INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH
Lifestyle Interventions for the Treatment of EOAD Study (LITES)
IRB# 14594
Sponsors: Alzheimer's Association, #AARG-22-926940
National Institute of Aging, #1K23AG080071-01

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 and Authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

STUDY SUMMARY

The purpose of the study is to test the feasibility and efficacy of a combined lifestyle training program on improving thinking and memory in patients with Early-Onset Alzheimer's Disease (EOAD).

Please review the rest of this document for more details about this study and the things you should know before deciding whether to participate in this study.

WHY IS THIS STUDY BEING DONE?

Despite the increased research on interventions for Alzheimer's disease (AD), treatment for patients diagnosed at a younger stage of life (aged 40 to 64 years old) has been overlooked. Identification of successful treatments for this condition would lead to improvements for patients and families across many areas of life.

There have been a lot of results showing that interventions using both cognitive (thinking) training and exercise training help thinking skills. When these trainings are combined together, they seem to lead to a stronger result. However, this has not been looked at for patients with EOAD, therefore this study will examine if these trainings are useful for patients with EOAD.

We are asking you if you want to be in this study because you have been identified through the Longitudinal Early-Onset Alzheimer's Disease Study (LEADS) as having EOAD.

This study is being conducted by Dustin B. Hammers, Ph.D., Fred Unverzagt, Ph.D., and Liana Apostolova, MD., at Indiana University School of Medicine.

This study is being sponsored by the Alzheimer's Association and the National Institute of Aging.

HOW MANY PEOPLE WILL TAKE PART?

You will be one of 60 participants taking part in this study. Participants will come from LEADS sites both at IU and throughout the multi-site study.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to participate in this study and sign the consent form, we will ask you to complete a series of remote computerized tests that measure your thinking abilities. We will also ask you and your study partner some questions about how well you can complete daily tasks (e.g., managing medications, preparing meals) and your mood. The thinking tests might ask you to remember images that are seen, solve problems, or track information on the screen. The first visit will allow us to establish a baseline for your thinking abilities and daily functioning. This visit should last about 3-4 hours.

You will then complete 14 weeks of cognitive and exercise training, which will include a brief assessment before and after training to observe if you learned the training measures. The cognitive and exercise training activities that you will complete will be assigned randomly. You will receive a participant manual to serve as a step-by-step guide for accessing the lifestyle training program. Staff will conduct a 15-minute telephone check-in with you every week, two weeks, or as needed to discuss your progress and answer questions.

After approximately 14 weeks of the cognitive and exercise training, you will return for another 3-4 hour remote session and complete the same thinking and daily functioning tasks that you completed in your first visit.

Approximately 6 months after you complete your training, you will return for a final 3-4 hour remote session and complete all of the same thinking and daily functioning tasks that you completed in your first visit.

In total, you will be part of this study for approximately 11 months.

We will be asking your study partner about your thinking abilities and daily activities throughout the study. We will also be asking you and your study partner about your medical history, current medications, and any changes in your health throughout the study.

The lifestyle training program: In this study, we are comparing two combined training programs.

For the cognitive training portions of both training programs, we will ask you to complete approximately 40 hours of cognitive training on a computer. You can complete your training in 45-minute sessions 4 times per week for about 14 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 or tablet. We will provide thorough instructions before all computer 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.

For the exercise training portion of both training programs, you will be observing and following along with recordings of exercise videos online that will be 10-30 minutes in length on a computer. You can complete your training in two sessions per week for about 14 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 or tablet. You can take part in the exercises regardless of your physical fitness – even from a sitting position. During these exercises, you will be asked to complete activities ranging from light stretching and deep breathing, to Tai Chi-based poses. For all exercise tasks, we encourage you keep a chair nearby if you feel that balance might be an issue.

You will not receive the results of any of these tests or procedures because they are being done only for research purposes.

REMOTE ASSESSMENT RESTRICTIONS

Due to the remote nature of this study, there may be times during the assessment that information is presented to you or your study partner over the computer screen. To ensure test security and avoid copyright violation, any information presented on the screen cannot be recorded (audio or visual), photographed, or captured using a screen shot.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

This study has minimal risk associated with participation. You will receive cognitive, functional, and mood assessments, which have the potential to create mild psychological discomfort or frustration, especially if you perceive that you are performing poorly. In our extensive experience conducting these evaluations clinically, the likelihood of such a reaction is minimal and the seriousness of such a reaction is mild.

