Official Title: U.S. Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk
NCT03688126
IRB Approval Date: 09/22/2022

U.S. POINTER

Informed Consent Form to Participate in Research

First Name Last Name, Degree, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because:

- You have a first degree family history (mother, father, sister, brother) of memory loss, Alzheimer's, or another type of dementia.
- You are not a regular exerciser.
- Your current health status may put you at increased risk of memory loss in the future.

Your participation is voluntary. Please take your time in reviewing this form as you make your final decision about participating in this study. Ask your study doctor or the study staff to explain any words or information you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see if lifestyle changes can protect memory and thinking (cognition) as we age. A recent study in Finland found that a combination of physical and cognitive exercise, diet, and social activity protected cognitive function in healthy older adults who were at increased risk of significant memory loss. So far no medications can rival this positive outcome. The point of POINTER is to test if lifestyle change can also protect against memory loss in Americans.

WHO IS SPONSORING THIS STUDY?

The Alzheimer's Association is sponsoring this study. The researchers will not financially benefit from this study.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

2000 people at 5 sites across the United States will take part in this study, including about 400 people in your area.

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HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for about 2 years. You can stop participating at any time.

WHAT IS INVOLVED IN THIS STUDY?

You will be randomized into 1 of 2 groups. Randomization means you are put in a group by chance, like flipping a coin. You will be put in either the Self-Guided Lifestyle Group (see *Appendix A*) or the Structured Lifestyle Group (see *Appendix B*).

CLINIC VISITS: BASELINE, 6, 12, 18, AND 24 MONTH VISITS

You will be asked to come to the clinic for the Baseline Visit (this visit), and every 6 months for 2 years. Some visits are about 2 hours long. Some visits are about 6 hours long and may take place over 2 days. Visits will be the same for both the Self-Guided Lifestyle Group and the Structured Lifestyle Group. Each visit will be a little bit different. Here are the things that will happen over the course of the 5 visits:

Memory Tests

At ALL visits, we will ask you to complete tests about your memory and thinking abilities. Some tests will involve paper and pencil, and some will be on a computer or iPad.

Personal Information

At some visits, we will ask you to give us some personal information such as:

- Your contact information and the contact information of a family member or friend. This person will give us some information about your health. If you are not able to provide contact information for a family member or friend, you will still be able to participate in the study.
- Any new health events, like a new diagnosis or a hospitalization.
- A list of all of your medications (prescription and non-prescription).
- Information about things like your physical activity, mood, sleep patterns, and the foods that you eat.

Physical Tests

At some visits, we will ask you to do things that test your physical abilities, like your balance. For example, we will ask you to walk a short distance without assistance. We will also ask you to stand up from a chair without using your arms.

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Medical Checkups

At some visits, we will complete a short medical checkup where we measure things like your height, weight, waist circumference, blood pressure, and heart rate. At the Baseline Visit we will also perform an electrocardiogram (ECG) to check your heart.

Blood Samples

At clinic visits, we will ask you to give a blood sample. We will use a needle to draw 3 to 5 tablespoons of blood from your arm. Before some of these visits, we will ask you to fast (consume no food or drink other than water) for 10 hours before your appointment. If the visit takes place over 2 days, you will not need to fast before the second day. After we draw your blood, we will give you a snack before you continue your visit.

We will use this blood to measure things that naturally occur within your body like blood sugar and cholesterol. We will also use a portion of this blood for genetic testing to determine your apolipoprotein E (ApoE) genotype and for DNA storage to advance science related to aging and Alzheimer's disease (AD).

If you give us permission, we will also store some of your blood for future research studies.

AUDIO

As part of this study, you may be audiotaped. We keep these recordings for study reports to make sure that the examiners are administering the memory tests the same to everyone. You may request that you are not audiotaped. You should also understand that you will not be able to inspect, review, or approve the audiotapes before they are used in this study.

HOW WILL I BE CONTACTED?

While you are participating in the study, you will be contacted by POINTER study staff and by your Intervention team.

