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A Cluster Randomized Controlled Trial Comparing Diabetes Prevention Program Interventions for Overweight/Obese Marshallese Adults

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Abstract

This study compared the effectiveness of two Diabetes Prevention Program (DPP) interventions on weight loss among overweight and obese Marshallese adults. The study was a two-arm cluster randomized controlled trial conducted in 30 churches in Arkansas and Oklahoma. Marshallese adults with a body mass index $\geq$25 kg/m^2 were eligible for the study. The study sample included 380 participants. Participants received either a faith-based adaptation of the DPP or a family-focused adaptation of the DPP, each delivered over 24 weeks. The primary outcome was weight change from baseline. Secondary outcomes included changes in Hemoglobin A_{1c}, blood pressure, dietary intake, family support for healthy behaviors, and physical activity. Outcomes were examined longitudinally using general linear mixed effects regression models, adjusting for baseline outcomes, sociodemographic covariates, and clustering of participants within churches. Reductions in weight were small for both groups. Overall, only 7.1% of all participants lost 5% or more of their baseline body weight. There were no significant differences in weight loss between the 2 arms at 6 months (P = .3599) or at 12 months (P = .3207). Significant differences in systolic and diastolic blood pressure were found between the 2 arms at 6 months (P = .0293; P = .0068, respectively). Significant within-arm changes were found for sugar-sweetened beverage consumption and family support for both arms at both follow-ups. Both interventions achieved a modest weight loss. While even modest weight loss can be clinically significant, future research is needed to identify chronic disease prevention interventions that can successfully reduce weight for this at-risk population.

Keywords

Diabetes Prevention Program, overweight/obesity, Marshallese, type 2 diabetes, cluster randomized controlled trial, Native Hawaiian and Pacific Islander

What do we already know about this topic?
The DPP has been shown to be effective at preventing T2DM across multiple settings in the general population and in multiple racial and ethnic populations.

How does your research contribute to the field?
The DPP had yet to be tested with Marshallese adults, who experience significant cardiometabolic health disparities compared with the general US adult population.

What are your research's implications toward theory, practice, or policy?
This study provides important information on an understudied community with significant health disparities; future research is needed to identify community members' barriers to weight loss, which can inform future intervention development.

Introduction

Native Hawaiian and Pacific Islander (NHPI) populations are the second fastest growing racial/ethnic group in the United States (US).[1,2] Much of the growth is concentrated in Southern and Midwestern states.[1,2] There are approximately 17 000 Marshallese Pacific Islander residents in Arkansas and Oklahoma; most reside in Springdale, Arkansas and Enid, Oklahoma.

Beginning in 2012, a community- and patient-engaged research team began conducting qualitative and quantitative needs assessments within the community.[3-6] Health screening events conducted with adults in the Marshallese community in Arkansas found significant health disparities disproportionate to the general US population. More than a third (38.4%) of participants (n = 401) had type 2 diabetes mellitus (T2DM).[7] This proportion is more than 3 times the rate of T2DM observed in the general US adult population.[8] Another 32.6% of Marshallese participants had prediabetes, and 89.7% were overweight or obese.[7] Excess body weight is the strongest modifiable risk factor for T2DM, and weight loss of 5-10% of a person's body weight can lead to clinically meaningful reductions in the risk of T2DM.[9-12]

In response to the aforementioned disparities, researchers and Marshallese stakeholders sought to discover an evidence-based weight loss intervention to reduce T2DM. The Diabetes Prevention Program (DPP) is a gold standard behavioral weight loss intervention that improves risk factors for T2DM. The DPP has decreased the incidence of T2DM by 58% across multiple settings in the general population and in multiple racial and ethnic populations including African American/Black and Hispanic communities.[13,14] While the DPP has been tested across multiple populations and settings, the DPP had yet to be adequately tested in Pacific Islander populations in general or the Marshallese population specifically.[15]

After reviewing many of the DPP interventions adapted for other populations, researchers chose 2 DPP adaptations that seemed the most salient to Marshallese and had potential to make significant changes in body weight and other T2DM risk factors: Partnership for Improving Lifestyle Intervention (PILI) DPP[16] and Wholeness, Oneness, Righteousness, Deliverance (WORD) DPP.[17] Both interventions incorporated all required components of the DPP. These interventions focus on increasing physical activity, eating healthily, and maintaining a healthy weight. The PILI 'Ohana DPP curriculum was adapted for implementation in Pacific Islander communities and tested in Hawai'i.[18,19] The WORD DPP is a faith-based curriculum which teaches participants to connect their faith to their health and the project's behavioral goals.

Purpose of the Study/Study Overview

Using a community- and patient-engaged approach, we worked with community stakeholders to design and conduct a cluster randomized controlled trial (cRCT). The primary aim of the study was to compare the effectiveness of 2 DPP curriculums (PILI and WORD) on weight loss among overweight and obese Marshallese adults. Given that the PILI DPP included more cultural components relevant to Marshallese and yielded significant weight loss in other NHPI populations, we hypothesized that participants randomized to the PILI DPP arm would show a significantly greater weight loss compared with those randomized to the WORD DPP arm.

Methods

The study was approved by the University of Arkansas for Medical Sciences Institutional Review Board (#207034) and registered in ClinicalTrials.gov (#NCT03270436) and HSRProj (#HSRP20181360).

