Michigan Men's Diabetes Project (MenD)
Diabetes Peer Leader Intervention IRB Protocol

NCT04760444

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1.0 PHASE II RESEARCH PLAN (PILOT RANDOMIZED CONTROL TRIAL, 3 MONTHS)

During Phase II we will be conducting a 3-month pilot randomized control trial (RCT) of virtual diabetes self-management education and support (DSMES) with peer leaders, (adapted in Phase I), to evaluate participant recruitment and retention rates, treatment and intervention satisfaction and estimate intervention effect sizes on our primary outcomes of self-management behaviors as well as on secondary outcomes such as glycemic control (HbA1c), diabetes social support, diabetes-related distress, and adherence to gender norms. This data will be collected at baseline and three months (treatment termination. Physiological data will be collected at St Patrick Senior Center or Ypsilanti Seventh Day Adventist Church and the self-report questionnaire data will be collected telephonically or virtually. Participants will be randomized to the virtual peer leader DSMES or a control group. All virtual DSMES sessions will be held on an online platform, Zoom Med. The baseline assessment and intervention period will consist of 16 weeks. In the first 2 weeks participants will complete baseline questionnaires, interviews, and physiologic testing at St. Patrick's or Ypsilanti Seventh Day Adventist Church, telephonically, or virtually. In weeks 3 to 8 participants will be simultaneously enrolled in 6 weekly virtual diabetes self-management education (DSME) classes with a certified diabetes care and education specialist (CDCES) and two peer leaders. In weeks 9 to 14 participants will be enrolled in diabetes-self management support (DSMS) sessions with two peer leaders (no CDCES). In weeks 15 and 16 of the intervention, participants will complete the post-treatment assessment battery (See Table 1). Each group will be invited to participate in the 3-month post-intervention assessment battery. Patients who do not complete the intervention phase will also be invited to participate in the 3-month assessment battery. The physiologic testing part of the assessment will be held at Ypsilanti Seventh Day Adventist Church or St. Patrick Senior Center, a non-profit that provides comprehensive services to a diverse population of more than 2,000 seniors living throughout metropolitan Detroit. Data analyses and dissemination of study findings are anticipated to be completed in months 11-12 of the study funding period. We will also be conducting qualitative interviews to better understand the acceptability and sustainability of the intervention as routine practice in a community-based clinic.

TIMELINE	Q1			Q2			Q3			Q4		
Study Activities	**Dec 20**	**Jan 21**	**Feb 21**	**Mar21**	**Apr 21**	**Jun 21**	**Jul 21**	**Aug 21**	**Sep 21**	**Oct 21**	**Nov 21**	**Dec 21**
Phase I												
Focus Group Recruitment												
Hire & Train Research Staff												
Conduct Focus Groups												
Analyze Focus Group Data												
Adapt Intervention Materials												
Intervention Recruitment												
Phase II RCT												
Randomization												
T0 Baseline Assessment												
T1 Post-Intervention Assessment												
Phase III Data Analysis												
Interviews and Focus Groups (participants and practitioners)												
Analyze and disseminate data												

Table 1. Detailed timeline of Phase I and Phase II

2.0 Background:

Diabetes is the 6th leading cause of death in Detroit. [14,15] One-third of people living in the city over the age of 50 have diabetes or pre-diabetes.[14,15] Michigan's age-adjusted diabetes death rates in 2009 were 26.6 for White males, 19.1 for White females, 44.7 for Black males, and 33.6 for Black females (deaths per 100,000 population).[14,15] Diabetes is highly prevalent in Black men and they are more likely to be diagnosed with T2D compared to non-Hispanic White men.[16] In addition, they are disproportionately more likely to have uncontrolled blood glucose levels than their non-Hispanic White counterparts.[17]

One factor that may account for diabetes health disparities is differences in diabetes management behaviors in Black men as compared to Whites.[18] Studies suggest that Black men in general are less likely to adhere to diabetes self-management regimens.[19,20] Although studies of older Black men are more limited, those that exist suggest that they are even less likely to engage in diabetes self-management behaviors (e.g. checking blood glucose levels daily).[7] Black men are also more likely to engage in behaviors that increase their risk for diabetes-related complications such as smoking and alcohol consumption than their non-Hispanic White peers.[21] Black men may also face unique barriers that interfere with healthy behaviors including a lack of social support, negative patient-provider relationships, high medical fees and long work hours.[22,23] While existing research clearly shows that older Black men are at elevated risk for poor diabetes management, they are also less likely to participate in interventions to improve diabetes management.[12] Specifically, in our systematic review of T2D self-management interventions, the percentage of male participants was typically less than 15%. This is also consistent with the finding that men are more likely to drop out of diabetes self-management intervention trials.[10,12, 24]