You may be contacted in the following ways:

- Text messages
- Phone calls
- Email
- Through an app on your smartphone or tablet (if you have one)

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If you have a smart phone, tablet, or iPad, you will be asked to install an application ("app") to help track your progress. Depending on the settings used on your phone or tablet, messages received through the app may appear on your device as soon as they are received, even when it is locked. These messages could be seen and read by others who are near your device when the messages are received.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

We hope the information learned from this study will benefit other people in the future. If you join this study, there could also be direct benefit to you, such as:

1. You will receive medical checkups and the results will be provided to you.
2. You will receive memory checkups and the results will be provided to you at the end of the study.
3. You will have access to a lifestyle coach to help you make lifestyle changes.
4. You will be provided with tools and support to help you accomplish your lifestyle goals.

WHAT ARE THE RISKS OF BEING IN THIS STUDY?

The risk of harm or discomfort that could result from being in this study is not expected to be more than in daily life or from routine physical or psychological exams or tests. If you have any questions, you should discuss them with the study staff. Here are the risks of participating:

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1. Cognitive testing may cause some people to get frustrated or tired. You have the right to decline to answer any questions that make you feel uncomfortable.

2. The blood draw may cause discomfort, bruising, and/or bleeding where the needle is inserted. Some people become dizzy, lightheaded, or feel faint. Infection may occur on rare occasions.

3. There is a risk of losing your balance and falling during physical testing at clinic visits. We will minimize the risk by being at your side if you need assistance.

4. There may be some discomfort related to physical activity. This could include some muscle and joint stiffness. This stiffness usually improves in 1 or 2 days and is not considered to be serious.

5. There is a chance that you may experience a health event when you participate in physical activity. This may include abnormal blood pressure, fainting, high heart rate, and, in rare instances, heart attack. Every effort will be made to minimize these risks by going over information about your health and fitness before activities begin.

6. There is always a slight risk of a breach of confidentiality. Taking part in this study may involve providing information that you consider confidential or private. We will keep your records secure and allow only authorized people to have access to research records. We will do our best to protect your confidential information.

7. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins, and supplements you take and any medical conditions you have. This may help avoid side effects, interactions, and other risks.

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A committee of health experts chosen by the Alzheimer's Association called the Data and Safety Monitoring Board will be reviewing all study activities regularly to make sure that the risks and benefits being described to you are true.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. The other option is to not participate. You do not have to be in this study to make lifestyle changes. You should talk to your doctor or other specialists in the community, such as a health coach or dietitian, about other choices you can make to have a healthier lifestyle.

WHAT IS THE COST TO JOIN THIS STUDY?

There is no cost to join this study. Costs for your regular medical care that are not related to this study will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid for each of your clinic visits that you complete. This payment is to cover the cost of your time and transportation. This will total up to $275. Here is the schedule for these payments:

Baseline	$75
6 Month	$25
12 Month	$75
18 Month	$25
24 Month	$75

To receive payment, you must provide your social security number, name, and address so that we can follow the IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information, you can still take part in this study but you will not be paid.

WHAT ABOUT MY HEALTH INFORMATION?

What is Protected Health Information (PHI)?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information (PHI). The information we will collect for this

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research study includes**:** your name, address, Social Security Number, phone number, date of birth, medical data, and laboratory results.

Will my PHI remain confidential?

We will make every effort to keep your PHI private. We will store records of your PHI in a cabinet in a locked office or on a password protected computer. Your identity and your PHI will not be shared unless it is required by law, it is necessary to protect the safety of yourself or others, or if you give us permission to share it.

Who has access to my PHI?

Your PHI may be given to others during and after the study. This is for reasons like carrying out the study, determining the results of the study, making sure the study is being done correctly, providing required reports, and getting approval for new products. Some of the people, agencies and businesses that may receive and use your PHI are:

- POINTER Investigators and staff
- Study doctors
- The Alzheimer's Association and their staff
- Representatives of the Alzheimer's Association assisting with the research
- Investigators at other sites who are assisting with the research
- Laboratories, reading centers or analysis centers
- Other companies who are assisting with the research, like Wellpepper
- The Institutional Review Board
- Representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital
- Representatives from government agencies that review our study for safety.

Some of these people, agencies and businesses may further share your PHI if they need to. Once they share your information, it may no longer be covered by federal or state privacy rules.

We might also have to share your information if required by law. If required by law or court order, we might have to share your PHI with a judge, law enforcement officer, government agencies, or others. If your PHI is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your original medical record for verification of clinical trial procedures or data, without violating your confidentiality and only to the extent permitted by other applicable laws.

