A Scalable Model for Promoting Functioning and Well-Being among Older Adults with Mild Cognitive Impairment via Meaningful Social Interactions: Project SPEAK!

IRB Approval Date: January 6, 2022

NCT04717479

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: A Scalable Model for Promoting Functioning and Well-Being among Older Adults with Mild Cognitive Impairment via Meaningful Social Interactions: Project SPEAK!

Company or agency sponsoring the study: National Institute on Aging, National Institutes of Health

Names, degrees, and affiliations of the principal investigator:
John D. Piette, Ph.D., Department of Health Behavior and Health Education, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to consent to the information in this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for older adults with symptoms of mild cognitive impairment. This research will test a program where older adults with symptoms of mild cognitive impairment (MCI) help English language learners (ELLs) improve their English skills by having conversations. The conversations take place by videoconference.

If you choose to participate, you will be asked to complete two surveys with research staff, one at the beginning of the study and another one about 8 weeks later. The surveys will be done in person, or over the phone, or via videoconference. We will pair you with an ELL and the two of you will have videoconference conversations every week for 8 weeks. Before the videoconference conversations begin, we will show you how to use videoconferencing. We will also send you a reminder before each of the videoconference conversations and surveys. The audio and video from the videoconference

conversations will be recorded for our study. Your health-related information will be collected for this research study.

This study involves a process called randomization. This means that the study group (either the active intervention group or the post-observation group) you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include emotional discomfort, breach of confidentiality (people outside the study seeing information about you), and that your videoconference conversations, video recordings, and reminders may be accessed by someone who is not on the study team (hackers watching or listening in). More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by providing a way for learning a new skill of using videoconferencing software, increasing a sense of social engagement and purpose which may improve mood, and possibly improving aspects of your memory or overall cognitive functioning. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately 8 to 16 weeks depending on your study group.

You can decide not to be in this study. Alternatives to joining this study include participating in other research studies or talking to your doctors about other options.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to test a program called "SPEAK!" (Seniors Promoting English Acquisition and Knowledge). In this program, older adults with symptoms of mild cognitive impairment help ELLs improve their English skills by having conversations. The conversations take place by videoconference. As part of testing the SPEAK! program, we will look at how to recruit participants, how to implement the program, how to retain participants, and the program's impact on the participants.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

In order to participate, you must be 55 years of age or older, a fluent speaker of English, and be able to participate in videoconference conversations. The videoconference conversations can be done on a smartphone, tablet, laptop, or desktop computer in your home or in the organization that referred you to this study. You must also report experiencing some symptoms that are associated with mild cognitive impairment, as confirmed during the screening. You will not be eligible if you have a history of stroke or traumatic brain injury, bipolar disorder, or schizophrenia, or current alcohol or drug abuse/dependence, that would affect your ability to participate in the study. You will also not be eligible if you have life-threatening health problems, for example active treatment for cancer other than skin cancer, advanced heart disease or COPD, or advanced dementia, that would affect your ability to participate in the study.

3.2 How many people are expected to take part in this study?

A total of 88 subjects are expected to participate (44 older adults with symptoms of MCI and 44 ELLs).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you choose to participate in this study, you will be asked to complete the baseline survey in person at the study office, or over the phone, or via videoconference during your first appointment. The baseline survey will ask you questions about topics like your memory and overall cognitive functioning, general health, well-being, quality of life, loneliness, depressive symptoms, health service use, and demographic information such as your age and education level.

After completing the baseline survey, if you are eligible, you will be randomized to one of the two groups in the study, either the active intervention group or the post-observation group. This means that the study group you receive is not chosen by you or the researcher. The study divides participants into the groups based on chance (like the flip of a coin).

<u>If you are randomized to the active intervention group:</u>

You will be given or sent the SPEAK! program materials and your first appointment will be finished. We will then contact you when the next ELL is available. We will pair you with an ELL and work with you and the ELL to find a day and time for the weekly videoconference conversations. You and the ELL will have videoconference conversations every week for 8

weeks. Before the videoconference conversations begin, we will show you how to use videoconferencing. The videoconference conversations will be facilitated by study staff and can be done from your home or from the organization that referred you to this study. Each week we will send you a phone, email, or text message reminder about the scheduled videoconference conversation. The audio and video from the videoconference conversations will be recorded so we can review how the conversations went.

After the 8 weeks of videoconference conversations, you will be asked to schedule the second appointment to complete the follow-up survey in person at the study office, or over the phone, or via videoconference. We will contact you to schedule and remind you about the second appointment. The follow-up survey will ask you questions about topics like your cognitive functioning, well-being, quality of life, loneliness, depressive symptoms, health service use, and program satisfaction. After completing the follow-up survey, your participation in the study will be complete.

