UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

Thank you for agreeing to join the study. Here is a copy of the consent form we talked about. Please keep it for your records. If you have any questions about this form, please contact us. Remember, you can stop participating at any time for any reason.

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Community-Embedded, Layperson-Supported Digital Mental Health Intervention for Homebound Older Adults with Depression: A Type 1 Hybrid Effectiveness- Implementation RCT
Principal Investigator: Xiaoling Xiang, PhD, MSW
Study Sponsor: National Institute of Health/National Institute of Mental Health

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Your decision to take part in this study will not affect any services you will receive from your provider.

2. PURPOSE OF THIS STUDY

The purpose of the study is to understand if an Internet educational program we developed can help lift people's spirits. We also want to see what it is like to provide this program through a social service agency.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? We are looking for seniors 50 years or older who are getting services from one of our partner organizations. To be eligible, they would also need to have at least mild depressive symptoms or concerns about their mood. People with dementia, a terminal illness or in hospice care, and a current drug or alcohol use disorder will not be eligible.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
Participants will be randomly assigned to two groups. One group of participants will be asked to do an online program right away, and the other group will receive a brief check-in call from research staff every other week for 10 weeks. Those in the waiting group will have the option to access the program after their last survey in 36 weeks or roughly 9 months. If you agree to participate, you must agree to be randomly assigned to either group.

For those asked to do the online program, you will receive a workbook in the mail. If you don't have a device or internet connection, we will provide a tablet and internet connection free of charge. Please understand that you don't get to keep the tablet afterward. We will pay for shipping and return shipping using UPS.

We will invite you to complete four surveys: one shortly after you agree to participate, the second at the end of 10 weeks, a third 12 weeks after, and a final survey after another 12 weeks.

A random group of participants will be asked to complete an interview about their experience. We use a digital recorder to record your answers. We record your answers because it would be difficult to remember everything you say to us. We will transcribe the recordings and then destroy them. We won't share your voice with anyone other than the study team members. We will always let you know and get your verbal consent before recording you. You do not have to agree to be recorded to participate in this study.

Additionally, we will select random coach calls to be observed. This would involve one of our study team members joining the call with your coach via Zoom or a three-way call. This observation is for us to learn more about the coaching process. Your coaching calls will not be recorded and any information from the calls will not be shared outside of the study team. We will let you know when one of the study team members is joining your call. You do not have to agree to have coach calls observed to participate in this study.

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

For those asked to try out the program right away, we will give you 10 weeks to try the program. You don't have to finish the program by then. You can watch the lessons wherever and whenever you want. The online program involves watching video clips and doing interactive exercises, like answering questions or reflecting on your life experience. The program has 9 lessons. Each takes about 30-40 minutes. During the 10 weeks, you will receive a brief check-in call every week from your agency coach, which will take about 15-20 minutes. The coaching calls are designed to support your experience with the online program. Your coach will be there to answer your questions, cheer you on, and personalize the lessons to fit your situations and needs.

For those who are in the waiting group, you will receive check-in calls from research staff every other week for 10 weeks; the call will take about 15 minutes every two weeks. During the check-in calls, the research staff will ask questions to assess your mood.

Both groups will be asked to complete four surveys over the phone, each taking about 60 to 90 minutes. We will schedule the survey at a time that is convenient for you. All the study activities will occur remotely. That means you will do them at home or wherever you like. You don't need to travel anywhere to participate.

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?
During the study, we ask personal questions. Some of the questions could make you feel uncomfortable. You could become upset or even reveal to us that you feel suicidal. There is also a risk of loss of privacy. We will try to minimize these risks by always being sensitive to your feelings. You may also choose not to answer questions you don't feel comfortable answering. If it is revealed to us that you have suicidal feelings or thoughts, a clinical social worker or other healthcare professional will be contacted. We will also encourage you to seek help from other healthcare providers or services.

Because this study collects information about you, one risk is a loss of confidentiality. We will discuss this in section 8 of this document.

5.2 How could I benefit if I take part in this study? How could others benefit? You will get free online lessons that may help lift your spirits and make you more active and connected with others. It might increase your sense of self-efficacy and help you feel more independent and less worried. It may also improve your quality of life. These benefits may last after the program is finished. However, everyone responds differently; we can't guarantee that the program will help you.

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. If you become ill or have a significant decline that is not caused by your study participation, we will work with you and your case manager to determine whether an early withdrawal is necessary. We may terminate your participation early if we deem it not in your best interest to continue. You are always free to withdraw early, no matter what the reason.

If you decide to leave the study before it is finished, please tell us. 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 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 be paid $30 for each of the four surveys in the study. If you are randomly selected to complete an interview, you will receive an extra $20 payment. This means that, in total, you could receive up to $140 for participation. All payments will be made via check or a gift card.

If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you

receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

Your research information will be stored electronically on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

8.1.1 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 information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse and some communicable diseases.
- 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 research if you wish.

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

If you tell us or we learn something that makes us believe that you or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies.

8.2 Who will have access to my research records?

Our main research team at the University of Michigan will have full access to your research records. Since we are collaborating with your social service provider, they will have partial access to your records. They will see the number of program sessions you complete and the results of key mental health assessments (like your depression, anxiety, and loneliness scores) to understand how the program is helping you. However, they will not have access to other information you share with us, such as your background details or other assessments not related to outcomes.

However, there are reasons why information about you may be used or seen by other authorized personnel during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

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

Your name and other information that can directly identify you will be stored securely and separately from the other research information we collected from you. We need your identifying information because we need to contact you again for the follow-up surveys. Once the study is over and we have verified your research information, your identifying information file will be deleted from our record. But we will keep the deidentified information you have provided us for future research. 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? The de-identified research data you provide us will be shared with the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). Sharing your de-identified study data helps researchers learn new and important things about brain science more quickly than before. We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you.

Researchers who wish to access your de-identified research data must obtain permission to access your data.

Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information.

You do not have to agree to storage and sharing of your information if you do not wish to. You may take part in this study even if you do not want us to share your information with other researchers. You will indicate your choice regarding storage and sharing of your information near the end of this document.

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. At most, the website will include a summary of the results. You can search this website at any time.

We will put the information we collect from you into a repository called the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). The repository contains information about many people. Your information will be deidentified.

9. 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 (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Xiaoling Xiang
Email: xiangxi@umich.edu
Phone: 734-763-6581

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 2144
Ann 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.