INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH
(Participant)

Promoting Reengagement in Daily Meaningful Activity Intervention for adults with mild cognitive impairment and their caregivers

Sponsor: National Institutes of Health (NIH), National Institute of Nursing Research (NINR)
Sponsor Protocol Number: 1R01NR018162

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the physicians at Indiana University Healthcare health system Clinics, Indiana University Women Health Clinic, or staff of the Alzheimer Associations Greater Indiana Chapter.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to provide this program for adults with memory concerns and their study partners to find out the best way to help adults with memory concerns and their study partner to support each other to engage in meaningful activities and to cope with memory concerns and evaluate how well it works to increase their health benefits.

You were selected as a possible participant because you may be experiencing memory concerns.

The study is being conducted by Dr. Yvonne Lu at the Indiana University School of Nursing. It is funded by the National Institute of Nursing Research at the National Institutes of Health.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 210 study partners and 210 adults with memory concerns taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

In this study, we are comparing two programs to find out the best way to help adults with memory concerns and their study partners to support each other to engage in meaningful activities to manage memory concerns.

If you and your study partner agree to be in the study, both of you will do the following things:

- Both of you will be randomly assigned (flip of coin) to Program A or Program B.

- Before you begin Program A or Program B, the research staff will call you and arrange a time convenient for both of you to complete a set of carefully chosen questions about your own experience of meaningful activity engagement and well-being. These questionnaires will be done by phone and you and your study partner will answer the questions separately.

- About 1 week after you complete a set of questions by telephone interview, you will receive mailed materials for the group that you have been assigned to i.e., either Program A or Program B.

- For both programs, you and your study partner will meet together with a study nurse for seven sessions; one session will be done in person* and 6 sessions will be done over the phone. The first session will be done at week 1, and other 6 sessions will be done every other week, so you will have completed the program in 12 weeks.

<u>Program A.</u>

If you and your study partner are randomly assigned to Program A, you will be called by the research staff to arrange a meeting schedule that is convenient for both of you. At this meeting, you will receive a written copy of the self-management tool kit to help you cope with memory concerns. Then you will have bi-weekly, 1 face-to-face* meeting, and then 6 telephone meetings with a study nurse who is a member of our study team. Each session may last up to 60 minutes. At each session, the study nurse will provide information about meaningful activity engagement and memory concerns, answer questions, and discuss more written tip sheets based on your needs and concerns. Each session will be audio-recorded for accuracy and quality control.

<u>Program B.</u>

If you and your study partner are assigned to Program B, you will be called by the research assistant to arrange a meeting schedule that is convenient for both of you. At this time, you will receive carefully selected educational materials about memory concerns developed by the Alzheimer's Association. Then you will have bi-weekly 1 face-to-face* meeting, and then 6 telephone meetings with a study nurse. Each session may last up to 30 minutes. At each session, the study nurse will answer your questions about the written educational materials. Each session will be audio-recorded to make sure the study nurse delivers the sessions in the way they were planned.

***During the COVID-19 health crisis, you have options to do the first session by phone or zoom.**

Research Study Evaluations

In both Program A and Program B, you and your study partner will be asked to complete a set of carefully chosen questions about your own experience of meaningful activity engagement, your perception of well-being, and satisfaction of participating in the program (for example, what types of meaningful activity you have done, the ways you did, what is helpful or not helpful, how you cope). You will be asked to complete these questions at four different times: (1) before your program's first face-to-face* meeting with the study nurse; (2) about 1 week after your 7 program sessions have been completed; (3) 90 days after the last session meeting; and (4) 180 days after the last session meeting. The questions will help us judge the quality of the programs and how things have gone for you. The research staff will call you to set up a time that is convenient for both of you to go over these questions. You and your study partner will have phone interviews separately and privately with a trained research staff. Each evaluation will take about 60 minutes for each of you. You and your study partner will also be asked to tell us your thoughts and feelings about the program. These interviews will be done separately and privately through telephone. Your name will not appear in the written copy of your interview. If you need help, the research staff will answer your questions by phone. Each session will be audio-recorded for accuracy and quality control.

***During the COVID-19 health crisis, you have options to do the first session by phone or zoom**.

All seven sessions and all telephone evaluations will be audio-taped for quality assurance and to record answers to questions that were asked by the research staff. No names will be used on the tape recordings, in any of the interview questionnaires, or in the final report so that all information will be kept confidential. After the recordings have been transcribed and data analysis has been completed, the audio recordings will be stored for a minimum of 3 years after study completion.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

There are no anticipated physical, social, legal, or other potential risks connected with the study. The risks of this study are:

- You may feel anxious or uncomfortable answering some of these questions.
- There is a risk of possible loss of confidentiality.
- There is a risk of experiencing some fatigue as a result of your study participation.

