Study Title: Comparative effectiveness of Family DSMES and Standard DSMES among diverse populations

Principal Investigator: Pearl Anna McElfish, PhD
University of Arkansas for Medical Sciences Northwest
Office of Community Health and Research
2708 S. 48th Street
Springdale, AR 72762
Telephone: 479-713-8680
Email: *pamcelfish@uams.edu*

Study location: University of Arkansas for Medical Sciences Northwest
4301 West Markham Street
Little Rock, AR 72205

Background and Rationale

Burden and impact of type 2 diabetes (T2D) on populations. The Centers for Disease Control and Prevention estimate that 29 million people (9%) in the United States (US) have T2D, and rates are expected to increase by over 33% over the next decade.[1] Approximately 363,781 individuals in Arkansas (14.8%) have T2D, and 797,000 (36.4%) have prediabetes.[2]

Clinic burden and impact of T2D on patients and family members. T2D has a devastating impact on patients and their families. T2D doubles the risk of heart disease; is the leading cause of kidney failure, lower limb amputation, and acquired blindness; and reduces life expectancy by as much as 15 years.[1] Because diverse, rural, and older adults bear a greater burden of diabetes and have poor diabetes outcomes, as outlined on page 6, the study is designed to include these populations in sufficient numbers to evaluate heterogeneity of treatment effects. T2D also affects the quality of life of patients and family members. In 2013, the second Diabetes Attitudes, Wishes and Needs (DAWN2) study assessed outcomes and unmet needs that are important to patients with T2D and their family members. The study surveyed 8,596 adults with diabetes and 2,057 family members across 17 countries including the US.[3-6] The DAWN2 study found that diabetes had a negative effect on several aspects of patients' and family members' quality of life. In addition, 44.6% of people with diabetes and 39.8% of family members reported high diabetes-related distress.

Context of T2D self-management and the importance of family. It is well-established that people with T2D who adopt recommended self-management practices are more likely to maintain glycemic control and experience fewer diabetes-related complications.[7-11] Self-management of T2D is complex.[12-14] Patients with T2D must adhere to complex medication plans, attend healthcare visits, and conduct many facets of self-care.[15] Poor self-management, while frequently attributed to the patient, is usually the product of her/his social, environmental context. A large and growing body of evidence documents that the primary context of diabetes self-management resides within the family.[3-6,15-22] Through communications, habits, and attitudes, family members influence patients' decisions to follow recommended treatment and self-care regimens.[15-21] Family members can also hinder effective diabetes self-management in how they shop, cook, communicate, and prioritize actions.[15-21] Positive support from family has been associated with improvements in medication adherence, glycemic control, self-management behaviors, and diabetes-related distress.[4,6,15-20] Therefore, numerous reviews have called for increased education for family members so that they can better support patients with T2D.[4,6,15-20]

Current evidence for comparators. As described, there is an evidence base for each comparator intervention. HbA1c is the most accepted measure of glycemic control used across multiple studies, meta-analysis, and systematic reviews.[7,9,23-26] Studies have found that each 1 unit (%) reduction in HbA1c is associated with significant improvements in clinical outcomes, including a reduction of 21% for deaths related to T2D, 14% for myocardial infarction, and 37% for microvascular complications.[8] Reductions of even 0.5 units have demonstrated clinical benefits.[27-29] Therefore, in evaluating the Family-DSME and Standard-DSME, a reduction in HbA1c is the primary outcome measure of effectiveness.[8] As documented, HbA1c was also chosen by patient and other stakeholders.

Current evidence for Standard-DSME. Based on more than 20 years of evidence, the American Diabetes Association (ADA), American Association of Diabetes Educators (AADE), and Academy of Nutrition and Dietetics have confirmed DSME is crucial for people with T2D.[7,9,23-26] Ten hours of DSME is considered a standard of care for patients with T2D.[7,9,23-26]

DSME is effective at improving patients' diabetes-related clinical outcomes including HbA1c, BMI, blood pressure, and lipids.[30-33] Standard-DSME has also been shown to improve self-efficacy and empowerment,[34] quality of life,[35-38] healthy coping skills,[39] and self-management behaviors,[40] and it has demonstrated reductions in diabetes-related complications,[8,41] diabetes-related distress,[42,43] and depression.[44] Across multiple studies and systematic reviews Standard-DSME has demonstrated clinically significant improvements in HbA1c.[7] Chrvala, Sherr, & Lipman's 2016 meta-analysis of 118 Standard-DSME interventions reported a median reduction of 0.6 units.[26]

Current evidence for Family-DSME. A growing body of literature demonstrates the effectiveness of family-centered models of DSME that explicitly address diabetes self-management within a family context by educating both patients and family members and focusing on family motivational interviewing, family goal setting, understanding supportive and nonsupportive behaviors, and family behavioral changes.[15-17] Recent systematic reviews (Baig et al., 2015 and Pamungkas et al., 2017) have documented the effectiveness of 26 studies of Family-DSME on a range of diabetes-related outcomes.[15,16] The reviewed studies demonstrated the potential of Family-DSME to reduce HbA1c by 0.8 to 1.4 units, with a median reduction of 1.1 units. Furthermore, the reviewed studies[15,16] have shown improvement in family support,[45-47] patient self-efficacy and empowerment,[34,40,48-51] patient and family quality of life,[48,50,52] positive emotional control,[53] and self-management behaviors;[40,47-52,54-59] and demonstrated reductions in diabetes-related complications, diabetes-related distress,[42,43,47] and depression.[47,50,51,60] The evidence documented in the reviews comes from multiple RCTs and pilot studies that primarily tested culturally-tailored models of Family-DSME.[15,16] Each study has tested their family model with a specific racial/ethnic group, including African Americans, Korean American immigrants, Pacific Islanders, Native Americans, and Hispanics/Latinos.[15,16]

Current evidence for comparison. As outlined above, the estimated change in HbA1c for Family-DSME (-1.10) is based on studies reviewed in Baig et al., 2015 and Pamungkas et al., 2017; the estimated HbA1c change for Standard-DSME (-0.6) is the median change reported by Chrvala, Sherr, & Lipman's 2016 meta-analysis.[15,16,26]

Aims

- **Aim 1: Compare** the effectiveness of Family-DSME to Standard-DSME in achieving patient-centered outcomes among diverse patient populations with T2D.
- **Aim 2: Compare** the effects of Family-DSME and Standard-DSME on family members.
- **Aim 3: Document** facilitators and barriers to implementation and dissemination of the Family-DSME.

