Study Title: Diabetes Prevention Program Lifestyle Intervention 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.

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.[1-7] Our review of local, national, and international data sources found estimates of diabetes in the Marshallese population (those living in the US and in the Republic of the Marshall Islands) ranging from 20% to 50%, compared to 8.3% for the US population and 4% worldwide.[2-5] 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 pilot research, which includes health screenings with the Marshallese community in northwest Arkansas (n=398), documented extremely high incidence of diabetes (38.4%) and pre-diabetes (32.6%). Our pilot data also revealed similar disparities in one of the strongest risk factors for diabetes—obesity—with 90% of Marshallese participants classified as overweight or obese.[9,10] Thirty-two percent of those who had pre-diabetes were also overweight or obese. Further compounding these significant disparities in diabetes prevalence and related risk factors, research indicates that Pacific Islanders living in the US are less likely than other racial/ethnic groups to receive preventative or diagnostic treatment, or diabetes education.[11-13]

Reducing disparities by reducing weight. Overweight/obesity is considered the strongest modifiable risk factor for type 2 diabetes,[14] and even a modest reduction in weight (5-10%) can be clinically meaningful.[15-17]

Specific Aim. Our aim is to compare the effectiveness of achieving weight loss between two Diabetes Prevention Program Lifestyle Interventions (DPP-LI), the WORD DPP-LI[18-20] and a culturally-adapted PILI DPP-LI[21-22], in the Marshallese population using a randomized controlled trial (RCT) with a goal of 378 participants.

Study design. The study design is a comparative effectiveness research (CER), RCT conducted in church settings or other community setting convenient to the participant group with the Marshallese population. Churches were selected as the primary setting based on stakeholder input.

Randomized participant assignment. Randomization will occur at the church cluster level, with 1:1 assignment of churches to each arm. In churches with more than one group (i.e., churches with more than 20 participants, necessitating more than one group within those churches), all groups within an individual church will be randomized to the same arm. Community location based participant groups will be treated the same as if they were a church based group in the randomization process. Randomization will be conducted by a biostatistician or designated investigator, who will have no interactions with potential participants and has no supervisory role with study staff responsible for recruiting, consent, and intervention process.

Churches and community based participant groups will be blocked (i.e., grouped into similar units) according to geographic region and approximate number of adult church members. Using

a computer generated algorithm for random assignment, equal numbers of churches within each block will be assigned to the WORD DPP-LI arm and the PILI DPP-LI arm of the study.

Recruitment and Consent
Participants will be recruited through churches from Arkansas, Kansas, Missouri, and Oklahoma. The recruitment will also occur through clinics serving the Marshallese community and through local media targeting the Marshallese community. The recruitment goal is up to 400 participants through the duration of the study.

During recruitment, Marshallese study staff will give presentations and distribute study information in English and Marshallese within local community churches and meeting places. Those who express interest will complete an eligibility screener, 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.

The recruitment materials will be distributed through clinics and community based organizations serving the Marshallese community. Clinic, Marshallese community based organization, and Marshallese targeted media recruitment efforts will include contact information for potential participants to reach bilingual/bicultural study staff. Marshallese study staff will schedule time to meet with potential participants to complete eligibility screening.

Inclusion Criteria

Participant inclusion criteria:
1) Self-reported Marshallese
2) 18 years of age or older
3) Have a body mass index (BMI) of ≥25 kg/m2

Exclusion Criteria

Participant exclusion criteria:
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. An opportunity will be provided to 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: Biometric and survey data will be collected during pre-intervention, post-intervention, and 12-month post-initiation events (which is 12 months from study initiation and six months after the first post-event data collection). The data collection window is up to nine weeks on each side of the data collection date to accommodate participant availability. The 12-month post-initiation event can be split into two data collection events. One for survey data collection using remote data collection methods and one for biometric data collection. 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.

Data Collection Instruments and Procedures

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).[23] 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.[21-22]
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 WORD DPP-LI[18-20], PILI DPP-LI[21-22], BRFSS, and NHANES.

The survey data collection includes 62 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).[24] Weight locus of control is measured using the Weight Locus of Control scale.[25] Exercise self-effiacy is measured using the self-efficacy for exercise and outcome expectations scale Resnick (2004).[26] 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).[27] Food insecurity is measured using questions from National Health and Nutrition Examination Survey (NHANES).[28] Questions about sugar sweetened beverage consumption and sleep quality and quantity are taken from the Behavioral Risk Factor Surveillance System (BRFSS).[29] 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.[30]

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 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. Survey data can be collected using remote data collection methods as needed.