A growing body of literature demonstrates the critical role of gender in the management of health behaviors and shows that male gender norms can conflict with both healthy behaviors and healthcare engagement.[25] Sex refers to biological differences (e.g. chromosomes and sex organs). Gender describes the characteristics that a society or culture delineates as masculine or feminine.[25] Among Black men specifically, the need to exhibit toughness, confidence, suppression of emotions and independence/control served as barriers to both accepting advice from care providers and accepting social support offered by family and community networks.[20] In a recent study, Black men reported encountering significant difficulty in accepting a caring environment, such as emotional support, as this was perceived as feminized behavior, which in turn served as a barrier to seeking care.[19] Gender-related norms among Black men also include "superman syndrome" or the ability to maintain their health without the assistance of doctors.[26] Recommendations for gender-specific programming have included using male interventionists to reduce stigma and embarrassment related to health care seeking, improve communication with health care providers and address specific beliefs that undermine health.[27] Peer leaders have been defined as trained lay individuals used to improve diabetes self-management in minority communities through provision of diabetes education, assistance with goal setting, problem solving, and social and emotional support.[28,29] In this context, peer leaders shared cultural identity and community ties are a critical component in improving diabetes management in minorities with T2D.[30-32] However, despite studies showing that interventions using peer

leader models have been successful in improving diabetes management (e.g. blood glucose monitoring) and clinical outcomes (e.g. HbA1c) among minority populations to date, these interventions have not been adapted to meet the needs of older Black men. In addition to the lack of tailoring of content or adjustment of messaging, as noted earlier, the majority of peer leaders used in these studies have been female, and in general, women are the majority of participants in diabetes intervention studies.[12] Matching lay interventionists for the race and gender of patients may be one way to increase the likelihood that both intervention content and messaging are appropriate.[12]

While there is a paucity of research using male peer leaders with Black men with T2D, male lay helpers have been used in other areas of health care to provide Black men with health education and support.[33] These interventions have included prevention of chronic illness (e.g. screening for hypertension) in intervention venues such as barbershops.[34] However, this research is limited and therefore additional work needs to be done to establish the efficacy of these approaches.[33,34] In addition, as the behavioral targets of these programs were primarily health promotion and/or prevention behaviors such as increasing condom use and disease screening, and not management of a chronic disease, it is important to assess whether use of male peers as interventionists can improve health outcomes among men already living with a chronic illness. As previously noted, there is a dearth of efficacious diabetes management interventions for Black men. While the effectiveness of peer-led interventions delivering diabetes-related education and support for short-term clinical, psychosocial, and behavioral improvements is well-established, older Black men in particular are less likely to participate and are at a higher risk of drop-out from these studies. The proposed research is innovative because:

1. interventions to date have not targeted older Black men, who are at highest risk for poor diabetes health;
2. peer-led interventions have not matched peer leaders based on the gender of intervention participants nor have they;
3. tailored the intervention content utilizing the perspectives of older Black men with T2D in the adaptation process to meet the specific needs of this understudied and at-risk population.

We propose to develop training for our male peer leaders to specifically encourage conversations regarding beliefs that affect men's health and to allow modeling of alternative views and perspectives that allow for successful disease management to be framed as competence and strength. Given that the life expectancy for Black men in the US is 71, we hypothesize that targeting men in earlier stages of T2D will assist greatly in facilitating healthy aging and improving diabetes-related health outcomes later in life.

