Official Study Title: Leveraging social networks: a novel physical activity intervention for senior housing

NCT Number: NCT06007664

Document: Informed consent document for participation

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Note: In the informed consent document, the name of the study community has been redacted to ensure confidentiality of study participants.

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Tele-Video to Improve Daily Activity (T-VIDA)

Principal Investigator: Noah J. Webster Ph.D., Institute for Social Research, University of Michigan

You are invited to take part in a research study that aims to determine if an Occupational Therapist (OT)-led program administered remotely is useful in helping residents of [redacted] increase their physical activity.

This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know about this study:

- The purpose of this study is to determine if an OT-led program administered remotely over the internet using Zoom is useful in helping residents of [redacted] increase their physical activity. Specifically, this study will identify which parts of the program work and which do not as well provide information on what changes could be made to improve the program.

- Another purpose of the program is to determine if involving respected members of the community in the program as Advisory Committee members has an impact on how much others participate in program activities and engage in behaviors discussed.

- If you choose to participate, you will be asked to: complete an interview over the telephone before you start and after you finish the program. Wear a physical activity monitoring device on your thigh for 7 consecutive days, before and after the OT program. As part of the program you will be asked to participate in two one-on-one virtual meetings with an OT at the beginning and end of the program that will last 60-90 minutes, participate in 4 weekly one hour virtual OT-led group sessions with other [redacted] residents, and participate in 4 weekly one-on-one meetings with the OT that will last 15-20 minutes.

- Potential risks or discomforts resulting from participation in this study include: physical injury or distress during physical activities engaged in or related to the program, developing skin irritation from the Tegaderm adhesive used to waterproof and attach physical activity monitoring device (i.e., activPAL accelerometer) to your thigh, emotional discomfort when answering some of the interview questions, and accidental breach or disclosure of your identifying information. If you become uncomfortable physically or emotionally during any part of this study you can choose to skip any aspect or stop participating at any time. Also, all possible precautions will be taken to keep your data secure to minimize this risk of disclosing your personal information.

- The direct benefits of your participation in this study include the opportunity to participate in an OT-led program from your home. Such participation may result in increased levels of physical activity, improved physical function, improved pain management, and potential improvements to your overall health.

Taking part in this study is voluntary. You do not have to participate and if you agree to participate you can stop participating at any time. As I go over this form, please stop and ask me to repeat any portion as well as ask questions before deciding whether to take part in this study.

2. PURPOSE OF THIS STUDY

Engaging in physical activity has many benefits for people, especially as they grow older. For example, regular activity can reduce the risk of multiple chronic illnesses and reduce pain. Despite these benefits, not many older adults engage in recommended levels of physical activity. Studies such as this one are needed to identify new ways to encourage people to engage in more activity as they grow older. This study is unique in that it will provide Occupational Therapy remotely over the internet using Zoom. Occupational therapists take a unique approach to encouraging people to be more active, which includes setting goals and addressing barriers. This study is also unique in its provision of Occupational Therapy in a group setting as well as the involvement of respected members of the community.

3. INFORMATION ABOUT STUDY PARTICIPATION

3.1 What will happen to me in this study?

- All study activities will take place in-person, over the phone, and virtually on Zoom.
- You will be asked questions about things you do, physical activities you engage in, your social relationships with other residents in the community, and your health through a phone interview.
- You will be asked to wear a physical activity monitoring device on your thigh for 7 consecutive days, before the OT program. This is a small device that would be placed on your thigh with the help of a gentle adhesive. This device will continuously monitor your physical activity including activities like sitting, standing, walking and/or running. When we retrieve this device from you, we will be looking at a number of values that tell us about your physical activity levels such as time spent sitting, standing, number of steps taken while walking and/or running, as well as estimated amount of energy spent per day. This device, and other study material, including the tablet and pedometer, will be dropped off to your apartment by a study team member. At this in-person visit, you will be trained on how to use these devices.
- You will be asked to meet individually at the beginning of the program with the OT for 60-90 minutes via Zoom. During this meeting the OT will:
  a) ask questions and if possible through the video observe how your apartment may be helping or preventing you from doing activities safely in your home;
  b) ask questions to better understand your ability to do the activities you want to do, your satisfaction with your ability, and things that may be preventing you from doing these activities;
  c) identify 3-5 short-term activity goals; and
  d) outline the beginning of a home exercise program specific to you.
- You will be asked to participate in 4 weekly one-hour OT-led group sessions with other residents remotely via Zoom.

