Consent Form Cover Page for Study NCT03036423

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Brief Title: Cognitive Training for Older Caregivers (CTC)
Official Title: Cognitive Training to Protect Immune Systems of Older Caregivers
Consent Title: Brain Training to Promote Health in Family Dementia Caregivers

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CONSENT FORM

Brain Training to Promote Health in Family Dementia Caregivers

Principal Investigator: Kathi L. Heffner, PhD

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 or at any time. 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 or support services you or your loved one may receive 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 caring for a loved one with dementia, and during the screening process you indicated that you are experiencing some stress.

This study is being conducted by Dr. Kathi Heffner of the University of Rochester's School of Nursing.

Purpose of Study

The purpose of this study is to test whether certain brain training activities can promote cognitive, emotional, and physical health in caregivers. We know caregiving for a loved one with dementia can be stressful, and can increase mental and physical health risks. We want to understand how to reduce those risks.

Information about safety in research during the COVID-19 pandemic:
The University of Rochester provides researchers with guidelines to help ensure study procedures are conducted safely during the COVID-19 pandemic. Safety precautions include pre-visit symptom screening, social distancing, and use of personal protective equipment (PPE). Study staff will keep you informed of the current safety guidelines as they apply to your participation in this study.

Description of Study Procedures

If you are eligible and agree to participate in this study, your participation will last 14 months and the study activities may take place in your home, or at the U of R if you prefer. The study activities involved can be categorized into two basic types: 1) **study visits** with study staff at either your home or the U of R (a trained aid can be available to provide support for your loved one at these visits), and 2) the **in-home training program** (computer activities) completed at your convenience.

Group assignment (randomization). All subjects will be randomly assigned (like flipping a coin) to do either computerized mental exercises *or* to select from a library of educational videos for viewing on the computer (self-guided video education). Both types of training entail using the computer to engage in the activities for 30-minutes, at least 3 times per week, for an 8-week period. Study staff will provide thorough in-person instruction on both activities and ongoing support by telephone as needed. If you do not have a computer or internet access, these will be provided for you.

Study visits

The term "study visit" as used in this form refers to a collection of various assessment procedures intended to occur on, or very close to, the same date. To increase safety in this time of COVID-19, portions of an assessment visit can be done remotely through a secure online survey system (called REDCap) and over the phone with study staff. Thus, a complete "visit" will often involve both a remote (online and by phone) *and* an in-person (with study staff) set of procedures.

There will be a total of 6 study visits across your roughly 14-month period of study enrollment. These visits can be done at the U of R, or staff can come to your home if you prefer and it can be conducted safely. Within the first month or so of enrollment, you will have 3 study visits: **1**) an initial visit for consent and further screening, **2**) a visit to conduct the first of four study assessment sessions, and **3**) a visit to show you how to do the training program on a computer which you will be doing at your convenience over the following eight weeks. The next study assessment visit will be soon after the eight weeks of computer activities. Then, another study visit will occur 6 months later, with the final study visit occurring 6 months after that (1 year after completing the in-home brain training program).

These visits are described in detail next:

1. **Initial study visit**. You will have an initial visit to discuss this informed consent form and further assess your eligibility for participation. This will involve an interview which includes assessments of your health and health-related behaviors, including your medical history, sleep, alcohol and substance use, and mental health. You will be asked about your role as a caregiver and what it has been like for you. You will also be asked about any medications you are taking. Certain medications will need to have been maintained on a stable regimen for at least 3 months prior to the first main assessment visit. Blood pressure medications may vary as necessary. This visit may last about 60-90 minutes.
   Following the initial visit, if you are eligible, the first assessment visit should ideally occur within the next couple of weeks. If that visit is delayed for several weeks, you may be asked to repeat some of the measures done at the initial visit in order to re-establish your eligibility for the study.

2. **First study assessment visit**.
   - At this visit, you will be asked to have 50 mL (about 3 1/3 tablespoons) of your blood collected by a certified phlebotomist using a standard needle, and have your height and weight recorded.
   - An electrocardiogram (ECG), using sensors attached to your chest and back, will be used to assess your heart activity.
   - You will be asked to complete questionnaires (most can be done remotely) about your emotional and physical status, and about your caregiving experience.
   - You will be asked to complete a series of cognitive measures of memory and thinking.

   The in-person portion of the visit is expected to last roughly 70 minutes; for the remote portions, the online surveys take about 30 minutes and the phone interview is about 50 minutes. Thus, the complete assessment visit activities (in-person, online, phone) take roughly 2.5 hours combined.

3. **Computer task instruction visit**. Study staff will let you know which computer activity (mental exercises or self-guided video education) you will complete for the 8-week computer task period. You will receive thorough instruction and demonstration on the use of the computer (as needed) and computer activity. You will receive information about how to contact staff for telephone support if any questions arise. This visit may last about 40 minutes.