Based on our previous work, the ***long-term goal*** of our research is to determine the most effective, practical, and sustainable approach to provide diabetes self-management education and support (DSMES) to older Black men. The ***objective*** of this proposal is to examine the relative effectiveness, feasibility, and acceptability of a peer-leader intervention for Black men with T2D. To accomplish this objective, we will engage in a developmental phase and a validation phase [pilot randomized control trial (RCT)]. The RCT will be conducted with N=60 Black adult residents of metro Detroit, MI. Participants will be randomized to an enhanced usual care group or the tailored peer-leader diabetes self-management support group (PLDSMS). We ***hypothesize*** that 1)

participants in the PLDSMS group will have improved outcomes over the control group, and 2) an evaluation of measures will confirm efficacy of the intervention. Measures will be collected at baseline, 3-months and a 3-month follow-up. The primary outcome will be change in self-management behaviors measured through completion of the Perceived Diabetes Self-Management Scale and a self-report questionnaire measuring a broad range of diabetes self-management behaviors post intervention and at 3-month follow up. Secondary outcomes will be change in A1c, weight, blood pressure, quality of life, diabetes related-distress, diabetes social support, and adherence to gender norms. We ***hypothesize*** that 1) participants I the PLDSMS group will have improved outcomes over the control group, and that 2) participants in the PLDSMS will achieve DSMES skills at significantly higher levels than participants in the control group.

3.0 Aims

Aim 1 (Phase 1): Refine existing intervention components from a previous peer leader trial to allow it to be best tailored to the needs of older Black men with T2D by:

- Conducting 10 interviews with older Black/African American men with T2D.

Aim 2: Conduct a pilot randomized controlled trial for older Black men with T2D based on what we learn from Aim 1. Development, adaptation, and refinement will involve:

- Developing a peer led diabetes self-management education and support intervention based on our interviews and previous research.
- Conduct an open pilot study to determine feasibility and acceptability of the peer led diabetes self-management support and estimate intervention effect size on our primary outcome of diabetes self-management behaviors and changes in A1C, as well as on secondary outcomes of change in weight, blood pressure, quality of life, diabetes related-distress, diabetes social support, and adherence to gender norms. Data from the pilot trial will help refine recruitment strategies, training materials, and protocol to be used in a larger clinical study.

Aim 3: Conduct a qualitative process evaluation of the implementation of peer led DSMS to determine feasibility and acceptability of the intervention by:

- Recruiting 10-12 stakeholders (facilitators, participants, peer leaders, and certified diabetes care and education specialists) and complete post intervention interviews to identify barriers, perceptions and beliefs surrounding peer led DSMS targeting older Black male populations.

Overall impact: Data from the pilot RCT will help refine recruitment strategies, training materials, and the study protocol to be used in a larger cluster RCT. Our study will also identify strategies to increase patient participation in intervention research and improve drop out rates. This goal is in line with the mission of NIDDK to disseminate science-based information on diabetes, to improve people's health and quality of life.

4.0 Participants and Recruitment

Participants will be 64 Black/African American men ages 55 years or older and meet the inclusion criteria listed below. During the Phase II pilot we will individually randomize each participant with a 50/50 randomization scheme to either the peer led DSMS or a control group. Four of the participants will attend 30- hours of training and function as peer leaders during the intervention DSMES.

Inclusion: Inclusion criteria for the Phase II (intervention) will include males age 55 or older who are Black/African American, and who've had diagnosis of T2D for a six-month duration or longer.

Exclusion: Exclusion criteria for Phase II will include: non-ambulatory, serious health conditions (morbid obesity and severe symptomatic heart disease, visual impairment, renal failure, and peripheral neuropathy), psychiatric illness (severity requiring hospitalization) or cognitive deficit (illness determined using the Montreal Cognitive Assessment tool) and serious diabetes complications (e.g. blindness) that would impede meaningful participation. We considered restricting eligibility to a higher-risk population of participants with A1c ≥ 8%. Preliminary data suggest that over 50% of the proposed study sample will have an A1c ≥ 8%. Focusing on all older Black men with T2D allows us to cast a wide net for secondary prevention and public health impact. Persons who meet eligibility criteria will be invited to participate in the baseline screening assessment. While we have chosen the above eligibility criteria based on previous work, we will make adjustments to the future, larger trial, based on results and feedback from our proposed pilot.