Study Setting

The study was conducted in 30 Marshallese churches in Arkansas and Oklahoma. As described in the study protocol,[20] Marshallese stakeholders selected churches as the preferred study setting. Prior assessments conducted with the Marshallese community in Arkansas found 96.5% of Marshallese report regular church attendance.[21]

Cluster eligibility. Because randomly assigning participants within churches to different interventions could cause issues of contamination, participants were clustered by churches. Churches with a minimum of 6 eligible participants were considered eligible. Churches with more than 20 eligible participants were split into at least 2 groups for intervention

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delivery; however, groups within an individual church were randomized to the same arm to prevent potential issues of contamination.

Participants

Inclusion and exclusion criteria. Marshallese adults (aged 18 and older) who had a body mass index (BMI) of $\geq 25\,kg/m^2$ (ie, those classified as overweight or obese) were eligible to participate in the study. Exclusion criteria included: (1) a medical condition likely to impact weight (eg, cancer, HIV/AIDS); (2) currently pregnant or breastfeeding an infant 6 months old or younger; or (3) conditions that make it unlikely that the participant will be able to follow the protocol, such as terminal illness, plans to move out of the area, or an inability to finish the intervention.[20,22]

Recruitment and consent. Church leaders within the Marshallese community were the first point of contact during the recruitment process. Once a church leader and their congregation agreed to participate in the study, Marshallese research staff held several informational sessions at the church to answer the congregation's questions. After the informational sessions, eligibility screening events were held at each church. All recruitment and consent materials were produced in the Marshallese and English languages.

Bilingual Marshallese research staff reviewed the consent information with groups of eligible persons. After review, Marshallese research staff addressed questions from the group and offered private discussions of the study and the consent document with persons before obtaining informed consent. Each participant received a copy of their consent form. Every member of the research team received training and underwent certification for participant consent procedures, study protocol, and the protections provided to human subjects.

Randomization. Randomization occurred at the church cluster level with a 1:1 assignment of churches to each arm (PILI DPP or WORD DPP). Churches were blocked according to geographic region and approximate number of adult church members. Within each cohort, randomization of churches was conducted utilizing a random number generation function that concealed the identities of the churches from the person making the assignment. Except for the investigator who conducted randomization, the allocation sequence for each cohort was concealed from study staff until after the cohort was recruited and randomized. Randomization was conducted by a biostatistician co-investigator who had no interaction with potential participants and had no supervisory role with study staff responsible for recruitment, consent, and/or intervention delivery.

Interventions

Both PILI DPP and WORD DPP focused on self-monitoring, behavioral strategies for weight loss, decreasing caloric intake for weight loss, and increasing physical activity. Both interventions were delivered by bilingual DPP educators in a group setting at the participating churches. Each educator received at least 40 h of DPP lifestyle coach training prior to the start of the interventions. Both interventions provided educational materials in Marshallese and English and offered makeup lessons for missed modules. Table S1 provides an overview of the specific topics covered in each lesson of each intervention. Articles discussing the adaptation of the interventions and integration of stakeholder input have been published previously.[20,22]

The two-phase PILI DPP curriculum integrated family and community support.[23] Phase 1 of PILI DPP included all original core DPP lessons, with additional topics specifically focused on the economics of healthy eating (ie, eating healthy within your budget) and talking with your doctor (ie, how to communicate effectively with your healthcare provider). Phase 2 integrated participants' families and friends in the study, which allowed the participants to proactively elicit specific support from their families and friends for their long-term behavior changes. Such support included family activities focused on eating and being active, managing challenging social situations, effectively communicating their healthy lifestyle goals, and identifying and utilizing community resources like parks and farmers markets. In this study, the PILI DPP intervention was delivered over 24 weeks in 90-min lessons (8 weekly lessons in phase 1 and 6 biweekly lessons in phase 2). The PILI DPP has slightly fewer contact hours compared to the WORD DPP, and the curriculum is culturally adapted to be relevant to Pacific Islanders. The cultural adaptation included a focus on family and leveraging the collectivist nature of the Marshallese community. In the Hawaiian language, *Pili* means "to be close to" or "together," and *'Ohana* means "family."[16] The curriculum emphasizes the importance and inclusion of a person's friends and family to support lasting lifestyle changes.

The WORD DPP is based on a community-engaged approach for rural African American communities of faith.[17] The research team, with input from stakeholders, made slight revisions to the curriculum. These revisions ensured relevance to Marshallese faith communities; however, the curriculum was not adapted for other aspects of Marshallese culture. The WORD DPP curriculum included 16 lessons delivered in 90-min lessons over 24 weeks. The first 8 lessons were delivered weekly before the curriculum switched to a biweekly schedule. The WORD DPP intervention encouraged participants to make healthy lifestyle changes by connecting their health to their faith. This included discussing bible verses and prayers selected by the community that focused on living a healthy lifestyle.

Data Collection

Data were collected at three-time points: baseline (pre-intervention), 6 months (immediate post-intervention), and 12 months (6 months after the immediate post-intervention).

All measures were administered at each time point. We used the formal study protocol to ensure that data were collected thoroughly and systematically from all study participants. Biometric and survey data were collected in the participating churches. Survey data were captured face-to-face with pencil and paper and then entered into REDCap.[24] After March 2020, biometric data were collected in a UAMS clinic, and survey data were collected remotely (via telephone, Skype, or Zoom) due to the COVID-19 pandemic. Data collection staff each had at least 3 years' experience collecting biometric and survey data. Study staff kept regular contact with participants through regular phone calls, text messages, and church visits to foster retention. All eligible participants were contacted to provide data at each data collection time point regardless of whether they had participated in the previous data collection event (ie, those who missed the 6 months data collection were contacted to participate in the 12 months data collection).

