Protocol and Statistical Analysis Plan

Study Title: A Web-based Problem-Solving Program for African American Patients with Type 2 Diabetes

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University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS
TEMPLATE WITH GUIDANCE

Version date: 4

Principal Investigator: Michelle L. Redmond, PhD

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Co- Investigator(s): Nicole Nollen, PhD, Paigton Mayes, PhD, Robert Badgett, MD

I. Purpose, Background and Rationale

A. Aim and Hypotheses

Significant disparities by race/ethnicity exist in the prevalence of type 2 diabetes and its health outcomes. In the US, diabetes affects 13.2% of African Americans, compared to 7.6% of Whites. Behavioral factors, such as poor diet, low physical activity, general lack of good self-management skills and self-care knowledge are associated with poor glucose control among African Americans African Americans are 77% more likely to develop diabetes and its associated health complications compared to non-Hispanic Whites. Thus, this higher disease burden and lower adherence to self-management among African Americans calls for innovative approaches to self-management training Problem solving is a reliable tool for the behavior change necessary to improve self-management, and the American Association of Diabetes Educators identifies it as one of 7 core diabetes self-management behaviors. One approach to helping African Americans develop the skills to solving problems is Problem Solving Skills Training (PSST). This therapeutic skill-training technique is delivered face-to-face to help patients identify their problems, learn skills to solve them, and implement solutions for particular challenges or obstacles in their disease self-management. Hill-Briggs and colleagues adapted PSST into a curriculum titled Decision-Making Education for Choices in Diabetes Every Day (**DECIDE**), which has successfully helped African American populations improve self-management behaviors, adherence, problem-solving and CVD clinical outcomes (HbA1c, Blood pressure, LDL, HDL). The specific aim is to:

1. Test eDECIDE in a pilot 18-week RCT, measuring change in HbA1c (primary outcome) and the following secondary outcomes: blood pressure, cholesterol, problem-solving skills, diabetes and cardiovascular disease knowledge, nutrition, and diabetes self-care behaviors.

   Primary Hypothesis: Participants randomized to eDECIDE (intervention group) will have comparable improvement in HbA1c compared to those randomized to traditional DECIDE (control group) at the end of 18-weeks.

   Secondary Hypothesis: Participants randomized to eDECIDE (intervention group) will have comparable improvement in problem-solving skills, diabetes self-management knowledge and behaviors, and clinical measures compared to traditional DECIDE (control group) at the end of 18-weeks.

B. Background and Significance

1. Study Significance: This web-based approach will allow for future studies (using mHealth mobile applications) that can examine best practices for which type of problem-solving skills training is most effective to improve diabetes health outcomes for individuals. Results will inform the development of interventions aimed at reducing complications from uncontrolled diabetes as well as interventions aimed at promoting problem-solving and self-management. Identifying how to make problem-solving interventions more accessible would strengthen current investigations into improving health outcomes among underserved populations. It is believed that the minimal risk involved in the proposed study is reasonable considering that it could lead to more effective ways to manage diabetes among vulnerable. Since participation in traditional diabetes self-management programs is low, delivering tailored problem-solving skills training could increase self-efficacy and adherence among *African American*s, thus improving glycemic control and further reducing health complications.

   We propose to design and test a web-based application of the DECIDE curriculum for African Americans with uncontrolled diabetes. According to a Pew Internet study, 62% of African Americans have home access to the Internet, [27] and a previous web-based intervention indicated 80% of urban African Americans living with diabetes were using computers.[28] This application is not only a feasible approach to skills training, but innovative and cost-effective, allowing more flexibility, control, and self-directed access to training than face-to-face group sessions do. This new modality to deliver problem-solving interventions has the potential to reach much more of the African American population by providing easier access to diabetes self-management education.

