Official Title: Cognitive Training RCT for Older Chinese Americans

NCT: NCT05355870

IRB Document Date: January 9, 2025

REDCap Consent - Co-Design Workshop (English)

We are asking you to take part in this research study because you are a Chinese older adult. You can choose whether or not you want to take part. As I discuss the study information with you, please ask me to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. Information about the study, including study activities and risks, will be presented and explained to you.

WHY IS THIS STUDY BEING DONE?
We are conducting this study to learn about the best ways to help older Chinese Americans maintain good cognitive function that may prevent them from developing memory problems such as Alzheimer's Disease and dementia. There is some evidence suggesting that cognitive training--one type of brain stimulating activity can help improve memory. We really want to know to what extent cognitive training activities that are designed and tailored to older Chinese Americans can help maintain cognitive function. In addition, we would like to assess the feasibility, acceptability, and satisfaction for older Chinese Americans to complete mobile-based cognitive training activities. The information will help us to identify how we can make the cognitive training better for older Chinese Americans.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
We will recruit about 42 older Chinese Americans in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, we will first ask you to consent to participate in this study. Next, we will ask you to complete a series of survey questionnaires. You may be asked to complete a series of cognitive training activities on your phone, tablet, or computer on a regularly basis. Below is a table that summarize the study activities

Overview of Study Activities

Visit	Activity	Location	Time
Baseline	Assessment & Randomization	Duke Health	1 hour
Intervention (12 weeks)	Cognitive Training/Waitlist Control	Home	For cognitive training, it takes about 10-15 min per day
Week 8 follow-up	Assessment	Duke Health	1 hour
Week 12 follow-up	Assessment	Duke Health	1 hour

Baseline, week 8 and week 12 visits

You will go to the Duke Health Center for Interprofessional Education and Care. At your baseline, we will ask you questions about your sociodemographic background, medical history and dementia knowledge. We will then randomly assign you (like flipping a coin) to 12 weeks of participation in a cognitive training intervention group or a waitlist control group on a 2:1 ratio. In other words, among the 42 older Chinese Americans, 28 will be assigned to the cognitive training intervention group, and the rest 14 will be assigned to the waitlist control group. If you are in the waitlist control group, you will still get access to the cognitive training activities that we designed for older Chinese Americans, but just 12 weeks later.

At each visit, we will:

• Assess your thinking abilities with cognitive (brain function) evaluations designed to examine your memory, processing speed and attention
• Assess your physical function and quality of life.

• Check your blood pressure
Each visit will take approximately 1 hour. You may take rest breaks between tasks or stop at any time.

Cognitive Training Intervention

If you are in the cognitive training group, we will ask you to complete approximately 10-15 min of cognitive training per day on a computer, phone, or tablet, whichever you prefer. You can complete more training if you would like. The training program last for about 12 weeks. The program does not require you to have any knowledge of how a computer works. You do not even need to own a computer, but you will need to have access to the internet on a laptop, phone, or tablet. We will provide thorough instructions before all training activities, and there is ample opportunity for practice. During these exercises you may be asked to do different things, such as remember images that are seen, solve problems, or track information on the screen. The exercises will start out easy, but get more challenging as your training continues. If you have a hearing aid or eyeglasses, you should use them during your training sessions.

Waitlist Control

If you are in the waitlist control group, we will provide you the same set of training and materials as the cognitive training group, but 12 weeks later. In the meantime, we will still ask you to complete the baseline, week 8 and week 12 study visits.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in the study will be about 12-week long. During the 12-week period, we will ask you to complete 3 study visits at baseline, week 8, and week 12. You may be asked to complete a series of cognitive training activities if you are in the cognitive training intervention group. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
This study poses little to no risk to participants. There is a small potential risk from loss of confidentiality. However, the information provided to us will be kept secure and confidential as required by law. Study staff will remove all identifying information from your interviews and we will keep it in a secure folder behind the Duke firewall.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
Participating in this study may help maintain cognitive function and prevent dementia. However, we do not know that for sure that there would be direct benefits to you from completing the cognitive training. We are doing this research study to find out if this training helps or not. Additionally, you and your study partner will be receiving free access to cognitive training for the duration of your involvement in the study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you and your loved one is kept privately, but we cannot guarantee that. You and your loved one's personal information may be viewed by individuals involved in this research and may be seen by people including other members of the research team, those who are funding the study and those who aim to protect the safety of participants in the study. Your information will be stored in a secured folder at Duke.

As part of the study, the data we collected from you, which is your research record may also be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board, the U.S. Food and Drug Administration (FDA) and the National Institutes of Health. We will keep the study results in your research record for at least six years after the study is completed. If we have to disclose this information to outside reviewers for audit purposes, the reviewers may further disclose the information, and may not be covered by federal privacy regulations. The information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, but we will never share personal information, including your name.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?
It does not cost anything to participate in this study.

WHAT ABOUT COMPENSATION?
You will be paid $40 for your participation at each visit, with a total up to $120.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study. If you agree to be in the study, you may stop participating in the study at any time. If you stop participating in the study, we will not collect any new data about you, except for any information we need to keep track of your withdrawal. We will use any data that have already been collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your and your loved one's access to health care at Duke. If you do decide to stop participating in this study, we ask that you contact Dr. Hanzhang Xu in writing at the following mailing address: 2200 West Main Street, Erwin Square, Suite 600, Durham, NC 27705.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Hanzhang Xu at 919-613-2196 during regular business hours and at 919-599-5831 after hours and on weekends and holidays. For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US 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.

Statement of Consent
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have been read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a copy of this consent form." By agreeing to participate, you acknowledge that you have been read the consent document.

_____ I wish to participate in the study

_____ I DO NOT wish to participate in the study

_____
Signature of Participant Providing Consent:

_____
Date:

_____
Would you like a copy of the consent form Emailed or Mailed
_____ Mailed?
_____ Emailed
_____ WeChat

What is your mailing address?
Street name:
_____
City:
_____
State:
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Zipcode:
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Email:
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WeChat ID:
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