T2DM (38.2%), pre-diabetes (32.6%), and overweight/obesity (90%) among the Arkansas Marshallese community [10].

Excess weight is considered the strongest modifiable risk factor for T2DM [11], and even a modest reduction in weight of 5–10% can have clinically meaningful outcomes [12–14]. The Diabetes Prevention Program (DPP) is an evidence-based program designed to reduce the risk of T2DM through lifestyle changes. Systematic reviews have documented the DPP's effectiveness in improving weight, Body Mass Index (BMI), HbA1c, blood pressure, eating habits, and physical activity in both community-based and clinical settings [15–22]. The DPP has been identified by the Centers for Disease Control and Prevention [23], American Diabetes Association [24], and National Institutes of Health [25] as one of most effective behavioral interventions to reduce weight and prevent T2DM in the general population [15–18,22,25].

The Social Ecological Model (SEM) provides a context for exploring interdependent levels of influence on obesity and T2DM [26–31]. The SEM represents interrelated levels of influence at the

individual/intrapersonal, interpersonal, organizational, community, and policy levels. The SEM asserts that individuals live within layers of social relations and dynamic systems that interact to influence their ability to live a healthy life. Single-level interventions focused on individual behavioral change alone may not be sufficient to produce or sustain widespread improvements among populations with significant health disparities. If individual change is not supported socially and structurally, behavior may revert to a pre-intervention state [32–34].

Multilevel interventions have shown promise in achieving sustained outcomes [9,35–39]. For example, Healthy Bodies Healthy Souls (HBHS) is a multilevel, faith-based intervention that focuses on reducing T2DM among urban African Americans by promoting weight loss [35–37]. The HBHS program was developed and implemented collaboratively with African American congregations using a community based participatory research (CBPR) approach. Gittelsohn et al. tested the intervention in a cluster-randomized trial that included nine African American churches [35–37]. Results found the HBHS intervention was successful at producing improvements in weight loss, BMI, and diastolic blood pressure [40]. The study also found that the participating churches made organizational changes to support healthier behaviors, including improvements in food preparation for church events, new physical activity programs, and increases in congregational engagement in health promotion activities [37].

While the DPP has been effective at improving outcomes among the general population and among racial and ethnic populations [15,18], its effectiveness has not been adequately tested among Pacific Islanders and a critical gap in knowledge remains. Furthermore, while multilevel

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interventions, such as HBHS, have demonstrated effectiveness in addressing health disparities, multilevel interventions have not been adequately tested in Pacific Islander communities. This study seeks to fill those gaps in literature by testing a multilevel intervention among Marshallese Pacific Islanders in Arkansas.

2. Materials and methods

Community Based Participatory Research. Successful multilevel interventions benefit from collaborative relationships among community and academic stakeholders [27,29,41,42], and CBPR can be an effective approach to designing and implementing multilevel interventions. CBPR engages community partners and honors their unique contributions at all stages of research [27,29,41]. The study will be conducted as part of a CBPR partnership between the Marshallese community in Arkansas and the University of Arkansas for Medical Sciences (UAMS). The CBPR partnership ensures that the multilevel intervention is informed by Marshallese cultural values, practices, and beliefs. UAMS used a CBPR approach to identify T2DM as the top concern of the community and prioritized prevention programs as the most appropriate action. Details on the needs assessment and full CBPR partnership are described elsewhere [8,43–46].

Aim. This study will test the primary feasibility, acceptability, and effectiveness of a multilevel intervention to prevent T2DM in the Marshallese community in Arkansas. The multilevel intervention includes a DPP program to address individual and interpersonal level changes and the HBHS intervention to address interpersonal and organizational level changes. The pilot study is a one arm trial with pre, post, and 12 month post outcomes.

Sample Size. The recruitment goal for this pilot study is 45 participants from two churches. **Study setting.** The intervention will be delivered in two churches in the rural areas of Carroll and Madison counties located in northwest Arkansas. Local pilot data documented that 96.5% of Marshallese report regular church attendance [8]. Churches, within Marshallese culture, signify more than religious affiliation. Pastors and madam pastors are highly respected leaders within the Marshallese community [47]. Churches are a primary social institution in the Marshallese community and often represent clan and atoll affiliation for Marshallese migrants [47].

