Alzheimer's Disease Cooperative Study
UC San Diego

Protocol Title:

Therapeutic Effects of Exercise in Adults with Amnestic Mild Cognitive Impairment

Protocol Short Title: EXERT
Protocol Number: ADC-041-EX

Informed Consent Form (ICF)

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Informed Consent to Participate in the Research Study Referred to as:

EXERT

This consent form describes a research study and your role as a research participant. This document is intended to inform you about the possible risks and benefits of the research study, other options that may be available to you and your rights as a research participant. Please read this consent form carefully and do not hesitate to ask the study doctor or study team any questions you may have about the study or the information provided below.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family and friends. The decision to participate or not is yours to make. If you choose to participate, you have the right to withdraw from the study at any time.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify you. The web site will only include a summary of the results when they become available. You may access this web site at any time.

Investigator(s)
Sample A Doctor, M.D.
Sample B Doctor, Ph.D.

Location
Site Address
Site Address
Site Address
Site Address

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Therapeutic Effects of Exercise in Adults with Amnestic Mild Cognitive Impairment

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ADC-041-EX

EXERT is being conducted by the Alzheimer's Disease Cooperative Study (ADCS), in conjunction with Wake Forest School of Medicine and the national office of the YMCA (Y-USA), through a grant from the National Institute on Aging (NIA).

Why Is This Study Being Done?

Exercise programs may improve memory and thinking abilities for adults with mild memory loss. The purpose of this research study is to examine the effects of stretching, balance, and range of motion exercise versus moderate-to-high-intensity aerobic exercise on memory and thinking skills. The effects of exercise on brain volume and blood flow, and on production of certain proteins and hormones in the body and brain will also be examined.

How Many People Will Take Part In This Study?

Up to 300 adults between 65 and 89 years old and with mild memory loss will be taking part in this study.

What Is Involved In The Study?

Your participation will involve coming to the clinic for up to 7 visits (including this visit for screening) over the next 22 months, and visiting the YMCA 4 times per week for 18 months. During this time you will be asked to:

- Be willing to participate in EITHER exercise group and complete only the assigned exercise activities while enrolled in the study
- Complete your assigned exercise program 4 times per week at a participating YMCA for 18 months
- Give blood samples (5 times)
- Receive brief physical and neurological exams (4 times)
- Take tests of memory and thinking, and complete questionnaires about your memory, mood, and daily activities (5 times)
- Receive a resting electrocardiogram (EKG) (1 time)
- Complete a timed 400 meter walk test (4 times)
- Receive a brain scan using magnetic resonance imaging (MRI) (2 times)
- Receive a lumbar puncture (LP) (2 times) (this procedure will be 'optional')

To participate in this study, you must be able to identify an individual (spouse, friend, or relative), called a "Study Partner," with whom you have contact on a weekly basis and who is willing to:

- Accompany you to most clinic visits
- Answer questions about your memory and daily functioning
- Complete a questionnaire about his/her own general health status and quality of life

As part of this research study, we will record your responses during some of the memory and thinking tests to make sure your responses are captured exactly as you say them. You will not be able to inspect, review, or approve the content of the audiotapes. You may request the recording be stopped at any time, and you can withdraw your consent to use the recorder before any information is transferred to a written form. All recordings will be erased once the data is reviewed for accuracy.

EXERT Exercise Programs

If the screening evaluations show that you are eligible to enroll into the study and your doctor has indicated that it is medically safe for you to do so, we will randomly assign you to one of the following physical activity groups: a stretching, balance, and range of motion (SBR) group or a moderate/high-intensity aerobic exercise (AX) group. You will have an equal chance (like flipping a coin) of being in either group.

You will come to the YMCA to exercise 4 times per week for 18 months. An individualized exercise program will be developed for you by our trained staff. A personal trainer will supervise the first 8 exercise sessions that you complete during the first 2 weeks of the program. After this time, your

Trainer will supervise 2 of your 4 weekly sessions through Month 12. At this time, you will 'graduate' to independent exercise and continue your assigned exercise program for the final 6 months of the study – without supervision. Whenever possible, your Trainer will provide supervision to small groups of participants (2-4 people) who have been assigned to the same group.