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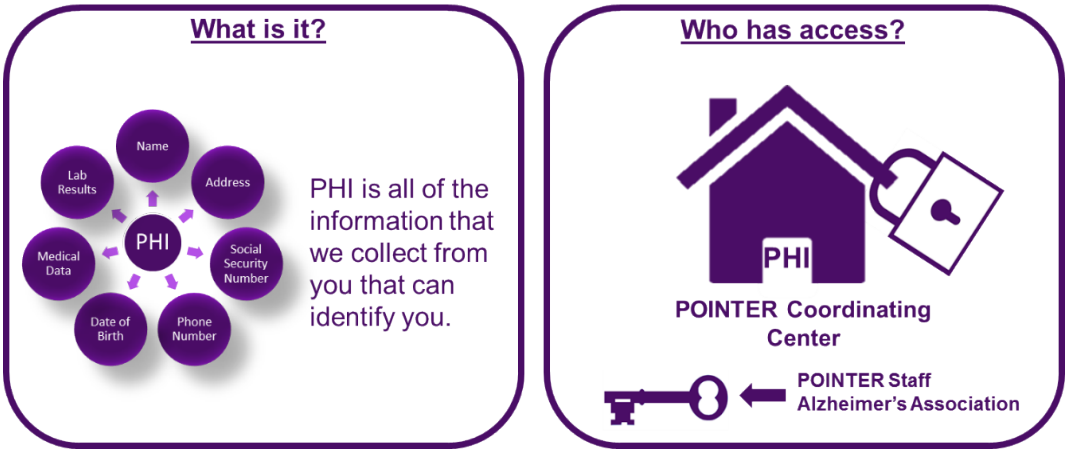

How long will you keep my PHI?

We will keep your PHI for at least two years after the study has ended, although by joining the study you are giving us permission to keep your information for as long as we need it. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your PHI in the research records until all activities in the study are completely finished.

What about my medical record?

If you choose to be in this study, your medical record at *[INSTITUTION NAME]* will show that you are in a research study. Information about our research may also be included in your medical record. Only people who normally have access to your medical record (like your doctor or nurses) will be able to see this part of your medical record.

If you are not a patient at *[INSTITUTION NAME]*, a medical record will be created for you anyway to make sure that this important information is available to doctors in case of an emergency.

Your laboratory test results and other medical reports created by this study may be entered into the computer systems of *[INSTITUTION NAME]*. Like all your other information, we will keep this data as safe and private as possible. Only people who have been trained to keep your information safe will be able to see these results, but they may not be directly involved with this research study. For example, they might work at a blood laboratory that we partner with.

Do I have to share my PHI with you?

No. You can tell [Principal Investigator's Name] that you want to take away your permission to use and share your PHI at any time by sending a letter to this address:

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Principal Investigator Name
Address
City, State, Zip

However, if you take away permission to use your PHI you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the research study. By signing this form you give us permission to use your PHI for this study.

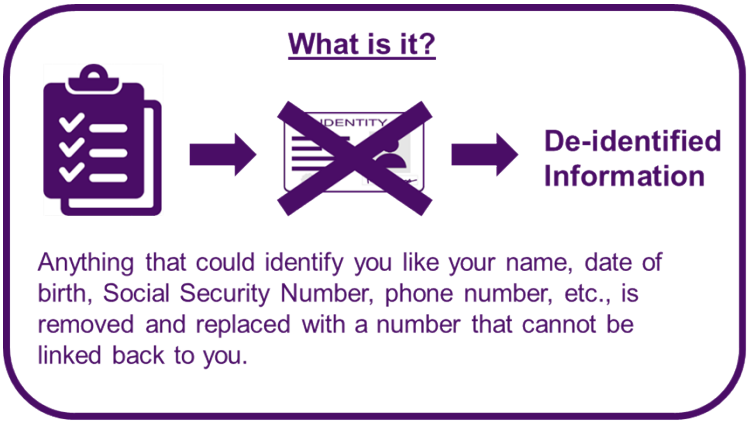
What is de-identified information?