Recruitment. Recruitment and enrollment is a multi-step process. First, bilingual Marshallese research staff will recruit churches who want to partner in implementing the study. Bilingual Marshallese research staff will work with the pastors and madam pastors to distribute study information in English and Marshallese within churches and to give presentations about the study after church service. All persons will be offered the opportunity to consent and participate in a health screening (described in data collection section below), whether or not they are interested in participating in the individual and interpersonal level intervention. Those who express interest in participation in the individual and interpersonal level DPP will complete an eligibility-screening instrument to determine eligibility. The eligibility-screening instrument captures information related to inclusion criteria.

Inclusion criteria. Inclusion criteria will be self-reported Marshallese and 18 years of age or older. To participate in the individual and interpersonal level DPP intervention, participants must have a BMI of ≥ 25 kg/m². Exclusion criteria for the DPP are a clinically significant medical condition likely to impact weight (cancer, HIV/AIDS, etc.); currently pregnant or breastfeeding an infant who is 6 months old or younger; any condition that makes it unlikely that the participant will be able to follow the protocol, such as terminal illness or plans to move out of the area within 6 months.

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 two physicians, a Marshallese family practice doctor, and an endocrinologist. 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 the DPP component of the study.

Consent. Information about the study and consent materials will be in English and/or Marshallese, and participants will be provided information and materials in the language of their choice. Persons deemed eligible based upon the eligibility-screening instrument will be given a copy of the study information and consent to review. They will have the opportunity to ask questions, consent, and enroll in the study. As discussed above, participants may consent to take part in the health screening data collection even if they choose not to take part in the individual and interpersonal level DPP intervention.

Description of the intervention at each level of the SEM. The intervention will be implemented at three levels of the social ecological model: the individual level; the interpersonal level; and the organizational.

At an individual level, participants will receive an adapted version of Yeary et al.'s (2015) Wholeness, Oneness, Righteousness, Deliverance (WORD) DPP intervention [48]. WORD DPP curriculum was developed for rural African American communities of faith using a CBPR approach and implemented in rural churches in Arkansas [48,49]. The intervention underwent minor adaptations to ensure relevance to Marshallese communities. These adaptations included translating into the Marshallese language, using culturally relevant pictures of Pacific Islanders and including Bible quotes that were well known in the Marshallese community. The adapted WORD DPP consists of 16 lessons that are approximately 90 minutes in length delivered over a 24-week period. The first eight lessons will be delivered weekly, and the next eight lessons will be delivered every two weeks. The intervention emphasizes meeting program goals to increase physical activity, increase healthy eating, and lose 7% body weight. Prior studies using WORD DPP with African American participants reported that 23.7% of all participants lost at least 5% of their baseline weight by six months [50].

The WORD DPP will be led by bilingual (Marshallese and English) lay health educators who received DPP lifestyle coach training. The lay health educators have also received 24 hours of community health worker training. Each lay health educator has at least two years' experience delivering behavioral interventions. The WORD DPP will offer materials in English and Marshallese. Makeup sessions for missed modules will be offered.

At an interpersonal level, the WORD DPP lessons will be delivered as a group session. Members will have the opportunity to support and encourage each other both during the group educational sessions and between the educational sessions. Participants also choose an encouragement partner and communicate with that partner about successes and challenges between sessions. Participants may also take part in a private Facebook group to promote interpersonal information sharing and support between educational sessions.

At an organizational level, the churches will incorporate policy, systems, and environmental changes within the church to support the weight loss and prevention of T2DM. The organizational level intervention is based on Gittelsohn et al.'s (2012) HBHS [40]. The organizational intervention will include the formation of a church health committee, which will identify and implement organizational changes. Each church will have five health committee planning meetings that last 90 min each. During the health committee planning meetings, study staff will guide the health committee through the process of developing and identifying policy priorities. During the first two health committee planning meetings, three organizational policies will be chosen by the committee. Subsequent health committee planning meetings will focus on implementation strategies for each of the three specific policy areas. Each policy chosen will be implemented and promoted for two months. The first policy will be maintained while the second policy is implemented and promoted for two months. Finally, the third policy will be implemented and promoted, with all three policy-level intervention activities implemented over the six months. Study staff will support the

committees through the development of culturally appropriate health education materials, cooking classes, nutrition education, and other supports identified by the health committees. The organizational changes to support healthier behaviors will focus broadly on improvements in food purchasing and preparation for events, physical activity programs, and increased congregational engagement in health promotion activities.^{91, 92} The church health committee will continue to meet monthly over a period of 12 months to implement the change. Each monthly meeting will be approximately 90 minutes. Since this is a feasibility study the implementation will be standardized across the churches. Health committees will be encouraged to continue to meet monthly after the intervention is complete.