4. **Remaining three study assessment visits**. After you complete the computer tasks for 8 weeks, you will have 3 more study assessment visits: the first visit will occur soon after the end of the 8-week period; the second will be 6 months after that, and the third will be 6 months after the second. These visits will entail the same activities as the first study assessment visit, including blood collection, heart activity and height/weight measures, questionnaires (online and by phone), and cognitive measures, and will require approximately 2.5 hours total.

Visit portions done remotely should be completed on, or as close as possible to, the day of the in-person visit. If there is a delay of several days between certain time-sensitive assessments of a particular visit, you may be asked to repeat some of the assessments that had been completed before the delay (typically a couple questionnaires, depending on the situation).

Computer Activities

As described above, you will be randomly assigned to complete mental exercises or to view educational videos that you select from a provided computer library; both activities are completed on the computer using a keyboard and mouse or touchpad.
You will be asked to complete the activity to which you are assigned for 30-minutes a day, at least 3 times per week, for 8 weeks (minimum goal of 90 minutes per week). You may complete these activities wherever you have access to a computer and the internet.

- For the *computerized mental exercises*, you will use a computer to do a variety of activities which will be customized to your own abilities and progress.

- For the *self-guided video education*, you will have computer access to a library of videos, including various lectures and demonstrations of interest, from which you can select and view.

The internet-based computer activities are highly secure. All data collected is coded with a unique identifier that only the study staff and investigators can link to you. During the 8-week period, study staff will regularly provide feedback to you (by telephone or email) about your study progress and can help you devise strategies if you are having difficulty completing at least 90 minutes of computer activity per week.

Number of Subjects

Approximately 240 subjects will take part in this study.

Risks of Participation

There are some risks to having your blood drawn. These risks include possible discomfort and/or a bruise at the needle puncture site. Once in a while, some people may faint; please inform the study personnel before having your blood drawn if this has happened to you in the past. It is rare, but some people may get an infection, form a small blood clot, get swelling of the vein and surrounding tissue or bleeding at the site of the needle puncture. You are encouraged to drink plenty of water prior to the blood draw as this may facilitate the process, and you will be seated during the blood draw to minimize

dizziness and any risk of falling. Pressure will be applied to the site after the draw and a bandage will be applied to minimize the risk of bleeding and infection.

Because you will be answering questions about your physical and emotional health and well-being on the questionnaires, you may experience some emotional discomfort. You are free to not answer any questions with which you feel uncomfortable. If we become concerned about your mental health or safety based on your responses to our questions and surveys, we may contact your primary care physician or other relevant health care provider. We will notify you of these concerns prior to contacting your provider. If we observe or learn about any situation that puts a child at risk, we are required to call Child Protective Services (CPS). Before we place any calls to a health provider or to CPS, we will discuss our concerns with you and review any safety planning that may be needed.

The cognitive measures of memory and thinking can be challenging. These measures are intended to be challenging and produce a mild stress response.

We will place hypoallergenic adhesive sensors on your chest and back to measure your heart activity (ECG). When the sensors are removed, you may experience some skin discomfort, such as you may feel when removing a bandage. Although rare, it is possible for skin reactions to occur from contact with the sensors. This typically results in minor itchiness and/or redness of the skin where a sensor was placed, and often resolves soon after the sensor is removed and the area of skin is cleaned.

Benefits of Participation

This study is not expected to directly benefit you. However, the knowledge gained from your participation may provide insights into your physical and emotional health and well-being.

Sponsor Support

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

Costs

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

Payments

You will receive $20 for the initial study visit, $75 for each of the four study assessment visits, and up to $80 for completing the eight-week training phase, for a total of up to $400. Payments are made by check (typically divided across four checks throughout the study) mailed to your home. Additional compensation cannot be provided for time-sensitive procedures repeated because of significant delay between assessments.

Confidentiality of Records and HIPAA 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, your information on “hard copy” forms will be kept in locked filing cabinets and any electronic information will be stored on secured, password protected computers accessible only by the investigators and study staff. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

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?
We will record and use your personal and medical information for this research. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you?

- The investigators and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- National Institutes of Health

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?
Yes. 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 staff. 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?
Yes. 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?
No. 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 emotional or physical discomfort please contact: Kathi Heffner, PhD at 585-273-4786.

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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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.

Saving your blood samples for future research:

It is possible that future analyses of your blood samples will be useful in better understanding possible links between immune system health and caregiver well-being. Therefore, after tests are done on your blood samples for the present study, we would like your permission to keep any remaining blood to use in possible future research studies. The remaining sample would be stored in a laboratory at the University of Rochester Medical Center, and would be used for future research purposes only; it will not be sold or used directly for the production of commercial products.

Your blood samples will be coded (made anonymous) and will not be linked to your name or other information that could identify you. Future reports about research that utilized your sample will not be added to your health records, and you will not be informed of the results of the future research as the sample will no longer be linked to your identity.

You can decide if you will allow your samples to be used for future research. *Indicate (✓) below:*

- ❒ **I consent** to have my de-identified specimen(s) saved for an indefinite period of time for future research as described above.
- ❒ **I do not consent** to have my unused specimens used for other future studies. Destroy my unused specimen(s) after analysis is complete for the present 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