Study Measures

Demographic measures included age, sex, marital status, education level, and employment status. Biometric measures included weight, height, HbA_{1c}, systolic blood pressure (SBP), and diastolic blood pressure (DBP). Participant weight was measured in light clothing to the nearest 0.5 lb. (0.2 kg) using a calibrated digital scale. Blood pressure was measured using a sphygmomanometer and stethoscope or digital blood pressure device, with the participant seated and arm elevated. Fingerstick blood collection was used to test HbA_{1c} using a Rapid A1c test kit and Siemens DCA Vantage Analyzer.

Sugar-sweetened beverage consumption over the past 30 days was assessed using 2 items from the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System.[25] Fruit and vegetable consumption was assessed using 3 items adapted from Shannon et al.[26] Family support for engaging in healthy behaviors was measured using 6 items adapted from Gruber.[27] Each of the 6 items is measured via 3 response options (Often = 2, Sometimes = 1, Never = 0), giving a possible range of scores of 0 to 12, with higher scores indicating higher perceived family support. Physical activity was assessed using 2 items adapted from the brief self-report Physical Activity Questionnaire, which assessed participants' frequency of engaging in moderate and vigorous levels of physical activity over the past month (more than 4 times a week, 2-4 times a week, about once a week, etc.).[19,28] Using methods developed by Marshall et al,[28] we created a total physical activity variable to estimate proportions of participants who engage in sufficient levels of physical activity. Each 4-point scale for moderate and vigorous physical activity was weighted: 0 = Rarely or Never; 1 = Once a week; 2 = 2-4 times a week; and 4 = More than 4 times a week. The weights for each participant's response to the moderate and vigorous physical activity variables were then summed and dichotomized: ≥ 4 = sufficient physical activity and <4 = insufficient physical activity.

Sample Size and Power Calculations

The primary objective of the study was to estimate the effect of the PILI DPP compared with the effect of the WORD DPP on weight loss from baseline. Based on prior PILI DPP research,[18] we hypothesized that the adapted intervention would result in 2.5 kg (SD = 7) larger weight loss than the WORD DPP (~4% body weight loss), which reflects a medium effect size of 0.36.[29] Using the randomized clustered design, a sample size of 32 churches (16 clusters per arm, with 12 participants per cluster) would total 384 participants. This structure achieved 91% power to detect a difference of 2.5 kg between the group means when SD = 7 (extreme spread [ES], 0.35) and the intraclass correlation (ICC) is .01, using a 2-sided *t*-test with a significance level of .05, or 80% to detect smaller effects (ES, 0.31), if observed. All power calculations were conducted with PASS12.[30]

Post-Hoc Detectable Effect Calculations

Post-hoc detectable effects were calculated based on the actual observed number of clusters, average participants per cluster, and ICC for the primary outcome. Sample sizes of 212 in WORD and 166 in PILI, which were obtained by sampling 16 churches with an average of 13 subjects each in WORD and 14 churches with an average of 12 subjects each in PILI, achieve 80% power to detect an effect size between the group means of at least 0.43, per 1 unit standard deviation assumed to be 1, which is close to a medium effect size. The ICC is assumed to be .08 based on the observed model data for weight at post-intervention. The coefficient of variation of cluster sizes is 0.65. A two-sided test was used with a significance level of .05. A one-sided test with a significance level of .05 and same observed data allows us to detect an effect size of 0.38, which is slightly lower than the two-sided test, for a small to medium effect. These effect sizes translate into group differences of approximately 0.5 kg per 1-unit standard deviation. In this study, that would indicate 1 to 1.5 kg detectable differences, given the observed standard deviation of the difference close to 3. This test used degrees of freedom based on the number of subjects. As executed, this study was powered to detect meaningful small to medium effects for primary and secondary outcomes.

Study Outcomes and Analytical Approaches

Descriptive statistics, including means, standard deviations, and proportions, were generated for all variables of interest included in the analysis, overall, and by intervention arm.

The primary outcome was the change in participant body weight from baseline. For the primary outcome analysis, we used linear mixed-effects regression model for repeated measures to examine the impact of the PILI DPP compared with the WORD DPP on change in weight. The model included intervention arm, time, and their interaction effect while adjusting for baseline weight, age, sex, marital status, education, and employment status, allowing us to examine and test weight change trajectories over time for both arms. The model also accounted for clustering of churches as a random effect with assumed compound symmetry as an underlying covariance structure. Treatment effects were estimated and tested by comparing the change in arm-specific means from baseline to the 2 post-intervention time points, conservatively adjusting for baseline weight differences. Data were examined for distributional normality and outliers prior to any analyses.

Secondary outcome measures that were continuous, such as HbA_{1c}, were modeled using the same approach used to test the primary outcome. Secondary outcomes that were discrete, such as engagement in sufficient physical activity, were modeled using logistic regression. Analyses were guided by intention-to-treat principle, without regard to intervention adherence. This allowed us to examine and test change trajectories over time for both groups using all available data. Potential differential effects of the DPP interventions among subgroups were evaluated to determine effectiveness in specific population segments. This was done by testing three-way interactions between intervention assignment, time, and covariate of interest. These covariates included sex and age. They were tested within the full model. All analyses were performed with SAS/STATv14.1.[31]

Results

Participant Flow

Figure 1 presents the study's CONSORT Flow Diagram. A total of 31 churches initially agreed to participate in the study and were randomized. Prior to delivery of the intervention, 1 church randomized to the PILI DPP arm ceased operation. One participant from this church joined a church also randomized to the PILI DPP arm so that they could participate in the study. Of the 386 participants consenting to be screened for eligibility, 380 were determined to be eligible and participated in the study arm to which the church was randomized (mean participants per church = 12.67). Two eligible participants did not provide baseline data during their data collection window. Although these participants were not administratively unenrolled from the study (ie, they were allowed to attend classes and provide data at follow-up data collection events), they are not included in outcomes analyses due to missing baseline data on the primary outcome. Reasons for ineligibility and incomplete follow-up data collections are provided in Figure 1. Because none of the churches discontinued participation after beginning the intervention, retention/attrition throughout the course of the study is shown for individual participants. Participants were included in counts if they provided any data at the respective data-collection event (ie, if participants provided only survey data or only biometric data, they are included in the numbers for that data-collection event).