Study Design and Procedures

We will conduct a fully-powered, comparative effectiveness RCT that includes an enrollment up to 600 patients with T2D and up to 600 of their family members. This will include a post attrition rate of up to 480 patients with T2D and up to 480 family members. Patients with T2D will be randomly assigned to either the Family-DSME or Standard-DSME, with an even distribution in each arm. In the Family-DSME arm, one of each patient's family members will take part in the educational sessions (family members defined below). Baseline and follow up data (post-

intervention, six-months post-intervention, and 12-months post-intervention) will be collected from patients and family members in both study arms. In the Standard-DSME arm, data will be collected from family members, but they will not participate in educational sessions. At the beginning and the end of the intervention, patients will be given pre and post assessments by the diabetes educator. In both arms, we will obtain a medical records release to abstract patients' outcomes at 18-months post-intervention.

Description of comparator interventions. The comparators are Family-DSME and Standard-DSME. Consistent with the National Standards for DSME from ADA and AADE, both Family-DSME and Standard-DSME cover the topics of healthy eating, being active, glucose monitoring, understanding blood glucose and taking medications, problem solving, reducing risks and healthy coping, mitigating complications of diabetes, and goal setting.[61] Both of the comparators are in current clinical practice. The intervention and care management elements for both interventions are summarized in **Table 1**.

Table 1. Description of the interventions

Care Management	■ Quarterly visits with primary care providers; missed visits will be rescheduled. ■ Pre-visit reminders from staff to schedule appointments and labs and remind patients of visit	
DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT		
Evidence-based DSME curriculum	Consistent with the ADA and AADE National Standards for DSME, both Family-DSME and Standard-DSME cover the topics of healthy eating, being active, glucose monitoring, understanding blood glucose and taking medications, problem solving, reducing risks and healthy coping, mitigating complications of diabetes, and goal setting.	
	Family-DSME	**Standard-DSME**
Approach	■ Family motivational interviewing techniques ■ Family goal setting ■ Understanding supportive and nonsupportive family behaviors ■ Family behavioral changes	■ Individual motivational interviewing techniques ■ Individual goal setting ■ Individual behavioral changes
Mode of Delivery	■ Group sessions delivered by a diabetes educator (DE) to patients and their family members	■ Group sessions delivered by a DE to patients
Dosage	■ 10 hours delivered in one-hour sessions over 10 weeks	■ 10 hours delivered in one-hour sessions over 10 weeks
Participants	■ up to 300 patients with T2D and up to 300 family members (family members will take part in educational sessions and data collection)	■ up to 300 patients with T2D (family members will take part in data collection but not educational sessions)

Recruitment, enrollment, consent, and randomization. We will recruit up to 600 patients who meet the inclusion criteria. We will monitor demographic characteristics of enrollees and adjust recruitment efforts to target a final sample of participants that includes approximately equivalent numbers of participants from each group: race/ethnicity (white, Hispanic, African American), age (under and over 65), sex (male/female) rural/urban. Up to 20% of our sample may be from other racial categories. Potential participants will be identified with the assistance of clinic physicians and staff, flyers posted at clinic sites and through medical record abstraction of clinic

patients meeting the inclusion criteria. The medical record abstraction at the selected clinic sites will consist of a monthly report including first name, last name, medical record number, date of birth, sex, race, ethnicity, HbA1c values for the prior 36 months, primary phone number, secondary phone number, email address, street address, and language preference. The monthly medical record abstractions will continue until the enrollment target is achieved. Patients identified in the medical abstraction will be sent a letter from the principal investigator with information about the study. A research staff at each clinic will follow-up with a phone call to these patients to confirm receipt of the letter and to share more about the study over the telephone. Patients may receive another letter if there is new information about the study. Prior to the follow-up phone call, research staff may conduct a medical record review. If a patient is not interested, a follow-up qualitative interview may be requested to help assess reason(s) for disinterest in taking part in the study. Participants who choose to participate in a follow-up qualitative interview to help assess reason(s) for disinterest in taking part in the study will be offered a $50 gift card. If patients are interested in participating in the study, a scheduled appointment will be made to conduct an eligibility screening for inclusion in the study. Research staff will conduct the eligibility screening, which will include a finger stick to determine HbA1c. If patient is determined to be eligible per eligibility criteria, the patient will be invited to consent and enroll. At their scheduled appointment times, research staff will approach patients for inclusion in the study.

All patients will be asked to invite one family member who is willing to attend each of the study's four data collection events. Patients who are assigned to the Family-DSME will be asked that the family member be willing to participate in the DSME sessions as well as data collection. If that family is not willing to participate, the patient will be invited to ask another family member, if they would be willing to participate. Family member consent will take place prior to the first data collection event using the same method as described above. Recruitment will happen on a continuous basis until enrollment is met. Reasons for refusal and demographic information about those who did not participate will be documented. Randomization will be conducted by the study biostatistician, who has no interactions with potential participants and no supervisory role with study staff responsible for recruiting, consent, and intervention processes. Participants will be randomized in a 1:1 fashion to the treatment arms via computer algorithm.

Change due to COVID-19. The survey instrument may be completed online prior to completion of the full consent form by adding an introductory consent statement to the online survey instrument. The full consent document may be completed remotely. The consent document will be provided by email or U.S. Postal service. If provided by email, a link to the consent video will also be provided. The Research Coordinator will schedule a telephone call to answer any questions about the consent document or the study. After the potential participant has reviewed the consent document and had any questions answered, they will sign and date the consent document. The potential participant will either scan or photograph the signed signature page of the consent document and send it to the Research Coordinator electronically (email, text, or fax). The Research Coordinator will print the signed signature page of the consent document, sign and date the document, and then return a copy of the fully executed consent document page to the enrolled participant. Participants will also be able to e-consent using REDCap. After consenting, participants will be provided with a downloaded copy of the fully executed consent document from REDCap by the Research Coordinator.

The study intervention will be delivered using a telemedicine/interactive video on a web-based platform. Specifically, we will use ZOOM on iPads. The iPads will be provided by the study team and purchased with study funds. This delivery method will meet social distancing and other public health recommendations, and will allow the study to commence and remain consistent throughout the project period. The aims, intervention content, randomization, and protocol will be the same. The delivery mechanism is the only thing that will change.