Participant Recruitment: We will put up flyers describing the study. The flyers will be posted at a Detroit-based senior center (St. Patrick's), Ypsilanti Seventh Day Adventist Church, and Michigan Center for African American Aging Research Participant Resource Pool (MCUAAAR PRP) community-partners. The MCUAAAR PRP is a research volunteer registry can be accessed by scholars conducting research of Black males, 55 years of age and older who meet their study criteria. Men with T2DM identified with the help of the MCUAAAR PRP will be called by study staff and invited to participate in the intervention. Dr. Hawkins will also be working with the Dr. Linda Nyquist, the Human Subjects Assessment Core Leader. Dr. Nyquist will run a search in the MICHR DataDirect PHI system and identify potential participants that meet study eligibility criteria. Dr. Nyquist will provide the research team with the names, addresses, phone numbers, and emails of potential participants on a password protected document. Men with T2DM identified with the help of Dr, Nyquist will be mailed and emailed recruitment letters. Study staff will provide follow up phone calls after the letters are sent to ensure potential participants received the letter. Men interested in participating in the study will call a central office phone number or be identified on follow-up calls then they will be scheduled for screening.

Peer Leader Participant Recruitment: Peer leaders will be recruited from the Phase 1 Interviews, MICHR DataDirect, or identified by St. Patrick Center staff.

5.0 PROCEDURES

Screening Individuals that are interested in participating in the study will be asked to complete a phone screen with a study team member. During the phone screen, the research staff will read a brief recruitment script and ask if the participant is interested in participating. If the individual is interested and willing, they are asked to complete a phone screen. The phone screen can be scheduled for immediately following the recruitment script or at a time convenient for the potential participant.

The phone screen will assess the following: basic demographic information and self-identified T2D diagnosis. Individuals will be eligible for a baseline interview if they meet demographic criteria (self identified as African American/black, and 55 years or older), self report having Type 2 Diabetes.

Upon completion of the phone screen, the study team member will inform the individual if they are eligible to complete the baseline interview. If the individual is eligible, a baseline assessment will be scheduled and details will be given to the individual. The purpose of this initial screen is to invite research candidates to additional eligibility screening (Baseline Assessment) having met initial criteria and for the research candidates to provide consent to answering questions at the in-person Baseline Assessment which involve Private Health Information, to be used for determining eligibility.

Baseline Assessment (Assessment Battery) All individuals that meet initial phone screening criteria and agree to participate will complete a baseline assessment. The physiological testing portion of the baseline assessment will be held in person at either St. Patrick Senior Center or Ypsilanti Seventh Day Adventist Church and the self-report questionnaire will be completed by the participant virtually or over the phone with a study team member. During the assessment the participant will be asked to complete questionnaires and interviews to determine if the participant is eligible to participate based on inclusion and exclusion criteria. Baseline assessments will last about two hours total. The PI will train all research staff in standardized data collection. Trained research staff will take biometric data of participants including height, weight, blood pressure, and A1c. Participant A1c values will be analyzed on site using a DCA Vantage Analyzer. All participants, including peer leader participants, will be paid $20 for completing the assessment and the same assessments at T0 (baseline) and T1 (post-treatment).

Randomization Participants will be randomized to the peer leader diabetes self-management support (DSMS) group or a control group using a 50/50 randomization scheme. Participants will be aware if they are in the intervention group or the control group.
Intervention (Peer Leader DSMS n=30) Participants randomized to the peer led DSMS group will receive 6 100-minute weekly sessions of diabetes self-management education (DSME) delivered by a certified diabetes care and education specialists (CDCES) and co-facilitated by a peer leader (PL) delivered via the Zoom for Health a U-M service may be used for Protected Health Information (PHI, regulated by HIPPA). Next, participants will transition into 6 90-minute weekly PL led DSMS sessions

intentionally designed for older Black men with T2D. The CDCES will provide oversight to the PL and be available by phone if any clinical questions arise during the session.

Control Group (Control n=30) Participants randomized to the control group will receive 6 sessions of group-delivered DSME provided by a CDCES; however they will not receive any DSMS or ongoing support from PLs and the PL will not participate in the DSME sessions. Based on several years of experience in Detroit, providing all participants with DSME and educational materials minimizes ethical concerns regarding assignment of underserved populations to receive a no-treatment control. To ensure treatment fidelity, three DSMS sessions will be selected at random and recorded and rated for fidelity by our research team.