Participant Characteristics

Table 1 presents the baseline characteristics of participants by study arm and overall. Of the 378 participants with baseline data, the mean age was 42.3 years (SD = 11.6; range = 18-74), and 56.6% were female. Mean weight was 84.5 kg (SD = 15.1). Overall, 26.5% of participants had prediabetes, and 48.2% had T2DM at baseline based on HbA_{1c}.

Table 2 presents unadjusted summary statistics for all primary and secondary outcomes by study arm for completers only (ie, only those with outcome data at all 3 time points).

Intervention Session Attendance

Participants in the WORD DPP arm attended a mean of 7.3 sessions (SD = 4.3) out of a possible 16 sessions, and participants in the PILI DPP arm attended a mean of 6.7 sessions (SD = 6.9) out of a possible 14 sessions. Within the WORD DPP arm, 44.3% of participants attended 50% or more of the 16 sessions. Within the PILI DPP arm, 47.0% of participants attended 50% or more of the 14 sessions. We found no significant differences between arms with respect to the mean number of sessions attended ($P = .1316$) or the proportion of participants attending 50% or more of intervention sessions ($P = .4693$).

Changes in Weight

Overall, 7.1% of all participants lost 5% or more of their baseline body weight by 6 months. Among those in the WORD DPP arm, 8.2% lost 5% or more of their baseline weight, and 5.4% of those in the PILI DPP arm lost 5% or more of their baseline weight. Comparing the mean change in weight between arms from baseline to each time point, linear mixed-effects adjusted models showed no difference in the changes for the PILI DPP arm compared with the WORD DPP arm at 6 months (between-arm difference = −2.07 kg; $P = .3599$) and no differences at 12 months (between-arm difference = −2.38; $P = .3207$) (Table 3).

Within-arm changes in mean weight from baseline to each time point are presented in Table S1. Participants randomized to the WORD DPP arm had no statistically significant mean change in weight from baseline to 6 months (estimated change = 0.03; $P = .9821$) or from baseline to 12 months (estimated change = −0.26; $P = .8625$). Participants randomized to the PILI DPP arm had no statistically significant mean change in weight from baseline to 6 months (estimated change = 0.08; $P = .9626$) or at 12 months (estimated change = −0.52; $P = .7776$). Further, no pre-planned three-way interactions from baseline to post-intervention (group × time × sex,