Inclusion Criteria

- adults ≥18 years of age
- have T2D (HbA1c ≥ 7.0)
- understands and communicates in English
- a family member willing to take part in the study

Exclusion Criteria

- have received formal DSME in the past three years
- have a condition that makes it unlikely for them to be able to follow the protocol

Family member inclusion. For the purposes of this study, stakeholders refined the definition to "a person living in the same household and/or assisting the patient with household matters." Additionally, family members or someone of the participants' choice may also include:

- Does not live in your household, but assists with household matters and other activities

Family members must be 18 years of age or older to consent and participate.
Because data will be collected from family members in both arms, a family member must join with the patient with T2D regardless of the arm to which the patient has been randomized. For patients randomized to the Family-DSME arm, family members will take part in the intervention with the patient. For patients randomized to the Standard-DSME arm, family members will take part in data collection events, but will not attend the intervention. Because the configuration of the household and the type of family member joining the study (e.g. spouse/significant other, child, sibling, grandchild, etc.) may vary greatly, demographic information on family structure and family support member taking part in the study will be collected and analyzed for heterogeneity of treatment effects.

Methods and approach for Aim 3. We will conduct a hybrid effectiveness-intervention type 1 analysis using qualitative methods focusing on the implementation of the Family-DSME.[62] Because Standard-DSME is the current standard of care, the implementation study will only focus on the Family-DSME. Type 1 studies include testing effects of a clinical intervention on relevant outcomes (Aims 1 and 2) while observing and gathering information on implementation (Aim 3).[62] The specific goals of this developmental formative evaluation are to provide data on: 1) how the F-DSME intervention might need to be adapted to ensure optimal uptake in real-world contexts; and 2) the key barriers and facilitators to implementation.[63-65]

The evaluation will focus on the clinics participating in the Family-DSME intervention. Semi-structured interviews will be used to collect data for this aim. Qualitative participants will be selected from three groups of stakeholders: participant and family members dyads (i.e., persons

participating in the intervention), personnel working in the clinics (e.g., providers, other staff), and relevant study personnel (e.g., the group leaders who deliver the F-DSME intervention).

From each clinic, we will recruit 3 participant and family member dyads (to be interviewed together). The participant and family member dyads will be approached by study staff and invited to participate in the interviews. We will take into account participant demographics in an effort to recruit a diverse range of participants according to race/ethnicity and gender. Further, we will seek participants who both completed the intervention and those who did not to get a range of perspectives.

From each clinic, we will recruit up to 5 staff members based on their roles in the clinic. For example, we expect to recruit at least one clinic director, one provider, one nurse, and one front desk staff from each clinic. Lastly, we expect to recruit up to 10 study personnel. Research coordinators at each site will share information about the study and invite clinic staff to participate in the interviews.

We will attempt to interview at least 6 group leaders—those study personal who delivered the F-DSME intervention. Other study personnel (no more than 4) who played a significant role at any clinic in terms of recruiting and supporting participants in the study might also be recruited (e.g., site research coordinators). Study personnel will contact potential interviewees, provide them the study information sheet relevant to their stakeholder group (attached), and answer any questions.

Semi-structured interviews will be used to elicit perspectives from each stakeholder group on the implementation potential of the F-DSME intervention in routine care. An implementation framework, the Consolidated Framework for Implementation Research (CFIR), has informed the structure of each interview guide (attached). The framework is useful in suggesting topic categories to explore in the interviews (e.g., characteristics of the intervention) as well as specific implementation determinants (e.g., an intervention's complexity and relative advantage compared to other options).

The analysis team, led by Drs. Curran and Teeter, will use established analytic methods to achieving reliability.[66] Interviews will be transcribed verbatim. Transcripts will be analyzed using thematic coding, with both *a priori* and emergent themes.[67,68] We will create the initial coding templates based on the CFIR framework. Coding will occur in an iterative fashion, expanding and refining the templates as needed. The final product of the data collection and analyses in support of Aim 3 will be a *Multi-Stakeholder Summary Report* focusing on: 1) recommendations for how the Family-DSME should be adapted to ensure optimal uptake in real-world contexts; 2) key barriers and facilitators to implementation upon which to target the selection/development of implementation strategies; and 3) recommendations for implementation/engagement strategies to be pursued in future implementation research.

Data collection

Due to social distancing and public health guidelines related to COVID-19 each of the clinical sites has established drive-thru clinics where participants can remain isolated in their vehicles while completing data collection. Participants may use these drive-thru clinics for consent and all biometric collection.

Baseline and follow up data (post-intervention, six-months post-intervention, and 12-months post-intervention) will be collected from patients and family members in both study arms. At six-months post intervention patients and family members in both study arms will only have HbA1c, BMI, and blood pressure biometric data will be collected.

Participants will have the option of having their 12-month HbA1c collected directly in a study visit or have it abstracted. Biometric results will be returned to participants at the end each data collection event. Parts of the follow up data collection events can be completed by telephone or by Zoom. There will be a 12-week data collection window on either end of the data collection event. The survey may be completed 48 hours before the biometric data collection event via an online survey if participants choose to do so, or it may be completed at the clinic if participants do not complete prior to the biometric data collection event. For those patients with biometric indicators of crisis at data collection events, the research coordinators will refer or connect those patients with medical staff at the clinic site.

If participants agreed to being contacted via text message, they will receive text message reminders notifying them of the date and time of their upcoming appointments. For participants who previously consented prior to the implementation of text message reminders, a letter will be provided to inform them of the addition. The text messages will be delivered using a third-party service. The third-party service will be provided the phone number of participants that agree to be contacted via text message. No other information participant information will be shared with the third-party text service.

In both arms, we will obtain a medical records release to abstract patients' outcomes at 18-months post-intervention. Biometric measures will include HbA1c, glucose, BMI, blood pressure, and lipids: total cholesterol, LDL, HDL, and triglycerides.

Survey Data

A survey instrument including questions from the Diabetes Care Profile (DCP) and the Behavioral Risk Factor Surveillance Survey (BRFSS) will be administered. A pre and post survey to assess knowledge of type 2 diabetes will be administered before and after classes. A diabetes specific medication inventory will be completed. Demographics and contact information will also be collected using study specific forms. These surveys/forms will be administered at each data collection event.

Table 2. Data Collection and Survey Instrument Description	
Biometric Measures	Biometric measures will include: HbA1c, glucose, weight and height to calculate BMI, blood pressure, and lipids: total cholesterol, LDL, HDL, triglycerides.
DSME Survey Instrument	About 154 item questionnaire that contains a total of seven modules: demographics, health status, education/advice received, understanding, sleep, perceived support and received support and telehealth.

Participant Contact Form	This information will include relevant contact and address information as well as contact permissions, in order to schedule and administer study activities. The form will be updated as necessary.
Family member Contact Form	This information will include relevant contact and address information as well as contact permissions, in order to schedule and administer study activities. The form will be updated as necessary.
Medication Inventory	Current medication inventory at each data collection event.
Knowledge Assessment	Pre and post-intervention questionnaire to assess knowledge of type 2 diabetes.