Your PHI may be used to create information that does not identify you. This de-identified information will not include anything that could identify you such as your name, date of birth, address, or Social Security Number. Your identity will be replaced with an ID number that cannot be linked back to you. Any publication or presentation that may result from this study will only report de-identified information. There is always some risk that even de-identified information might be re-identified.

Who has access to my de-identified information?

Your de-identified information will be shared in a few ways:

- Your de-identified information will be shared on secure websites and research databases. For example, a description of this study will be on http://www.ClinicalTrials.gov, as required by U.S. Law. This website does 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.
- We will share the results of this study at scientific meetings and we will publish the data in scientific journals.
- Lastly, your de-identified information will be shared with researchers in the future. Researchers want to study your data to make new discoveries and help cure diseases.



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What is the difference between PHI and de-identified information?

De-identified information will not identify you in any way. Your identity will be replaced by an ID number that cannot be linked back to you. Protected Health Information (PHI) will include things like your name and address but this information will be heavily protected.

How will my blood and genetic samples be used?

During this study, blood samples will be collected from you for genetic and biomarker research. The samples will be sent to a laboratory at the University of Southern California for processing and storage.

Previous studies have shown that a gene called apolipoprotein E (ApoE) may affect the rate of dementia progression or a person's response to treatment. We will test your blood to see what form of the ApoE gene you have.

The results of these tests will be shared with a national database. These results are important only for research - not for helping to care for you. For this reason, the results will not be released to you or your family. No information regarding your genetic or

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biomarker research will be entered into your regular medical record or shared with other POINTER sites, insurance companies, employers, or other individuals or organizations. This research might help people who have memory loss, dementia or other diseases at some point in the future.

Will my samples be used in future research?

If you agree, future researchers will use your blood and genetic samples. Your samples will be coded. Your name, address, social security number, etc., will never be shared with future researchers and neither will the information that links the code with your identifiable information. Only researchers that have their research approved by the U.S. POINTER Steering Committee and Institutional Review Board (IRB) may use your coded sample.

In the future, researchers may like to know more about your health. Your samples will be stored as long as researchers need them. More research may be done on your coded samples at a future date. You will not be notified when this additional research is done, and we will not ask for your permission again. While future researchers may be given reports about your health, they will not be given any identifying information about who you are, unless you agree to be contacted in the future by the Principal Investigator or other researchers.

WHAT HAPPENS IF I GET INJURED OR SICK FROM BEING IN THIS STUDY?

EACH SITE MUST USE THE LANGUAGE PROVIDED BY THEIR SPECIFIC INSTITUTION

If you think you are injured or become sick because you are taking part in this study, you should contact us.

You do not give up any legal rights if you join POINTER. For more information on medical treatment for research related-injuries or insurance information you should call *PI's Name* at *telephone number (also include after-hours number)*.

DO I HAVE TO BE IN THE STUDY?

No. Being in this study is voluntary. You may choose not to take part or you may leave the study at any time, but if you are thinking about stopping the study, you should talk to POINTER study staff first. If you don't join the study or leave the study at any time, your normal medical care will not be affected. We will always give you any new information we find that might make you want to stop being in the study. Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens the reasons will be explained.

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WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about the study or you have an injury caused by the study, please call our team at [INSTITUTION NUMBER XXX-XXX-XXXX]. If you have concerns about your information privacy, your rights when you are in the study, or any problems you experience, you should call the Institutional Review Board (IRB). The IRB is a group of people who review the research to protect your rights. You can call the Chairman of the IRB at [redacted].

PARTICIPANT'S STATEMENT OF CONSENT FOR U.S. POINTER

I have had the opportunity and enough time to review the study information and ask questions about this study, and my questions have been answered. I understand the study, and I have been informed of the possible risks and benefits of taking part in this study. I am willing to be assigned to either group.

Participant Name (Printed):_____

Participant Signature:_____

Date:_____Time:_____

Person Obtaining Consent Name (Printed):_____

Person Obtaining Consent Signature:_____

Date: _____Time:_____

Please review each question below and place your initials in the space that goes with your answer. You can still participate in this study even if you answer NO to any of the following questions.

AGREEMENT TO REPORT RESULTS TO YOUR DOCTOR

Do you agree to have medical results from your study tests or exams reported to your doctor?