If you are randomized to the post-observation group:

Your first appointment will end with scheduling the second appointment to complete the follow-up survey in person at the study office, or over the phone, or via videoconference. The second appointment will happen about 8 weeks after the first appointment. During the 8 weeks between your first appointment and second appointment, there will not be any study activities. We will contact you before your second appointment as a reminder and to confirm the appointment with you. The follow-up survey that will be completed during the second appointment will ask you questions about topics like your cognitive functioning, well-being, quality of life, loneliness, depressive symptoms, health service use, and program satisfaction.

After you complete the follow-up survey, you will be given or sent the SPEAK! program materials and your second appointment will be finished. We will then contact you when the next ELL is available. We will pair you with an ELL and work with you and the ELL to find a day and time for the weekly videoconference conversations. You and the ELL will have videoconference conversations every week for 8 weeks. Before the videoconference conversations begin, we will show you how to use videoconferencing. The videoconference conversations will be facilitated by study staff and can be done from your home or from the organization that referred you to this study. Each week we will send you a phone, email, or text message reminder about the scheduled videoconference conversation. The audio and video from the videoconference conversations will be recorded so we can review how the conversations went. After the 8 weeks of videoconference conversations, your participation in the study will be complete.

If you choose to participate in this study, you will be asked to provide your name, mailing address, a telephone number, and an email address. Your identifying information is needed in order for study staff to contact you and to send study reminders, materials, and gift cards. You will also be assigned a unique study identification (ID) number that will be used for the duration of the study. All the data collected about you as part of this study, including the recordings, will be entered and maintained in your study record under your study ID number (not under your name or other identifying information).

4.2 How much of my time will be needed to take part in this study?
Participants will be asked to complete one baseline survey and one follow-up survey in person at the study office, or over the phone, or via videoconference. Each survey is expected to take about one and a half hours. Before the videoconference conversations begin, we will show you how to use videoconferencing. That is expected to take about one hour. Participants will be asked to participate in one videoconference conversation each week for 8 weeks as part of the study. Each videoconference conversation is expected to take about one hour.

4.3 When will my participation in the study be over?
If you are randomized to the active intervention group, your participation in the study will be over after about 8 weeks.

If you are randomized to the post-observation group, your participation in the study will be over after about 16 weeks.

4.4 What will happen with my information used in this study?
Your collected information may be shared with the National Institute on Aging.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

If you have questions about who might be able to access your research data, please talk to the study team about this.

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 potential risks for this study are: emotional discomfort, breach of confidentiality (people outside the study seeing information about you), and the rare possibility that your videoconference sessions, video recordings, or session reminders sent via phone, email, or text message may be accessed by someone who is not on the study team (hackers watching or listening in).

The researchers will try to minimize these risks. Any recorded videos containing your face or identifying information will be deleted at the end of the study. You can discontinue an interview or videoconference conversation that you find bothersome at any time. You do not have to answer any questions you do not want to answer. You can also drop out of the study at any time. The study staff will be available if you want to discuss any problems or concerns you have about the study.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. You might benefit from being in the study by learning a new skill of using videoconferencing software, increasing a sense of social engagement and purpose which may improve mood, and possibly improving aspects of your cognitive functioning.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Check with your doctors to discuss other options.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
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. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no harm in leaving the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.

- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study.

By consenting to this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive a $25 gift card for completing the baseline survey and a $25 gift card for completing the follow-up survey. In total, you may receive up to $50 in gift cards for completing both surveys. You are free to withdraw from the study at any time, however, you will only receive payment for the surveys that you complete. The payment will be mailed to you after completing each survey.

8.3 Who could profit or financially benefit from the study results?
The researchers conducting the study and the University of Michigan:
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?
We will protect the confidentiality of your study records, including the recordings, by assigning you a unique study identification number that will serve as your primary identifier for the duration of the study. We will create a secure electronic tracking file that is only accessible to the PI and authorized staff members that links your identifying information to the study ID number. A hard copy of that file will be maintained in a locked file cabinet separately from other study-related documents. The research data collected as part of the study will only be accessible to the PI and authorized staff members.

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 Institute on Aging 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 adult abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Consenting to this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study may be published in an article or presented at a scientific meeting. If your name or other information that might identify you will be used in the publications or presentations, the researchers will ask for your separate permission. If your name and pictures will be used in any publications or presentations, the researchers will ask for your separate permission.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 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 or treatments
- Talk about study-related costs to you or your health plan
- 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

Principal Investigator: John D. Piette
Mailing Address: 2800 Plymouth Road, Building 16, Floor 3, Ann Arbor, MI 48109-2800
Email: **SPEAK-Study@med.umich.edu**

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
Your agreement given in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. CONSENT TO PARTICIPATE

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with research staff. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I consent to participate in the study and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Consent to video/audio recording solely for purposes of this research

This study involves video and/or audio recording. If you do not agree to be recorded, you cannot take part in the study.

Please tell the research staff member whether you agree to participate in the research study, whether you agree to participate in conversation sessions with the partner you will be paired with, and whether you agree to be video/audio recorded.