Peer Leaders (n=4) Participants recruited to be PLs for the intervention group will attend PL training (described below), co-facilitate DSME sessions with a CDCES, lead DSMS sessions, and complete the same battery of assessments as all other participants in the study.

Peer Leader Training: The peer leader training curriculum will be based on materials used by Dr. Piatt and her research group. Thirty hours of training will be conducted over 6 weeks. PLs will receive training in facilitation skills, coping strategies, and empowerment-based communication skills. As noted in Phase 1, training will be adapted to include a focus on men's health issues. Training will be group-based and include both the knowledge and skills needed to implement empowerment-based DSMS. A CDCES who was involved in the development and implementation of the training curriculum in previous projects, will conduct the training. This training will support the PLs in developing communication, facilitation, and behavior change skills and opportunities to apply those skills in an experimental setting. To ensure that PLs are supported, 3-monthly meetings will be held with all PLs so that they may exchange information and support each other. As noted above, it is expected that this content will be adapted to include men's health concerns based on Phase 1. PLs will be identified from interviews, based on recommendations from the senior center, and/or from the DataDirect participant pool. PLs will be compensated at $10/ hour for the duration of the study to defray the cost of their time and expenses.

Follow-Ups The follow up assessment for both the peer led DSMS group and control group will occur at three months (post-treatment assessment). All participants, including peer leader participants, will return to the St. Patrick's Senior Center or to Ypsilanti Seventh Day Adventist Church for physiological testing and complete the self-report questionnaire telephonically, or virtually. The same measurements and surveys will be completed. Participants will be compensated $20 for completing this assessment. Data will be stored in REDCap, a secure, web-based application hosted at UM.

Maintenance of Samples Strategies will be used to encourage attendance of group sessions and to complete follow up interviews. Reminder emails, texts and/or calls will be sent before each session to remind participants by the study team. In addition, the study team will collect participant contact information from baseline to

follow up phase. The study team will also ask participants to provide additional contact person(s) that the study team can contact if they cannot reach the participant.

Participant Retention The following procedures will be used to minimize participant attrition: 1) Data collection sessions will be completed at the Senior Center site or the Ypsilanti Seventh Day Adventist Church in order to maximize the convenience of data collection for subjects, and 2) multiple techniques are used to increase the likelihood that participants will keep their data collection appointments, including advanced scheduling, multiple reminder letters, and phone reminders. Participants who withdraw will still be asked to participate in study data.

Data Collection & Data Safety For Phase II (intervention), data will be collected through the following methods: finger stick capillary blood samples, blood pressure measurements, weight, height, exit interviews regarding treatment satisfaction, surveys, audio recorded interviews and treatment sessions, and transcribed interviews and treatment session recordings. Data that are obtained specifically for research purposes will be collected only with informed consent. All data will be collected over the course of the award period.

At the time of study enrollment, participants will be assigned a study identification number to be used in all study materials and data for the duration of the study. All identifying information will be separated from the data and laboratory values. A master list that contains participants names and study identification number will be kept in a locked filing cabinet within a locked office in the School of Social Work at the University of Michigan. Audiotapes of treatment sessions will be stored securely on a password protected computer only accessible to study personnel and will be destroyed upon study completion. We will use DropBox, a secure platform to share these recordings, transcriptions, and other study data between study team members.

The principal investigator (Dr. Hawkins) and the research assistants will be the only persons who have access to the file linking study participant identification number to each subject, and this will be stored separately from study data. Participants will be assured that all data they provide to the study will be confidential to this study, unless it is necessary to “alert” the patient and possibly also their physician because of a laboratory value outside of the normal ranges that reflects a risk requiring immediate medical attention. All reports will use aggregate data. Subject names or other identifiers will not be reported. All quotes shared collected from the interviews will be de-identified for privacy. No persons from the recruitment sites will handle or have access to personal health information or participant survey data.

Data will be stored in REDCap, a secure, web-based application hosted at the University of Michigan. Analyses will be conducted using Atlas.ti. This data will be used to conduct a final refinement of treatment content as needed.

To ensure the proper monitoring of the safety of all participants and the quality of data collected, a Data Safety and Monitoring Board (DSMB) will be established that will

follow techniques suggested in the literature (Damocles, et al, 2005). The board will consist of Drs. Hawkins, Piatt, and Alexander. In addition, five outside members, who are not involved with the study, will serve on the DSMB **as voting members** and will be identified at a later date. Voting members will consist of University professors with experience and expertise in clinical diabetes intervention research to ensure consistency and quality of input.