_____ YES _____ NO

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AGREEMENT TO REPORT COGNITIVE CHANGES TO YOUR DOCTOR

Do you agree to have test results reported to your doctor if there is a concerning change either in your cognitive function or in your mood?

_____ YES _____ NO

AGREEMENT TO CONTACT ME FOR FUTURE RESEARCH STUDIES

Do you agree to be contacted for future research studies?

_____ YES _____ NO

AGREEMENT TO STORE MY BLOOD FOR FUTURE RESEARCH STUDIES

Do you agree to provide blood to be stored for use in future research?

_____ YES _____ NO

AGREEMENT TO PARTICIPATE IN FUTURE GENETIC RESEARCH

Do you agree to allow your genetic sample (DNA) to be used in future research?

_____ YES _____ NO

AGREEMENT TO LONG TERM FOLLOW-UP

Do you agree to allow the POINTER study team to collect data from your medical records, health care provider, or national research databases until 2032?

_____ YES _____ NO

AGREEMENT TO SHARE MY DATA WITH NATIONAL DATABASES

Do you agree to allow your data to be shared with national research databases?

_____ YES _____ NO

AGREEMENT TO AUDIOTAPE ME FOR FUTURE STUDIES

Do you agree to allow audiotapes of you to be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB? (You will not be able to inspect, review, or approve their future use.)

_____ YES _____ NO, destroy audiotapes of me once their use in this study is finished.

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Appendix A: Self-Guided Lifestyle Group

If you are randomized (like flipping a coin) to the Self-Guided Lifestyle Group, you will create your own lifestyle program that will fit your needs and schedule.

You will be assigned to a Lifestyle Navigator and to a Team of about 12 participants who are all in the same group. The Navigator will work with you to help plan your self-guided lifestyle program and to provide support and tools as needed. You will go to 5 Team meetings during the 2-year study: 3 meetings in the first year and 2 meetings in the second year. The Navigator will lead these meetings, which will be held at a neighborhood facility.

You will get gift cards during Team Meetings that can be used to buy items to support your self-guided lifestyle program, such as specific foods, cookbooks, activity trackers, or tickets to cultural events.

PHYSICAL EXERCISE

During Team Meetings, the Navigator will give you information about health-related topics like physical exercise. The Navigator will also help you to create individualized plans and will be there for support as you work toward your goals.

HEALTHY EATING

The health information given during Team Meetings will also focus on diet. The Navigator will help you find ways to add more heart-healthy foods into your diet.

COGNITIVE EXERCISE

During Team Meetings, you will be encouraged to find new activities that are social and mentally stimulating. You will also receive information on events happening in your area that might be of interest to you.

HEALTH CHECKUPS

You will have blood collected twice per year to measure blood sugar and cholesterol. You will be encouraged to check your blood pressure on a regular basis.

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Appendix B: Structured Lifestyle Group

If you are randomized (like flipping a coin) to the Structured Lifestyle Group, you will follow a structured program that includes weekly assignments that will help improve your health.

You will be assigned a Lifestyle Navigator and to a Team of about 12 participants who are all in the same group. The Navigator will work with you to assist you in completing your weekly assignments.

You will go to Team Meetings led by the Navigator and a health professional (called an "Interventionist"). These meetings will take place at a neighborhood facility every week during the first 4 months, 2 times per month in months 5 and 6, and once per month for the rest of the study. The Navigator will check in with you on a regular basis.

PHYSICAL EXERCISE

You will follow a structured program that includes exercise 4 times per week for about 45 minutes each time. You will be asked to keep track of the length and difficulty of each exercise session and will be given a wrist monitor (like a watch) that will record information about your physical activity and heart rate throughout the day.

HEALTHY EATING

An Interventionist will help you follow a healthy diet by checking in with you during regular phone calls and at Team meetings. You will be asked to keep track of the foods you eat while you are in the study.

COGNITIVE EXERCISE

You will do cognitive exercises using a computer or tablet 4 times per week for 30 minutes each time. These exercises can be done at home or wherever you can access the internet. At Team Meetings, you will be encouraged to find new activities that are social and mentally stimulating.

HEALTH CHECKUPS

You will have a checkup every 6 months with a Medical Advisor that includes a review of your blood sugar, cholesterol, and blood pressure measurements. In addition, you will check your blood pressure monthly and review the results with your Navigator every 3 months.

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