**Study Title**: Healthy Body Healthy Souls: A weight loss intervention using Diabetes Prevention Program Lifestyle Intervention (DPP-LI) with Church Level Systems Change in the Marshallese Population.

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**Background and Rationale**

**Disparities in type 2 diabetes, pre-diabetes, and obesity among the Marshallese and Pacific Islanders**. This study focuses on the Marshallese living in Arkansas. The Marshallese are a Pacific Islander population experiencing significant health disparities, with some of the highest documented rates of type 2 diabetes of any population group in the world.[1-3, 4, 5-7] Our review of local, national, and international data sources found estimates of diabetes in the Marshallese population (in the US and the Republic of the Marshall Islands) ranging from 20% to 50%, compared to 8% for the US population and 4% worldwide (**Table 1**).[1-3, 5]

**Table 1.** Diabetes rates

| **Documented rates of diabetes in Marshallese population** | % |
|---|---|
| US (IDF) | 8 |
| World Wide (IDF) | 4 |
| Marshallese (Yamada) | 20 |
| Marshallese (Minegishi) | 31 |
| Marshallese age 15+ (LeDoux) | 28 |
| Marshallese age 35+ (LeDoux) | 50 |
| Marshallese (Woodall) | 30 |

While national prevalence data are limited, 23.7% of Pacific Islanders surveyed by the Centers for Disease Control and Prevention (CDC) in 2010 reported a diagnosis of type 2 diabetes – more than all other racial/ethnic groups.[8] Our preliminary research, which included health screenings with the Marshallese community in Northwest Arkansas ($n$ = 401), documented extremely high incidence of diabetes (38.2%) and pre-diabetes (32.4%). Our pilot data also revealed similar disparities in obesity, one of the strongest risk factors for diabetes; 90% of Marshallese participants were classified as overweight or obese.[9, 10] Further compounding these significant disparities, Pacific Islanders living in the US are less likely than other racial/ethnic groups to receive preventive or diagnostic treatment or diabetes education.[11, 12, 13, 14, 15]

This study addresses an urgent need for interventions to reduce obesity and diabetes disparities in the Marshallese community and will employ a culturally appropriate, multilevel approach. The scientific premise of our study includes four main points. **First,** the Arkansas Marshallese suffer from a significant and disproportionate burden of type 2 diabetes and lack access to effective prevention and treatment due to a dearth of research with Pacific Islanders.[16-19, 20, 21,22,13] **Second,** the association between weight gain and risk for type 2 diabetes is strong. Overweight/obesity is considered the strongest modifiable risk factor for type 2 diabetes,[23] and even a modest reduction in weight (5-10%) is clinically meaningful.[24-26] **Third**, research demonstrates the effectiveness of multi-level lifestyle interventions in reducing weight and the onset and impact of diabetes.[27-33] **Fourth,** to be effective among Pacific Islanders, interventions must be developed to address influences at multiple levels[34-36, 37-39, 40] and should be culturally adapted to incorporate Pacific Islanders' worldviews and cultural values.[20,41-49] Prior research indicates the importance of using a Community Based Participatory Research (CBPR) approach to understand and integrate cultural nuances during the cultural adaptation process and implementation of multilevel interventions.[34-39, 50-61] A CBPR approach is also essential to conducting ethical, valid health research in populations whose health beliefs and behaviors have been shaped by historical trauma.[59, 62, 63] **Finally,** churches are primary social institutions of Pacific Islander health.[64-68] Faith-based interventions are effective at improving behavioral and anthropometric outcomes within collectivistic communities and therefore hold great promise for Marshallese and other Pacific Islanders.[42,43,69-73]

**Reducing disparities by reducing weight.** Overweight/obesity is considered the strongest modifiable risk factor for type 2 diabetes,[74] and even a modest reduction in weight (5-10%) can be clinically meaningful.[75-77]

**Specific Aim.** Our aim is to pilot test a weight-loss intervention referred to throughout the proposal as Healthy Bodies Healthy Souls (HBHS) in a single arm study. The intervention includes the Diabetes Prevention Program Lifestyle Intervention (DPP-LI) with the additional enhancement of working with Marshallese churches to implement organizational/institutional level changes to support the individual behavioral intervention of the DPP-LI. Because the DPP-LI intervention and data collection are the same as the approved UAMS IRB #207034, the study team may compare the outcomes of this pilot study to the outcomes of the DPP-LI.

**Study design**
Up to four Marshallese churches will be recruited.

The *primary* outcome is percentage of body weight loss. *Secondary* variables include: 1) HbA1c, 2) blood pressure, 3) changes in food and physical activity related behaviors, and 4) changes in self-efficacy and perceived social and environmental support for healthy lifestyle changes.