Participants will be given the opportunity during the consent process to allow investigators to link the data collected in this study to data obtained from the Arkansas All-Payer Claims Database (APCD). For those participants that provide consent, investigators will analyze the cost of participants' care relative to their risk factors.

Remuneration

Remuneration will be provided to participants. Participants (patients and family members) will be offered a $100 Walmart gift card or Tango gift card as compensation for their time for each data collection event. Participants will only receive gift cards for the data collection events they complete. Each participant will be eligible to collect one $100 card for each of the four data collection events for a total of $400 for those who participate in all four data collection events.

Those who have already consented and enrolled in the study (and received $20) will be provided with an additional $80 to receive the adjusted $100 incentive amount.

Patient and family participants in the qualitative interviews will be offered a $50 gift card each for participating in interviews for a total of $100 for the household or family unit. Clinic staff and group leaders who choose to participate in the qualitative interviews will each receive a $50 gift card.

Risks and Benefits

A risk to study participants is the potential for loss of confidentiality of study data. Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section. Another risk includes the potential for increased conflict with family members who take part in the study with you.

Potential benefits include improved ability to manage T2D and knowledge gained from the study could potentially benefit patients in the future.

Data Handling and Recordkeeping

The principal investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject material will be assigned a unique identifying code or number. The key to the code will be kept in a locked file cabinet in a locked file room in the Office of Community Health and Research. Only

the principal investigator and the study coordinator will have access to the code and information that identifies the subject in this study. At the conclusion of the study, the data will be permanently de-identified.

The study will comply with UAMS Admin Guide Policy 3.2.01 – research data, reports and analyses be retained for seven years after final reporting or publication of a project, or longer if required by a sponsor or regulation.

Data Analysis

Overall causal model underlying the research question and analytic plan for Aim 1. The research question is: "Compared to Standard-DSME, does Family-DSME yield improved outcomes among diverse patient populations with type 2 diabetes (T2D) and their family members?" The causal model underlying this comparative effectiveness randomized controlled trial is straightforward. We expect Family-DSME and Standard-DSME interventions to reduce HbA1c among T2D patients from pre-intervention to immediate post-intervention. We expect Family-DSME to be comparatively more effective in improving HbA1c and other outcomes for patients. To explore potential mechanisms for the differential effectiveness of each intervention in improving patients' HbA1c and other outcomes, we will evaluate changes in perceived family support and family member self-efficacy for providing support as potential partial mediators of changes in outcomes. We will evaluate potential heterogeneity of treatment effects (HTE) according to rural/urban, race/ethnicity, age, sex, and type of family member variables. The primary outcome for patients (Aim 1) is change in HbA1c between baseline and post-interventionWe will also examine the duration of treatment effects by comparing change in HbA1c at six-, 12-, and 18-months post-intervention. Aim 2 will compare the interventions' effects on family members . We will use a similar causal model as Aim 1, but we will not include some patient-specific outcome variables and we will omit the mediation analyses, as well as the 18-month data abstractions. Aim 3 will conduct an implementation study of the Family-DSME to inform implementation and dissemination. While a causal model is not appropriate for Aim 3, we expect Aim 3 to produce evidence that will guide stakeholders' decisions and inform the implementation and dissemination of Family-DSME.

Sample size, power and effect sizes. Power calculations were performed with Optimal Design and assumed a two-sided $\alpha = .05$.[69] The primary outcome for Aim 1 is immediate post-intervention treatment arm difference in HbA1c change. We used a Cohen's *d* type effect size based on expected change (i.e., post- minus pre-intervention) in HbA1c for Family-DSME minus expected change in HbA1c for Standard-DSME divided by a pooled standard deviation (SD) for the change scores. Expected change in HbA1c for Family-DSME (1.10 units) was based on the studies reviewed in Baig et al., 2015 and Pamungkas et al., 2017, which included data from more than 2500 patients receiving family models of DSME.[15,16] Estimated HbA1c change for Standard-DSME (0.60 units) was the median change reported by a 2016 meta-analysis that included data from more than 11,000 patients.[26] Estimated pooled SD of the change scores (1.34%; $\sqrt{(\sigma^2_{PRE} + \sigma^2_{POST} - 2r\sigma_{PRE \times} \sigma_{POST})}$) assumed a SD of 1.5% for pre- and post-intervention and a Pearson correlation of r=0.6 between pre- and post-intervention HbA1c scores. Our estimated effect size for the standardized mean difference in change scores is 0.5 HbA1c units (i.e., 1.10 minus 0.60) divided by 1.34, or d = 0.37. Delivery of the intervention in a group setting may induce clustering which could impact power. To identify an estimate of the intraclass correlation (ICC) for the power analysis, we reviewed: diabetes research in primary

care clinics (ICCs. = 006-.037)[70] and DSME interventions that address ICC for HbA1c (ICCs = .018 - .10).[71-74] We chose to use two ICC's for sample size estimates, .05 as a plausible value given empirical reports and .10 to represent an extreme value. There will be 30 classes of 10 patients in each of 2 treatment arms (30×10×2) for a total of up to 600 patients. Conservatively assuming 80% retention at post- intervention (our recent study had retention of 89%) each of the 30 classes would have 8 patients for both treatments (30x8x2) for a total of 480 patients. Additional classes may be scheduled as needed. Assuming an ICC of .05, a sample size of 480 would give us 80% power to detect an effect as small as $d = 0.30$ (0.40 HbA1c units). Assuming the largest reported ICC of .10, our sample of 480 would yield 80% power to detect an effect as small as $d = .34$ (0.46 HbA1c units). These power estimates also apply to the analysis of the Aim 2 family member outcomes. Very little outcome data exist for family members; for this reason, Aim 2 is an exploratory aim.[7,9,23-26] It is not straightforward to estimate power for the proposed mediation analyses because the indirect effect is the product of two regression coefficients and is not usually normally distributed.[75] However, Fritz and MacKinnon (2007) provide empirically based guidelines that suggest using a bias-corrected bootstrap method for the indirect effect.[76] Using this approach, our attrition adjusted sample size of 480 would provide 80% power to detect even an indirect effect composed of two small constituent effects. For the interaction effects or HTE by location, race/ethnicity, and sex involving comparisons of treatment effects by subgroups, assuming an ICC of .05 we would have 80% power to detect medium sized effects (e.g., $d = .4$ for comparing treatment effects for two equal groups) depending on subgroup levels and sample size (two levels for sex, three levels for race/ethnicity). Even using conservative estimates for retention and ICC, the proposed study is adequately powered to detect an empirically based estimate of comparative effect size for Aim 1 and a standardized difference as small as 0.34 for Aim 2. In addition, there should be adequate power for secondary mediation and HTE analyses to detect relatively small indirect effects and medium sized interaction effects.

