

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications



journal homepage: www.elsevier.com/locate/conctc

Feasibility and efficacy of a pilot family model of diabetes self-management intervention in the Republic of the Marshall Islands

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ARTICLE INFO

Keywords: Type 2 diabetes mellitus Diabetes self-management education HbA1c Pre- and post-intervention Marshallese

ABSTRACT

Background: The Republic of the Marshall Islands (RMI) faces numerous health disparities, including one of the highest prevalence of type 2 diabetes mellitus (T2DM) in the world. Diabetes self-management education and support (DSMES) has shown efficacy in improving glycemic control and through increases in knowledge and self-management activities; however, there is limited research on DSMES in the RMI. This study evaluated the feasibility and efficacy of a culturally adapted family model of DSMES (F-DSMES) in the RMI. The F-DSME included 8 h of group educational classes delivered in churches by a community health worker.

Methods: This pilot study assessed retention and dosage rates (e.g., class attendance) among the participants with T2DM (n = 41). Efficacy was evaluated by examining pre- and post-intervention differences in HbA1c, knowledge, family support, and self-management activities among those who completed the post-intervention data collection (n = 23).

Results: The results indicate completion of post-intervention data collection and attendance were associated; 70% of participants who completed the post-intervention data collection received at least 6 h of intervention compared to 3 h for those who did not. Although the reduction in HbA1c was not statistically significant, participants demonstrated statically significant increases in knowledge, family support, and an increase in self-management including in checking of blood glucose and feet.

Conclusions: This study provides important information to help address T2DM disparities in the RMI, including the feasibility and efficacy of F-DSMES. Additional research will help in understanding how to translate improvements in knowledge, family support, and self-management activities into improvements in HbA1c. This may include addressing social ecological factors that affect glycemic control.

Background

The Republic of the Marshall Islands (RMI), an independent United States (US) Affiliated Pacific Island nation, faces significant health disparities [1,2]. Nuclear testing conducted in the RMI by the US Military in the 1940s and 1950s intensified these health disparities in two important ways [1,3–5]. The first stems from research conducted by American scientists of the effects of nuclear fallout on the Marshallese population, without consideration of language differences or informed consent, thus

creating distrust in outside researchers [3]. The second stems from the nuclear fallout that led to the contamination of local fresh food sources, creating a reliance on highly processed commodity foods (e.g. rice, canned meat) [3–7]. The dependence on commodity foods has increased the intake of simple carbohydrates and fats while simultaneously reducing the intake of fresh fruits and vegetables [5,6]. Given the transition from the traditional diet of natural, whole foods to a diet high in processed foods, health disparities now experienced by the Marshallese population in the RMI include a higher than average rate of type 2

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https://doi.org/10.1016/j.conctc.2021.100824

Received 26 October 2020; Received in revised form 6 July 2021; Accepted 24 July 2021 Available online 30 July 2021

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diabetes mellitus (T2DM) [8–11]. Over 30% of Marshallese adults in the RMI have T2DM, a rate much higher than experienced by the general population in the US (13.3%) and globally (9.3%) [8,12].

Diabetes self-management education and support (DSMES), an evidence-based intervention, has shown to improve risk factors for diabetes as well as assist people diagnosed with diabetes and effectively manage the condition [13-16]. Although DSMES has resulted in improvement of diabetes self-management, the results are not universal across racial/ethnic groups, leading to the need to adapt DSMES interventions to improve efficacy in marginalized communities [17-19]. Culturally appropriate family models of DSMES (F-DSMES) have shown improvements in diabetes management for marginalized communities, including African American, Latinx, and Native American communities [16-22]. There is limited research on the effectiveness of F-DSMES in the RMI. The one currently published study of DSMES in the RMI did not document an effect on diabetes related outcomes, including glycemic control, and did not include family members [23]. Given the historical trauma and resulting health disparities, including the high rate of diabetes in the RMI, it is crucial to address the disparate rate of diabetes in ways that are sensitive to the culture and experiences of the Marshallese population of the RMI.