- You will be asked to meet briefly with the OT remotely 4 times for about 15-20 minutes to go over any questions or address any problems.
- Following completion of the group OT-led sessions, you will be asked to again meet individually with the OT for about 60 minutes via Zoom to discuss next steps.
- You will be asked to complete a post-program phone interview.
- Finally, you will be asked to wear a physical activity monitoring device on your thigh for 7 consecutive days after the OT program.

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

Participants will be asked to:

- If eligible for the study, complete a 30-minute pre-program interview over the phone;
- Wear a physical activity monitoring device on your thigh for 7 consecutive days, before the OT program.
- At the start of the OT program, meet individually with the OT for 60-90 minutes remotely via Zoom;
- Participate in 4 weekly one hour OT-led remote group sessions remotely via Zoom
- Participate in 4 weekly 15-20 minute individual meetings with the OT remotely via Zoom;
- At the end of the program, meet individually with the OT for 60 minutes remotely via Zoom;
- Complete a 40-minute post-program interview over the phone.
- Wear a physical activity monitoring device on your thigh for 7 consecutive days, after the OT program.

This study will include two different groups of participants, starting after one another. If the number of interested participants for the first group exceeds 12, interested participants will still be asked to complete the pre-program interview at time of initial interest, but will participate in the remaining study activities, including completing the pre-program interview again, with the second group.

3.2.1 When will my participation in the study be over?

From start to finish, this study will take up to 10 weeks.

3.3 If I decide not to take part in this study, what other options do I have?

There may be other ways or programs available to help you becoming more physically activity if you do not want to be in this research study. Check with your health care provider to discuss other options.

4. INFORMATION ABOUT STUDY RISKS AND BENEFITS

4.1 What risks will I face by taking part in the study?

There are four types of potential risks that participants in this study may experience including:

1) Minimal risk of emotional distress from answering some of the questions in the pre and post-program interviews. If you become uncomfortable during either interview, you can choose to skip any question or stop participating at any time. You do not have to answer any questions you do not want to answer.

2) Risk of developing skin irritation from the Tegaderm adhesive used to waterproof and attach physical activity monitoring device (i.e., activPAL accelerometer) to your thigh.

3) Potential risk of physical injury or distress during activities related to and engaged in throughout the OT program, which will include establishing and working toward plans to gradually become more physically active. This could include increasing mobility and engaging in low to moderate intensity physical activities during program activities.

4) Minimal risk of an accidental breach or disclosure of identifying information.

What will the researchers do to protect me against these risks?

- The researchers will try to minimize these risks by taking all possible precautions to keep you and your information safe.

- The interviewers conducting the pre- and post-program interviews will be trained to be sensitive to distress among participants. If a participant shows any signs of emotional distress the participant will be provided with a document listing the contact information of agencies they can consult with to receive counseling.

- To minimize risk of physical injury during the OT program activities, medical exclusion criteria common in mobility, function, and physical activity programs will be used. This includes excluding individuals for whom participation is not likely to be safe as well as more broadly those not likely to derive benefit from participation in this program. At any point during the study, the OT may determine that it is not safe for participation to continue and you will be withdrawn from the study. The OT will also work with all participants individually to create a personalized plan that is safest and most beneficial to each participant. Also, during the 4 weekly brief (15-20) individual meetings, the OT will inquire about the experience of any physical injury or discomfort related to the program activities.

- See Section 7 of this document for information on how the study team will protect your confidentiality and privacy by keeping your data secure to prevent accidental breaches or disclosure of data collected as part of this study.

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

- Your potential benefits of participating in this study include the opportunity to participate in an OT-led program from your home. Such participation may result in increased levels of physical activity, improved physical function, improved pain management, and potential improvements to your overall health.

- Practical contributions of this study include identifying which parts of the program work and which do not as well as providing information on what changes could be made to improve the program.

- Scientific contributions of this study include potentially identifying new ways to improve physical activity as people grow older through a combination of Occupational Therapy administered remotely via Zoom in both group and one-on-one settings as well as the benefit of involving respected members of the community.

4.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, we will tell you if we learn of important new information during the study that may change your willingness to continue participating in this study.

5. ENDING PARTICIATION IN THE STUDY

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

If you wish to leave the study before it is finished, please tell one of the persons listed in Section 8. “Contact Information”. You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you choose to tell the us why you are leaving the study, your reasons may be kept as part of the study records. We will keep the information collected about you for the study unless you ask us to delete it from our records. If we have already used your information in a research analysis it will not be possible to remove your information.