   Literature Review: Novel interventions are needed to promote diabetes self-management among African Americans to improve glycemic control and reduce the risk for diabetes-related adverse events. Type 2 diabetes is a major public health concern that disproportionally affects African Americans, with more than 4.9 million adults 20 years or older living with the disease. African Americans experience worse health outcomes from diabetes complications compared to non-Hispanic whites. Uncontrolled, it can lead to both macrovascular (e.g., coronary artery disease [CAD], stroke, lower-extremity amputations) and microvascular complications (blindness, renal or nervous system damage). A healthy diet, regular physical activity, medication/insulin adherence, and monitoring blood glucose are all important self-management behaviors for proper glycemic control. Previous studies have examined the relationship between diabetes self-management and race/ethnicity, with significant differences between African Americans and non-Hispanic whites. Kieffer and colleagues found African Americans struggle the most with self-management behaviors centered on dietary factors (food preparation, cost, preferences, and family support) and physical activity barriers (lack of childcare, social support, and safety). African Americans with uncontrolled diabetes require some level of behavior change to increase knowledge of and adherence to self-management behaviors, ultimately lessening the impact of associated poor health outcomes. Problem-solving skills training is beneficial in increasing success with maintaining certain self-management behaviors, while improving health outcomes. In diabetes self-management, problem-solving refers to applying the process of recognizing and identifying problems, generating solutions, and making decisions to surmount specific barriers to completing self-management tasks. For example, patients may struggle with following a prescribed diet, but problem-solving skills can help them identify which barriers impede them the most, whether selecting the right foods when eating out or finding solutions to preparing healthy meals for an entire family, so interventions are needed to help patients reach optimal problem-solving skill.

C. Rationale

1. The *long-term goal* is to understand how problem-solving skills training, delivered by novel technology, can improve self-management in African American patients with uncontrolled diabetes. The *objective of this application*, which is our first step in pursuit of that goal, is to translate the evidence-based DECIDE curriculum into a user-centered web-based program (*e*DECIDE). In previous study phases we have conducted a task analysis and usability testing. Now, we are focusing on the pilot RCT. Our current aim is to test the *e*DECIDE application in a pilot, 18-week randomized controlled trial with participants randomized to either *e*DECIDE (intervention group) or traditional DECIDE (control group).
2. Problem-solving skills training interventions have typically used group methods, one-on-one sessions, and DVDs. Currently, no studies have been conducted on the delivery and potential efficacy of problem-solving skills training for diabetes self-management behavior in a web-based format. Delivering a problem-solving intervention through a web-based component is an innovative way to reach the desired underserved population that is the focus of this application. This approach will empower the population with greater resources and tools to improve self-management and health outcomes. In addition, the web-based format allows participants to receive tailored real-time feedback on potential problem-solving issues that emerge (e.g., dietary and other self-care issues), on self-management knowledge and skills in a more self-directed manner, allowing for future studies of mobile applications to examine best practices for the type of problem-solving skills training most effective to improve diabetes health outcomes.
3. The proposed study will be the first to use a website (eDECIDE) to deliver problem-solving skills training for African Americans with Type 2 diabetes. This is significant because it has the potential to extend the reach of DECIDE with its proven efficacy in community settings.

II. Research Plan and Design

A. Study Objectives: The goal of this research is to conduct a 18-week randomized controlled trial pilot of eDECIDE that tests the feasibility of adapting DECIDE into eDECIDE, in an effort to lower HbA1c levels among African Americans, by promoting the use of problem-solving skills.

B. Study Type and Design: This study is a randomized controlled trial pilot that will occur over an 18-week period. Participants will be recruited from local community health clinics and screened for A1C over 7.0% and clinical health measures (based on medical chart review), readability, Internet access, and cognitive impairment. Participants will be randomized into either the traditional DECIDE group (control) or the eDECIDE group (intervention). Traditional DECIDE consists of the regular 18-week in-person group sessions led by the candidate, as facilitator. The eDECIDE group sessions will consist of the newly translated online method. To assess problem-solving, diabetes self-care behaviors, diabetes and CVD knowledge, and dietary habits, participants will be administered the validated instruments listed in Table 5 at baseline, post-intervention, then at 3-month follow-up. Once participants are screened and randomized, they will be enrolled in the web-based program or the traditionally based program and complete a total of 18 weekly sessions. For eDECIDE, participants will have access to the weekly curriculum through a password-protected, interactive website. Participants in the intervention group will be asked to input their HbA1c number on the eDECIDE website. They will also be asked to create a unique username and password to login and use the eDECIDE website. All stored data will be secure and encrypted. Website is in development. Participants will be prompted to complete their workbook pages and answer any problems about barriers for the week. After prompting, participants will have the opportunity to submit their