F-DSMES in the RMI

Social Cognitive Theory (SCT) is the basis for F-DSMES interventions. SCT recognizes interactions between individuals, their environment, and their behaviors that are active and reciprocal [24,25]. Moreover, SCT recognizes that human health is a social matter, an important aspect of the successful implementation of F-DSMES interventions. Social and environmental context is particularly important in understanding self-management behaviors. Individual attribution ignores the influence of the social, cultural, and environmental context on the ability to adhere to diabetes treatment and self-management plans [22,26-38]. Family members, through interactions with the person with T2DM, may sway choices to follow recommended treatment and self-care regimens. The goal of the F-DSMES curriculum is to engage family members as active participants in diabetes care and to include them in the setting of goals and planning strategies to manage T2DM, with the intention of increasing social support for self-management behaviors and ultimately improving health outcomes for the person with T2DM and potentially for the family member [39,40].

The authors developed an F-DSMES intervention in conjunction with the Marshallese community in Arkansas. The Arkansas F-DSMES curriculum is asset-based, identifying and leveraging culturally specific facilitators of healthy behavioral change to overcome barriers to effective self-management. Multiple articles have described the F-DSME intervention [41–43]. When the Arkansas F-DSMES intervention was compared to a standard DSMES intervention in a randomized controlled trial (RCT), the Arkansas F-DSMES demonstrated a 1.15% reduction in mean HbA1c (p < .001) immediately post intervention and 0.87% reduction at 12 months (p < .001) [41].

Given the success of the RCT in Arkansas, the curriculum was pilot tested in the RMI in cooperation with the local community leaders and the Ministry of Health and Human Services. This article presents the initial evaluation of the piloted F-DSMES in RMI and its effect on glycated hemoglobin levels (HbA1c), diabetes knowledge, and family support for diabetes care for the Marshallese participants. The article also describes the feasibility of conducting a trial in the RMI [43].

Methods

Study setting

In Arkansas, the F-DSMES intervention was delivered to a participant with T2DM and at least one family member. F-DSMES sessions held in the home were facilitated by a bilingual community health worker (CHW) and a certified diabetes educator (CDE) over the course of eight weeks. Although the F-DSMES using these methods demonstrated efficacy in the Marshallese community in Arkansas, the RMI lacks resources including CDEs and homes large enough to facilitate family education sessions [41,42,44]. Therefore, the F-DSMES offered in the RMI used trained CHWs without a CDE present and group-based education sessions delivered in local faith-based organizations (FBOs) [43]. CHWs received 40 h of general CHW training, plus 40 h of F-DSMES curriculum and study specific training. All the CHWs were local Marshallese living in the RMI. The eight weeks of F-DSMES provided 10 h of diabetes education to participants and their family members, with an additional two-week window for make-up classes, as needed.

Recruitment

Faith and FBOs are an important part of Marshallese culture, and prior reports indicate 96.5% of the Marshallese population report regular church attendance [45]. Recruitment took place during informational sessions at four FBOs where the group educational classes for participants and family members were later held [43].

Inclusion criteria

The inclusion criteria for participants included: (1) Marshallese descent; (2) at least 18 years of age; (3) a diagnosis of T2DM (defined as having an HbA1c \geq 6.5); (4) a family member willing to participate in the program; and (5) a commitment to attend and participate in all educational sessions and data collection events. Exclusion criteria included: (1) having participated in a DSMES in the past five years; (2) plans to leave the area during the study; or (3) reporting a condition which would make it unlikely for the participant to complete the program [43].

Informed consent

Bilingual research staff completed a written informed consenting process with all interested and eligible participants.

Data collection

The study protocol and materials were reviewed and approved by the University of Arkansas for Medical Sciences Institutional Review Board (#239272), adapted from the instruments and protocol developed as part of the Adapted Family Model of DSME RCT (UAMS IRB#203482) (Clinical Trial #NCT02407132) [41,46]. The RMI Ministry of Health and Human Services reviewed and approved the study for conduct in the RMI. Each of the eight 75-min sessions recorded class attendance. Data collection took place pre-intervention and immediately post-intervention. At each time point, the researchers collected biometric data, including HbA1c, and survey data. Researchers only collected data from those who consented to participate in the study. Participants could refuse any aspect of the data collection and continue in the F-DSMES program. Researchers provided the participants with a copy of their biometric screening results and provided participants with confidential health counseling and referral information to a local healthcare provider as needed. Additionally, participants were given a glucometer and were provided a supply of tests strips during the study.

