Consent Form

August 31, 2023

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

PI: M Redmond

Clinical Trials.gov # NCT03855449

CONSENT FORM

A Web-based Problem-solving program for African American Patients with Type 2 Diabetes

Michelle L. Redmond,PhD

mredmond@kumc.edu

316-293-1813

You are being asked to participate in a research study with the University of Kansas School of Medicine – Wichita. You are being asked to participate because you have been identified as a person with a diagnosis of diabetes mellitus. Participation in this study is completely voluntary, you do not have to participate. If you do wish to participate you may change your mind, and choose to stop the study early, at any time with no penalty to you.

This consent form explains what the study is about, what you must do if you want to participate in this study, and any risks and benefits of participation. Please read this carefully and ask as many questions as you need to, before joining the participate. This study will take place through a website platform or through a self-study workbook depending on study arm with Michelle Redmond, PhD, as the principal investigator.

PURPOSE
The purpose of this project is to conduct a web-based diabetes self-management intervention based on using problem-solving techniques. This program is eDECIDE, the Decision-Making Education for Choices in Diabetes Every Day is a problem-solving program that will develop self-management behaviors for managing your diabetes. By doing this study we hope to learn about the impact of eDECIDE on behavioral change.

How many People will Participate in this Study?
A total of 70 people aged 18-75 will be recruited for this study. All study sessions and activities will take place virtually (website/e-learning platform, Zoom, text message). Participation in this study will last 30 weeks.

PROCEDURES: What will happen if I take part in this study

Before you begin the study: Before you begin the study: You will need to provide a recent HbA1c reading and complete the prescreen interview to see if you are eligible for the study to verify your diagnosis of type 2 diabetes. Thus, the following items will be collected at the beginning of the study (baseline), at the end of the 18-week eDECIDE curriculum (post-intervention), and at the final 3-month follow-up:

- Blood draw- approximately 2 tablespoons- to measure HbA1c, done by the study nurse free of charge at a partnering laboratory (CCR- Wichita Campus, CTSU Rainbow or Fairway- Kansas City Campus)

- Behavioral questionnaires: The Summary of Diabetes Self-Care Activities Measure, Health Problem-solving scale, and Starting the Conversation Food Frequency Scale

If you have had a recent blood draw within 3-month of study enrollment you can use your current clinical numbers for the baseline measurers and may not need to be repeated.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups similar to flipping a coin. Neither you nor the researcher can choose the group you will be in. You will have a 50/50 chance of being placed in any group. The intervention group will participate in bi-weekly sessions for 18 weeks via recorded sessions on a web-based platform. The control group will complete the traditional DECIDE program in a self-study mode via paper workbook.

If you are eligible and decide to participate in this study, prior to the study activities you will be asked to complete a demographic survey which takes 15 minutes. After completing the prescreen and labs as well as this short survey and randomization, you will begin the 18-week program. The initial 18-week eDECIDE curriculum, followed by a 3-month follow-up for a total of 30 weeks. You will complete bi-weekly sessions for the initial 18 weeks. Participants will also receive bi-weekly phone calls and or text message reminders from the health coach (Dr. Redmond). If randomized to the intervention group, the study will take place virtually through the website and check-ups will be via phone call or Zoom visits. If you are randomized to the control group, the study will take place via workbook and check-ups will be via phone call or Zoom visits. All personal information such as name and face will be removed and blurred if video clips are used in an academic or conference setting. Only participant ID numbers will be used when analyzing or presenting data. The recordings (both audio and video) of the sessions will be destroyed 12 months after publication of the research results. During the 18-weeks you will complete the additional eight sessions, that will take approximately one hour per session. Sessions 1-9 cover the following topics:

- Session 1: educational information about diabetes and diabetes self-management
- Session 2: introduction to problem-solving skills training,
- Session 3: problem-solving and stress,
- Session 4: problem orientation,
- Session 5: recognizing your problems and goal setting,
- Session 6: problem definition and formulation,
- Session 7: generation of alternative solutions,
- Session 8: decision-making,
- Session 9: solution implementation and verification.

Follow-up after the study:

Once the study is complete (18-week eDECIDE curriculum) you will need to have another reading of your HBA1c done by the study nurse. Blood pressure and cholesterol measures will need to be provided from your latest doctor visit. In addition, you will complete the behavioral questionnaires.

RISKS

The risks associated with this study are moderate. If randomized into the intervention group, you will participate virtually through a web-site portal. The web-site portal is minimal risk. The site is hosted on the KUMC web server and no PHI is collected on the portal. You will assign yourself a username and password to login. You may choose not to answer any questions within the sessions. Risks associated with Zoom visits include both image and voice will be recorded but will be stored securely and destroyed after the study. There may be other risks of the study that are not yet known. Study personal will monitor all study events and will have a plan in place for unforeseen adverse events.

BENEFITS

Findings from this research have great potential for being translated into better health outcomes in the future. We hope our study will shed new light on ways to help improve and build web-based interventions for chronic health management.

COSTS AND PAYMENT
There is no cost for being in the study.

PAYMENT TO SUBJECTS

All eligible subjects will receive $145 for participation in the eDECIDE study on a study Clincard. We will need to collect your social security number or tax identification number to set up the ClinCards and provide you the incentive payment. Participants will receive $20 for completion of the eligibity screen, $25 after the completion of the first informational session, $75 will be added to your Clincard after completion of the eDECIDE curriculum, and a final $25 will be added after completion of 3-month follow-up.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION
The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect self-reported information from study questionnaires and a qualitative interview. Your health information will be used at The University of Kansas School of Medicine-Wichita by Dr. Redmond and members of the research team, KUMC IRB, and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research if a regulatory review takes place.

All study information that is sent outside the research team will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your health information will not expire unless you cancel it.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you in response to a court order. This does not stop you from voluntarily releasing information about yourself or your participation in this research. One exception to the Certificate only occurs if you agree that we can give out research information with your name on it. This includes any purposes described in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

QUESTIONS

Before you sign this form, Dr. Redmond or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. Dr. Redmond can be reached at (316) 293-1821. If you have questions, concerns or complaints about your rights as a research subject or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee through the Office of Compliance at (316) 293-2600. You may also write the KUSM-W Office of Compliance, AFS Department, 1010 N. Kansas, Wichita, KS 67214.

CONSENT

Dr. Redmond or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By verbal agreement, you say that you freely and voluntarily consent to participate in this research study. You have heard the information and your questions answered. You will be given a copy of the consent form to keep for your records.

CONSENT

_____

Type/Print Subject's Name

_____
Signature of Subject Giving Consent

_____
Type/Print Name of Person Obtaining Consent