Study Title: Online Diabetes Education Project: Virtual Diabetes Self-Management Education and Support

NCT04743778

Protocol Approved by University of Michigan IRB on 8/17/2021

Online Diabetes Education Project: Virtual Diabetes Self-Management Education and Support Intervention IRB Protocol

1.0 PHASE II RESEARCH PLAN (Pilot Randomized Control Trial, 3 months)

During Phase II we will be conducting a 3 month pilot randomized controlled trial (RCT) of Virtual Diabetes-Self Management Education and Support (DSME/S), the treatment adapted in Phase I, to evaluate participant recruitment and retention rates, treatment and intervention satisfaction and estimate intervention effect sizes on our primary outcome of glycemic control (HbA1c) as well as on secondary outcomes such as diabetes-related distress, self-management behaviors and diabetes social support at baseline and treatment termination. Data will be collected at baseline and three months (treatment termination) at a federally qualified health center, telephonically, or virtually. Participants will be randomized to the virtual empowerment-based DSMES or a control group. All virtual DSME intervention group sessions will be held on an online platform, Zoom Med. The baseline assessment and intervention period will consist of 14 weeks. In the first 2 weeks participants will complete baseline questionnaires, interviews, and physiologic testing at a federally qualified health center, telephonically, or virtually. In weeks 3 to 10, participants will be simultaneously enrolled in 8 weekly virtual DSME classes. In weeks 13 and 14 of the intervention, participants will complete the post-treatment assessment battery (See Table 1). Patients who do not complete the intervention phase will also be invited to participate in the treatment termination assessment. The physiologic testing part of the assessment will be held at Detroit Community Health Connection, Inc. (DCHC) and other community-based locations TBD, based on participant feedback, telephonically, or virtually. DCHC is a non-profit community-based primary care organization that provides medical and dental services to the insured, uninsured and underinsured at six federally qualified health centers in the city of Detroit. Data analyses and dissemination of study findings are anticipated to be completed in months 11-12 of the study funding period. In Phase III of this project, we will be conducting qualitative interviews to better understand the acceptability and sustainability of the intervention as routine practice in a community-based clinic.

Table 1. Detailed timeline of Phase I and Phase II

TIMELINE	Q1			Q2			Q3			Q4		
Study Activities	**Dec 20**	**Jan 21**	**Feb 21**	**Mar 21**	**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												

2.0 BACKGROUND

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

Diabetes self-management education and support (DSME/S) is a cornerstone of successful diabetes management. Various methods have been used to reach the increasing numbers of patients with diabetes, including Internet-based education. A 2015 review found that DSME/S delivered via the Internet is effective at improving measures of glycemic control and diabetes knowledge compared with usual care. In addition, results demonstrate that improved eating habits and increased attendance at clinic appointments occur after the online DSME/S, although engagement and usage of Internet materials wane over time. Interventions that include an element of interaction with healthcare providers were seen as attractive to participants. Internet-delivered diabetes education has the added benefit of easier access for many individuals, and patients can self-pace themselves through materials. More research on the cost-benefits of Internet diabetes education and best methods to maintain patient engagement are needed, along with more studies assessing the long-term impact of Internet-delivered DSME/S.

Based on our previous work, the ***long-term goal*** of our research is to determine the most effective, practical, and sustainable approaches to provide virtual diabetes self-management education and support (DSME/S) to increase accessibility to DSME/S in clinical and non-clinical settings. The ***objective*** of this proposal is to examine the relative effectiveness, feasibility and acceptability of virtual DSME compared to a control group. To accomplish this objective, we will engage in a developmental phase and a validation phase [pilot randomized controlled trial (RCT)]. The RCT will be conducted with N=60 Black adult residents of Detroit, MI. Participants will be randomized to an enhanced usual care group or to the tailored virtual DSME/S. We ***hypothesize*** that 1) participants in the virtual diabetes approach 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 and 3-months. The primary outcome will be change in A1c, depression, and self-management behaviors at baseline and post-intervention. Secondary outcomes include changes in weight, blood pressure, quality of life, and diabetes related distress. We ***hypothesize*** that 1) participants in virtual DSME/S approaches will have improved outcomes over the control group, and that 2) participants in the empowerment-based virtual DSME/S will achieve DSME/S skills at significantly higher levels than participants in the control group.

3.0 AIMS

Aim 1 (Phase I HUM00170437): Identify barriers and facilitators to mental health care utilization, diabetes self-management, and internet/computer accessibility and acceptability by:

- Conducting 15 interviews with African American women and 15 interviews with African American men with diabetes
- Conducting semi-structured stakeholder interviews including mental health care providers at a Detroit-based health clinic.

Specific Aim 2: Develop a virtual empowerment-based Diabetes Self-Management Education and Support (DSME/S) intervention to work in a community-based clinic based on what we learn in Aim 1. Development, adaptation and refinement will involve:

- Developing an empowerment-based DSME/S based on our interviews and previous research.