Measures. Researchers utilized a finger stick, blood collection process with a Rapid A1c test kit (Siemens DCA Vantage Analyzer) to measure HbA1c, the primary outcome. HbA1c is a continuous measure of glycated hemoglobin, representing an average level of blood glucose over the previous three-month period. Pre- and post-intervention body mass index (BMI) was calculated using the participant's height and weight collected in normal street clothes without shoes ((weight in pounds/[height in inches]²) *703). Researchers also used an OMRON digital blood pressure monitor to measure systolic and diastolic blood

pressure while the participant was seated with arm elevated.

In addition, participants completed a survey instrument previously piloted in the Arkansas F-DSMES program, utilizing questions from the Behavioral Risk Factor Surveillance System (BRFSS) and Healthcare Access Modules and the Diabetes Care Profile. The survey questions included basic demographic questions (e.g., age, sex, education) and additional questions regarding diabetes knowledge, family support, and diabetes self-care behaviors. The diabetes knowledge and family support questions used a three point Likert scale (0 = none, 2 = a lot). Self-care behaviors are a categorical variable of the reported number of self-checks of blood sugar and feet done daily, weekly, monthly, yearly, or never.

Analysis

The current study reports retention and dosage information. Descriptive statistics, including means and standard deviations for

continuous variables and proportions for categorical variables, are presented to characterize all participants with T2DM (n = 41) who enrolled in the study and assess differences between those who completed the post-intervention data collection (n = 23) and those who did not (n = 18). The researchers used a Wilcoxon signed-rank test to evaluate the differences in HbA1c, diabetes knowledge, and family support, and an exact McNemar test was used to evaluate differences in self-checks pre-intervention and immediately post-intervention due to the non-normal distribution of the data.

The purpose of the pilot study was to assess the preliminary effectiveness of the intervention; thus, the size, direction of the effect sizes, and the clinical meaningfulness (e.g., 0.5-1% reduction of HbA1c level) were included in interpreting the results [47–49]. The analyses were conducted using STATA version 15.1, and p-values less than 0.05 were considered statistically significant.



Fig. 1. Enrollment and retention of study participants.

Results

Recruitment

One-hundred and twenty-six participants from four FBOs were screened for inclusion in the RMI F-DSMES intervention, (Fig. 1). One person was deemed ineligible due to a preexisting health condition, and ten required waivers from the intervention team's physician. One-hundred and twenty-five agreed to be enrolled in the study. Twenty-eight participants did not return for the primary data collection, with a final intervention sample of 97, including 41 participants with diabetes and 56 family members. This article focuses on the 41 participants with diabetes. The final analysis includes 23 participants with T2DM who returned for the post-intervention data collection (Fig. 1).

Demographics, retention, and dosage

Table 1 reports the characteristics of the sample. The mean age of participants was 51.5 years (\pm 12.4) and the majority (78.3%) were female. Over half of participants had not graduated high school (60.9%), and less than 9% had attended at least some college. Fifty-seven percent of the participants were married or cohabitating. Overall, the 41 participants with T2DM completed a mean of 5.4 (\pm 3.6) h of education classes; 17% (7) completed 8–10 h; 34% (14) completed 5–7 h; 49% (20) completed four or less hours of the intervention.

Of the 41 participants with T2DM, only 56.1% (n = 23) participated in post-intervention data collection (Table 1.). The mean number of hours of education for those who completed the post-intervention data collection was 7.1 (±3.1) hours, compared to 3.2 (±3.0) for the noncompleters. Table 1 details comparisons of the baseline measures for participants who completed the HbA1c test post-intervention (n = 23) to those who did not (n = 18); the only statistically significant difference between the two groups were in the number of education sessions completed (p < .001).

At baseline, the participants had a mean HbA1c of 9.9% (\pm 2.6%) and a post-intervention mean HbA1c of 9.8% (\pm 2.6%). Mean BMI for the participants showed a slight reduction, from a mean of 31.8 (\pm 5.7) to 31.5 (\pm 5.7).

Changes in HbA1c

Table 2 reports the results of the Wilcoxon Signed Rank Test for preand post-intervention HbA1c. Results did not show a significant difference in median HbA1c pre- and post-intervention (p = .78). Eight of the participants showed a decrease in their HbA1c; however, fourteen showed an increase in HbA1c. One participant had a pre- and postintervention HbA1c that remained unchanged.