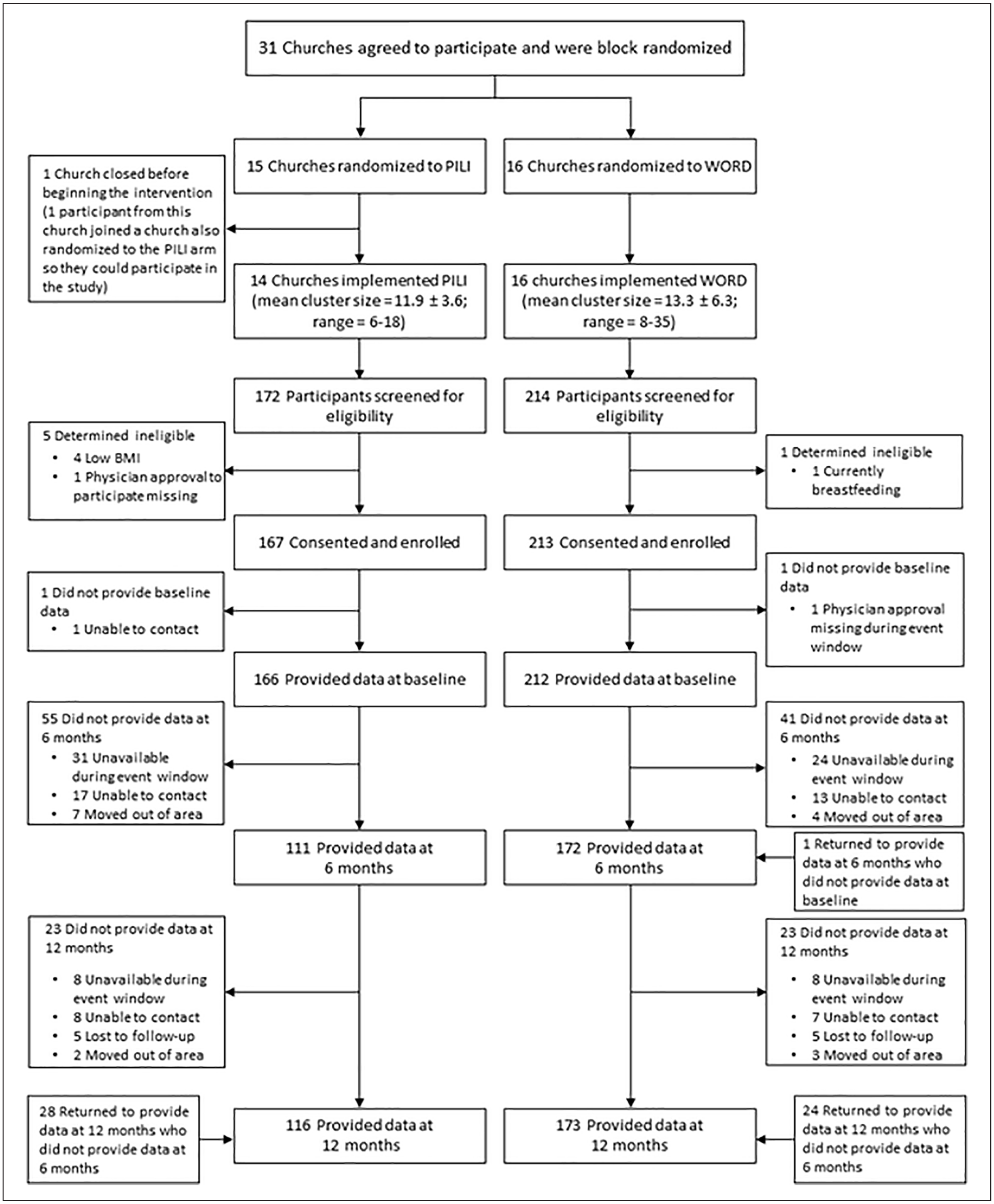

Figure 1. Modified Cluster Trial CONSORT Flow Diagram: Cluster and Participant Randomization, Enrollment, and Retention.

Table 1. Baseline Characteristics of Participants, Mean (Standard Deviation), or %.

	PILI DPP (N = 166)	WORD DPP (N = 212)	Total (N = 378)[a]
Age (years)	41.4 (12.8)	42.9 (10.6)	42.3 (11.6)
Male	41.6	44.8	43.4
Married/partnered	80.1	84.9	82.8
Education			
Less than HS	48.8	48.6	48.7
HS/GED	37.9	32.6	34.9
Higher than HS	13.3	18.8	16.4
Employed	50.0	58.0	54.5
Weight (kg)	83.4 (14.3)	85.4 (15.6)	84.5 (15.1)
HbA_{1c} (%)	7.8 (2.9)	7.5 (2.6)	7.7 (2.8)
SBP (mmHg)	128.8 (20.9)	131.3 (18.6)	130.2 (19.7)
DBP (mmHg)	78.4 (10.4)	80.1 (11.6)	79.5 (10.6)
T2DM status[b]			
Prediabetes	26.5	26.4	26.5
Diabetes	50.0	46.7	48.2

Note. DPP = Diabetes Prevention Program; PILI = Partnership for Improving Lifestyle Intervention; WORD = Wholeness, Oneness, Righteousness, and Deliverance; HS = high school; GED = graduate equivalency diploma; HbA_{1c} = Hemoglobin A_{1c}; SBP = systolic blood pressure; DBP = diastolic blood pressure.
[a]N = 378 due to missing baseline data for 2 participants.
[b]T2DM status was determined based on participant HbA_{1c} reading. Prediabetes was defined as HbA_{1c} 5.7% to 6.4%; diabetes was defined as $HbA_{1c} \geq 6.5\%$.

Table 2. Primary and Secondary Outcomes: Unadjusted Means and 95% Confidence Intervals by Study Arm and Time, among Those with Outcome Data at All 3 Time Points.[a]

	Baseline	6 Months	12 Months
Weight (kg)			
WORD DPP (n = 128)	86.67 (83.80-89.54)	86.10 (83.29-88.91)	85.80 (82.95-88.65)
PILI DPP (n = 72)	83.83 (80.75-86.91)	83.71 (80.67-86.75)	83.41 (80.23-86.6)
HbA_{1c} (%)			
WORD DPP (n = 128)	7.53 (7.07-7.99)	7.58 (7.10-8.06)	7.55 (7.05-8.05)
PILI DPP (n = 72)	8.09 (7.39-8.78)	8.05 (7.36-8.75)	8.13 (7.42-8.85)
SBP (mmHg)			
WORD DPP (n = 128)	133.09 (129.95-136.22)	130.00 (125.89-134.11)	124.55 (120.97-128.14)
PILI DPP (n = 72)	132.06 (126.52-137.59)	123.86 (117.53-130.19)	120.26 (115.62-124.91)
DBP (mmHg)			
WORD DPP (n = 128)	80.99 (79.15-82.83)	79.59 (77.41-81.76)	77.74 (75.57-79.92)
PILI DPP (n = 72)	78.88 (76.45-81.30)	74.28 (71.66-76.90)	75.51 (72.73-78.29)
SSB consumption			
WORD DPP (n = 148)	1.38 (1.11-1.64)	1.03 (0.82-1.23)	0.92 (0.67-1.17)
PILI DPP (n = 88)	1.67 (1.23-2.11)	1.16 (0.84-1.48)	1.31 (0.92-1.70)
F&V consumption			
WORD DPP (n = 146)	3.49 (3.27-3.72)	3.80 (3.58-4.02)	4.05 (3.83-4.27)
PILI DPP (n = 87)	3.47 (3.20-3.74)	3.72 (3.42-4.03)	3.78 (3.46-4.10)
Family support			
WORD DPP (n = 144)	4.88 (4.51-5.26)	6.24 (5.80-6.69)	6.17 (5.71-6.62)
PILI DPP (n = 86)	5.15 (4.59-5.71)	6.33 (5.74-6.91)	6.02 (5.44-6.60)
Sufficient physical activity, no. (%)			
WORD DPP (n = 148)	82 (55.4)	93 (62.8)	85 (57.4)
PILI DPP (n = 87)	30 (34.5)	52 (59.8)	45 (51.8)

Note. Decreases in SSB consumption, and increases in all other outcomes, are considered beneficial.
DPP = Diabetes Prevention Program; PILI = Partnership for Improving Lifestyle Intervention; WORD = Wholeness, Oneness, Righteousness, Deliverance; HbA_{1c} = hemoglobin A_{1c}; SBP = systolic blood pressure; DBP = diastolic blood pressure; SSB = sugar-sweetened beverage; F&V = fruit and vegetable.
[a]The means, confidence intervals, numbers, and percentages presented here do not take into account clustering of participants within churches.

