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Author manuscript *Fam Syst Health.* Author manuscript; available in PMC 2021 June 01.

Published in final edited form as: *Fam Syst Health.* 2020 June ; 38(2): 121–129. doi:10.1037/fsh0000470.

## Effects of a Family Diabetes Self-Management Education Intervention on the Patients' Participating Supporters

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## Abstract

**Introduction**—Diabetes self-management education (DSME) programs that engage the families of patients with diabetes have shown to be effective in improving diabetes-related outcomes of the patients. The health effects of these "family models" of DSME on participating family members are rarely studied. Opportunity exists for the participating family members to benefit from the healthy lifestyle recommendations offered though such programs.

**Method**—Using data from a randomized control trial to assess the effect of Family DSME compared to standard DSME among Marshallese adults with type 2 diabetes, this study examined baseline to 12-month changes in A1c, BMI, food consumption and physical activity among participating family members, comparing outcomes of family members based on attended at least one (*n*=98) vs. attended no (*n*=44) DSME sessions.

**Results**—Overall, family member attendance was low. There were no differences in the level of change from baseline to 12 months for A1c, BMI, food consumption and physical activity between groups. After controlling for attendance and socio-demographic measures, lowering of BMI was the only significant predictor of not having an A1c level indicative of diabetes at 12 months.

**Discussion**—Future research on Family DSME should consider ways to improve family member attendance, have them set their own health improvement goals, and integrate healthy lifestyle education, such as healthy eating and being physically active, along with the DSME core content to create an added benefit of diabetes prevention for participating family members. The limitations of this study and recommendations for future research are provided.

## Keywords

diabetes; Marshallese; family support; diabetes self-management education

Type 2 diabetes (T2D) is a chronic disease affecting 8.5% of adults globally (WHO, 2016). Poorly managed T2D can lead to kidney and nerve damage, amputation, and death. Persons with T2D are recommended to complete diabetes self-management education (DSME) to ensure they have the knowledge and skills to properly manage the condition (Funnell et al., 2012).

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DSME improves health and quality of life outcomes for patients with T2D when delivered one-on-one and in groups, and when culturally adapted for racial and ethnic populations (Collins-McNeil et al., 2012; Ferguson, Swan, & Smaldone, 2015; Funnell et al., 2012). Family support is one of the most consistent predictors of treatment adherence among patients with T2D (Glasgow & Toobert, 1988). Studies have shown that DSME modified to include family members of patients with T2D (hereafter Family DSME) lead to lower A1c and blood pressure and increased diabetes-related knowledge and self-efficacy (Baig, Benitez, Quinn, & Burnet, 2015; Hu, Amirehsani, Wallace, McCoy, & Silva, 2016; McElfish et al., 2019; Pamungkas, Chamroonsawasdi, & Vatanasomboon, 2017). The mechanism through which Family DSME is thought to "work" is instrumental and social support by family members for the person with T2D (Baig et al., 2015; Pamungkas et al., 2017; Rosland & Piette, 2010). However, more research has been suggested to specific types of support needed from family members (Miller & Dimatteo, 2013).

Another area for study around Family DSME is its impact on participating family members. Standard DSME curriculum includes education on and encourages healthy behaviors, such as healthy diet and exercise (Funnell et al., 2012), that are beneficial regardless of whether one has had diabetes or not (2018 Physical Activity Guidelines Advisory Committee, 2018; U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015). Given that family history of diabetes is one of the strongest predictors of developing diabetes (InterAct Consortium et al., 2013), Family DSME may also serve as a diabetes prevention program for participating family members without T2D.

There is currently a dearth of literature about the impact of Family DSME on participating family members. A systematic review on Family DSME by Baig et al. (2015) found that few studies reported family member outcomes (which included improvements in weight, disease knowledge and healthy behaviors). They noted "…failure to separately assess effects on both the patient and family member provides an incomplete picture regarding [these programs'] effectiveness " (Baig et al., 2015). In this paper, we help fill this gap by reporting on the outcomes experienced by family members who attended a Family DSME program for Marshallese adults with T2D residing in the U.S.

#### **Background on Participant Population**

Pacific Islanders, including those from the Republic of the Marshall Islands, have one of the highest rates of T2D in the world (Cheng, 2010). Among Marshallese living in the U.S., the prevalence of T2D is 38.2% (McElfish et al., 2017) compared to 8.5% among other Americans (Galinsky, Zelaya, Simile, & Barnes, 2017). Survey results from Marshallese adults with T2D showed low rates of most diabetes self-care behaviors and just 37.8% reported completing DSME (Felix et al., 2018). Culturally adapting DSME can facilitate participation in DSME (Castro, Barrera, & Martinez, 2004).