Changes in diabetes knowledge

Table 3 reports the results of the Wilcoxon Ranked Sign Test for the questions regarding knowledge about T2DM for the participants who reported having been told by their physician that they have diabetes. Pre-intervention scores indicated that the participants had little to no knowledge of diabetes care and management. A significant improvement between the pre-intervention and post-intervention scores on knowledge questions was reported, including: (1) how food, diet, and exercise can affect blood sugar levels (p < .001); (2) preventing high (p < .001) and low (p < .001) blood sugar levels; and (3) how to prevent complications from diabetes (p < .001).

Changes in family support

Post-intervention scores show an improvement in all categories of family support. Table 4 details the results of the Wilcoxon Ranked Sign Test for each of the questions regarding the participant's level of support from their family members. Prior to the F-DSMES intervention, the participants reported little support from their family in following their diabetes care plans. Post intervention, there were significant improvements in family support reported, including (1) following a meal plan (p = .007); (2) remembering medications (p = .006); (3) foot care (p = .004); (4) blood sugar testing (p < .001); and (5) dealing with feelings about diabetes (p < .001).

Changes in self-care behavior

Participants who indicated they had been previously told they had diabetes (N = 18) were asked pre- and post-intervention how often they were performing self-care behaviors, including self-checks of blood

Table 1

Comparison of demographics and biometrics for participants with complete and incomplete HbA1c data.

Measures	Complete Cases (n=23)	Incomplete Cases (n=18)	Fisher Exact/Two Sample Wilcoxon Ranked Sum Test
	Mean (±SD) / n (%)	Mean (±SD) / n (%)	p
Age	51.5 (± 12.4)	52.2 (± 12.0)	.87
Sex			.49
Male	5 (21.7)	6 (33.3)	
Female	18 (78.3)	12 (66.7)	
Marital Status			.51
Married or Cohabitating	13 (56.5)	11 (61.1)	
Single	10 (43.5)	7 (38.9)	
Education			.49
Less than a HS Diploma	14 (60.9)	14 (77.8)	
HS Diploma	7 (30.4)	4 (22.2)	
Beyond HS Diploma	2 (8.7)	0 (0.0)	
Work Status			.73
Employed	7 (30.4)	4 (22.2)	
Unemployed	16 (69.6)	14 (77.8)	
Number Of Hours Attended	7.1 (± 3.1)	3.2 (± 3.0)	< .001
Pre-Intervention HbA1c	9.9 (± 2.6)	10.3 (± 2.4)	.51
Pre-Intervention BMI	31.7 (± 5.7)	29.1 (± 6.4)	.13
Has a doctor told you that you have Diabetes?			.49
No	5 (21.7)	6 (33.3)	
Yes	18 (78.3)	12 (66.7)	

Notes: Totals may not add to 100% due to rounding. SD: Standard Deviation.

Table 2

Wilcoxon signed rank test of pre and post intervention HbA1c of participants with T2DM (n = 23).

	Mean Pre- Intervention HbA1c	Mean Post- Intervention HbA1c	Count of Positive Signs (Post A1c Lower)	Count of Negative Signs (Post A1c Higher)	Count of Ties	Ζ	d	р
Comparison of Pre- and Post- Intervention HbA1c	9.9 (±2.6)	9.8 (±2.6)	8	14	1	27	04	.78

Notes: d = Cohen's d effect size.

Table 3

Changes in diabetes knowledge from pre-to post-intervention.

Measures of Diabetes Knowledge	Pre-Intervention (n = 18 ^a)	Post- Intervention (n = 17 ^a)	Wilcoxon Ranked Sign Test	
	Mean (±SD)	Mean (±SD)	p	
Do you understand how .				
To manage your diabetes?	.89 (±.47)	1.71 (±.47)	<.001	
To cope with stress?	.94 (±.58)	1.71 (±.59)	.006	
Food affects your blood sugar?	.89 (±.58)	1.71 (±.47)	.002	
Exercise affects your blood sugar?	.89 (±.47)	1.76 (±.44)	<.001	
To take your diabetes medications?	1.11 (±.83)	1.76 (±.56)	.030	
To use you blood sugar results?	1.11 (±.83)	1.88 (±.33)	.005	
Diet, exercise, and medicines affect blood sugar levels?	.89 (±.47)	1.88 (±.33)	<.001	
To prevent high blood sugar?	.67 (±.59)	1.94 (±.24)	<.001	
To prevent low blood sugar?	.78 (±.65)	1.76 (±.56)	<.001	
To prevent complications from diabetes?	.78 (±.55)	1.82 (±.39)	<.001	
To care for your feet?	.89 (±.68)	1.94 (±.24)	<.001	
The benefits of managing your diabetes?	.89 (±.58)	1.94 (±.24)	<.001	

^a Note: Responses limited to participants who stated a physician or other HCW said they have diabetes (Pre-Intervention n = 18, Post-Intervention n = 17).

