Applying a Person-Centered Approach to Enhance Cognitive Training in Senior Living Community Residents with Mild Cognitive Impairment (CogT-PACT study)

Informed Consent Form

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UNIVERSITY of ROCHESTER MEDICAL CENTER

CONSENT FORM

Applying a Person-Centered Approach to Enhance Cognitive Training in Senior Living Community Residents with Mild Cognitive Impairment (CogT – PACT Study)

Principal Investigator: Feng (Vankee) Lin, RN, MB, PhD & Benjamin Chapman, PhD, MPH
Co-Investigator: Anton Porsteinsson, MD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you are at least 60 years of age, and indicated that you notice some mild memory deficits (also called mild cognitive impairment, MCI), as determined by the screening.

This study is being conducted by Drs. Lin, Chapman, and Porsteinsson of the University of Rochester's School of Nursing and Departments of Psychiatry, School of Medicine and Dentistry.

Purpose of Study

The purpose of this study is to assess the feasibility and effect of a series of computer-based cognitive training programs in older adults with MCI who are current residents of area senior living communities (SLCs).

Description of Study Procedures

If you decide to take part in this study, you will be asked to meet us for a total of four assessments and to participate in a 10-week cognitive training program. All of the assessments and cognitive training will occur at a private room in your senior living community. We describe the details of these activities in the order of the timeframe:

(1) For the baseline assessment, we will ask questions about your background (e.g., age, education, and marital status), attitudes toward computer use, mood, personality, any medical problems, leisure activities, and any medications you have taken or are taking now. We will also ask you to complete paper and computer-based tests related to your memory and problem-solving abilities. The interview will take around two hours.

(2) After the baseline assessment, you will be assigned randomly (using a computer code) to one of the following two intervention groups, both of which include computerized programs: Red or Yellow. Both programs will last for 10 weeks.

   a. For the Red group, there will be 4 sessions per week for 10 weeks. Each session will take 1 hour.
   b. For the Yellow group, no training will take place during the first 4 weeks. After this period, in the last 6 weeks, there will be 4 sessions per week. Each session will take 1 hour.

   At each session, we will ask you to complete several computer-based exercises that are related to your problem-solving abilities. At the first session, we will give you your own account and password, and teach you how to get access to and use each computer program. We will provide you with a computer (or portable device). If you have your own iPad or computer that you would prefer to use, you may choose to do some of the sessions with your personal device. Our research team will provide assistance as needed throughout the training sessions.

(3) At the end of week 4, after the entire 10 week cognitive training period, and at 3-month follow-up, you will be invited to participate in additional follow-up assessments. Again, we will ask you about your attitudes towards computer use, and ask you to complete several paper-and-pencil tests and computer-based tests related to your problem-solving abilities. The interviews will take around two hours.

Upon your participation, we will provide you with a worksheet that describes all activities (i.e., assessments and cognitive training sessions) you will be involved in. The worksheet will be tailored to your schedule based on your discussion with the staff. If you have any technical questions or questions related to the study, the staff can be reached via the number provided on the worksheet.

Number of Subjects

Approximately 50 subjects will take part in this study.

Duration of the Study

Your participation in the study will last for around 5 months, including a 10-week computer training program and four assessments before, during, and after the program.

Risks of Participation

You may find the interview questions, the memory tasks, or the computer cognitive exercises tiring or burdensome. Under either circumstance, you can stop the interview questions or the memory and computer tasks at any time, or refuse to answer any questions you don't want to answer for any reason. If any psychological stress continues after the interview section, we may communicate with

your physician in the event we become concerned for your safety and well-being, following the same procedure listed below:

The cognitive assessments at baseline and follow-up are similar to the memory tests you may have had before at some doctor visits. You may find some tests challenging or frustrating. You can refuse to answer any question in any test. We do not expect any mental or emotional concerns to arise from participating in this study. However, in the event that the investigators become concerned for your safety or well-being, we may ask the co-investigator and board certified geriatric psychiatrist, Dr. Porsteinsson, to assess these concerns. In such cases, it is possible Dr. Porsteinsson may communicate the events with your physician or study staff. If any concern does arise, you will be informed about it prior to any action being taken and will be notified about any next steps.

Benefits of Participation

The potential benefit to you from being in this study might be to improve your memory or problem-solving abilities. In this study, we are comparing the effect of two types of training programs on your memory or problem-solving abilities. After collecting and analyzing the data, if we find one training program to be superior to the other training program in improving participants' cognitive performance (e.g. - memory or problem-solving abilities), we will provide all participants with information on how to access the more beneficial training program.

Sponsor Support

The University of Rochester is receiving payment from National Institute of Health for conducting this research study.

Costs

There will be no cost to you to participate in this study.

Payments

You will be paid $20, $10, $20 and $20 for the four assessments separately. Together, you will be paid up to $70 for participating in this study. If you do not complete all sessions, you will be paid for the portion that you completed.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, all materials and data will be kept in a locked research office in a locked file cabinet. No one other than the investigators and their assistants will have access to the data. At the completion of your participation or coding of data, the data would be de-identified to further protect your privacy and confidentiality of the data. Once data have been entered on computer, only code numbers (not names) will be associated with your responses to the questionnaires. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. While others normally protect the privacy of the

information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. We will use your research record, including your medical diagnoses and medication related to cognitive ability, caridovascular diseases, or anti-inflammatories from your medical record, your cognitive assessment results, your ECG data, and information collected from the questionnaires about your background.

Who may use and give out information about you?
- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:
- The Department of Health and Human Services
- The University of Rochester
- Your SLC staff and physicians
- Your primary care physician

Why will this information be used and/or given to others?
- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Vankee Lin at (585) 276-6002.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation
Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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Consent Form Questions:

What are two potential risks?

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What is expected from you?

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What if you don't want to continue?

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What if you experience discomfort?

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How is it decided who gets which training program?

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SIGNATURE/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date