completed workbook homework to their personal health coach (PI: Michelle Redmond). Homework and sessions will be delivered through an eLearning system accessible through the eDECIDE website. Participants retrieve feedback via the website when logging back into their account. The personal health coach will not deliver problem-solving content. All content is scripted on the website and eLearning portal. Each week for 18 weeks, participants are asked to log on at least once for a total of 1 hour to complete the bi-weekly problem-solving training for that week. The training would include completing workbook pages and submitting responses to the coach. Participants in both groups will receive $75 in gift cards ($15 at first session, $20 at completion of the 18 weeks, then $20 at 3-month follow-up

C. Sample size, statistical methods, and power calculation

The primary outcome of interest is HbA1c measurement in the traditional DECIDE (control) group and eDECIDE (intervention) group. A .5% change in HbA1c has been considered clinically meaningful. The standard deviation in both arms is assumed to be 1.3%.[61] Based on 2 sample t-test, assuming type I error rate of 5%, and attrition rate of 20%, with 35 participants in each group, the study is powered at 80% to detect a change in HbA1c level of at least 1% between the 2 groups. Hill-Briggs' intervention was successful in detecting HbA1c change of at least 1% in a previous study. We will recruit 100 participants allowing for attrition to reach our goal of 70 for the pilot RCT. Block randomization with block size of 10 will be employed. Within each block 5 participants will be assigned at random to control and 5 to intervention group using computer derived labels.

For baseline characteristics of data, descriptive statistics will be reported as mean and standard deviation for continuous variables, and as count and percentage for categorical variables. Depending on the distribution of the continuous variables Wilcoxon rank sum test or t-test will be used to test for difference in continuous variables across the control and intervention group. Chi-Square test of independence will be used to assess the association between categorical variables and the two groups. The analysis will be based on "Intention-to-treat" principle. A 2-sided p-value of 0.05 will be used to assess statistical significance. Missing Data: If the proportion of missing data is small (5%), complete case analysis will be carried out. If the proportion is higher, then multiple imputations will be used to impute missing values.

The post-intervention HbA1c levels in the intervention group will be compared to the control group using linear regression model after adjusting for baseline HbA1c levels. Additionally, average percentage change in HbA1c level across the 2 groups will be computed and compared using 2 sample t-test or Wilcoxon rank sum test (depending on the distribution of data).

The secondary outcomes of interest are additional clinical measures (blood pressure, LDL, HDL), dietary habits, diabetes self-management behaviors, Diabetes and CVD knowledge, and problem-solving skills for health-related problems as assessed by instruments listed in Table 5.

1. **Blinding Procedures:** This study will not involve blinding (masking). Participants and research staff will be aware of random group assignment.

2. **Subject Enrollment:** The primary outcome of interest is HbA1c measurement in the traditional DECIDE (control) group and eDECIDE (intervention) group. A .5% change in HbA1c has been considered clinically meaningful. The standard deviation in both arms is assumed to be 1.3%.[61] Based on 2 sample t-test, assuming type I error rate of 5%, and attrition rate of 20%, with 35 participants in

each group, the study is powered at 80% to detect a change in HbA1c level of at least 1% between the 2 groups.[24-25] Hill-Briggs' intervention was successful in detecting HbA1c change of at least 1% in a previous study.[24-25] We will recruit 100 participants allowing for attrition to reach our goal of 70 for the pilot RCT. Block randomization with block size of 10 will be employed. Within each block 5 participants will be assigned at random to control and 5 to intervention group using computer derived labels.