6.0 GROUP LEADERS & TRAINING

To ensure staff participation in data safety and monitoring activities, all members of the project team (research assistants and staff) will be trained on the specifics of the data safety and monitoring plan. Field staff will be trained on what constitutes an adverse event to a participant and instructed to report any adverse events immediately to the principal investigator, Dr. Jaclynn Hawkins.

All questionnaires and instrumentations are standardized measures that have been used in our own trials and in other diabetes research and there are no significant risks anticipated related to the completion of them. However, breaks will be given as needed to reduce fatigue, or measures read to adolescents, and research assistants will be appropriately trained to obtain personal information in a sensitive fashion. Research staff will be trained in research ethics, confidentiality protection, and HIPAA prior to and throughout the study period. All CDCESs in this study are either a Registered Dietitian Nutritionist RDN) or Registered Nurse (RN) and are certified through the Certification Board for Diabetes Care and Education. The extensive CDCES certification process ensures health care professionals possess comprehensive knowledge and experience in prediabetes, diabetes prevention, and diabetes management. Katherine Kloss, RDN, CDCES has been working with people with diabetes for 6 years and a CDCES for 2 years. Robin Nwankwo, MPH, RDN, CDCES has been working with people with diabetes for 28 years and a CDCES for 24 years.

The PI will monitor adverse events throughout the clinical trial period. To ensure staff participation in data safety and monitoring activities, all members of the project team (research assistants and staff) will be trained on the specifics of the data safety and monitoring plan. Field staff will be trained on what constitutes an adverse event to a participant and instructed to report any adverse events immediately to the principal investigator, Dr. Jaclynn Hawkins.

The principal and co-investigators on the proposed study make up a trans-disciplinary, accomplished and collaborative team of community-based behavioral and clinical researchers. Together, our research team has a strong history of successfully implementing and publishing our work regarding diabetes interventions in high-risk communities. Most notably, Drs. Piatt and Herman of the Michigan Center for Diabetes Translational Research (MCDTR), collaborated on Praise I and II, T2D randomized controlled trials of the effectiveness of church-based diabetes self-management support being conducted with Black adults in Toledo, Flint, and Metro Detroit of which Dr. Piatt is PI. Dr. Hawkins is currently a co-investigator on Praise 2 (R01DK104733-02). Also, as part of the MCDTR, Dr. Hawkins is an early career trainee and Dr. Piatt served as Dr. Hawkins' primary mentor for the last 3 years. All are members of BRIDGE.

7.0 MEASURES

Primary Outcome Measures

Regimen adherence will be measured using the Perceived Diabetes Self-Management Scale, a self-report questionnaire used to measure a broad range of management behaviors, such as insulin management, dietary management, blood glucose monitoring, symptom response, and parent assistance/supervision.

Metabolic Control will be measured via hemoglobin A1c (HbA1c). HbA1c will be collected using the DCA 2000 point-of-care testing instrument.

Secondary Outcome Measures

Adherence to gender norms will be measured using the Male Role Norms Inventory-Short Form. BMI will be calculated using height and weight. Height will be measured using a stadiometer. Weight will be measured on a high quality, calibrated digital scale. BP will be measured using a digital sphygmomanometer.

Diabetes Social Support will be measured using the Diabetes Social Support Questionnaire. Diabetes-related Distress will be measured using Diabetes Distress Scale (SF-12) and lastly, a validated Diabetes Quality of Life will be used to measure quality of life. Participants will also complete questionnaires that assess socio-demographic, behavioral, psychosocial, and health services utilization and are validated in diverse populations with diabetes.

Specific Aim 1: Qualitative analyses will be conducted during the development phase and on the post-intervention focus groups and interviews. First, we will develop codes utilizing a grounded theory approach and will start with the formulation of categories and definitions developed directly from the text. Content from transcripts will be coded for themes and patterns. Through this process a coding manual and definitions will be finalized. The refined manual will be used to guide ongoing coding and pairs of coders will read subsequent transcripts keeping codes that achieve 80% agreement on code application. Analyses will be conducted using Dedoose. This data will be used to conduct a final refinement of treatment content as needed.