**Recruitment and Consent**
Participants will be recruited through churches from Arkansas, Kansas, Missouri, and/or Oklahoma. The recruitment goal for the church level intervention is up to 40 participants per church for up to four churches for a total of 160 participants through the duration of the study. The recruitment goal for the DPP-LI is up to 18 participants per church for up to four churches for a total of up to 72 participants through the duration of the study.

During recruitment, Marshallese study staff will give presentations and distribute study information in English and Marshallese within churches. All persons in attendance will be offered the opportunity to participate in the health screening. Those who express interest in participation in the DPP-LI will complete a screening instrument to determine eligibility – see Inclusion/Exclusion criteria. The eligibility screener will include systolic and diastolic blood pressure and height and weight measurements to calculate BMI.

Church-based recruitment is specified by stakeholders as culturally appropriate and the community's preferred recruitment method.

Inclusion Criteria

Participant inclusion criteria:

1) Self-reported Marshallese
2) 18 years of age or older
3) To participate in the DPP-LI, have a body mass index (BMI) of ≥25 kg/m2

Exclusion Criteria

Participant exclusion criteria for the DPP-LI:

1) A clinically significant medical condition likely to impact weight (cancer, HIV/AIDS, etc.)
2) Currently pregnant or breastfeeding an infant who is 6 months old or younger.
3) Have any condition that makes it unlikely that the participant will be able to follow the protocol, such as terminal illness, plans to move out of the area within 6 months, and inability to finish the intervention, etc.

Two physicians, a Marshallese family practice doctor and an endocrinologist, make up the data safety monitoring team, and will review the Eligibility Screener forms to determine if persons screened have clinically significant medical conditions that will exclude them from the DPP-LI component of the study.

All study information and consent materials will be provided in English and/or Marshallese based upon the participants' preferences. Eligible participants will be provided a copy of the consent to review, and participants will have the opportunity to ask questions, consent, and enroll in the study. The consent process will include providing information to the potential participants and the opportunity to have bilingual Marshallese staff answer questions regarding study participation. The consent document will be given to the participant, and the informed consent process will be documented in the participant's research record. The consent document will be reviewed with the group and questions will be answered by research staff. Experience working with the Marshallese population and input from both advisory groups and Marshallese staff support providing consent information to potential participants in a group setting. This is consistent with Marshallese cultural practices and does not preclude the provision of the opportunity for all potential participants for individual, private discussion of the study and the consent document before they sign the consent. All members of the research team will be trained and certified in participant consent procedures, the study protocol, human subjects protection, and HIPAA regulations. After the consent process, a participant contact information form will be completed.

**Data Collection Instruments and Procedures**

Biometric and survey data will be collected during pre-intervention, post-intervention, and twelve months post-initiation on both persons who only participate in the health screening and those who participate in the DPP-LI. The data collection window is up to six weeks on each side of the data collection date to accommodate participant availability. In the event missing data is identified, participants will be contacted to collect the missing data.

Participants may be invited to participate in a qualitative interview to understand participants' perceptions of the intervention and implementation process. Participants may refuse any data collection or any questions within a data collection event.

Biometric Data

Biometric measures include: HbA1c, weight, height, BMI (calculated by height and weight), waist measurement, and blood pressure. Participants' weight will be measured in clothing to the nearest 0.5 lb. (0.2 kg) using a calibrated scale. Height (without shoes) will be measured to the nearest 0.25 inches using a stadiometer. Weight and height will be used to compute a continuous measure of BMI using the Quetelet Index (kg/m2).[78] Systolic and diastolic blood pressure will be measured using a sphygmomanometer and stethoscope or digital blood pressure device with the participant seated and arm elevated. Finger stick blood collection will be used to test HbA1c using a Rapid A1c test kit and Siemens DCA Vantage Analyzer. The biometric data collection will be completed by qualified, trained research staff. Bilingual study staff will be present for each biometric collection.

Survey Data

The survey data collection instruments include:

| **Data collection measures** | **Description of outcomes measured and validated scales/instruments** |
|---|---|
| Eligibility Screener | Name, phone number, identification as Marshallese, date of birth, age, weight, height, calculated BMI, interest in participation, physical limitations, dietary restrictions, related co-morbidities, and a brief suitability for physical activity screener.[79-80] |
| Biometric measures | HbA1c, weight, height (only at pre-intervention), calculated BMI, waist measurement, and blood pressure. |
| Demographic | Age, sex, marital status, pregnancy status, number of persons in home, education, employment, health status, select co-morbidities, insurance status, and ability to access health care will be captured. |
| Diabetes related behaviors | Diabetes related behaviors will be collected based on measures from the DPP-LI[81-83], Behavioral Risk Factor Surveillance System (BRFSS)[69], and National Health and Nutrition Examination Survey (NHANES)[84]. |