Additionally, the cognitive training exercises in the experimental condition are designed to be challenging, which could also lead to temporary feelings of discomfort or frustration. However, in several studies using various versions of these cognitive training exercises, no serious adverse reactions have been reported. For the physical training exercises, there is a possibility that you could lose your balance as a result of following along with the exercise videos, therefore anyone with balance concerns should have a chair nearby when exercising.

Finally, given the follow-up period of this study (e.g., approximately 6 months), it is possible that some individuals' disease will progress during this period. Being involved in this study on the cognitive effects of EOAD could heighten your awareness of your cognitive symptoms, which could lead to some emotional distress.

RESEARCH-RELATED INJURY

If you are injured as a result of participating in this study, you will be responsible for seeking medical care and for the expenses associated with any care received. 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. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

Participating in this study may lessen the symptoms of your disease. However, we do not know that for sure. It is unclear if there would be any direct benefits to you from completing the cognitive training and physical exercises. We are doing this research study to find out if this treatment helps or not. Additionally, you and your study partner will be receiving free access to cognitive and exercise training for the duration of your involvement in the study.

WILL I BE PAID FOR PARTICIPATION?

Participants will be directly compensated for their participation in the study in the following amounts: $20.00 for completing the pre-treatment visit, $20.00 for completing the post-treatment visit, and $20.00 for completing the 40 Week Post Intervention Follow-up visit.

You will be paid following each of the pre-treatment, post-treatment, and 40 Week Post Intervention Follow-up visits. At the start of the study, you will receive a rechargeable debit card that has a balance of $0. Following completion of each of these three visits, a $20 credit will be loaded onto the card, which can be used immediately.

For local participants choosing to attend their visits in-person, parking reimbursement and lunch will be provided for lengthy research visits.

WILL IT COST ME ANYTHING TO PARTICIPATE?

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

WHAT ARE THE OTHER TREATMENT OPTIONS?

Currently, there are no other lifestyle treatments for EOAD.

HOW WILL MY INFORMATION BE USED?

The information released and used for this research will include study data from the Longitudinal Early-Onset Alzheimer's Disease Study (LEADS). Your decision whether or not to participate in the current study will not impact your status in LEADS.

If you agree to participate, you authorize the following to disclose your medical record information:

- LEADS.

The following individuals and organizations may receive or use your identifiable research data:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US government agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- The following research sponsors: Alzheimer's Association, National Institute of Aging
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - The United States Food and Drug Administration (FDA)

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.

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. There is a slight risk that there could be a breach in the security of research database systems resulting in the access of information. Safeguards are in place to minimize this risk. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations. The Certificate also does not stop sharing of information required by the Food and Drug Administration (FDA).

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

We are giving you this information so you can decide if this affects your willingness to participate in this study. If you would like more information, please ask the researchers or study staff.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

If you have questions, complaints, or concerns about this study, you can contact Dustin B. Hammers, Ph.D, at 317-948-5450 during normal business hours or after hours at 317-944-5000. If you think you may have been harmed from being in this study, please call Dustin B. Hammers, Ph.D, who can be reached during normal business hours.

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 Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with Indiana University or Indiana University Health.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please let the research doctor know. That way you can find out what should be done about your normal medical care outside of the study.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Hammers, Department of Neurology, 355 W. 16th Street, Indianapolis, IN 46202. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigator can withdraw you without your approval if you do not comply with study procedures (e.g., not completing the recommended number of hours of training). We do not expect any adverse effects on your health or welfare if you are withdrawn from the study.

ELECTRONIC COMMUNICATION

Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, such as protected health information, could be accessed or read by someone other than you. Although secure electronic messaging is preferred to unsecure email or text messaging for communication of protected health information, unsecure email or text communication containing sensitive health information can be sent between the **LITES Team** and the **participant/LAR or guardian**. We might use text or email to: for example, send you reminders about upcoming visits or appointments, check on how you are doing, or tell you about the progress of the research.

This authorization of electronic communication is voluntary. You have the right to revoke this authorization at any time by informing the LITES team. If you choose to revoke authorization, it will not apply to any information already released as a result of this acknowledgment. Only a minimum amount of information will be included in communications and this authorization is for communication related to the LITES research study listed above.

PARTICIPANT'S CONSENT AND AUTHORIZATION

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

Participant's Printed Name: _____
Participant's Signature:_____**Date:**_____
Participant's Address:_____

Printed Name of Person Obtaining Consent:_____
Signature of Person Obtaining Consent:_____**Date:**_____

Printed Name of LAR:_____
(Legally authorized representative)
Signature of LAR:_____**Date:**_____
□ Not applicable (check this box if the signature of legally authorized representative is not required)