Specific Aim 2: The proposed study includes a sample size of 64 Black men, 30 in the intervention arm, 30 in the control arm and 4 trained as peer leaders for the intervention arm. We will assess the impact of the intervention on diabetes management and HbA1c (primary outcomes) and on secondary outcomes using multilevel modeling, with intervention group as a between-subjects factor (2 levels) and time as a within subjects factor (3 levels). HbA1c, diabetes self-management, and social support at baseline, 3 and 6 months will be used as the dependent variables. Independent variables include intervention group, time of assessment, and interaction between time and intervention

group. Random effects will be allowed for the intercept (to allow differences in baseline measurements) and the slope (to allow differences in the trajectories of change). Covariates e.g. length of time since diabetes diagnosis, age will be tested as predictors of the outcome and retained if significant at $p < .10$.

Power Analysis: Assuming 20% attrition, we expect a final sample size of 48, approximately 12 per group (with 2 groups in the treatment arm). If we assume correlations of 0.25 between successive measurements of HbA1c, then this sample size will yield power of 0.8 to detect a difference of 0.6 standard deviation between average values of HbA1c in treatment and control groups.

8.0 PROTECTION OF HUMAN PARTICIPANTS

The protocol for this study will meet approval by the University of Michigan Institutional Review Board prior to initiating any of the described study activities.

D 1. Human Participants Involvement And Characteristics Removing Participants From The Protocol.

Respondents who meet eligibility criteria will be invited to participate in the baseline screening assessment. While we have chosen the above eligibility criteria based on previous work, we will make adjustments to the future, larger trial, based on the results and feedback from our proposed pilot.

D 2. Sources Of Materials

For Phase II (intervention), data will be collected through the following methods: finger stick capillary blood samples, blood pressure measurements, weight, and height. Data that are obtained specifically for research purposes will be collected only with informed consent. All data will be collected over the course of the award period.

D 3. Potential Risks

Participation in this study involves minimal foreseeable risks. Participants will be asked to provide finger stick capillary blood samples during assessments. Risks associated with finger stick capillary blood draws include: minor discomfort from obtaining the blood sample, minor pain, bruising, or bleeding at the puncture site similar to any other routine blood sample collections. With self-report surveys, there is also the small risk that prompting patients to review their diabetes care practices and providing them with feedback about their diabetes-related health outcomes (e.g., A1C, blood pressure) could cause some emotional discomfort or anxiety. Such discomfort would likely prime patients and their primary care physician or group facilitator to address any problems identified. Other risks include breach of confidentiality of study data.

Protection Against Risk

All questionnaires and instrumentations are standardized measures that have been used in our own trials and in other diabetes research and there are no significant risks anticipated related to the completion of them. However, breaks will be given as needed to reduce fatigue, or measures read to adolescents, and research assistants will be appropriately trained to obtain personal information in a sensitive fashion. Research staff will be trained in research ethics, confidentiality protection, and HIPAA prior to and throughout the study period. All peer leaders must pass standardized training prior to providing service to participants and will also be trained in protection of participant confidentiality.

At the time of study enrollment, participants will be assigned a study identification number to be used in all study materials and data for the duration of the study. All identifying information will be separated from the data and laboratory values. A master list that contains participants names and study identification number will be kept in a locked filing cabinet in the School of Social Work. Audio/visual recordings of the intervention for fidelity purposes will also be stored securely on a password protected computer only accessible to study personnel and will be destroyed upon study completion. The principal investigator (Dr. Hawkins) and the research assistant will be the only persons who have access to the file linking study ID# to each subject. Participants will be assured that all data they provide to the study will be confidential, unless it is necessary to "alert" both the patient and their physician because of a laboratory value outside of the normal ranges that reflects a risk requiring immediate attention. Participant's physicians will receive a report of participant laboratory values after each assessment. All reports will use aggregate data. Subject names or other identifiers will not be reported. No persons from the senior center, Ypsilanti Seventh Day Adventist Church, or other community based location will handle or have access to personal health information or participant survey data.