D. Subject Criteria (See Vulnerable Populations appendix, if applicable): While uncontrolled diabetes affects more than one racial/ethnic group, our study will focus on African American adults because the burden of disease and consequent health complications is greatest among this population, particularly in the state of Kansas. Here, African Americans have the highest diabetes prevalence (15.7%) compared to 8.7% for non-Hispanic whites. In Sedgwick County (the county in which KUSM-W is located), African Americans make up 9% of the population, but have the highest prevalence of diagnosed diabetes within the county at 15%, with Non-Hispanic whites at 8.1%.[54] This study will take place in our local community where improvements and innovations in access to diabetes self-management services are greatly needed. Examining multiple racial/ethnic groups is beyond the scope of the current application. Our intent is to determine the efficacy of eDECIDE with a focus on our most at-risk group (i.e., African Americans). Future studies will allow the resources and time to expand the study population beyond African Americans.

1. Inclusion criteria: Potential participants will be initially screened based on clinic (KU Internal Medicine Clinic) databases. They will be included if they have an HbA1c of > 7%, absence of significant comorbidities that limit adherence to self-management protocol, or expected to limit lifespan to < 3 years (chest pain, amputation, cancer diagnosis) based on medical chart audit review, are deemed suitable by clinicians, are African American, and are at least 21 years and older. The candidate will contact those who meet inclusion criteria to further undergo a telephone eligibility screen. The screen will ascertain eligibility based on no current participation in a self-management program and daily access to the Internet (in a home or private location).
2. Exclusion criteria: During the baseline visit, potential participants will then be screened for exclusion criteria: visual and cognitive impairment, [51-52] inability to give informed consent, and unable to complete baseline assessment (clinical measures, study questionnaires, venipuncture).

3. Withdrawal/Termination criteria: Subject's participation will be terminated if requested by the subject. Subject's will need to continue to meet eligibility requirements to remain in the study (i.e. Internet access, etc.) to remain in the study.
4. A study subject can't participant in another study that is related to diabetes self-management as this may compromise out study outcomes.

E. Specific methods and techniques used throughout the study

1. **Laboratory tests:** Our study will collect and possibly perform blood draws (approximately 2 tablespoons)- to measure HbA1c and Cholesterol level. This blood draw would be collected at baseline, post-intervention (18 weeks) and again at 3-month follow-up. The laboratory test would be conducted either by the participating clinic or a contracted laboratory for participants to visit.

   Behavioral questionnaires: Health-problem-solving survey, Diabetes self-care survey,

patient-provider communication survey

2. Study Procedures: Participants will be randomized into either the traditional DECIDE group (control) or the eDECIDE group (intervention). Traditional DECIDE consists of the regular 9 in-person group sessions delivered bi-weekly. The eDECIDE group sessions will consist of the newly translated online method. To assess problem-solving, diabetes self-care behaviors, diabetes and CVD knowledge, and dietary habits, participants will be administered the validated instruments at baseline, post-intervention, then at 3-month follow-up. Once participants are screened and randomized, they will be enrolled in the web-based program or the traditionally based program and complete a total of 18 weekly sessions. For eDECIDE, participants will have access to the weekly curriculum through a password-protected, interactive website. Participants will be prompted to complete their workbook pages and answer any problems about barriers for the week. After prompting, participants will have the opportunity to submit their completed workbook homework to their personal health coach (who will be hired for the RCT and work closely with Dr. Redmond for review and feedback through a Dropbox embedded within the web page. Participants retrieve feedback via the website when logging back into their account. The personal health coach will not deliver problem-solving content. All content is scripted on the website. Each week for 18-weeks, participants are asked to log on at least once for a total of 1 hour to complete the weekly problem-solving training for that week. The training would include completing workbook pages and submitting responses to the coach. Participants in both groups will receive $50 in gift cards ($10 at first session, $20 at completion of the 9 weeks, then $20 at 3-month follow-up. Surveys will be administered that are suited to measure diabetes self-care behaviors, dietary patterns, diabetes and CVD knowledge, and barriers to problem-solving for specific health behaviors. Diabetes Self-management behaviors will be measured by SDSCA. Dietary habits will be measured by STCFFS. Problem-solving ability for related health problems will be measured by HPSS.
3. The initial HbA1c reading to check study eligibility would be a routine test performed at the clinic (chart audit). It is also possible if a study participant had a recent HbA1c reading the study could use this as well.
4. Any laboratory test will be either conducted through a contracted laboratory (CTSU- Wichita Campus). Study personnel will not collect any body components. Study personnel will only receive a written lab report.