Given the importance of family in their culture (McLaughlin & Braun, 1998), Marshallese community members specifically requested that researchers include family in interventions to address diabetes (Felix et al., 2019; McElfish et al., 2015). A culturally-adapted Family DSME program was subsequently developed and tested in a randomized controlled trail

(Yeary et al., 2017; Yeary, Long, Bursac, & McElfish, 2017). The present study utilized the trial data to assess how the program affected participating family members.

## Method

#### Design

A two-arm randomized controlled trial (ClinicalTrials.gov Identifier: NCT02407132) was used to assess the effect of the Family DSME compared to the Standard DSME on A1c levels of Marshallese adults with T2D. Full details on the trial's methods have been described by Yeary et al. (2017) and are generally described below. The trial showed that those randomized to Family DSME had a significantly greater reduction in their A1c levels from baseline to 12 months compared to those randomized to Standard DSME (McElfish et al., 2019). The present study assessed the effect of the program on participating family members using a pre-post with comparison group design. It was expected that family members who attended the Family DSME would experience better outcomes than those who did not attend.

#### **Primary Participants and Family Members**

Primary participants, Marshallese adults (18 years) who had been diagnosed by a healthcare provider with T2D, were recruited from community-based organizations, clinics, and advertisements. Bilingual study staff screened and consented primary participants in private locations (e.g., homes, clinics). T2D was subsequently confirmed with an A1c 6.5 collected prior to the intervention.

Primary participants were then randomized (*n*=221) to the Family DSME (*n*=110) or the Standard DSME (*n*=111). Those in the Family DSME invited adult family members to participate (*n*=221). Family members were defined by the community-academic partnership that developed the trial as members of the household with whom the main participants regularly shared meals. Some Family members with A1c levels indicative of diabetes (*n*=73) were excluded from the present analysis as its intent was to determine whether Family DSME could serve as a diabetes prevention program among participating family members at risk of developing diabetes.

#### Family DSME Intervention

The cultural adaption of the Family DSME has previously been reported (Yeary et al., 2017). Both the Family DSME and the Standard DSME included 10 hours of content covering the recommended core elements of DSME (American Association of Diabetes Educators, 2014). Didactic education, food and anatomical models, story-telling, question and answer sessions, and culturally-specific examples and beliefs were included in the eight 75-minute classes over eight weeks in the participants' homes by bilingual Marshallese community health workers (CHWs) who could consult with Certified Diabetes Educators as needed (Yeary et al., 2017). Family members were encouraged (not but required) to attend and set goals for how they could support the primary participant's self-management.

**Community health workers**—Bilingual Marshallese adults serving as CHWs taught the curriculum. They included both males and females, and ranged in age from 35 to 45 years old. They completed 60 hours of CHW training and 40 hours of intervention-specific

**Data collection process**—Data were collected by research faculty, bilingual research staff, and research nurses from the primary participants and family members at baseline, immediately after the intervention at nine weeks, at six-months post-intervention, and then at 12-months post-intervention. The results presented herein are baseline and 12-month post-intervention as development of diabetes among family members was of primary interest. Participants and family members were contacted prior to data collection time points to schedule data collection appointments at convenient times and in a private space within participants' preferred location. Data were collected from all participants and family members at each data collection appointment, regardless of whether they had missed a previous appointment. Primary participants and family members each received a \$20 gift card for every data collection appointment attended.

training, and each month completed four hours of continuing education.

**Data collection instruments**—Family members consented to provide the same measures collected from primary participants: A1c was assessed through finger prick blood collection, using a Rapid A1c test kit and Siemens DCA Vantage Analyzer; fasting glucose was assessed using a glucometer; weight was measured in light clothing to the nearest 0.5 lb (0.2 kg) using a calibrated digital scale; height (without shoes) was measured to the nearest 0.5 cm using a stadiometer; and blood pressure was measured using a sphygomometer and stethoscope with participants seated and arm slightly raised. Physical activity over the past month was assessed by a seven-item Rapid Assessment of Physical Activity (Jiang et al., 2016; Topolski et al., 2006). Food intake over the past month was assessed through a 16-item food frequency questionnaire (Teufel-Shone et al., 2015). The study protocol and fidelity monitoring ensured consistency in data collection.