General analytical considerations and descriptive statistics. Analyses will be performed with SAS/STATv14.1. Data will be examined for distributional normality and outliers prior to analyses. Descriptive statistics will be generated for all variables of interest overall and by treatment arm. Univariate comparisons will consist of chi-square tests, two-sample *t*-tests, and their respective non-parametric counterparts for categorical/continuous variables, respectively. We will use similar analytical methods to compare baseline characteristics between study completers and non-completers at all follow-up time points. For all analyses, we will adopt an intent-to-treat approach such that data from all randomly assigned patients will be included in all analyses and patients will always remain a member of the treatment arm to which they were initially assigned, regardless of the amount of treatment received.

Primary analytic approach. The primary outcome for patients (Aim 1) is change in HbA1c between baseline and immediate post-intervention. Our primary analytic approach will use general linear models (GLM), including mixed effects linear regression models for continuous repeated measures to model the mean outcome difference and covariance structures between the treatment arms. Using these models, treatment, time, and interaction effects will be estimated and tested by comparing group-specific means at post-intervention, while adjusting for baseline differences in the demographics, socioeconomic characteristics, and clinical variables, all within repeated mixed linear regression models. Clustering effects within the intervention delivery groups (i.e., within the DSME classes) will be accounted for in the model as a random effect. We will adjust for potential clinic variations as a dummy coded variable in our model.

Analysis of secondary outcomes. Analytic strategies similar to those used with the primary outcome will be used to examine the secondary measures. We will examine treatment arm differences in HbA1c at 6, 12, and 18 months to determine whether post-intervention effects are sustained over time. We will examine treatment effects, time effects, and the interaction between them on secondary measures (blood pressure, glucose, lipids, BMI, self-management behaviors, medication adherence, self-efficacy, diabetes related distress, diabetes related quality of life, and diabetes related complications) using general linear mixed effects models or general estimating equations (GEE), depending on the measurement scale. Covariates (e.g., demographics and socioeconomic factors) will be included for adjustments and to examine their associations with the outcomes. Finally, we will examine the association between treatment adherence (e.g., participation) and the outcome measures in order to determine the magnitude of impact each additional session has on the change in the outcome.

Mediation analysis. An innovative aspect of the study is the examination of the potential mediation effect perceived family support and family member self-efficacy for providing support have on patients' outcomes. We will formally test this separately for the two potential mediator variables by specifying the model of the mediator variable as a function of intervention assignment, and the model of the primary outcome as a function of intervention and the mediator variable. The product of the effect of intervention in the first model and the effect of the mediator variable in the second model is the estimate of the indirect effect. Given that sampling distributions for indirect effects are typically not normal, we will use a Monte Carlo confidence interval approach to estimate a 95% confidence interval for the indirect effect.[77,78] A CI that does not contain zero will be considered evidence of a nonzero indirect effect.[79] Given the measurement scale of the outcome and mediator, this will be done with mixed effects regression similar to one proposed for the primary and secondary continuous outcomes.

Missing data. To minimize loss of power resulting from missing data, we will use either multiple imputation or full-information likelihood estimation to make use of all available data. We will also carry out sensitivity analysis without addressing missing values (complete case analysis), but adjusted for baseline covariates, intervention assignment, the observed outcome values, and baseline predictors of the outcomes. Finally, we will record and report all reasons for dropout and missing data for all patients in reports (MD-3). All methods to prevent and monitor missing data will be clearly described in the study protocol.

Heterogeneity of treatment effect analyses. We will evaluate potential heterogeneity of treatment effects according to clinic locations (rural: urban), race and ethnicity (non-Hispanic White: non-Hispanic Black: Hispanic: Other), age, gender, and aspects of the PWD-family member relationship (romantic partner: other relationship, co-residing; living separately), based on prior literature that indicates potential for differential effects. This will be done by estimating the treatment effect and associated 95% confidence interval for each subgroup to assess effectiveness within each group. Differential effectiveness will also be tested using two-way interactions between intervention assignment and covariates of interest.

Analytic plan to address Aim 3. Interviews will be transcribed verbatim. Transcripts and field note summaries will be analyzed using thematic coding, with both *a priori* and emergent themes.[67,68] We will create the initial coding templates based on the CFIR framework described on page 4.[86,87] Coding will occur in an iterative fashion, expanding and refining the templates as needed. Data will be uploaded and analyzed in the MAXQDA qualitative coding software. The final product of the data collection and analyses in support of Aim 3 will be a *Multi-Stakeholder Summary Report* focusing on: 1) recommendations for how the Family-DSME should be adapted

to ensure optimal uptake in real-world contexts; 2) key barriers and facilitators to implementation upon which to target the selection/development of implementation strategies; and 3) recommendations for implementation/engagement strategies to be pursued in future implementation research.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. The survey instrument may be completed online prior to completion of the full consent form by adding an introductory consent statement to the online survey instrument. All subjects for this study will be provided a consent form describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place in a quiet and confidential area, and subjects may take as much time as needed to make a decision about their participation. Participants will also be provided the option to consent remotely following procedures outlined under “Changes Due to COVID-19”. Participation privacy will be maintained and questions regarding participation will be answered.

A request for waiver of documentation of consent will be provided to study staff, clinic personnel and participant/family members who choose to participate in the qualitative interviews for aim 3 of this study. This will be provided in the information sheets before interviews are conducted. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, and requirements of the study. The consent process will take place in a quiet and confidential area, and subjects may take as much time as needed to make a decision about their participation

No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject or legally authorized representative and the person obtaining the consent. A copy of the consent will be given to the participant, and the informed consent process will be documented in the research record.

The research team may analyze outcomes across these multiple studies if participants provide permission in the consent process.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant. The study will be listed on clinicaltrials.gov in accordance with (funder and/or journal) requirements. Aggregated results may be returned to participants in an infographic that is provided in person, e-mail and/or mailed to the participants. We will also work with stakeholders to disseminate aggregated information in town hall meetings.