Table 3. Longitudinal Analysis: Estimated Means, Percentages, Regression Coefficients, and 95% Confidence Intervals for Biometric Outcomes by Study Arm and Time.[a].

		Baseline	6 Months	12 Months	Between-arm difference[b]					
Outcome	Study arm	Est. mean (95% CI)	Est. mean (95% CI)	Est. mean (95% CI)	Base	*P* value	6 Months	*P* value	12 Months	*P* value
Primary outcome										
Weight	WORD DPP	86.44 (83.14; 89.76)	86.47 (83.02; 89.92)	86.18 (82.49; 89.86)	−2.12 (−6.22; 1.98)	.3042	−2.07 (−6.58; 2.43)	.3599	−2.38 (−7.14; 2.38)	.3207
(kg)	PILI DPP	84.32 (80.70; 87.93)	84.40 (80.44; 88.36)	83.80 (79.59; 88.01)						
Secondary biometric outcomes										
HbA1c	WORD DPP	7.27 (6.67; 7.86)	7.32 (6.70; 7.95)	7.25 (6.59; 7.92)	0.39 (−0.35; 1.13)	.2942	0.23 (−0.58; 1.05)	.5698	0.36 (−0.51; 1.22)	.4106
(%)	PILI DPP	7.66 (7.00; 8.31)	7.55 (6.84; 8.27)	7.61 (6.85; 8.37)						
SBP	WORD DPP	129.42 (124.63; 134.21)	126.83 (121.87; 131.78)	120.75 (115.04; 125.99)	−1.22 (−7.14; 4.71)	.6818	−7.18 (−13.61; −0.75)	**.0293**	−2.45 (−9.19; 4.28)	.4686
(mmHg)	PILI DPP	128.20 (122.98; 133.42)	119.65 (114.00; 125.30)	118.30 (112.35; 124.24)						
DBP	WORD DPP	79.60 (77.35; 81.86)	78.50 (76.12; 80.88)	76.41 (73.82; 79.01)	−1.27 (−4.05; 1.50)	.3614	−4.42 (−7.57; −1.28)	**.0068**	−0.17 (−3.54; 3.19)	.9181
(mmHg)	PILI DPP	78.33 (75.88; 80.78)	74.08 (71.31; 76.85)	76.24 (73.25; 79.23)						

Note. Statistically significant *P* values are bolded.
CI = confidence interval; DPP = Diabetes Prevention Program; WORD = Wholeness, Oneness, Righteousness, and Deliverance; PILI = Partnership for Improving Lifestyle Intervention; HbA_{1c} = Hemoglobin A_{1c}; SBP = systolic blood pressure; DBP = diastolic blood pressure.
[a]Estimates from mixed-effects regression models adjusted for baseline outcome, intervention, time, and intervention × time interaction, state of residence, age, sex, marital status, education level, and employment status. The model also accounts for clustering of participants within churches as a random effect. The model uses all available data from all participants at each time point.
[b]The estimated group contrast of the changes from baselines corresponds to the estimates of the arm × time interaction.

$P = .2580$; group × time × age, $P = .9723$) or including all 3 time points (group × time × sex, $P = .5029$; group × time × age, $P = .9936$) were detected, suggesting reasonable homogeneity of treatment effects across time for these key demographic variables.

Changes in Secondary Biometric Outcomes

Table 2 presents unadjusted summary statistics for HbA_{1c}, SBP, and DBP. Comparing mean change between arms at each time point relative to baseline, linear mixed-effects adjusted models showed there were no significant differences in mean HbA_{1c} change at 6 or 12 months (between arm difference = 0.23, $P = .5698$; between arm difference = 0.36, $P = .4106$) (Table 3). Similarly, there were no significant mean changes in HbA_{1c} within either study arm (Table S2).

With respect to blood pressure, there were significant differences between arms for SBP and DBP at 6 months (SBP = −7.18, $P = .0293$; DBP = −4.42, $P = .0068$) but not at 12 months (SBP = −2.45, $P = .4686$; DBP = −0.17, $P = .9181$) (Table 3). Participants randomized to the WORD DPP arm had no statistically significant mean reduction in SBP from baseline to 6 months (estimated change = −2.59; $P = .1803$) but had statistically significant mean reduction from baseline to 12 (estimated change = −8.67; $P < .0001$). Participants randomized to the PILI DPP arm had statistically significant mean reductions in SBP from baseline to 6 months (estimated change = −8.55; $P = .0005$) and at 12 months (estimated change = −9.90; $P = .0002$) (Table S2). Participants randomized to the WORD DPP arm had no statistically significant mean reduction in DBP from baseline to 6 months (estimated change = −1.10; $P = .3451$) but had statistically significant mean reduction from baseline to 12 months (estimated change = −3.19; $P = .0114$). Participants randomized to the PILI DPP arm had statistically significant mean reduction in DBP from baseline to 6 months (estimated change = −4.25; $P = .0034$) but not at 12 months (estimated change = −2.09; $P = .1601$) (Table S2).

Changes in Secondary Health Behaviors and Psychosocial Outcomes

Table 2 presents unadjusted summary statistics for the measures of health behaviors and perceived family support. We examined the effect of the interventions on changes in these 4 self-reported health behavior and psychosocial outcomes from baseline. Among these 4 secondary outcomes, results showed no significant differences between the arms at either follow-up time point (Table 4).