Remuneration: Participants will be offered a $20 Walmart gift card as remuneration for their time for their pre-intervention data collection event, $30 Walmart gift card as remuneration for their post-intervention data collection event, and a $40 ($20 for survey data collection and $20 for biometric data collection) Walmart gift card as remuneration for their 12month post-initiation event. The 12-month post-initiation event can be split into two data collection events. One for

survey data collection using remote data collection methods and one for biometric data collection. A $20 electronic gift card for participation in the remote data collection will be provided by email or mailed through the postal service consistent with the participant's preference. The $20 gift card for participation in the biometric data collection will be completed with physical gift cards. 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 who participate in the qualitative interview will be provided a $20 Walmart gift card for their participation. A participant who completes all data collection events and the interview will receive a total of $110 in gift cards.

Intervention Description. Participant groups will either receive the WORD DPP-LI or the PILI DPP-LI. Both intervention modules will be delivered at a group setting at a church or other community location convenient to the group and participation in discussion will be encouraged. Both 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 WORD DPP-LI is a faith-based diabetes prevention curriculum that teaches participants to connect faith and health to have a healthy weight, eat healthy and be physically active. The WORD DPP-LI includes 16 modules that are intended to be delivered over a 24 week period, each module approximately 90 minutes in length. The first 8 modules are intended to be delivered weekly. The last 8 modules are intended to be delivered every other week. Participants in the WORD DPP-LI will be encouraged to maintain a daily weight, nutrition, physical activity and prayer log.

The PILI DPP-LI is a family and community based diabetes prevention curriculum that teaches participants to engage their social support to have a healthy weight, eat healthy and be physically active. The PILI DPP-LI includes 14 modules that are intended to be delivered over a 24 week period and each module approximately 90 minutes in length. The first 4 modules are intended to be delivered weekly. The last 10 modules are intended to be delivered every other week. Participants will be encouraged to track their weight, physical activity and their nutrition in a log on a daily basis.

The PILI DPP-LI has fewer contact hours and is culturally adapted with examples relevant to Pacific Islanders.[21-22]

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. Both interventions will

offer materials and survey instruments in English and Marshallese. Each intervention will also offer makeup sessions for missed modules.

Within three months of the conclusion of the educational modules, all participants will be invited to participate in a qualitative interview to collect information regarding their experience.

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. 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 Analysis

Power, sample size, and detectable effects. All of the power calculations were conducted with PASS12.[31] The primary objective of the analysis is to estimate the effect of the PILI DPP-LI relative to the effect of the WORD DPP-LI with respect to the percentage of weight loss from pre- to post-intervention. Based on prior PILI DPP-LI research,[21] it is hypothesized that the adapted intervention will result in 2.5kg weight loss (SD=7) larger than the WORD DPP-LI (this is ~4% body weight loss), which reflects a medium effect size of 0.36.[32] Using the randomized clustered design, it is estimated that a sample size of 32 churches (16 clusters per arm with 12 individuals per cluster) would total N=384. This achieves 91% power to detect a difference of 2.5kg between the group means when the standard deviation is 7 (ES=0.35) and the intra-cluster correlation is 0.01 using a two-sided *t*-test with a significance level of 0.05, or 80% to detect smaller effects (ES=0.31) if observed. It is planned to impute missing data (see below), therefore all randomized participants will be included in the analysis according to an intention-to-treat protocol.

Statistical analysis plan. All of the analyses will be performed with SAS/STATv14.1. Data will be examined for distributional normality and outliers prior to any analyses. Descriptive statistics will be generated for all variables of interest included in the analysis, overall, and by intervention assignment. Univariate comparisons will consist of *t*-tests and ANOVA, and of chi-square and other non-parametric tests, if needed, for continuous and categorical variables, respectively. Randomization validity will be assessed by comparing intervention arms on baseline measures using *t*-test, chi-square test, ANOVA, and other appropriate tests. If imbalances are found, adjusting the between-group analyses for potential confounders will be considered. Primary analyses will be intention-to-treat, without regard to intervention adherence. Multivariable linear ANCOVA regression models will be used for continuous outcomes accounting for clustering effect within groups, to model and compare the PILI DPP-LI to the WORD DPP-LI (Aim 1). Using these models, treatment effects will be estimated and tested by comparing change in group-specific means at the post-intervention assessment, conservatively adjusting for baseline differences (which should be minimal by virtue of randomization) and taking in account intracluster correlation by assuming compound symmetry covariance structure.