5. Timeline:

Recruitment	**Enrollment-Starts**	**Baseline Visit**	**eDECIDE Sessions 18- weeks (Intervention)**	**Traditional DECIDE Sessions 18-weeks (Control)**	**Post-Intervention Visit (After 18weeks)**	**3-Month Follow-up- post intervention Visit**
June-August	September	Behavioral Questionnaires-Virtual	Delivered over 18 weeks (9 sessions) online self-directed	Delivered over 18 weeks (9 sessions) self-directed-paper	Behavioral Questionnaires-Virtual	Behavioral Questionnaires-Virtual
	Conduct prescreen	First Laboratory Blood Draw	Will receive weekly email/text reminders	Will receive weekly email/text reminders	2nd Laboratory Blood Draw	Last Laboratory Blood Draw
	Medical Chart Audit (HbA1c)					

F. Risk/benefit assessment:

1. Physical risk There are no known physical risks of subjects participating in a web-based study.
2. Psychological risk There are no known psychological risks of subjects participating in a web-based study. If an adverse event should occur, the subject will have the opportunity to withdraw from the study. Dr. Nicole Nollen (Primary Mentor) will be available for consultation should an adverse event happen. Throughout the study, research personnel will monitor for issues related to safety of subjects as well as privacy of data. Should an adverse event occur, research personnel will document it. The following information will be monitored throughout the study: number of subjects screened and enrolled drop-outs, and serious and non-serious adverse events. This data, with the exception of serious adverse events, will be reported every 12-months. Because no serious adverse events are anticipated in this study, any such events will be immediately reported to the KUSM-W Human Subjects Committee. If the severity of an adverse event requires emergency medical attention, appropriate KUSM-W providers/staff will be contacted to provide medical attention.

3. Social risk There are no known risks of subjects participating in a web-based study. Previous studies have successfully conducted web-based interventions and maintained confidentiality of subjects.[59-60] To minimize potential issues with confidentiality subjects will receive a secure password protected login for the duration of the 18-week web-based portion of this study. All communication via the Internet will take place across a secure server. Medical chart data will be collected in person by the PI from a designated medical staff person at the participating clinic.

   A potential risk of participating in the study is a breach of confidentiality and loss of privacy. To further address privacy, as well as to ensure confidentiality, the investigators will ensure the following measures are taken. All data obtained in the study will be kept confidential. The only parties having access to the data in the proposed study will be the Principal Investigator (Dr. Redmond), Mentor (Dr. Nicole Nollen) and appropriate research staff, and the KUSM-W Human Subjects Committee.

   Hardcopies of completed subject questionnaires will be locked in a secure file cabinet in the PI's office. Responses to the surveys and the clinical/treatment/surveillance information obtained from the EHR will be maintained on the KUSM-W REDCap database. Only the necessary members of the research team will have access to the REDCap database. After a member of the research team initially enters the data, an additional member will review the data and identify errors. A log will be kept of all data collection and analysis steps completed for each subject. For the task analysis and usability testing, a research log will be kept by the research technician regarding steps completed and any errors detected.
   Participants in the intervention group are asked to input their HbA1c number on the eDECIDE website. They will also be asked to create a unique username and password to login and use the eDECIDE website. All stored data will be secure and encrypted. Website is in development.