**Measures**—Socio-demographic measures included age (years of age), sex (female vs. male), marital status (married or member of an unmarried couple vs. single, divorced, separated or widowed), education level (less than high school [HS] education, HS education or GED, or more than HS education), and employment status (currently employed vs. not employed, student, retired or homemaker). Health-related measures included body mass index (BMI), A1c, the Healthy Food Consumption Score, the Unhealthy Food Consumption Score, and level of physical activity (sedentary, underactive, and active). Collected height and weight were used to calculate BMI using the standard formula of weight in pounds/ (height in inches)<sup>2</sup> multiplied by 703 (NHLBI Obesity Education Initiative Expert Panel, 1998). The Healthy Food Consumption Score ranged from 5 to 30, with the lower score representing the healthiest food consumption, and the Unhealthy Food Consumption Score ranged from 11 to 66, with the lower score representing the unhealthiest food consumption (Teufel-Shone et al., 2015). The physical activity measure ranged from one to five, with 1 representing sedentary, 2 to 4 representing underactive, and 5 representing active. Class attendance was measured by number of classes attended (0-8) and dichotomized as any classes attended vs. no classes attended.

**Statistical analyses**—Analyses were conducted in Stata 15.1 (StataCorp, 2015) for descriptive statistics and regression, and SAS 9.4 (SAS Institute Inc., 2002–2012) for multiple imputation. Descriptive statistics were used to profile the health-related and socio-demographic characteristics of family members. Tests of comparison (e.g., t-test, chi-square) were used to assess differences in family members by class attendance group (attended any class vs. no classes).

Multivariate logistic regression was used to assess the effect of class attendance of family members on preventing the development of T2D by 12-months post-intervention. The primary variable of interest in this analysis was exposure to the Family DSME through class attendance. Ideally, outcomes of family members of primary participants randomized to the Family DSME would be compared to family members of those in the control group. However, family members of primary participants in the control group were not engaged in the study and no data on them were available. Therefore, a comparison group was constructed using family members who had enrolled in the trial but attended no Family DSME classes (*n*=44) and had no exposure to the program (non-attendance group). Family members who attended at least one class (and had some exposure to the program) were in the intervention group (attendance group). Additional co-variates in the model included age, sex, marital status, education level, and the 12-month post-intervention values for BMI, the Healthy Food and the Unhealthy Food Consumption Scores, and physical activity. All tests were two-tailed with statistical significance set at .05.

**Multiple imputation**—Several variables included in the analysis had missing 12-month values (>5%). Multiple imputation (PROC MI and MIANALYZE procedures) was used for handling missing data. Missing data patterns were checked separately for the two groups. PROC MI revealed a monotone pattern for the attendance group and an arbitrary pattern for the non-attendance group across four repeated measures. For attendance group members whose missing data pattern was monotone, the MONOTONE REG procedure (linear regression) was used for continuous variables (e.g., A1c, BMI). For example, the MI model for A1c at 12 months included multiple mixed variables (continuous and categorical sociodemographic variables and class attendance) and A1c for the other data collection time points. For binary/ordinal variables, the MONOTONE LOGISTIC procedure (logistic regression) was used. For non-attendance group members whose missing data exhibited an arbitrary pattern, the FCS REG procedure (Fully Conditional Specification regression) was used for continuous variables, and the FCS LOGISTIC (Fully Conditional Specification logistic regression) was used for binary/ordinal variables (Berglund & Heeringa, 2014). All models included socio-demographic variables, class attendance and the dependent variable as covariates.

**Research ethics review**—The study protocol was approved by the University of Arkansas for Medical Sciences' Institutional Review Board (#203482).

## Results

Family members (n=138) enrolled in the Family DSME attended a mean of 2.7 classes (SD=2.8). However, 68.1% (n=94) attended at least one class, while 31.9% (n=44) attended no classes. Of those who attended one class, the mean attendance was four classes (SD=2.6).

Family members were on average 34.1 years old (*SD*=12 years), with no difference in age by attendance group. Half of family members overall were female (55.1%); significantly more females were in the attendance group than the non-attendance group (61.7% vs. 40.9%, p=.022). Overall, 63.8% of family members were married; significantly more married family members attended no classes compared to attended class (79.6% vs. 56.4%, p=.008). Nearly half of the family members had greater than a HS education (46.4%), while 38.4% had completed HS, and 15.2% had less than a HS education. There was no difference in the education levels between the two groups. Family members were nearly equally employed (46.4%) and not employed (53.6%). Significantly more family members in the attendance group were unemployed (59.6%) and more family members in the nonattendance group were employed (59.1%, p=.040).

Family members' mean A1c and BMI were 5.48 (SD=.46) and 30.92 (SD=6.33), respectively. There was no difference in these measures by attendance group. Similarly, there was no difference between groups in the Healthy Food and the Unhealthy Food Consumption Scores, with overall means of 17.01 (SD=3.94) and 43.16 (SD=6.60), respectively. Family members were mostly physically underactive (n=72, 52.2%), with no group difference detected. See Table 1.