The hypothesis is that participants randomized to the PILI DPP-LI will show a significantly higher percentage of weight loss compared to those randomized to the WORD DPP-LI. The main independent variable of interest is intervention assignment (PILI DPP-LI vs. WORD DPP-LI) and the primary outcome is percent body weight loss from pre- to post-intervention

assessment. Measures of weight will be obtained at multiple points during the study (pre-intervention, post-intervention, and 12-months post-intervention), and both post-intervention and 12-months (six months post-initiation) will be modeled, but in separate models. General linear and mixed ANCOVA regression models for continuous measures with clustering will be utilized, with treatment effect estimated as the distance between the fitted group-specific means at the post-intervention assessment, while adjusting for the fitted distance between them at baseline, conservatively. In addition, an adjustment will be made within the model for demographic factors and other covariates listed above. In order to model the outcome at the 12-month time point, a similar model to the one described above will be applied with repeated measures, and incorporate intervention, time, and their interaction effect, while adjusting for the same covariates as in the first model. This will allow examination and test weight change trajectories over time for both groups. Secondary outcome measures that are continuous in nature, such as HbA1c, will also be modeled using the same approach used to test the primary outcome (a general linear mixed model). Secondary outcomes that are discrete will be modeled using logistic regression or generalized estimating equations (GEE) for repeated binary measures accounting for the correlation within groups.

Additional analysis will be done to: 1) determine if aspects of participants' built environment as measured by Google StreetView influence effectiveness of the project's intervention, 2) determine if aspects of the food environment based on Business Analyst in ArcGIS influence effectiveness of the project's intervention.

Sensitivity analyses to determine the impact of key assumptions. We will examine the distributional assumptions for our outcome measures, which may prompt transformations if justified. We will also compare the results of parametric and non-parametric univariate tests (for instance Wilcoxon test, Kolmogorov-Smirnov test, or Fisher's Exact test, respectively) as a sensitivity step to confirm the inferences. In a case where distributional assumptions are not met, non-parametric tests will be applied. While we will track and analyze the effect of dosage (number of sessions completed), we will use an intention-to-treat analysis. To account for missing data we will compare imputation methods under several assumed missing data mechanisms, missing completely at random (MCAR), missing at random (MAR), and missing not at random (MNAR), in order to determine which underlying mechanism best fits our data.

Plans to address missing data. The study team will minimize missing data by using highly qualified staff to systematically collect data from all participants. Furthermore, we will use REDCap to monitor the occurrence of missing data during field collection. REDCap has a standard missing data report to facilitate the identification of missing data fields, which allows for continuous data quality monitoring so that missing data can be immediately collected. If a participant drops out, the study team will document why the drop out occurred. The study team will continue to collect information on all outcomes from participants, unless consent is withdrawn. Given recent advances in handling missing data in longitudinal studies, we have several reasonable approaches that we will apply and compare. We will compare the results of the analysis using three approaches as a comprehensive sensitivity check: 1) use a random effects model in SAS PROC MIXED (or weighted GEE for discrete outcomes) that makes use of all available data when assuming observations are missing completely at random (MCAR); 2)

perform multiple imputations (N=25) in SAS PROC MI when assuming observations are missing at random (MAR); and 3) perform pattern-mixture model imputations in SAS PROC MI when assuming observations are missing not at random (MNAR). To address this potential source of inferential error, we will use monotone regression-based, multiple random imputations of the outcomes. These imputations will help minimize loss of power resulting from attrition. We will use demographic covariates and prior weight measurements that are available in this predictive model. The analysis will then be carried out in multiple data sets, and the results combined using standard methods in SAS PROC MIANALYZE to produce summary effect and standard error estimates that incorporate the imputation error.[33-34]

Plans to address heterogeneity of treatment effect. Potential differential effects of the PILI DPP-LI among subgroups will be evaluated to determine its effectiveness in specific population segments. This will be done by testing two-way interactions between intervention assignment and covariates of interest. These include sex, age, education, insurance status, and marital status. Bonferroni correction will be applied to control p-values for multiple comparisons. For these exploratory comparisons, we will report all relevant subgroup outcomes analyzed.

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.

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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