Table 4

Changes in family support from pre-to post-intervention.

	Pre-Intervention $(n = 18^{a})$	Post-Intervention $(n = 17^{a})$	Wilcoxon Ranked Sign Test			
	Mean (±SD)	Mean (±SD)	р			
Does your family help you to						
Follow your meal plan?	1.33 (±.69)	1.94 (±.24)	.007			
Remember your medications?	1.11 (±.76)	1.88 (±.49)	.006			
Remember to check your feet?	.89 (±.83)	1.71 (±.69)	.004			
Remember to check your blood sugar?	1.22 (±.73)	2.00 (±.00)	<.001			
Deal with your feelings about diabetes?	1.28 (±.67)	2.00 (±.00)	<.001			

^a Note: Responses limited to participants who stated a physician or other HCW said they have diabetes (Pre-Intervention n = 18, Post-Intervention n = 17).

glucose levels and self-checks of foot health. Pre-intervention, over half of the participants asked were not performing these self-care behaviors daily as recommended (Table 5). An exact McNemar's test determined there was not a statistically significant difference in the proportion of when self-checks of the feet were performed pre- and post-intervention (p = .22). Although not statistically significant, we note an improvement

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Changes in self-care behaviors from pre-to post-intervention.

Measure	Pre-Intervention (n $= 18^{a}$)	Post-Intervention (n $= 17^{a}$)	Exact McNemar's Test		
	n(%)	n(%)	Р		
Self-Check Feet			.22		
Never or No Feet	10 (55.5)	5 (29.4)			
Daily	4 (22.2)	10 (58.8)			
Weekly	-	1 (5.9)			
Monthly	2 (11.1)	1 (5.9)			
Yearly	2 (11.1)	-			
Self-Check			.001		
Glucose					
Never	4 (22.2)	-			
Daily	3 (16.7)	17 (100)			
Weekly	5 (27.8)	-			
Monthly	2 (11.1)	-			
Yearly	4 (22.2)	-			

^a Responses limited to participants who stated a physician or other HCW said they have diabetes (Pre-Intervention n = 18, Post-Intervention n = 17).

in participants checking their feet. Self-checks of blood glucose levels improved post-intervention, with all participants reporting checking their blood glucose daily compared to 16.7% reporting daily checks at pre-intervention (p = .001) (Table 5).

Discussion

Overall retention in the RMI F-DSMES was low with only 56% completing post-intervention data collection. Although overall intervention dosage was moderate, with a mean of 5.4 (\pm 3.6) hours of diabetes education per participant, those who provided post-intervention data completed a mean of 7.1 (\pm 3.1) hours of diabetes education per participant. These results are compared to a retention rate of 97% in post intervention data collection for the F-DSME in Arkansas and a mean dosage rate of 8 h of diabetes education. These results demonstrate promise but also show that improvement in retention methods is needed.

There are a number of issues that may have affected retention for a study in the RMI. Overall, the reaction to the F-DSMES intervention was positive; participants felt the classes and resources were helpful and informative for themselves and their family members. However, a lack of transportation to and from the intervention site may have constrained participants' ability to attend multiple class sessions and data collection events [50,51]. In addition, the intervention was held in the RMI during an important and controversial election and an outbreak of Dengue Fever, which may have limited attendance and participation in classes and post-intervention data collection [51–53]. Future research should attempt qualitative interviews with those who do not attend classes or post-intervention data collection and work to address the availability of transportation that may limit full participation in the F-DSMES intervention.