To describe participants' health behaviors and perceived family support over time within each study arm, within-arm changes from baseline to each time point are presented in Table S3.

Participants randomized to the WORD DPP arm had statistically significant mean reductions in SSB consumption from baseline to 6 months (estimated change = −0.41; $P = .0348$) and at 12 months (estimated change = −0.47; $P = .0165$). Participants randomized to the PILI DPP arm also had statistically significant mean reductions in SSB consumption from baseline to 6 months (estimated change = −0.79; $P = .0009$) and at 12 months (estimated change = −0.75; $P = .0013$).

Participants randomized to the WORD DPP arm had statistically significant mean increases in fruit and vegetable consumption from baseline to 6 months (estimated change = 0.35; $P = .0147$) and from baseline to 12 months (estimated change = 0.50; $P = .0006$). Participants randomized to the PILI DPP arm had no statistically significant mean increases in fruit and vegetable consumption from baseline to 6 months (estimated change = 0.02; $P = .8860$) or at 12 months (estimated change = 0.10; $P = .5388$).

Participants randomized to the WORD DPP arm had statistically significant mean increases in perceived family support from baseline to 6 months (estimated change = 1.67; $P < .0001$) and at 12 months (estimated change = 1.49; $P < .0001$). Participants randomized to the PILI DPP arm also had a statistically significant increase in perceived family support from baseline to 6 months (estimated change = 0.88; $P = .0092$) and at 12 months (estimated change = 0.96; $P = .0041$).

Participants in both arms showed statistically significant increases in the proportion of individuals who engage in sufficient levels of physical activity at 6 months. We observed more than a 50% increase in odds of engaging in sufficient physical activity for both WORD DPP and PILI DPP arm participants ($P = .0261$ and $P = .0388$, respectively). The observed increases deteriorated at 12 months and were no longer significant for either arm.

Discussion

The primary aim of the study was to compare the effectiveness of the WORD DPP with the PILI DPP in achieving weight loss among overweight and obese Marshallese adults. We hypothesized that the PILI DPP intervention would produce greater weight loss than the WORD DPP intervention. However, there were not significant differences in weight change between the PILI DPP arm and the WORD DPP arm. Only 7.1% of participants lost at least 5% of body weight, which is considered clinically meaningful.[9-12] This is a lower proportion of study participants than what has been found in previous studies. Whittemore's[32] systematic review showed a range of 11% to 64% met the 5% weight loss goal at follow-ups of 3 to 12 months.

Regarding secondary outcomes, there were no significant changes in HbA_{1c}. This is in contrast to prior studies of

Table 4. Longitudinal Analysis: Estimated Means, Percentages, Regression Coefficients, and 95% Confidence Intervals for Secondary Outcomes by Study Arm and Time.[a]

		Baseline	6 Months	12 Months	Between-arm difference[b]					
Outcome	Study arm	Est. mean (95% CI)	Est. mean (95% CI)	Est. mean (95% CI)	Base	*P* value	6 Months	*P* value	12 Months	*P* value
SSB consumption	WORD DPP	1.65 (1.33; 1.97)	1.24 (0.89; 1.58)	1.18 (0.84; 1.53)	0.51 (0.11; 0.91)	**.0141**	0.12 (−0.34; 0.59)	.5984	0.22 (−0.24; 0.68)	.3376
	PILI DPP	2.16 (1.81; 2.51)	1.36 (0.96; 1.77)	1.40 (1.00; 1.80)						
F&V consumption	WORD DPP	3.59 (3.29; 3.90)	3.94 (3.62; 4.25)	4.10 (3.78; 4.41)	0.10 (−0.27; 0.48)	.5888	−0.22 (−0.64; 0.20)	.2960	−0.30 (−0.71; 0.11)	.1519
	PILI DPP	3.70 (3.67; 4.03)	3.72 (3.36; 4.08)	3.80 (3.44; 4.16)						
Family support	WORD DPP	4.99 (4.49; 5.50)	6.66 (6.12; 7.20)	6.48 (5.94; 7.02)	0.50 (−0.13; 1.13)	.1150	−0.28 (−1.01; 0.44)	.4322	−0.02 (−0.73; 0.69)	.9529
	PILI DPP	5.50 (4.95; 6.05)	6.38 (5.75; 7.00)	6.46 (5.84; 7.08)						
Sufficient physical activity[c]		N (%)	N (%)	N (%)	OR	*P* value	OR	*P* value	OR	*P* value
	WORD DPP	112 (52.8)	108 (63.2)	99 (57.9)	0.79 (0.53; 1.19)	.2596	0.77 (0.47; 1.25)	.2824	0.93 (0.73; 1.26)	.7547
	PILI DPP	78 (47.0)	63 (56.8)	65 (56.0)						

Note. Decreases in SSB consumption, and increases in all other outcomes, are considered beneficial. Statistically significant *P* values are bolded.
CI = confidence internal; DPP = Diabetes Prevention Program; WORD = Wholeness, Oneness, Righteousness, and Deliverance; PILI = Partnership for Improving Lifestyle Intervention; SSB = sugar-sweetened beverage; F&V = fruit and vegetable; OR = odds ratio.
[a]Estimates from mixed-effects regression models adjusted for baseline outcome, intervention, time, and intervention × time interaction, state of residence, age, sex, marital status, education level, and employment status. The model also accounts for clustering of participants within churches as a random effect.
[b]The estimated group contrast of the changes from baselines corresponds to the estimates of the arm × time interaction.
[c]Logistic regression was used to model the physical activity outcome.