Data collection. A mixed methods data collection approach will be used with quantitative and qualitative measures at the individual, interpersonal, and organizational levels. Data collection will be conducted in the church by trained research staff. Bilingual lay health worker will be available at each study visit to interpret for participants if needed.

Data will be collected at pre-intervention (baseline), post-intervention (six months after pre-intervention), and 12-month post-intervention (i.e., 12 months from study initiation and six months after the first post-intervention data collection). Weight loss is the primary outcome of interest. Biometric measures include: weight and height, blood pressure, and hemoglobin A1c (HbA1c). Weight without shoes will be measured to the nearest 0.5 lb. (0.2 kg) using a calibrated scale. Height without shoes is measured to the nearest 0.25 inch using a stadiometer. Weight and height are used to compute BMI using the Quetelet Index (kg/m^2) [51]. Systolic and diastolic blood pressure are measured with the participant seated and arm elevated using a digital blood pressure device or stethoscope and sphygmomanometer. HbA1c is tested using a Rapid A1c test kit and Siemens DCA Vantage Analyzer with finger stick blood collection [52].

The survey instruments have all items listed in both English and Marshallese. Data is captured on paper instruments and then entered to the Research Electronic Data Capture (REDCap) platform. Data will be continually monitored for the occurrence of missing data after field collection [53]. It will take participants approximately 20 minutes to complete the survey instrument which includes 62 items adapted from valid and reliable scales. Fruit and vegetable consumption will be measured using a questionnaire by Shannon et al. (1997) [54]. Sugar-sweetened beverage consumption will be assessed with items from the Behavioral Risk Factor Surveillance System (BRFSS) [55]. Psychosocial variables including social support and self-efficacy for body weight, diet, and physical activity will be assessed. Weight locus of control is measured using the Weight Locus of Control scale [56]. Interpersonal support for exercise and healthy diet will be measured by items from Gruber (2008) [57]. Exercise self-efficacy will be measured using the self-efficacy for exercise and outcome expectations scale by Resnick et al. (2004) [58]. Self-efficacy scales for health related diet and exercise behaviors will also be assessed using Clark et al.'s (1991) measure [59]. Other variables that will be assessed will include food insecurity from the National Health and Nutrition Examination Survey (NHANES) [60], sleep quality and quantity items from the BRFSS [55], and church attendance using an item from Koenig & Büssing's survey (2010) [61]. At an organizational level, we will use items from Ayers et al. (2010) [62] to assess how often participants receive health messages at church. These instruments have been successfully utilized in the Marshallese population in similar studies [63,64].

Because this will be a pilot study, the feasibility of implementation is a primary objective. Therefore, recruitment and retention rates will be meticulously captured with reason for refusal and drop out documented. In addition, attendance rates and engagement at the intervention sessions will be documented. At an intrapersonal level, usage of the Facebook group will be documented, and at an organizational level, documentation of the number, reach, and description of organizational policy changes will be documented.

Participants will be invited to take part in focus groups or individual interviews to collect qualitative data regarding their experience and the acceptability of the intervention. Interviews will take place at the conclusion of the intervention to collect information regarding their experience. Interviews will explore the acceptability of the intervention, interpersonal support participants received, and organizational changes participants' observed. A semi-structured interview guide will allow participants to speak in-depth about their experiences, yet also ensure that all focus groups or individual interviews cover the same topics. The semi-structured interview guide will focus on participants' understanding of organizational level policy changes, and the translation of churches' organization policies into healthy behaviors at the individual level. Additional interview questions cover participants' experience and perceptions of the intervention, and preferences around dissemination and returning of results. Each interview will have an anticipated duration of 1 hour.

