Cover Page for ClinicalTrials.gov

Document: Informed Consent

Study Title: Improving Physical and Psychosocial Functioning in Underserved Older Adults: A Community Health Worker-Led Intervention

Document Date: 8/22/2024

NCT Number: NCT05451589

HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

RESET Informed Consent Form

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: RESET (Re-Engaging in Self-care and Enjoying Today)
Principal Investigator: Mary Janevic, PhD, University of Michigan School of Public Health
Co-Investigator(s): Sheria Robinson-Lane, PhD, University of Michigan School of Nursing; Susan Murphy, PhD, University of Michigan School of Medicine; Robin Brewer, PhD, University of Michigan School of Information; Peter Song, PhD, University of Michigan School of Public Health; Afton Hassett, PsychD, University of Michigan School of Medicine
Agency sponsoring the study: National Institute of Nursing Research (NINR) (1 R01 AG071511-01)

You are invited to take part in a research study that is a collaboration between the University of Michigan and the Detroit Health Department. This form contains information that will help you decide whether to join the study.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

RESET has been developed to help older adults improve their mood and functioning. We give special attention to the challenges posed by the pandemic. The purpose of this study is to test the effectiveness of a program called RESET that may help older adults improve their quality of life.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

This study is for adults, ages 50 and over, who are experiencing symptoms of depression, anxiety, loneliness, stress, pain, or fatigue. We plan to recruit 456 participants for the study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to be part of this study, you will be assigned to either the RESET intervention group or the Wellness Check group. In this study, there will be two participants assigned to the RESET intervention group for every one participant assigned to the Wellness Check group (2:1 ratio). Participants are assigned to groups randomly, like flipping a coin.

All participants will be asked to complete three telephone surveys over an 8-month period: an initial baseline survey, a 2-month survey, and an 8-month survey. Each survey takes about 60 minutes for most participants to complete.

If you are assigned to the RESET intervention group, you will also:

- Have an orientation session with a Community Health Worker shortly after the initial baseline survey. The orientation can be done in-person, virtually, or over-the-telephone, based on your preferences. It takes most people 60 minutes or less to complete, and your Community Health Worker will get you set up with all the materials and information for the program.
- After the orientation, you will begin the RESET program, which takes place over 7 weeks. Each week you will participate in a 1-hour telephone group session with the Community Health Worker and 4-6 other study participants. These sessions cover health-related topics like physical activity, healthy eating, relaxation and stress reduction, and more. They are a blend of group discussion as well as information provided by the Community Health Worker.
- Before each group session, you will listen to a podcast episode on that week's topic (like a radio show). These are about 20-30 minutes each. You can call in to listen at any time with your telephone or find recordings on the study website.
- In between group sessions, you will be asked to try some new activities related to health and wellness. You can put as much time into practicing these activities as you'd like. Group telephone sessions will be audio recorded for research purposes. These recordings will not be shared outside of the research team and will only be used to make sure the program is being delivered appropriately. You do not have to share anything you're not comfortable sharing in the group sessions.
- Finally, we will ask you to use the activity tracker that you received at orientation to track your step counts each day, during waking hours, over the 7-week program. Each evening, you will receive a text message from the study team to report your day's step count.

If you are assigned to the Wellness Check group, you will:

- Complete the three telephone surveys mentioned over the 8-month study period.
- After the initial baseline survey, you will have a one-on-one telephone check-in with a Community Health Worker to discuss helpful community resources. The check-in will be about 30 minutes for most participants to complete.
- After the final 8-month survey, you will be invited to participate in the full 7-week RESET intervention as I described (with group telephone sessions and podcasts).

4.2 How much of my time will be needed to take part in this study?

In total, we anticipate that RESET intervention group participants will spend no more than 13 hours total on study activities over 8 months.

Wellness Check group participants will spend about 3.5 hours total on study activities over 8 months.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The researchers have taken steps to minimize the risks of this study. Even so, you may still experience some risks related to your participation, even when the researchers are careful to avoid them.

Because we will collect information about you, the primary risk of this research is a loss of confidentiality. There is a small chance that the information you provide could be unintentionally disclosed. The researchers will try to minimize this risk by keeping confidential all information that identifies you by name. All information will be kept in locked file cabinets or a password-protected database, using state-of-the-art electronic security measures. At the end of the study, the links between your name and the information we collect will be destroyed.

Although unlikely, you may experience some psychological distress while answering some survey questions. Some people may find it uncomfortable or upsetting to answer questions or talk about their health. Please keep in mind that if there are any questions you do not feel comfortable answering or information you do not wish to share, you do not have to answer. You don’t have to tell us why.

5.2 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefit from being in this study. It is possible that you will learn things that you find helpful for improving your emotional and physical well-being. It is also possible that you will make positive changes in your lifestyle, such as increased walking. However, the researchers cannot guarantee benefits.