Although results indicate significant improvements in diabetes knowledge, self-care behaviors, and support from family members, there was little reduction in HbA1c or BMI. Prior research has demonstrated that improvements in knowledge, self-care behavior, and family support can also improve health outcomes and, specifically, HbA1c [54,55]. The results of the F-DSMES pilot indicates some potential to lower HbA1c levels in those with diagnosed T2DM in the RMI, but mean HbA1c was only reduced by 0.10%. The lack of a significant reduction in HbA1c is consistent with prior studies conducted in the RMI and among Marshallese in Hawaii [23,56]. However, these pilot results are disappointing and in contrast to the results of the F-DSME RCT conducted with Marshallese in Arkansas, where the mean reduction in HbA1c was 1.15% [41]. Several differences exist between the Arkansas-based F-DSMES and the RMI-based F-DSMES. In the RMI, there are no CDEs; therefore, solely a Marshallese CHW, without a CDE present, led the educational sessions. CDEs have additional training in addressing glucose control and complications experienced by their patients and are a valuable resource during diabetes education interventions. Although prior studies have shown the effectiveness of DSMES delivered by a CHW, the curriculum may need additional adaptation for implementation in the RMI without a CDE present, and the CHW may need additional training or ongoing support from other health care providers in the RMI or elsewhere [57,58].

Furthermore, there are additional social ecological barriers in the RMI, which may make achieving changes in diet, exercise, and self-care behaviors more difficult even if knowledge and support are increased. Unemployment in the RMI is high (36%), and the national minimum wage is low, making fresh, healthy foods difficult to obtain [1]. Fresh foods, especially produce, are often viewed as less filling and prohibitively expensive in comparison to cheaper and more filling options, including rice and processed foods [23]. Few roads have sidewalks, and there are limited exercise facilities, which may make exercise difficult. Prior research has shown that a majority of Marshallese in the RMI reported no source of regular healthcare, as well as difficulties affording testing supplies and medication. Although glucose testing supplies were provided by the study, the financial costs of care may still constrain self-care behaviors even if knowledge and support are improved [59]. Although the F-DSMES increased knowledge about lifestyle changes and family support for those changes, actual lifestyle changes may be more difficult to navigate given social ecological barriers in the RMI. Future research should focus on understanding and addressing these barriers in the unique social ecological contact of the RMI.

The post-intervention improvement in knowledge, self-care behaviors, and family support may be the first step in the process of addressing T2DM in this population, and an improvement in HbA1c may follow at later data collection dates as the participants gain more confidence in their knowledge and ability to manage their T2DM. Future work will need to consider how improvements in proximal outcomes of selfmanagement behaviors translates into improvement of distal outcomes measured by biometric measures within the social ecological context of the RMI.

Limitations and strengths

There are several limitations to recognize when interpreting the results of the study. First, the sample size is small (n = 41), and only 56% (23) of participants with T2DM were retained for post-intervention data collection. The study only included Marshallese in the RMI. The RMI presents a unique social ecological context; therefore, the results are not generalizable to other populations or to other geographic regions. However, the study does provide insights into how social ecology may influence outcomes more than knowledge and support.

Another limitation is the use and interpretation of HbA1c as an endpoint. HbA1c is highly dependent on the length of survival of hemoglobin cells, which is highly individual. On average, research has demonstrated hemoglobin cells survive for 115 days, with a range of 70–140 days [60]. With this in mind, HbA1c may not be reflective of the overall change in glucose levels even at the 12-week mark. Moreover, HbA1c tests are influenced by the overall physical health of the person from whom the sample is drawn. It may be, given the history of nuclear

fallout exposure in the RMI, inhabitants of the RMI may have undetected health conditions (e.g. anemia) limiting the accuracy of HbA1c tests [61].

Despite the limitations, this article adds important and significant information to the literature. This is the first Family DSMES study to be implemented in the RMI and the first DSMES to be implemented in the RMI with CHW. Although the F-DSMES did not yield results similar to those achieved in Arkansas, the pilot does provide important information as the authors, other researchers, and policy makers address the significant diabetes health disparities evident in the RMI. Future research should consider multi-level interventions that address social ecological factors, consider further adaptation, and consider additional training for CHWs for implementation of DSME in the RMI and other areas where health care workers are limited.

Funding

UAMS Translational Research Institute funding awarded through the National Center for Research Resources and National Center for Advancing Translational Sciences of the National Institutes of Health (NIH) (number 1U54TR001629-01A1) supported the community engagement efforts. An award from the Sturgis Foundation supported the DSME pilot study.

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The IRB Protocol Number is #239272.

Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Declaration of competing interest

The authors have no potential conflicts of interest.

Acknowledgements

This study was made possible because of a community-based participatory research partnership with local Marshallese faith-based leaders, the RMI Ministry of Health & Human Services, Kora In Jiban Lolorjake Ejmour (KIJLE), and the Marshallese Consulate General in Springdale, Arkansas.

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