Remuneration: Participants will be offered a \$20 gift card at the first data collection event; a \$30 gift card at the post-intervention data collection event; and a \$40 gift card at their 12 month post-intervention data collection event. Participants will only receive a gift card for completed data collection events. In addition, those who complete a focus group or individual interview will be offered an additional gift card of \$20. Each participant will be eligible to collect four gift cards, for a total of \$110 for those who participate in all three data collection events and a qualitative interview.

Data analysis. The proposed study is a pilot, so the focus is not on testing hypotheses⁹³ but instead on evaluating preliminary effectiveness, feasibility, and acceptability of the multilevel intervention. In addressing the question of preliminary effectiveness, the pilot study data will be used to estimate parameters and effect sizes needed to better plan a larger study.⁹⁴ Focus will be on point estimates and confidence intervals instead of *p*-values from hypothesis tests. Judgment of the preliminary effectiveness of the intervention on weight loss and other outcome variables will be based on the estimated mean difference between the groups and the range of plausible values for that parameter from the confidence interval. Emphasis will be on examining whether the effect is in the right direction (consistent with the intervention being effective) and whether the estimate would be clinically meaningful. To assess preliminary effectiveness of the intervention, pilot data will be analyzed with SASv9.4⁹⁵ following the plan for a larger study. This will include screening for outliers and violations of model assumptions.

Linear mixed-effects models will be used to test the effect of the HBHS intervention, while controlling for demographics and relevant covariates. These analyses will provide information about possible problems with measures and data collection procedures. The pilot data will also be used to explore within- and between-cluster variability and the intraclass correlation. Based on review of the relevant literature, a 2.5 kg (SD = 7 kg; Cohen's $d = 0.36$) difference in weight loss (primary outcome) from pre-intervention to post-intervention is anticipated.⁹⁶ Although the pilot study is not adequately powered to evaluate the effectiveness of the intervention, we will have an adequate sample size to estimate means, standard deviations, effect sizes, and confidence intervals that will provide preliminary information for planning the full scale evaluation of the intervention.

Feasibility will be evaluated through recruitment, retention, and attendance rates. A recruitment rate of $\geq 70\%$ of all eligible participants and a retention rate of $\geq 80\%$ through the 12 month data collection time point will indicate feasibility. An attendance rate of $\geq 50\%$ of educational sessions will indicate feasibility.

Acceptability will be evaluated through the responses to the semi-structured interviews regarding cultural appropriateness. The interviews will be recorded and transcribed. Data will be imported into MAXQDA qualitative software [65] and analyzed using content analysis related to the acceptability of the intervention.

Ethical Considerations. This study will be conducted in accordance with all applicable government regulations and UAMS research policies

and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board to conduct the study.

Dissemination. Dissemination of research results is a crucial part of translational research and of CBPR [66–69]. Dissemination efforts will be at three levels: participants, the broader Marshallese community, and the scientific community. In all dissemination, we will ensure that participant confidentiality is maintained. Our first priority will be to disseminate results back to participants. Participants will be provided a one-page summary of their personal results and a one-page summary of the aggregated results. Both summaries will be formatted as infographics. The infographics will be presented in English on one side and in Marshallese on the other side. The infographics will use plain language suitable for low literacy and low health literacy [70]. Culturally relevant pictures and examples will be used in the infographic. During enrollment, participants will indicate if they want the results mailed or e-mailed to them, and results will be provided in the manner they requested. Participants will be provided an opportunity to follow up with the research team to have any questions answered.

Through our CBPR collaborative, we will also provide study updates and a summary of the aggregated results back to the broader Marshallese community. We will share study updates during biannual town hall meetings. We will share the study results at a town hall meeting at the end of the study. The town hall meetings will be hosted by the Marshallese Education Initiative, the study's community-based partner. Town hall meetings will be facilitated by the bilingual Marshallese lay health educators and Marshallese community co-investigators. Study updates will also be shared on social media, which is a primary means of communication within the Marshallese community.

Academic dissemination will focus on peer-reviewed journals and academic conferences. All publications will use CONSORT reporting guidelines for trials.⁷¹ Marshallese community members are invited to co-author and co-present research, and are co-authors of the present paper.

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