There were significant baseline to 12 months increases in BMI (+0.38 points, p=.020), A1c (+0.24 points, p<.001), and the Unhealthy Food Consumption Score (+3.21 points, p<0.001). See Table 2. At baseline, no family members had an A1c level indicative of diabetes; but by 12 months, 10.1%, had an A1c level indicative of diabetes (p<.001). There were no significant baseline to 12 months changes in the Healthy Food Consumption Score (p=.084) or physical activity (sedentary=-5.1 percentage points, underactive=+5.1 percentage points, active=0.0 percentage points, p=.605). No statistical difference in change between the two groups was observed.

The results showed no significant difference between the attendance group and the nonattendance group in developing diabetes by 12 months, after controlling for other characteristics (OR=0.51, SE=0.41, p=.400). The only characteristic that was significantly associated with not having diabetes at 12 months was lower BMI (OR=0.85, SE=0.05, p=.006).

## Discussion

Family DSME is successful in helping individuals with T2D manage their condition (Baig et al., 2015; McElfish et al., 2019; Pamungkas et al., 2017; Rosland & Piette, 2010). However, information about how such programs affect family members has heretofore been unavailable (Baig et al., 2015). We anticipated that Family DSME would also benefit family members. There was no support found for this assumption. In fact, at baseline, no family

member had diabetes; yet by 12 months, 10.1% had diabetes (p < .001). There was no statistical difference in the increased diabetes rate based on class attendance, even after controlling for other characteristics.

The study found no significant improvements overall or by group in individual diabetes risk reduction behaviors in contrast to another study's finding of significant improvements in BMI among participating family members (Hu, Amirehsani, Wallace, McCoy, & Silva, 2016). Overall, attendance was low, with one-third of the enrolled family members' not attending even one class. Among family members who did attend at least one DSME class, only half of the classes were attended. This is an important observation as it could partly explain why positive outcomes for family members were not observed given previous research has shown that higher dosages of interventions increases the probability of achieving positive change (McElfish et al., in press).

It is not clear why family members did not attend more classes as data were not collected on reasons for attendance or non-attendance. Non-attendance could indicate scheduling conflicts or lack of interest. It is also possible that family members did not attend classes as they did not feel directly engaged in them. Family members were encouraged to set goals for how they could support the primary participants, but not for how they could improve their own health. However, such goal setting is important for behavior change (Epton, Currie, & Armitage, 2017). Future studies should follow-up with family members regarding their participation, and use collected data to modify Family DSME to directly benefit family members.

The Family DSME was developed through a strong community-academic partnership, in which community members requested family members' inclusion (Felix et al., 2019; McElfish et al., 2015). However, the focus of the intervention remained on the primary participants with diabetes with family members involved to support the primary participant's self-management. Future Family DSME research may want include family members and discuss ways to directly engage them, such as through incorporating specific information about diabetes prevention into program content and having family members set goals for their own health improvement.

Family members in the study were on average 34.1 year old, married females. For comparison, Hu et al. (2016) also reported that mostly married females participated as family members in their Family DSME. However, their participants were older (*Mage*=40.6) than those in the present study. Family members in the present study also had more education (46.4% vs. 13.0% with more than a HS education). Differences in these and other characteristics between family members in the two studies may have contributed to the differences in the findings.

## Limitations and Strengths

Family members were defined as those who regularly shared meals with the primary participant and could include friends and neighbors as well as more immediate family members (e.g., spouse, parent, child). Although it is possible that family closeness could

affect outcomes, data were not available on the exact nature of the relationship between the family members and the primary participants. Future studies should capture data on the nature of the relationship between family members and primary participants. Family members' attendance at DSME classes was low, and this study did not assess why their attendance was not more robust. Future research should collect data to better understand constraints to their engagement.

This study did not have a "true" control group. Family members in our comparison group did not attend any classes, yet some contamination could have occurred, thereby weakening our ability to detect differences between the groups. For example, the Family DSME addressed healthy cooking. If the primary participant was the meal preparer for the household, a family member could have been exposed to a healthier diet without having attended any classes. Future trials should include a family member control group to truly evaluate the effect of Family DSME on family members.

While results did not support our hypothesis that family members would benefit from Family DSME, they do contribute to the literature by helping fill a gap in the current and identifying areas for enhancement of future studies.

## Conclusion

DSME that engages family members can improve diabetes-related outcomes for individuals with diabetes. Our preliminary research did not find that benefits extended to participating family members as anticipated. However, poor attendance by family members likely affected the potential impact. Future research on Family DSME should consider ways to improve family member attendance and engagement in program activities to facilitate the possible added benefit of diabetes prevention for participating family members.