The survey data collection includes 57 items adapted from valid and reliable scales, which will take participants approximately 20 minutes to complete. Family support for exercise and healthy diet is measured by items from Gruber (2008).[85] Weight locus of control is measured using the Weight Locus of Control scale.[86] Exercise self-efficacy is measured using the self-efficacy for exercise and outcome expectations scale Resnick (2004).[87] Eating habits are measured by self-efficacy scales for health related diet and exercise behaviors from Clark et al (1991). Fruit and vegetable consumption is measured by Shannon et al., (1997).[89] Food insecurity is measured using questions from National Health and Nutrition Examination Survey (NHANES).[84] Questions about sugar sweetened beverage consumption and sleep quality and quantity are taken from the Behavioral Risk Factor Surveillance System (BRFSS).[69] There is one item about church attendance from the Koenig & Büssing (2010), and items regarding how often participants receive health messages at church adapted from Ayers et al.[88]

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 and post-intervention data collection events. All surveys will be administered by a qualified study staff who have completed all required trainings (see protections against risk). A bilingual Marshallese staff will be present for all sessions and data collection events.

**Remuneration:** Participants who only participate in the church health screening will be offered a $20 Walmart gift card for each data collection event and an additional $20 gift card if they participate in the qualitative interview. Participants who participate in all three data collection events and a qualitative interview will receive a total of $80 in gift cards. Participants will only receive gift cards for the health screenings they complete.

Participants that are in the DPP-LI classes will be offered a $20 Walmart gift card as remuneration for their time for their pre-intervention data collection event, a $30 Walmart gift card as remuneration for their post-intervention data collection event, and a $40 Walmart gift card as remuneration for their 12 month post-initiation event. Participants will only receive gift cards for the data collection events they complete. Each participant will be eligible to collect three gift cards, for a total of $90 for those who participate in all three data collection events.

Participants that are in the DPP-LI classes and who participate in the qualitative interview will be provided a $20 Walmart gift card for their participation. A DPP-LI class participant who completes all three data collection events and the interview will receive a total of $110 in gift cards.

**Intervention Description**. Participant groups will receive the DPP-LI. The intervention modules will be delivered at a church group setting and participation in discussion will be encouraged. The interventions' core curricula emphasize increasing physical activity, eating healthy, and sustaining motivation. Participants will be invited to join a private Facebook group to facilitate providing reminders and sharing information between educational sessions. The private Facebook group will be created and managed by study staff. Participation will not be a required component of the study. The intervention includes 16 modules that are delivered over a 24 week period, each class will last about 90 minutes and may include up to 30 minutes of physical activity. The first 8 modules are delivered weekly and the last 8 modules are intended to be delivered every other week. Participants will be encouraged to maintain a daily weight, nutrition, physical activity, and prayer log. Persons who do not want to participate in the study or choose to stop participating in the study can still attend the classes.

Each group will be led by bilingual (Marshallese and English) DPP-LI lay educators who will each receive no less than 40 hours of DPP-LI lifestyle coach training provided by Dr. Karen Yeary, an expert in DPP. The lay educators have also receive 24 hours of training as Community Health Workers. Each of these lay educators have at least two years' experience delivering health education interventions. The intervention will offer materials and survey instruments in English and Marshallese. Makeup sessions for missed modules will be offered.

Within three months of the conclusion of the educational modules, participants may be invited to participate in a qualitative interview to collect information regarding their experience. Qualitative data will be collected from participants in focus groups or individual interviews. A semi-structured interview guide will be used to allow participants to speak in-depth about their experiences, yet also ensure that all focus groups or individual interviews cover the same topics. Each focus group or individual interview will have an anticipated duration of one hour.

In addition to the DPP-LI provided to the church members, organizational/institutional change level support will be provided to the church. The organizational/institutional intervention will include meeting with church leadership and church health committee members approximately monthly to identify what organizational changes they want to make. The facilitated meetings to identify changes that the church wants to make will last approximately 2-3 hours. The organizational/institutional systems, policies, and environmental changes will be developed collaboratively with church leaders/members. Organizational/instructional changes to support healthier behaviors include improvements in food purchasing and preparation for events, physical activity programs, and increased congregational engagement in health promotion activities.[91, 92] Example changes could include: starting a walking club, implementing a policy to not included sugary beverages at church meals, implementing a healthy potluck policy. The number of church leaders and health members who will attend per church will be determined by each church. Process notes will document changes made by each church. Church leaders and health committee member will not be consented unless they take part in the DPP-LI and/or they take part in the focus groups.