4. Economic risk There are no known economic risks of subjects participating in a web-based study.

5. Potential benefit of participating in the study
   a. Delivering a problem-solving intervention through a web-based component is an innovative way to reach the desired underserved population which is the focus of this application. This approach will allow for greater resources and tools at the disposal of subjects involved in the study, thus improving their self-management and health outcomes related to their disease.

b. In addition, the web-based format allows subjects to receive tailored real-time feedback on potential problem-solving issues that emerge (i.e. dietary and physical activity issues, other self-care issues), on diabetes self-management knowledge**.**

c. This approach (web-based) will allow for future studies (using mHealth mobile applications) that can examine best practices for which type of problem-solving skills training is most effective to improve diabetes health outcomes for particular individuals. Results will inform the development of interventions aimed at reducing complications from uncontrolled diabetes as well as interventions aimed at promoting problem-solving and self-management. Identifying how to make problem-solving interventions more accessible would strengthen current investigations into improving health outcomes among underserved populations. It is believed that the minimal risk involved in the proposed study is reasonable considering that it could lead to more effective ways to manage diabetes among vulnerable. Since participation in traditional diabetes self-management programs is low, delivering tailored problem-solving skills training could increase self-efficacy and adherence among *African American*s, thus improving glycemic control and further reducing health complications.

G. Location where study will be performed: This study will take place at the University of Kansas School of Medicine-Wichita.

H. Collaboration (with another institution, if applicable): No collaboration with other institutions.

I. Single IRB Review for a Multi-site study (if applicable): N/A only singe site IRB needed.

1. For which sites will KUMC serve as the IRB of record? All
2. Indicate which study activities will occur at each site. If all study procedures will be identical across study sites, state this. **KUMC Only Site**
3. Describe how you will assess the capacity of each site to perform the research (e.g., expertise, staffing, space, equipment, etc.) If applicable, include site evaluation tools in your IRB submission. **KUMC is the only site**
4. Describe how the lead investigators will ensure that all participating sites use the IRB-approved version of the protocol, consent, recruitment materials and other study documents. **KUMC Only site**
5. Describe how the lead investigators will communicate with and disseminate new information to other sites (e.g., training meetings, regularly-scheduled conference calls, notifications, etc.) **KUMC Only site**
6. Describe how the lead investigator will assess protocol compliance, unanticipated problems and adverse events at other sites. **KUMC Only site**
7. Name the member of the KUMC study team who will be the point of contact to coordinate oversight and communication with the sites. **KUMC Only site**

J. Community-Based Participatory Research (if applicable)

1. Participants and the nature of their involvement: Target community is African Americans in Sedgwick County, KS. In the prior study (phase II) of this research we got input from community members on the build and design prototype of the eDECIDE website. Therefore, this work is being created with the user perspective included. We have also added an aim to the current study to get feedback on the eDECIDE intervention, overall.

2. Cultural issues: We do not anticipate there being problems with cultural or community attitudes towards this research. We will recruitment with a community perspective in mind. Our recruitment materials are culturally specific for race, age, and gender. All reading materials and curriculum material was created for a 5th grade reading level to be accessible to all. The eventual website will also use this same rule of 5th grade reading level.

3. Origin of the research question: From the researcher. The community has participated in previous studies and members of the community participated in a qualitative study indicating an interest in the study topic.

4. Risks and Benefits: The risk to the community is minimal the benefit will be the availability of novel technology to help manage type 2 diabetes.

5. Study Description and Process: Previously, participants recruited by the same means as the current study, conducted usability testing with the researchers to ensure that the program platform and design was feasible, usable, and that participants who used it were satisfied with the overall intervention.

6. Return of results: Community and study participants will be able to access any study results through community presentations, peer reviewed journal articles and more.

7. Sustainability: No current plan. No partnership currently exist.

K. Personnel who will conduct the study, including:

1. Indicate, by title, who will be present during study procedure(s): Dr. Michelle Redmond, Study PI
2. Primary responsibility for the following activities, for example:
    a. Determining eligibility: Research Assistant/ Principle Investigator
    b. Obtaining informed consent: Research Assistant/ Principle Investigator
    c. Providing on-going information to the study sponsor and the IRB: Research Assistant/ Principle Investigator
    d. Maintaining participant's research records: Research Assistant/ Principle Investigator
    e. Completing physical examination: Research Assistant/ Principle Investigator
    f. Taking vital signs, height, weight: N/A
    g. Drawing / collecting laboratory specimens: N/A- contracting out to a 3rd party
    h. Performing / conducting tests, procedures, interventions, questionnaires: Research Assistant/ Principle Investigator
    i. Completing study data forms: Research Assistant/ Principle Investigator
    j. Managing study database: Research Assistant/ Principle Investigator

L. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. Elements of the plan include:
    a. Persons/groups who will review the data (study team; independent safety monitor, data monitoring committee or formal DSMB) Study team
    b. Data/events that will be reviewed Timeline for data collection points, REDCap data entry process and logon's to eDECIDE website
    c. Frequency of review: Will review daily/weekly and as needed to maintain study schedule
    d. Types of analyses to be performed: Will run basic statistics or log entry to see how often participants log on to website. Will monitor computer security to ensure participant's confidentiality remains in take per HIPPA guidelines.
    e. Safety-related triggers that would cause the PI to stop or alter the study Any breach in confidentiality based on the website
2. **Describe how adverse events and unanticipated problems will be ascertained and handled. Explain exactly which type of problems will be considered serious and reported to the IRB. The reporting timeframe should also be detailed.** Because we are conducting a virtual/online intervention one concern is a data breach. We are working with our web designers and OIS to ensure all data transmitted will be through an encrypted secure mechanism through KUMC. This is also why the website and eLearning site will be hosted on the KUMC server to ensure data safety and security of participants. We do not anticipate major physical adverse events which could be tied to the activities of this study. Participants are only being asked to share information about obstacles or issues that impede their managing their diabetes. We will not ask participants to engage in any physical activity or weight loss. Another anticipated event might be blood draws. As stated early we will utilize a laboratory (likely CTSU-Wichita Campus) to arrange for participants to receive their blood draw or the KU Internal Medicine Resident Clinic.
3. If a participant should encounter an adverse event. Participation will cease. The case will be reviewed by the study team and notify the IRB.

III. Subject Participation

A. Recruitment:

1. Recruitment will take place in a community setting (clinics, distribution of filers)
2. Filers will be disbursed traditionally and though social media (Facebook, Twitter, etc.)
3. See attached letter
4. Planned distribution will be to clinic providers and if applicable in terms of community presentations a letter will be sent out to request a recruiting meeting

B. Screening Interview/questionnaire: Participants will call or email if interested in participating in the study. They will answer the screening questions and based on responses will be able to move to the next study phase. Consent to participate in the screening process will consists of a question: "Do you consent to the prescreen questionnaire?"

C. Informed consent process and timing of obtaining of consent

1 Study personnel,

2 Consent call- calling participant to go over the consent, answer questions, obtain consent. Due to current COVID protocol, we will obtain an e-consent through REDCap. Study personnel will call potential participants, go over the prescreen and then complete the consent.

D. Alternatives to Participation: There are no alternatives

E. Costs to Subjects: No cost to subjects

F. How new information will be conveyed to the study subject and how it will be documented: Written format by a letter if new information needs to be shared.

G. Payment, including a prorated plan for payment: Participants receive a gift card for incentive.

H. Payment for a research-related injury: There will be no payment for research related injury as participants are not being asked to engage in any type of physical activity or any activity which should result in injury.

IV. Data Collection and Protection

A. Data Management and Security:

The group sessions will not ask for any protected information or unique identifiers. All data collected will be evaluated and analyzed only as group data and no specific participants will be identified in presentation or publication of study results. All demographic data will be stored in REDCap on a secure KU serve (P-drive). Only study personnel will have access to collected data. All data will be stored on the KU server (P-drive). Items will be stored on a password protected laptop or computer.

The only party having access to the dataset other than the PI and investigators is the HSC2. The data will only be reviewed by non-investigators when required by law or by the governing IRBs. Following completion of the study, research data will be archived on password-protected computers restricted to research personnel. No direct identifiers will be included with this data.