References

1. Centers for Disease Control and Prevention. *National Diabetes Statistics Report, 2017: Estimates of Diabetes and its Burden in the United States*. 2017. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf
2. American Diabetes Association. The burden of diabetes in Arkansas. Accessed December 15, 2017, http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/arkansas.pdf
3. Peyrot M, Burns KK, Davies M, et al. Diabetes Attitudes Wishes and Needs 2 (DAWN2): a multinational, multi-stakeholder study of psychosocial issues in diabetes and person-centred diabetes care. *Diabetes Res Clin Pract*. Feb 2013;99(2):174-84. doi:10.1016/j.diabres.2012.11.016
4. Holt RI, Nicolucci A, Kovacs Burns K, et al. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national comparisons on barriers and resources for optimal care--healthcare professional perspective. *Diabet Med*. Jul 2013;30(7):789-98. doi:10.1111/dme.12242
5. Kovacs Burns K, Nicolucci A, Holt RI, et al. Diabetes attitudes, wishes and needs second study (DAWN2): cross-national benchmarking indicators for family members living with people with diabetes. *Diabet Med*. Jul 2013;30(7):778-88. doi:10.1111/dme.12239
6. Nicolucci A, Kovacs Burns K, Holt RI, et al. Diabetes Attitudes, Wishes and Needs second study (DAWN2™): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabet Med*. Jul 2013;30(7):767-77. doi:10.1111/dme.12245
7. Powers MA, Bardsley J, Cypress M, et al. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Diabetes Care*. 2015;38(7):1372-1382. doi:10.1177/0145721716689694
8. Stratton IM, Adler AI, Neil HAW, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ*. Aug 12 2000;321(7258):405-12.
9. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care*. 2002;25(7):1159-1171.
10. Renders CM, Valk GD, Griffin SJ, Wagner EH, Eijk Van JT, Assendelft WJ. Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. *Diabetes Care*. 2001;24(10):1821-1833.
11. American Diabetes Association. Standards of Medical Care in Diabetes - 2017. *Diabetes Care*. 2017;40(S1):1-132.
12. Walker RJ, Gebergziabher M, Martin-Harris B, Egede LE. Independent Effects of Socioeconomic and Psychological Social Determinants of Health on Self-Care and Outcome in Type 2 Diabetes. National Institute of Health; 2014 p. 662-668.
13. Weaver RR, Lemonde M, Payman N, Goodman WM. Health capabilities and diabetes self-management: the impact of economic, social, and cultural resources. *Soc Sci Med*. Feb 2014;102:58-68. doi:10.1016/j.socscimed.2013.11.033

14. Gonzalez-Zacarias A, Mavarez-Martinez A, Arias-Morales C, Stoicea N, Rogers B. Impact of demographic, socioeconomic, and psychological factors on glycemic self-management in adults with type 2 diabetes mellitus. *Front Public Health*. 2016;4:195. doi:10.3389/fpubh.2016.00195
15. Baig A, Benitez A, Quinn M, Burnet D. Family interventions to improve diabetes outcomes for adults. *Ann N Y Acad Sci*. Sep 2015;1353:89-112. doi:10.1111/nyas.12844
16. Pamungkas RA, Chamroonsawasdi K, Vatanasomboon P. A Systematic Review: Family Support Integrated with Diabetes Self-Management among Uncontrolled Type II Diabetes Mellitus Patients. *Behav Sci (Basel)*. Sep 2017;7(3)doi:10.3390/bs7030062
17. Rintala TM, Jaatinen P, Paavilainen E, Astedt-Kurki P. Interrelation between adult persons with diabetes and their family: a systematic review of the literature. *J Fam Nurs*. Feb 2013;19(1):3-28. doi:10.1177/1074840712471899
18. Mayberry LS, Rothman RL, Osborn CY. Family members' obstructive behaviors appear to be more harmful among adults with type 2 diabetes and limited health literacy. *J Health Commun*. 2014;19 Suppl 2:132-43. doi:10.1080/10810730.2014.938840
19. Bennich B, Roder M, Overgaard D, et al. Supportive and non-supportive interactions in families with a type 2 diabetes patient: an integrative review. *Diebetology & Metabolic Syndrome*. 2017;9:57-65.
20. Mayberry LS, Osborn CY. Family support, medication adherence, and glycemic control among adults with type 2 diabetes. *Diabetes Care*. 2012;35(6):1239-1245.
21. Fisher L, Chesla C, Bartz R, et al. The Family and Type 2 Diabetes: A Framework for Intervention. *The Diabetes Educator*. 1998;24(5):599-607.
22. Denham SA, Ware LJ, Raffle H, Leach K. Family inclusion in diabetes education: a nationwide survey of diabetes educators. *Diabetes Educ*. Jul-Aug 2011;37(4):528-35. doi:10.1177/0145721711411312
23. Norris SL, Nichols PJ, Caspersen CJ, et al. Increasing diabetes self-management education in community settings. A systematic review. *American Journal Of Preventive Medicine*. 2002;22(4 Suppl):39-66.
24. Norris SL, Nichols PJ, Caspersen CJ, et al. The effectiveness of disease and case management for people with diabetes. A systematic review. *Am J Prev Med*. May 2002;22(4 Suppl):15-38.
25. Stellefson M, Dipnarine K, Stopka C. The chronic care model and diabetes management in US primary care settings: a systematic review. *Prev Chronic Dis*. 2013;10:E26. doi:10.5888/pcd10.120180
26. Chrvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. *Patient Educ Couns*. 06 2016;99(6):926-43. doi:10.1016/j.pec.2015.11.003
27. Internal Clinical Guidelines Team. *Type 2 Diabetes in Adults: Management*. vol NICE Guideline, No. 28. National Institute for Health and Care Excellence; 2015.
28. Little RR, Rohlfing CL, Sacks DB. Status of hemoglobin A1c measurement and goals for improvement: from chaos to order for improving diabetes care. *Clin Chem*. Feb 2011;57(2):205-14. doi:10.1373/clinchem.2010.148841
29. Nathan DM, Buse JB, Davidson MB, et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a

consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. Jan 2009;32(1):193-203. doi:10.2337/dc08-9025
30. Yuan C, Lai CW, Chan LW, Chow M, Law HK, Ying M. The effect of diabetes self-management education on body weight, glycemic control, and other metabolic markers in patients with type 2 diabetes mellitus. *J Diabetes Res*. 2014;2014:789761. doi:10.1155/2014/789761
31. Brunisholz KD, Briot P, Hamilton S, et al. Diabetes self-management education improves quality of care and clinical outcomes determined by a diabetes bundle measure. *J Multidiscip Healthc*. 2014;7:533-42. doi:10.2147/jmdh.s69000
32. Atak N, Gurkan T, Kose K. The effect of education on knowledge, self-management behaviours and self efficacy of patients with type 2 diabetes. *Australian J Adv Nurs*. 2008;26:66-74.
33. Wattana C, Srisuphan W, Pothiban L, Upchurch S. Effects of a diabetes self-management program on glycemic control, coronary heart disease risk, and quality of life among Thai patients with type 2 diabetes. *Nurs Heal Sci*. 2007;9:135 - 141.
34. Tang TS, Funnell MM, Oh M. Lasting effects of a 2-year diabetes self-management support intervention: outcomes at 1-year follow-up. *Prev Chronic Dis*. 2012;9:E109.
35. Deakin T, Mcshane C, Cade J, Williams R. Group based training for self management startegies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2005;Issue 2:1.
36. Trento M, Passera P, Borgo E, Tomalino M, Bajardi M, Cavallo F. A 5-year randomized controlled study of learning, problem solving ability, and quality of life modifications in people with type 2 diabetes managed by group care. *Diabetes Care*. 2004;112:670 - 675.
37. Toobert DJ, Glasgow RE, Strycker LA, et al. Biologic and quality-of-life outcomes from the Mediterranean Lifestyle Program: a randomized clinical trial. *Diabetes Care*. Aug 2003;26(8):2288-93.
38. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educ*. 2008 Sep-Oct 2008;34(5):815-23. doi:10.1177/0145721708323640
39. Thorpe CT, Fahey LE, Johnson H, Deshpande M, Thorpe JM, Fisher EB. Facilitating healthy coping in patients with diabetes: a systematic review. *Diabetes Educ*. 2013 Jan-Feb 2013;39(1):33-52. doi:10.1177/0145721712464400
40. Toobert DJ, Strycker LA, King DK, Barrera M, Osuna D, Glasgow RE. Long-term outcomes from a multiple-risk-factor diabetes trial for Latinas: ¡Viva Bien! *Transl Behav Med*. Sep 2011;1(3):416-426. doi:10.1007/s13142-010-0011-1
41. Nathan DM, Genuth S, Lachin J, et al. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 09 1993;329(14):977-86. doi:10.1056/NEJM199309303291401
42. Fisher L, Hessler D, Glasgow RE, et al. REDEEM: a pragmatic trial to reduce diabetes distress. *Diabetes Care*. Sep 2013;36(9):2551-8. doi:10.2337/dc12-2493
43. Siminerio L, Ruppert K, Huber K, Toledo FG. Telemedicine for Reach, Education, Access, and Treatment (TREAT): linking telemedicine with diabetes self-management

education to improve care in rural communities. *Diabetes Educ*. 2014 Nov-Dec 2014;40(6):797-805. doi:10.1177/0145721714551993
44. Hermanns N, Schmitt A, Gahr A, et al. The effect of a Diabetes-Specific Cognitive Behavioral Treatment Program (DIAMOS) for patients with diabetes and subclinical depression: results of a randomized controlled trial. *Diabetes Care*. Apr 2015;38(4):551-60. doi:10.2337/dc14-1416
45. Barrera M, Toobert DJ, Strycker LA. Relative contributions of naturalistic and constructed support: two studies of women with type 2 diabetes. *J Behav Med*. Feb 2014;37(1):59-69. doi:10.1007/s10865-012-9465-6
46. Gilliland SS, Azen SP, Perez GE, Carter JS. Strong in body and spirit: lifestyle intervention for Native American adults with diabetes in New Mexico. *Diabetes Care*. Jan 2002;25(1):78-83.
47. Aikens JE, Rosland AM, Piette JD. Improvements in illness self-management and psychological distress associated with telemonitoring support for adults with diabetes. *Prim Care Diabetes*. Apr 2015;9(2):127-34. doi:10.1016/j.pcd.2014.06.003
48. Hu J, Wallace D, McCoy T, Amirehsani K. A Family-Based Diabetes Intervention for Hispanic Adults and Their Family Members. Family Diabetes Education. *The Diabetes Educator*. 2013;39(6)doi:10.1177/0145721713512682
49. Rosal MC, Ockene IS, Restrepo A, et al. Randomized trial of a literacy-sensitive, culturally tailored diabetes self-management intervention for low-income latinos: latinos en control. *Diabetes Care*. Apr 2011;34(4):838-44. doi:10.2337/dc10-1981
50. Kim MT, Han HR, Song HJ, et al. A community-based, culturally tailored behavioral intervention for Korean Americans with type 2 diabetes. *Diabetes Educ*. 2009 Nov-Dec 2009;35(6):986-94. doi:10.1177/0145721709345774
51. Islam NS, Wyatt LC, Patel SD, et al. Evaluation of a community health worker pilot intervention to improve diabetes management in Bangladeshi immigrants with type 2 diabetes in New York City. *Diabetes Educ*. Jul-Aug 2013;39(4):478-93. doi:10.1177/0145721713491438
52. Samuel-Hodge CD, Keyserling TC, Park S, Johnston LF, Gizlice Z, Bangdiwala SI. A randomized trial of a church-based diabetes self-management program for African Americans with type 2 diabetes. *Diabetes Educ*. 2009 May-Jun 2009;35(3):439-54. doi:10.1177/0145721709333270
53. Fall E, Roche B, Izaute M, Batisse M, Tauveron I, Chakroun N. A brief psychological intervention to improve adherence in type 2 diabetes. *Diabetes Metab*. Oct 2013;39(5):432-8. doi:10.1016/j.diabet.2013.05.003
54. Brown SA, Hanis CL. A community-based, culturally sensitive education and group-support intervention for Mexican Americans with NIDDM: a pilot study of efficacy. *Diabetes Educ*. 1995 May-Jun 1995;21(3):203-10. doi:10.1177/014572179502100307
55. Brown SA, Garcia AA, Kouzekanani K, Hanis CL. Culturally competent diabetes self-management education for Mexican Americans: the Starr County border health initiative. *Diabetes Care*. Feb 2002;25(2):259-68.
56. Corkery E, Palmer C, Foley ME, Schechter CB, Frisher L, Roman SH. Effect of a bicultural community health worker on completion of diabetes education in a Hispanic population. *Diabetes Care*. Mar 1997;20(3):254-7.