**Risks and Benefits**
Potential risks to study participants are minimal and no greater than usual care or standard health screenings. The physical activity may result in fatigue or soreness. 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. The alternative to participating in the interventions is to not participate in the interventions. Further, any participant can choose to leave the study at any time.

**Protections against risk.** All data collectors involved in the interventions will have received training on: participant consent procedures, the study protocol, human subjects protection, HIPAA regulations, survey administration, biomedical data collection (including finger stick blood collection), maintaining confidentiality of study participants, mandatory reporting, and appropriate treatment of participant data. Collection, transport, and storage of data, and subsequent access will be limited to only those personnel who need it to complete relevant job duties. All data, regardless of whether it is identifiable or not, will be stored in a locked file cabinet in a locked room, or on a secure UAMS server that requires two-factor authentication.

Medical related risks identified by study staff or reported by participants will be referred to Dr. Sheldon Riklon for consultation and response.

**Potential Benefits of the Proposed Research to Human Subjects and Others**
Individuals may experience positive health benefits throughout the period of the study. The intervention has the potential to improve healthy behaviors and facilitate weight loss that can reduce the risk of diabetes. However, these benefits are not guaranteed. It cannot be predicted how each participant will respond to intervention education and activities. By following each individual participant, the study will acquire new information regarding effective methods to influence risk factors for diabetes among Marshallese community members. Results of the study will inform future interventions and can provide benefits to future participants and the broader community. The opportunities for improved health, coupled with the fact that this is minimal risk behavior-modification research, creates an ideal benefit-to-risk ratio.

**Data Capture**
Survey, biometric, and other instrument responses will be captured with paper and pencil instruments or through a computerized data collection tool. All survey data collection instruments will include English and Marshallese versions. A computer database will be used to manage study data after it is collected.

**Data Handling and Recordkeeping**

The Principal Investigator and study team will carefully monitor study procedures to protect the safety of research subjects, the quality of the data, and the integrity of the study. Collection, transport, and storage of data, and subsequent access will be limited to only those personnel who require it to complete relevant job duties and who have completed all required trainings for study activities and in maintaining confidentiality. Detailed procedures will be developed for data collection, transfer, and storage, but will at minimum require that data is always in a locked transfer case, in a locked storage unit, or on a secure, password-protected server. Participant identification numbers will be used to track study forms. Access to files will be limited to select study personnel as designated in the delegation log. All records will be retained consistent with the UAMS Administrative Guide (seven years after final reporting or publication of a project).

Data collected from participants who indicate on the consent form that their information may be used for future diabetes related research will be retained indefinitely.

**Data analysis.** The proposed study is a pilot, so the focus is not on testing hypotheses;[93] the focus is on culturally adapting the HBHS intervention and evaluating its feasibility, acceptability, and preliminary effectiveness of the adapted 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] Using pilot data, the results will be compared to the results of protocol #207034 testing DPP-LI in the Marshallese community without the organizational/institutional level intervention. Focus will be on point estimates and confidence intervals instead of *p*-values from hypothesis tests. Judgment of the preliminary effectiveness of the intervention will be based on the estimated mean difference between the groups and the range of plausible values for that parameter from confidence interval. Attention will be on 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. To assess feasibility of the analysis plan for the larger study and the preliminary effectiveness of the intervention, pilot data

will be analyzed with SASv9.4[95] following the plan for a larger study. This will include screening for outliers and violations of model assumptions. Using linear mixed-effects models to test the effect of the HBHS intervention, 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 estimate within- and between-cluster variability and the intraclass correlation (using protocol #207034 data as a comparator). Based only on review of the relevant literature, a 2.5 kg (SD = 7 kg; Cohen's $d = 0.36$) difference in weight loss between the groups is anticipated.[96] For context, the proposed pilot study would have 80% power to detect an effect size of 0.68 (calculated with PASS12; two-sided alpha = .05; ICC = .01). Although the pilot study is not adequately powered as a full scale RCT 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 and prove invaluable in planning the full scale evaluation of the intervention.

**Qualitative data analysis.** The 10 post-intervention interviews will be recorded and transcribed, and then imported into MAXQDA qualitative software.[97] Transcripts will be analyzed using content analysis related to the feasibility and acceptability of the intervention.

**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 involved in 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. Subjects may take as much time as needed to make a decision about their participation. 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.

**Data and Safety Monitoring Plan.** This is no more than a minimum risk study however, a Data and Safety Monitoring Plan has been submitted as a separate document.

**Dissemination of Data.** The data gained from the proposed research will help providers offer effective diabetes prevention programs 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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