The University of Kansas School of Medicine-Wichita employs a "private" TCP/IP addressing scheme for on-campus workstations and file servers, ensuring that they cannot be seen from outside computers. The network is also protected by a next generation firewall system that includes intruder detection/prevention as well as malware and threat prevention. University managed workstations are encrypted with hardware encryption and malware detection software. Authentication to the network requires unique user ID's, and complex passwords that require changing every 180 days. Sensitive information stored on network file shares is encrypted with file level encryption.

1. Following completion of the study, research data will be archived on password-protected computers restricted to research personnel. Data will be kept for at least seven years, in accordance with the KUMC research record retention policy. No direct identifiers will be included with this data
2. We will always use a study id to identify a participant other than the raw database which will be kept in a secure REDCap database.
3. The Study team (PI, Research Assistant & Statistician) will have access to REDCap database with linked study IDs & participants full name.
4. linked by study ID in REDCap Secure Database.
5. REDCap Database, which is a secure password, protected program. Only study team members with access will be able to view the REDCap database.
6. study will test a website that will involve participants creating a username and password
7. Data will not be sent outside of KUMC

B. Sample / Specimen Collection: No samples will be collected at sites. Any laboratory collections will be done through a contracted provider or review of medical chart audit.

C. Tissue Banking Considerations: This is not relevant to this study. No tissue banking will take place.

D. Procedures to protect subject confidentiality: This study will use a secure website, hosted on KUMC server. Any and all data that must be transmitted will be encrypted and secure. No personal health information will be stored on

the website other than the participants chosen username and password. Website is underdevelopment and will be built to met HIPPA qualifications.

E. Quality Assurance / Monitoring

1. Data will be kept in REDCap and maintained in this database to ensure data collection goals are meet and subjects are monitored
2. No plans for 3rd party monitoring

V. Data Analysis and Reporting Stop Here

3. **Statistical and Data Analysis:**

For baseline characteristics of data, descriptive statistics will be reported as mean and standard deviation for continuous variables; and as count and percentage for categorical variables. Depending on the distribution of the continuous variables Wilcoxon rank sum test or t-test will be used to test for difference in continuous variables across the control and intervention group. Chi-Square test of independence will be used to assess the association between categorical variables and the two groups. The analysis will be based on "Intention-to-treat" principle. A 2-sided p-value of 0.05 will be used to assess statistical significance. Missing Data: If the proportion of missing data is small (5%), complete case analysis will be carried out. If the proportion is higher, then multiple imputations will be used to impute missing values.

A. The post-intervention HbA1c levels in the intervention group will be compared to the control group using linear regression model after adjusting for baseline HbA1c levels. Additionally, average percentage change in HbA1c level across the 2 groups will be computed and compared using 2 sample t-test or Wilcoxon rank sum test (depending on the distribution of data).

B. Outcome: The post-intervention HbA1c levels in the intervention group will be compared to the control group using linear regression model after adjusting for baseline HbA1c levels. Additionally average percentage change in HbA1c level across the 2 groups will be computed and compared using 2 sample t-test or Wilcoxon rank sum test (depending on the distribution of data). The secondary outcomes of interest are additional clinical measures (blood pressure, LDL, HDL), dietary habits, diabetes self-management behaviors, Diabetes and CVD knowledge, and problem-solving skills for health-related problems as assessed by instruments listed in Table 5.

C. Study results to participants: We will make available any published study results. Our study team will also make available any community presentations to allow participants to learn about the final findings of the study and next steps.

D. Publication Plan: We will publish study results to peer-reviewed journals: preliminary findings and a protocol paper. All identifying information will be removed before publication.

VI. Bibliography / References / Literature Cited: see attachment

APPENDIX I: VULNERABLE POPULATIONS

I. Groups below are not part of the active recruitment pool or target groups

II. **Cognitively or decisional impaired individuals**: Those with cognitive or decisional impairment will not be eligible for the study.

III. **Children**: Children will not be eligible for the study.

IV. **Pregnant women:** Women who are currently pregnant or have gestational diabetes will not be eligible for this study.

V. **Prisoners:** Prisoners are not an eligible population for this study.

VI. **Students and/or Employees**: This is a community recruitment effort. KUMC Students and Employees will not be recruited for this study.