## Acknowledgments

Financial support for the study was provided by the Patient-Centered Outcomes Research Institute (grant no. AD-1310-07159). Initial funding for a pilot project of the study was provided by a University of Arkansas for Medical Sciences College of Medicine Intramural Sturgis Grant for Diabetes Research from the Sturgis Foundation. Additional support for the community-based participatory research team was provided by the Translational Research Institute at the National Center for Advancing Translational Sciences, National Institutes of Health (grant no. 1U54TR001629-01A1).

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#### Table 1

Baseline characteristics of Participating Family Members without Type 2 Diabetes, Overall and by Family DSME Sessions Attendance

Measure	All family members (n=138)	Attended 1 session (n=94)	Attended no sessions (n=44)	t(136)	р
Classes attended	$2.70\pm2.80$	$4.00\pm2.60$	-	-	-
Age, in years	$34.10\pm12.00$	$34.60 \pm 13.20$	$33.20\pm9.30$	-0.65	.517
A1c	$5.49\pm0.46$	$5.48\pm0.48$	$5.49\pm0.43$	0.09	.925
BMI	$30.92\pm 6.33$	$31.54 \pm 6.46$	$29.58 \pm 5.90$	-1.71	.090
Healthy Food CS	$17.01\pm3.94$	$16.59\pm3.94$	$17.90\pm3.85$	1.83	.070
Unhealthy Food CS	$43.16\pm6.60$	$42.86\pm6.64$	$43.80\pm6.54$	0.70	.438
				$\chi^2 d$	р
Attended any class	94 (68.1)	-	-	-	-
Sex				5.24	.022*
Female	76 (55.1)	58 (61.7)	18 (40.9)		
Male	62 (44.9)	36 (38.3)	26 (59.1)		
Marital status				6.96	.008 **
Married <sup>a</sup>	88 (63.8)	53 (56.4)	35 (79.6)		
Single <sup>b</sup>	50 (36.2)	41 (43.6)	9 (20.5)		
Education				0.81	.666
<hs< td=""><td>64 (46.4)</td><td>42 (44.7)</td><td>22 (50.0)</td><td></td><td></td></hs<>	64 (46.4)	42 (44.7)	22 (50.0)		
HS/GED	53 (38.4)	36 (38.3)	17 (38.6)		
>HS	21 (15.2)	16 (17.0)	5 (11.4)		
Employment				4.20	.040*
Employed	64 (46.4)	38 (40.4)	26 (59.1)		
Not Employed <sup><math>C</math></sup>	74 (53.6)	56 (59.6)	18 (40.9)		
Physical Activity				-	.533
Sedentary	7 (5.1)	5 (5.3)	2 (4.6)		
Underactive	72 (52.2)	46 (48.9)	26 (59.1)		
Active	59 (42.8)	43 (45.7)	16 (36.4)		

Note. CS=Consumption Score; DSME=Diabetes Self-Management Education; GED=General Equivalency Degree; HS=High School.

<sup>a</sup>Married includes married or member of an unmarried couple.

 $^{b}$ Single includes single, divorced, separated, or widowed.

 $^{c}$ Not employed includes student, unemployed, retired, unable to work, or taking care of family at home.

dDue to small cell sizes, Fisher's exact test was used for comparison of physical activity levels. This test does not have a test statistic. Values are  $M \pm SD$  or n (%).

\* p .05

\*\* =p .01.

#### Table 2

#### Differences in Baseline to 12-month Changes in Diabetes-Related Outcomes, Overall and by Group

	All Family Members	Attended 1 session	Attended 0 sessions		
	<i>n</i> =138	<i>n</i> =94	<i>n</i> =44	Group Difference in Baseline to 12 month Change	
	B-12 Month Change	B-12 Month Change	B-12 Month Change	z	р
BMI	0.3	0.47	0.19	0.80	.425
A1c	0.24	0.27	0.17	1.73	.084
Healthy Food CS	0.72	1.07	-0.03	1.29	.199
Unhealthy Food CS	3.21	3.65	2.28	0.95	.342
Physical Activity				-0.98	.329
Sedentary	-5.10	-5.30	-4.60		
Underactive	5.10	9.60	-4.50		
Active	0.00	-4.30	9.10		
A1c 6.5 <sup><i>a</i></sup>	10.10	11.50	6.80	0.14	.886

Note. B=Baseline; BMI=Body Mass Index; CS=Consumption Score.

 $^{a}$ A1c 6.5 is indicative of diabetes. Comparison made using two-sample z test.

\* p .05

\*\* =p .01.