57. Two Feathers J, Kieffer EC, Palmisano G, et al. Racial and Ethnic Approaches to Community Health (REACH) Detroit partnership: improving diabetes-related outcomes among African American and Latino adults. *Am J Public Health*. Sep 2005;95(9):1552-60. doi:10.2105/AJPH.2005.066134
58. Mendenhall T, Seal K, GreenCrow B, LittleWalker K, BrownOwl S. The Family Education Diabetes Series: Improving Health in Urban- Dwelling American Indian Community. *Qualitative Health Research*. 2012;22(11):1-11.
59. Williams IC, Utz SW, Hinton I, Yan G, Jones R, Reid K. Enhancing diabetes self-care among rural African Americans with diabetes: results of a two-year culturally tailored intervention. *Diabetes Educ*. 2014 Mar-Apr 2014;40(2):231-9. doi:10.1177/0145721713520570
60. García-Huidobro D, Bittner M, Brahm P, Puschel K. Family intervention to control type 2 diabetes: a controlled clinical trial. *Fam Pract*. Feb 2011;28(1):4-11. doi:10.1093/fampra/cmq069
61. Beck J, Greenwood DA, Blanton L, et al. 2017 National Standards for Diabetes Self-Management Education and Support. *Diabetes Educ*. Feb 2018;44(1):35-50. doi:10.1177/0145721718754797
62. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. Mar 2012;50(3):217-26. doi:10.1097/MLR.0b013e3182408812
63. Stirman SW, Miller CJ, Toder K, Calloway A. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci*. Jun 2013;8:65. doi:10.1186/1748-5908-8-65
64. Brownson R, Jacobs J, Tabak R, Hoehner C, Stamatakis K. Designing for dissemination among public health researchers: findings from a national survey in the United States. *American Journal of Public Health*. 2013;103(9):1693-1699.
65. Powell BJ, Beidas RS, Lewis CC, et al. Methods to Improve the Selection and Tailoring of Implementation Strategies. *J Behav Health Serv Res*. Aug 2015;doi:10.1007/s11414-015-9475-6
66. Campbell J, Quicy C, Osserman J, Pederson O. Coding in-depth semistructured interviews: Problems of unitization and intercoder reliability and agreement. *Sociological Methods and Research*. 2013;42(3):294-320.
67. King N, Cassell C, Symon G. Using templates in the thematic analysis of text. In: Cassell C, Symon G, eds. *Essential guide to qualitative methods in organizational research*. Sage Publications; 2004.
68. Crabtree B, Miller W. A Template Approach to Text Analysis: Developing and Using Codebooks. In: Miller B, Miller W, eds. *Doing Qualitative Research*. SAGE; 1992.
69. *Optimal Design Software for Multi-level and Longitudinal Research (Version 3.01)*. William T. Grant Foundation; 2011. www.wtgrantfoundation.org
70. Littenberg B, MacLean CD. Intra-cluster correlation coefficients in adults with diabetes in primary care practices: the Vermont Diabetes Information System field survey. OriginalPaper. *BMC Medical Research Methodology*. 2006-05-03 2006;6(1):20. doi:doi:10.1186/1471-2288-6-20

71. Samuel-Hodge CD, Keyserling TC, France R, et al. A church-based diabetes self-management education program for African Americans with type 2 diabetes. *Prev Chronic Dis*. Jul 2006;3(3):A93.
72. Khan MA, Walley JD, Ali S, et al. Process evaluation of integrated diabetes management at primary healthcare facilities in Pakistan: a mixed-methods study. 2018-12-01 2018;doi:10.3399/bjgpopen18X101612
73. Branda ME, LeBlanc A, Shah ND, et al. Shared decision making for patients with type 2 diabetes: a randomized trial in primary care. *BMC Health Serv Res*. Aug 8 2013;13:301. doi:10.1186/1472-6963-13-301
74. Rossi MC, Lucisano G, Funnell M, et al. Interplay among patient empowerment and clinical and person-centered outcomes in type 2 diabetes. The BENCH-D study. *Patient Educ Couns*. Sep 2015;98(9):1142-9. doi:10.1016/j.pec.2015.05.012
75. Selig JP, Preacher KJ. Mediation Models for Longitudinal Data in Developmental Research. research-article. *http://dxdoiorg/101080/15427600902911247*. 1 Jun 2009 2009;doi:Research in Human Development, Vol. 6, No. 2-3, April-September 2009: pp. 144–164
76. Fritz MS, Mackinnon DP. Required sample size to detect the mediated effect. *Psychol Sci*. Mar 2007;18(3):233-9. doi:10.1111/j.1467-9280.2007.01882.x
77. Preacher KJ, Selig JP. Advantages of Monte Carlo Confidence Intervals for Indirect Effects. research-article. *https://doiorg/101080/193124582012679848*. 8 Jun 2012 2012;doi:Communication Methods and Measures, Vol. 6, No. 2, April-June 2012: pp. 77–98
78. MacKinnon D. *Introduction to Statistical Mediation Analysis*. Routledge; 2019.
79. Kenny D, Kashy D, Bolger N. Data analysis in social psychology. In: Gilbert D, Fiske S, Lindzey G, eds. *The Handbook of Social Psychology*. 4th ed. McGraw-Hill; 1998:233-265.
80. Little R, Rubin D. *Statistical analysis with missing data*. Wiley; 1987.
81. Schafer JL. *Analysis of Incomplete Multivariate Data*. Chapman and Hall; 1997.
82. McElfish P, Goulden P, Bursac Z, et al. Comparative effectiveness of family model versus standard diabetes self-management education in a US Pacific Islander community: results of a randomized controlled trial. In preparation;
83. Peyrot M, Egede LE, Funnell MM, et al. Ethnic differences in family member diabetes involvement and psychological outcomes: results from the second Diabetes Attitudes, Wishes and Needs (DAWN2) study in the USA. *Curr Med Res Opin*. 2015;31(7):1297-307. doi:10.1185/03007995.2015.1043251
84. Peyrot M, Egede LE, Campos C, et al. Ethnic differences in psychological outcomes among people with diabetes: USA results from the second Diabetes Attitudes, Wishes, and Needs (DAWN2) study. *Curr Med Res Opin*. Nov 2014;30(11):2241-54. doi:10.1185/03007995.2014.947023
85. Ricci-Cabello I, Ruiz-Perez I, Rojas-Garcia A, Pastor G, Rodriguez-Barranco M, Goncalves DC. Characteristics and effectiveness of diabetes self-management educational programs targeted to racial/ethnic minority groups: a systematic review, meta-analysis and meta-regression. *BMC Endocr Disord*. Jul 19 2014;14:60. doi:10.1186/1472-6823-14-60
86. Miles M, Huberman M. *Qualitative Data Analysis: An Expanded Sourcebook (2nd Edition)*. SAGE; 1994.

87. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. Aug 2009;4:50. doi:10.1186/1748-5908-4-50