D 6. Potential Benefits Of The Proposed Research To The Participant And Others
Participants will have the potential to benefit from the study by receiving free diabetes self-management education and support from the intervention and also an opportunity to discuss barriers and facilitators to recruitment and retention of men and women in a large-scale intervention. There are also benefits to society from the research through its potential to improve diabetes self-management interventions for persons with Type 2 diabetes. We feel the benefits of participating in this study significantly outweigh the risks.

9. DATA AND SAFETY MONITORING PLAN

Adverse Events: The PI will monitor adverse events throughout the clinical trial period. To ensure staff participation in data safety and monitoring activities, all members of the project team (research assistants and staff) will be trained on the specifics of the data safety and monitoring plan. Field staff will be trained on what constitutes an adverse event to a participant and instructed to report any adverse events immediately to the principal investigator, Dr. Jaclynn Hawkins.

For the purposes of this study, adverse events will be considered any undesirable sign, symptom, or medical condition occurring during the study, whether or not related to the intervention. Adverse events include new events not present during the training period or events that were present during the training period but increased in severity over time. Each adverse event will be recorded and assessed for its date of onset, duration, severity, seriousness, and relationship to study treatment, and any action/treatment that is required. All adverse events will be collected, analyzed, and monitored using an adverse event form. Furthermore, the committee will establish "alert" values for A1C and blood pressure. The PI will notify the subject and the subject's physician whenever there are laboratory results above these values because of the clinical implications of a value substantially out of normal range.

All serious medical events will be reported within one business day of their identification. All serious, fatal or life-threatening adverse events will be reported to UM IRB and the NIH within 24 hours of its identification. All causes of death are considered to be serious medical events. Unexpected moderate or severe adverse events will be reported in writing to the IRB and NIH. Serious medical events will be collected throughout the intervention phase of the study. The PI, along with the study physician, Bill Herman, and/or co-Investigator Gretchen Piatt, will adjudicate whether or not each serious adverse event may be attributable to study participation. Events that involve an unexpected adverse event and are possibly or probably related to participation in the study will be reported to the IRB at University of Michigan within one business day. Annual reporting of aggregate adverse events to the IRB and NIH will be performed. All research project personnel will complete training in the protection of human research participants. The PI and research assistant will verify appropriate reporting of adverse events, quality of data collection, and adherence to the study protocol. Participant dropout rate will also be monitored and reviewed for needs or trends based on specific participant characteristics.

Data Safety & Monitoring Board: The DSMB will hold a minimum of two conference calls over the award period (approximately two hours per call) to discuss the progress of the intervention and review research results, if applicable. At the first meeting, the board will elect a chair of the DSMB. To facilitate these conference calls, the principal investigator will prepare a report on the progress of the project to date. This report will be circulated well in advance of the conference call to allow all members ample time to read it. These calls will be scheduled and organized by the study coordinator and will be held at a time convenient for all members.

The DSMB is responsible for assuring that study participants are not exposed to unnecessary or unreasonable risks and that the study is being conducted according to high scientific and ethical standards. Specifically, the DSMB will:

1. Assess the performance of the study with respect to subject recruitment, retention and follow-up, protocol adherence, and data quality and completeness, in order to ensure the likelihood of successful and timely milestone completion.

2. Monitor interim data regarding the safety of the study, including adverse events. The DSMB may, at its discretion, examine effectiveness data as well.

3. Review abstract and publications of main findings prior to submission to ensure the study is being reported appropriately.

4. Review and consider any protocol modifications or ancillary studies proposed by the study investigators after the main study begins to ensure that these do not negatively impact on the main trial.

5. Advise the NIA and the study investigators as to whether a protocol should continue as scheduled or undergo a modification due to a finding from the monitoring process.

6. Make recommendations to the NIDDK and principal investigator concerning continuation or conclusion of the trial.

10.0 STUDY SITES

Virtual empowerment-based DSME/S sessions: All DSME/S sessions will be held virtually via HIPPA compliant Zoom med. Baseline, post-treatment and follow-up assessment self-report questionnaire will take place telephonically or virtually and the physiological part of those assessments will take place at St. Patrick's senior center, a non-profit that provides comprehensive services to a diverse population of more than 2,000 seniors living throughout metropolitan Detroit, or Ypsilanti Seventh Day Adventist Church.

Elements Unique to this Site In each location, rooms with doors and telephones will be available to facilitate privacy, confidentiality, and safety of assessments.