6. FINANCIAL INFORMATION

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

- You will receive $25 for completing the 30-minute pre-program interview, and $30 for completing the 40-minute post-program interview. Additionally, you will receive $10 to wear an activity monitor for seven consecutive days pre and post-program (total $20).

- In total, if you participate in all parts of this study just described, you will receive $75. You will receive payment in cash for each activity soon after completion of the activity either in-person at [redacted] or sent via the mail.

7. PROTECTING AND SHARING RESEARCH INFORMATION

7.1 How will the researchers protect my information?

We will do multiple things to protect you data and ensure your confidentiality. This will include:

1) In terms of the responses you provide during the pre and post-program interviews:

- We will use of an online computer program (Qualtrics) to enter the responses you provide us during your pre and post-program.
- The program uses encryption and firewalls to ensure your data are not accessed by people outside of the study team.
- Your name and other identifying information (phone number and address) will not be entered into the program. We will identify you in the program with a study ID consisting of only numbers.
- Study data will be downloaded from the program and stored on a secure University of Michigan computer network where only study team members will have access.

- Only study team members will have access to a password protected file that connect you to your study ID. Additionally this file will be stored on a secure University of Michigan computer network and accessed from password protected computers.

2) In terms of the data collected using the activity monitoring device:

- Data collected via the activity monitoring device (activPAL) will only be accessible using a vendor provided docking station and software.
- Your data will only be downloaded from the device using a password protected computer at the University of Michigan and stored on a secure computer network.
- Your data will be deleted from the device before the device is used again with another study participant.
- There is a serial number located on the device, which will be linked to your unique study ID, which will be stored in the aforementioned password-protected file at the University of Michigan.
- If the device is lost or stolen, it will not be possible for the data stored on the device to be linked back to you.

7.1.1 Special Protections

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

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share your de-identified information with other researchers.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of elder abuse.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this study if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://grants.nih.gov/policy/humansubjects/coc/what-is.htm

7.2 Who will have access to my research records?

- Members of the study team will have access to your study data.

- Information about you may be used or seen by people other than the study team either during or after this study. For example, University officials, government officials, study sponsors or funders (i.e., the National Institutes of Health), auditors, and/or the University Institutional Review Board (IRB) may look at or receive copies of information in your study record to make sure that the study is done in a safe and proper manner. Your name, contact information, address, and other identifiable information will not be shared with these individuals and will be stored separately.

7.3 What will happen to the information collected in this study?

- The information we collect will be used for research purposes only

- Personal information you provide will not be shared with [redacted] staff, other residents, or other people you mention during the interview; and your participation and the answers you give will not put at risk your living situation here at [redacted].

- As we mentioned before, your name and any other identifying information will be secured and stored separately from your study data. This identifying information will be kept by our study team after the study ends in case there is an opportunity to invite you to participate in another study.

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

- A description of this study will be publicly available on www.ClinicalTrials.gov, as required by U.S. law. This description will not include information that can identify you. At most, the description posted on this website will include a summary of the results. You can search this website at any time.

7.4 Will my information be used for future research or shared with others?

- We may use your identifying information that you provide for this study to invite you to participate in a future study. The study may be similar in topic or different. We will ask for your consent to do so at the end of this form. You can be a part of this current study without agreeing to this future use of your identifying information.

- We may also share your study data with other researchers. It we do so, the data 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 to share your de-identified data.

8. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

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

Principal Investigator: Noah J. Webster Ph.D.

Email: njwebs@umich.edu

Phone: 734-936-3075

Researchers can also be reached at TVIDA-study@umich.edu .

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 (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.
Research Program ID: HUM00224610

9. YOUR CONSENT

Consent to Participate in the Research Study

- We have provided you with two copies of this document. We will ask you to sign one and the other please keep for your records.
- We will store your signed copy with our study records in a locked filing cabinet at the University of Michigan.
- By signing this document, you are agreeing to be in this study.
- Please make sure you understand what the study is about and all your questions have been answered before you sign. If you have any questions about the study after you sign this document, you can contact the study team at any time using the information in Section 8 provided above.
- Below, please print your name, sign and date this document

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent for your de-identified study data to be retained and possibly shared with other researchers.

I give permission for my de-identified study data to be retained for future studies and possibly shared with other researchers. YES_____ NO_____

Please sign here: _____

Consent to be contacted for participation in future research

I agree to be contacted for participation in future research. YES_____ NO_____

Please sign here: _____