Specific Aim 3: Assess the impact intervention strategies developed in Aim 1 by:

- conducting a pilot study of our DSME/S to evaluate participant recruitment and retention rates, treatment and intervention satisfaction and estimate intervention effect sizes on our primary outcome of glycemic control (HbA1c) as well as on secondary outcomes such as self-management behaviors, depression and diabetes social support at baseline and 3 months. Data from the pilot trial will help refine recruitment strategies, training materials, and protocol to be used in a larger clinical trial.
- conducting qualitative interviews to better understand the acceptability and sustainability of the intervention as routine practice in a community-based clinic.

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 dropout 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 60 Black men and women that are 18 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 virtual empowerment based DSME/S or a control group.

Inclusion: Inclusion criteria for the Phase II (intervention) will include participants with all of the following identities: age 18 or older, Black, a diagnosis of T2D for six months duration or longer, ambulatory status, and currently under a physician's care.

Eligibility will be determined using a telephone screening (administered by a research assistant or project coordinator). Respondents who meet eligibility criteria will be invited to participate in the baseline screening assessment.

Exclusion For Phase II (intervention) 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 Black/African American men and women with type 2 diabetes 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.

Recruitment We plan to utilize the following strategies to enhance and maintain participation in the proposed study: Patients currently at the DCHC clinic and eligible for the study will be identified via electronic medical record (EMR) by DCHC facility

staff and provide the UM study team with names, phone numbers, and emails of eligible patients. The UM study team will then contact the potential subjects via email and by phone. The UM study team will not have access to patient EMRs. Flyers describing the study will be posted at each of the 6 DCHC clinics and in community-based locations. Interested participants will call the UM study team's central office phone number where they will be scheduled for screening. We also plan to recruit from the Michigan Center for Urban African American Aging Research Participant Resource Pool (MCUAAAR PRP). Flyers describing the study will be posted at the MCUAARP center, including the central phone number for participants to reach the research staff. The research staff will be given a list of eligible male and female candidates from the research pool who have a Type 2 diabetes diagnosis; and a self-identified Black/African American identity from the MCUAAAR PRP will be invited to participate in the intervention. The MCUAAAR PRP is a research volunteer registry can be accessed by scholars conducting research of Black makes, 55 years of age and older who meet their study criteria. Dr. Hawkins has previously conducted studies using older Black males with T2D recruited from the PRP. There are currently a total of 1424 active PRP members and 60.1% of male PRP members have T2D.

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 over eighteen years old), and 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. Baseline assessment will be held in person at Detroit Community Health Center (DCHC), by phone or virtually with a study team member. During the assessment the participant will be asked to complete the informed consent (with electronic signature using SignNow), questionnaires, interviews, and physiologic testing to determine if the participant is eligible to participate based on inclusion and exclusion criteria. Baseline assessments will last about sixty minutes. The PI will train all research staff in standardized data collection. Participants will be paid $20 for completing the assessment and the same assessments at T0 (baseline) and T2 (treatment termination).

Randomization Participants will be randomized to the virtual empowerment based DSME/S 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 (virtual empowerment-based DSME/S n=30) Participants randomized into the virtual empowerment-based DSME/S group will receive 10 hours of DSME/S delivered by a Certified Diabetes Care and Education Specialist (CDCES) over 8 weeks delivered via the Zoom for Health at U-M service may be used for Protected Health Information (PHI, regulated by HIPAA). To ensure treatment fidelity, three DSME/S sessions will be selected at random and recorded and rated for fidelity to the above content by our research team.

Control Group (Control n=30) Participants randomized to enhanced usual care will receive referrals to community mental health providers, pedometers, gym memberships to a community-based venue, and intervention patient manuals. Based on several years of experience in Detroit, providing all participants with referrals, pedometers, and educational materials minimizes ethical concerns regarding assignment of underserved populations to receive a no-treatment control.

Follow-Ups Follow up assessments for both the virtual empowerment-based DSME/S group and control group will occur at three months (post-treatment assessment). Participants will return to the DCHC for follow-up assessments, telephonically, or virtually and the same measurements and surveys will be completed. Participants will be compensated $20 for completing each 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 through the 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 DCHC site 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), research 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. All data will be obtained specifically for research purposes and will be collected only with informed consent 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 interviews and 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

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

Depression will be measured using the PHQ-9 (score >=10) and The BDI-II, a 21-item self-administered questionnaire used to assess symptoms of depression. Depression will be measured using the Beck Depression Inventory (BDI-II). BDI-II items have been designed to correspond with DSM-IVTR diagnostic criteria. The BDI-II has been shown to have excellent test-retest reliability and validity when used in general populations as well for use with diabetes samples.

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.

Secondary Outcome Measures

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 the auscultatory method.

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 60 Black men and women, 30 in the intervention arm and 30 in the control arm. We will assess the impact of the intervention on HbA1c (primary outcome) and diabetes management (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, depression symptoms, diabetes self-management, and social support at baseline and 3 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.

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. 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. All reports will use aggregate data. Subject names or other identifiers will not be reported. No persons from the DCHC 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 psychologist Dr. Mary de Groot 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 NIA 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 and post-treatment assessments will take place telephonically, virtually or at DCHC is a non-profit community-based primary care organization that provides medical and dental services to the insured, uninsured and underinsured at six federally qualified health centers in the city of Detroit.

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