There is a minimal psychological risk as some of the questions during the study sessions may make you feel uncomfortable. If that happens, you can tell the study nurse or the research assistant immediately, and you can decide to take a break, stop the session, or reschedule the meeting. At any time, if either of you feel discomfort, you may also call **Dr. Yvonne Lu at 317-278-2042** from 8:00 AM to 5:00 PM, Monday

through Friday, to talk about your uncomfortable feeling or ask any questions that either of you might have.

To maintain confidentiality, your personal information such asyou/your study partner's name, address, phone number, and health-related information will be kept private. We will assign a special ID number to your information file. All information we collect will be linked to this number so there is no direct connection of such information with your name. We will keep a master list of names in a password protected file, as we will with all information entered into the study's computer. Paper copies of any information will be protected in locked file cabinets and/or on a secure, password protected computer. All research members in our study have completed education on the protection of human subject's health information and are committed to protect the privacy of all research participants.

The final risk is the possibility that you and your study partner may experience some fatigue as a result of your study participation. Should you experience any fatigue while answering study questionnaires or while participating in a study session, you/your study partner can ask for a break or ask to end or reschedule it.

In the event of extreme psychological distress, such as severe depression or suicidal thoughts, you will be encouraged to contact Eskenazi Mental Health Center (317) 880-8491, the 24-hour Suicide Hotline (317) 251-7575 or any resource from where you typically receive care. In the event of suicidal thoughts, the investigator may notify a health care provider on your behalf so he/she can contact you to determine if treatment is necessary.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

Participating in this study may help you or your loved one learn ways of support in managing memory concerns. Your feedback and information. learned from this study will help other adults with memory concerns and their study partners in the future.

WILL I RECEIVE MY RESULTS?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. We will perform a depression assessment, an anxiety disorder assessment, and other screening assessments that may be important to your health or to your treatment. After the assessments are completed, if the scores are high, we will encourage you to contact your primary physician to receive additional treatment. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which

could identify you will be shared in publications about this study. All seven sessions and all telephone evaluations will be audio-taped for quality assurance and to record answers to questions that were asked by the research staff. No names will be used on the tape recordings, in any of the interview questionnaires, or in the final report so that all information will be kept confidential. Only members of the study team will have access to the recordings, and they will be destroyed after data analysis has been completed, the audio recordings will be stored for a minimum of 3 years after study completion.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the National Institutes of Health (NIH), National Institute of Nursing Research and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the Office for Human Research Protections (OHRP), and for research funded or supported by National Institute of Nursing Research (NINR) at the National Institutes of Health (NIH).

In addition to participating in this study, you may also participate in a study with the Indiana Alzheimer's Disease Research Center (IADRC). IADRC contains some of the same or similar procedures as this study. Information about the IADRC is in a separate informed consent document. If you choose to participate in both this study and in the IADRC (and sign both consent forms), your data will be shared across the two studies.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. 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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you and your study partner for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent. We may ask permission to use any shared photographs of an identified meaningful activity as part of this study for educational purposes, academic conferences, presentations, and trainings. Your face will not be shown, and your name will not be used.

WILL I BE PAID FOR PARTICIPATION?

You and your study partner will receive payment for taking part in this study. Each of you will receive a $20 gift card by mail for each telephone evaluation: at the beginning of the study, 1 week after completing the program (7 nurse sessions), 90 days after completing the program (7 nurse sessions), and 180 days after completing the program (7 nurse sessions).

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, **contact the researcher Dr. Yvonne Lu at (317) 278-2042,** the **Project Manager, Amy Katz at (317) 274-4330** during regular business hours (i.e. 8:00AM-5:00PM) or email **prima@iu.edu.** If you experience emotional distress, you may contact Eskenazi Mental Health Center (317) 880-8491, the 24-hour Suicide Hotline (317) 251-7575, or any resource from where you typically receive care.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with physicians and clinical personnel with at Indiana University Healthcare health system Clinics, Indiana University Women Health Clinic, or Indiana University. You don't have to be in this study, and you can say "no" to the interviews at any time. Your participation is completely voluntary.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: You or your family member with memory concerns is no longer able to participate the study; or you or your family member with memory concerns is not completing study procedures.

AGREEMENT TO BE CONACTED BY TEXT AND/OR EMAIL

We would like to communicate with you about this study by text message and/or email. We might use text or email to communicate information such as but not limited to, telephone call reminders, study material(s) and/or activities throughout your participation.

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____ I authorize the researchers to send me emails related to this research study

Email address for this communication: _____

_____ I authorize the researchers to send me text messages related to this research study

Phone number for this communication: _____

You can still participate in this study even if you do not want us to contact you by text or email.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.