Document Coversheet

Study Title: Seed-alter Dyad Social Support Intervention for Rural Dwelling Older Adults With T2DM

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KEY INFORMATION FOR
RURAL DWELLING OLDER ADULTS WITH TYPE 2 DIABETES- SEED

You are being invited to take part in a research study about self-management of T2DM and social support.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

By doing this study, we hope to learn if self-management educational sessions and support from friends or family help improve self-care in individuals with Type 2 Diabetes. You will be asked to participate in an interview and six 2-hour self-care sessions focused on Diabetes management. Your participation in this research will last about six weeks.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer for this study if you want to learn how to better manage your Type 2 Diabetes and want to partner with someone in your social group of friends and/or family to learn more about self-care. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might NOT want to volunteer for this study if you do not have the time to attend a 2-hour session once a week for 6 weeks, or if you are not interested in changing the way you self-manage your Type 2 Diabetes. For a complete description of risks, refer to the Detailed Consent/Appendix.

If you choose not to participate in the study, you can still receive Type 2 Diabetes self-management tips from your regular doctor or endocrinologist.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Brittany Smalls, PhD of the University of Kentucky, Center for Health Services Research. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is:

Email: Brittany.smalls@uky.edu; Phone: 859-323-4619; Mailing address: 2195 Harrodsburg Road, Suite 125, Lexington, KY 40504.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You may not qualify for this study if you do not have Type 2 Diabetes, do not speak English, or are not over the age of 18.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at organizations in your community such as the senior citizen center, a local church, or a community center. You will need to come 6 times during the study. Each of those visits will take about 2 hours. The total amount of time you will be asked to volunteer for this study is approximately 12-15 hours over the next 2 months.

WHAT WILL YOU BE ASKED TO DO?

First, you will be asked to complete an interview with the research team. During this interview, we will ask you about the close members of your social group like friends and family and your health behaviors.

Then, we will ask one of your friends or family members that you identified as part of your social support network to form a partnership with you. You and your supporter will attend six 2-hour educational sessions conducted by a research assistant from University of Kentucky. The sessions will cover information about Type 2 Diabetes self-care.

Finally, we will ask you to complete several surveys and interviews so we can understand if the sessions and partnership with your supporter are beneficial.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

We do not anticipate many risks or discomfort to you as a participant in this study, however there are a few potential risks we want you to know. There is a potential that you may feel emotional distress from discussing your health and health behaviors. There is also the possibility that your confidential information is breached. We will take all possible precautions to ensure this does not happen.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, some people have experienced improved self-care of their Type 2 Diabetes, improved clinical outcomes, and improved social support when taking part in self-care sessions with a supportive partner. Additionally, information learned in this study may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

Therefore, these costs will be your responsibility.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Any information you give us will be kept on a password-protected secure server at the University of Kentucky. All audio files will be encrypted and kept on a locked recording device. You should know there are some circumstances in which we may have to show your information to other people because that information directly affects your health and wellbeing. For example, the law may require us to share

your information with a Geriatric Specialist if you are at risk for certain age-related symptoms or authorities if you report information about a child being abused, if you pose a danger to yourself or someone else.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to the server.

Certificates of Confidentiality (CoC):

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or elderly abuse.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention will no longer be provided to you. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You should not take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WILL YOU BE CONTACTED ABOUT PARTICIPATION IN FUTURE STUDIES?

The research staff would like to contact you with information about participating in additional studies. If so, it will be limited to 4 times per year.

Do you give your permission to be contacted in the future regarding your willingness to participate in future research studies?

☐ Yes ☐ No Initials_____

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should first call your doctor, and then inform the principal investigator, Brittany Smalls at 859-323-4619 as soon as you can It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive $20 for completing the initial interview and surveys. You will then be paid $15 for each self-care session and 6- and 12-month study check-ins you attend with your support partner. If you choose to withdraw early, you will only be paid for the sessions you completed. If you complete the full study, you will receive $140 in total. All payments will be in the form of a gift card.

STUDY TIMELINE AND COMPENSATION

Data Collection Tool/ Study Activity	Data Collection Point	Compensation
RedCap Surveys **a.** Patient Demographics **b.** MOS Social Support **c.** Diabetes Knowledge **d.** Diabetes Self-Management questionnaire **e.** Brooks Medication Adherence **f.** Charlson Comorbidity Index **g.** EuroQol-5D	Baseline	
In Person Surveys **a.** Social Network Questionnaire **b.** Vital Signs **c.** MOCA-B **d.** Mini Nutritional Assessment **e.** Fried Frailty Index **f.** Lawton's Instrumental Activities for Daily Living Scale **g.** Get up and Go Test **h.** Geriatric Depression Scale: Short Form	Baseline	$20
DROP education session 1	Week 1	$15
DROP education session 2	Week 2	$15
DROP education session 3	Week 3	$15
DROP education session 4	Week 4	$15
DROP education session 5	Week 5	$15
DROP education session 6	Week 6	$15
Post Intervention Survey	3 months post intervention	$15
Post Intervention Survey	6 months post intervention	$15

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by a Geriatric Specialist to determine if it is in your best interest to contact you or your primary care physician.

If so, your physician will contact you using the information you provided. With the help of a Geriatric Specialist they will present possible risks or benefits of receiving the information. At that time you can choose to receive or refuse the result or finding. If you would like more information about this, call Brittany Smalls, PhD, at 859-323-4619.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 262 people to do so. The National Institutes of Health is providing financial support for this study. A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

No biological samples will be collected for this study. Data will be de-identified where your name, date of birth and other identifiable information will be removed. This data may be shared with researchers in the future. Because this research study is funded by the NIH, all de-identified data can be made available upon request from other research entities due to NIH requirements.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

weight, height, pulse, systolic blood pressure, diastolic blood pressure, LDL, Hemoglobin A1C levels and lipid panels.

The Researchers may use and share your health information with:

- The National Institutes of Health
- University of Kentucky Representatives
- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- Health Systems outside of UK for which you have a patient relationship;

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans
- Eligibility for benefits

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Brittany Smalls, PhD at 2195 Harrodsburg Road, Suite 125, Lexington, KY 40504 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

You understand that you will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you will have the right to access the information.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184

INFORMED CONSENT SIGNATURE PAGE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____	_____
Signature of research subject	**Date**
_____	
Printed name of research subject	
_____	_____
Printed name of [authorized] person obtaining informed consent/HIPAA authorization	Date
_____	
Signature of Principal Investigator or Sub/Co-Investigator	