Although you may not directly benefit from being in this study, other people may benefit in the future because we may learn more about how to help people improve their overall health and well-being.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time with no penalty. If you leave the study before it is finished, please tell one of the study staff or one of the people listed at the end of the consent document provided to you. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you

ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

You will receive a $20 check in the mail after completing the first telephone survey and another $20 check after the 2-month telephone survey. You will also receive a $25 check for completing the final 8-month telephone survey, for a maximum total of $65. If you decide to withdraw early, you will still receive checks from any surveys you already completed. However, you will not receive any checks for the surveys you did not complete.

All participants will be invited to keep the activity tracker after the study ends. You will not be held financially responsible if you lose or damage your activity tracker during the study, but we may not be able to replace it.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

As previously mentioned, to keep your information safe, the study team will keep all information in locked file cabinets or a secure, password-protected database. Only selected persons involved with this study can see this information.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means no one can make us give your information to anyone else unless we have your permission. However, you are welcome to talk about your involvement in this research if you wish.

The Certificate does not stop researchers from reporting suspected abuse, neglect, or risk of substantial harm to self or others.

If we share any information with other researchers or in reports, it will not allow someone to identify you.

If you have more questions about Certificates of Confidentiality and the protections they provide, there is a link on your copy of the consent form where you can find more information. If you'd like also like to write it down, I'm happy to give you the link now too:

(if participant would like to write it down give them this link - https://grants.nih.gov/policy/humansubjects/coc.htm)

8.2 Who will have access to my research records?

Only selected persons involved with this study can see this information. This includes the study team, research sponsors (National Institute of Nursing Research) and the

University of Michigan Institutional Review Board, which oversees the safety of study participants.

8.3 What will happen to the information collected in this study?
We will keep the information we collect about you during the research for future research projects and for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. After seven years, all identifiable data (names and contact information) will be deleted, and only de-identified data will be kept.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?
Researchers at the University of Michigan may use or share your research information for future research studies. If we share your information with other researchers, it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. The website will include a summary of the results. You can search this website at any time. This website will also be listed on your copy of the consent document.

We will put the information we collect from you into a repository. The repository contains information about many people. Your information will be de-identified, again this means no names or contact information. Processes used to protect participant confidentiality include rigorous review to assess risk, modifying data if necessary to protect confidentiality, and limiting access to datasets. Data will be managed in a secure non-networked environment using virtual desktop technology.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed at the bottom of your consent document to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Would you also like me to give you the contact information over the phone today? (If yes, provide the contact information below)

Principal Investigator: Mary Janevic
Email: mjanevic@umich.edu
Phone: 734-647-3194

Study Coordinator: Rebecca Lindsay
Email: reblin@umich.edu
Phone: 734-763-6369

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board

Telephone: 734-936-0933 or toll free (866) 936-0933
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent to use audio recordings for purposes of this research.
In this study, we will audio record the telephone group sessions (for the RESET intervention group) for quality control purposes. Only research staff associated with the study will have access to these audio recordings. If you do not agree to be audio recorded for the telephone group sessions, we, unfortunately, cannot enroll you in the study at this time.

Do you agree to be recorded for telephone group sessions? [Yes or No]
If yes: *Indicate response in REDCap database*
If no: *Indicate response in REDCap database and thank them for their time and interest*

We will also ask you if we can audio record your telephone survey responses, for quality control purposes. This audio recording will be optional. Again, only research staff will have access to these audio recordings, and we will always ask you before we begin audio recording in case you change your mind. Do you consent to have your telephone surveys audio recorded?

☐ Yes, I agree to have my telephone surveys audio recorded

☐ No, I do not agree to have my telephone surveys audio recorded

If yes: *Indicate response in REDCap database*

If no: *Indicate response in REDCap database and tell them that's perfectly ok and we will note this in our records*

Consent to Participate in the Research Study
Thank you for answering those questions! By verbally consenting, you are agreeing to be in the study.

If the participant preferred to be mailed a consent document after verbally consenting: After we complete the consent, you will be mailed or emailed (based on your preference) a copy of this document for your records.

If the participant already has a copy of the consent: The copy of the consent document that you have is for your records.

You do not have to mail anything back to us.

Remember that you are always free to leave the study at any time. Also, please be sure that questions you have about the study have been answered and that you understand what you are being asked to do. You may contact the study team if you think of a question later.

Do you have any questions about the study? I want to be sure I explained things ok and that you understand what you'll be asked to do in the study.

If yes: *Answer their questions.*
If no: *Let them know if they have any questions later, they can contact us.*

Do you agree to participate in the study?

If yes: *Indicate verbal consent response in REDCap database with date of consent, along with initials of person administering consent*
If no: *Indicate response in REDCap database and thank them for their time and interest in the study.*

11. OPTIONAL CONSENT

Consent to be Contacted for Participation in Future Research

There is just one additional question, and this is totally optional.

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project. Would you like to be contacted about future research opportunities?

☐ Yes, I agree for the researchers to contact me for future research projects.

☐ No, I do not agree for the researchers to contact me for future research projects.

If yes: *Indicate response in REDCap database*
If no: *Indicate response in REDCap database and tell them that's perfectly ok and we will note this in our records*

Thank you so much for participating in the RESET Study! The next step is to schedule your initial baseline survey.