diabetes self-management education adapted for the Marshallese population.[33] However, there were significant improvements within arm for blood pressure, and there were significant differences between arms in SBP and DBP reductions at 6 months in favor of PILI DPP arm. Not only were these reductions statistically significant, but based on prior research, they are likely to be clinically meaningful for participants as well. Prior research has noted that thresholds for clinically meaningful improvements in blood pressure tend to start at reductions of 5 mmHg for SBP and 2 mmHg for DBP.[34,35] Reboldi et al[35] found a reduction in SBP of 5 mmHg resulted in a 13% decreased risk of stroke, and reduction in DBP of 2 mmHg resulted in an 11.5% decreased risk of stroke. At 12 months, the reductions in SBP and DBP observed within each arm eclipsed this threshold, with significantly larger reductions in SBP for both arms. A more recent study found that for every 10 mmHg reduction in SBP, the risk of coronary heart disease decreased by 21%.[36] The reductions in SBP observed in the PILI DPP arm (−9.90 mmHg) may result in similar reductions in risk for those participants. Given that the reductions in SBP observed at 12 months for both arms were greater than the reductions observed at 6 months, these reductions may be maintained beyond the life of the study. However, it should be noted that these reductions cannot be attributed solely to the adoption of positive lifestyle modifications resulting from the DPP interventions; it is possible that participants initiated or began to adhere to previously prescribed blood pressure medications.

There were observed improvements within arms for SSB consumption in both interventions, with the PILI DPP arm reducing almost a full drink per day, which is a nutritionally meaningful change. There were significant improvements within the WORD DDP arm for fruit and vegetable consumption. Within both arms, there were significant improvements in the proportion of participants who engaged in sufficient levels of physical activity at 6 months. There were significant improvements within both arms for perceived family support at 6 and 12 months. While only the PILI DPP specifically focused on increasing family support, the WORD DPP also increased family support. This could have been the result of delivering the interventions in a close-knit community setting (ie, within churches).

While neither intervention facilitated significant weight loss, there is potential for the results to help stakeholders make decisions. The null results may indicate the presence of social ecological barriers to weight loss and diabetes prevention. Prior research has shown that social, economic, and environmental determinants are significant predictors of being overweight/obese and having pre-diabetes or diabetes and may inhibit weight loss success.[37-40] Marshallese communities face many social, economic, and environmental challenges.[5,41-44] Prior studies have shown that Marshallese and other Pacific Islanders have significant food insecurity,[45-47] and food insecurity has been linked to both higher BMI and T2DM in other populations.[48-51] Similarly, research has documented that a large proportion of Marshallese live in low-income and unstable housing.[21,52] Environmental determinants such as housing have been associated with increasing BMI.[37-40]

Future Research

Our findings were in contrast to prior literature which has demonstrated the effectiveness of DPP.[14,15] Our findings demonstrate the importance of specific research on understudied populations rather than assuming that the findings from research that did not include Pacific Islander or Pacific Islander subpopulations such as the Marshallese are effective. Future research should incorporate qualitative methods to better understand Marshallese community members' barriers to weight loss. In addition, research focused on family models of DPP may be successful given the prior success of a family model of diabetes self-management education and support.[33] Future research should also focus on policy-level and multi-level interventions that move beyond solely focusing on individual-level behaviors and instead focus on social, economic, and environmental aspects of obesity and diabetes prevention. For example, there is emerging research on the effectiveness of policy-level interventions to address obesity among minority populations.[53] Multi-level interventions that have focused on the individual level as well as social, economic, and environmental aspects of obesity and diabetes prevention have also shown success; however, most multi-level obesity and diabetes prevention studies have been conducted with children.[54]

Strengths and Limitations

The study has both strengths and limitations. Class attendance and retention were not as strong as our prior studies, especially at 12 months, where the COVID-19 pandemic heavily affected our ability to collect data in the community. It is possible that the similarity of the 2 interventions contributed to the lack of differences in baseline to follow-up changes in the primary outcome. Despite each intervention being adapted (ie, PILI for Pacific Islanders and WORD for faith communities), the content of both the PILI DPP and the WORD DPP was aligned with that of the original DPP curriculum. Further, the shared setting (ie, churches) in which both interventions were conducted may have contributed to the interventions being too similar despite the tailoring of the interventions. The WORD DPP was specifically tailored to incorporate faith, while the PILI DPP was not conceived to include this aspect; however, conducting the PILI DPP intervention in churches may have resulted in some aspects of faith being brought into the intervention even if not explicitly mentioned by the educators. Similarly, some educators were involved with leading classes for both the PILI DPP and the WORD DPP, which may have further contributed to the interventions being too similar. The study focused on

Marshallese participants from 2 geographic areas, so findings may not hold for other populations or Marshallese communities in other geographic areas. Though we used survey measures that have been shown to be valid and reliable in other populations, there are no measurement studies to our knowledge that have validated survey measures in the Marshallese language or among Marshallese participants. Despite limitations, this study provides important information on an understudied community with significant health disparities. This study fills an important gap in the current literature in several ways. To our knowledge, this study is one of only 2 RCTs conducted with the Marshallese community. This study was also one of the first DPP trials to be conducted solely with Pacific Islander participants in the continental US. Despite showing no difference in the effectiveness of the interventions, the study was methodologically sound and powered to detect a small effect. This provides an important example for others conducting cRCTs that are methodologically rigorous, patient-centered, and community-engaged.

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Declaration of Conflicting Interests

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Ethical Approval

The study was approved by the University of Arkansas for Medical Sciences Institutional Review Board (#207034) and registered in ClinicalTrials.gov (#NCT03270436) and HSRProj (#HSRP20181360).

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Supplemental Material

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