During your supervised sessions, your progress through the study will be regularly reviewed by the Trainer and your goals will be assessed and adjusted as needed. Any concerns about your exercise program can be discussed with your Trainer during these appointments. At any time during the study, our staff members will also be available to answer questions.

All participants will be asked to maintain an activity diary (Physical Activity Log) that will be completed at every session. This diary will contain information about when and how long you exercised, and what activities you completed. This diary will be reviewed by the YMCA Trainer during supervised sessions, and by the study staff during your clinic appointments.

All participants will also receive a heart rate monitoring device to wear while exercising. The heart rate monitor includes a watch-like device and a chest strap, and will be used to help make sure your heart rate goals are met and that physical exertion is completed at a safe level.

When you begin exercising, your activities will be increased gradually, starting at about 15-20 minutes per session and increasing to 45 minutes per session over the first 6 weeks, which you will then continue for the remainder of the study. It will be important that you try your best to complete the majority of your exercise sessions to make sure that you receive the right 'dose' of exercise while in this study. If you plan to travel during the 18-month study, we will work with you to come up with an alternate plan for exercise so that you can continue to meet your study goals while you are away.

- **Stretching, Balance, and Range of Motion (SBR) Program**

  The SBR program is designed to help you increase your flexibility and balance, and to help your joints work better. It consists of stretching, balance, and range of motion activities for the whole body, which will include some yoga poses that are designed for older adults. Your Trainer will provide instruction about how to safely complete all of your exercises. All SBR exercise sessions will include warm-up and cool-down activities, and will be adapted to meet any specific physical limitations. Once you become familiar with your exercises and show that you can consistently meet study goals, you will be provided with the opportunity to participate in approved YMCA stretching, balance, range of motion, and gentle yoga classes.

- **Aerobic Training (AX) Program**

  The AX program will consist of walking on a treadmill or an elliptical trainer, or cycling on a stationary bicycle. Each exercise session will include warm-up and cool-down periods. Exercise intensity will be gradually increased until the individualized target heart rate "training zone" is reached. This training zone is determined using your age and resting heart rate. The

training zone will be altered as needed by your Trainer to ensure that exercise can be completed comfortably and safely, and at the right 'dose' throughout the study.

Description of Study Visits

Screening (Visit 1)

During your **Screening** appointment we will determine your eligibility to enroll in EXERT. This visit may be conducted over multiple days. You and your study partner must first sign this consent form before any other screening procedures can be completed. The study staff will explain all of these procedures and answer any questions that you and your study partner may have.

It is important that you are fasting for this in-person screening visit so that the blood tests provide the most accurate assessment of your overall health. You should not have consumed any food or drink, except water, for the 12 hours before you arrive. We will give you a snack after blood collection. If you are not fasting, we may ask you to return to the clinic at another time for your screening blood tests.

The following tests and procedures will be performed during this screening visit:

- Your general medical history will be recorded. We may request additional records if we have questions about your medical history. We will ask you to sign a 'Release of Information' form to obtain these medical records, if needed.
- We will review your current medications.
- You will receive brief physical and neurological exams.
- Your weight, height and vital signs (blood pressure, heart rate, temperature, and respiration rate) will be measured.
- We will collect about 3 tablespoons of blood from your arm for routine laboratory tests to make sure you have no medical conditions that prevent your participation in this study.
- We will use a portion of the blood that we collect 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).
- We will ask you to complete questionnaires about your memory and thinking skills, about other activities you complete throughout the day, and about your mood.
- You will be asked to complete a timed 400 meter walk test using our walking course. We will measure your heart rate and breathing rate before, during, and after the walk to estimate your current physical fitness level.
- An electrocardiogram (EKG) will be performed. An EKG is a tracing that measures electrical signals of your heart.
- If you meet all other qualifications for enrollment into EXERT, you will receive a brain scan using magnetic resonance imaging (MRI).
- Following completion of screening you will wear a wristwatch like device (called an ActiGraph) continuously for 10 days, day and night, without taking it off, so that we can measure your total

activity. The ActiGraph is waterproof. You should keep it on while bathing, swimming and doing household chores that involve water, such as washing dishes. We will provide you with an addressed and stamped envelope to return the device to the clinic at the end of the 10-day period, or you will bring it back to the Baseline appointment.

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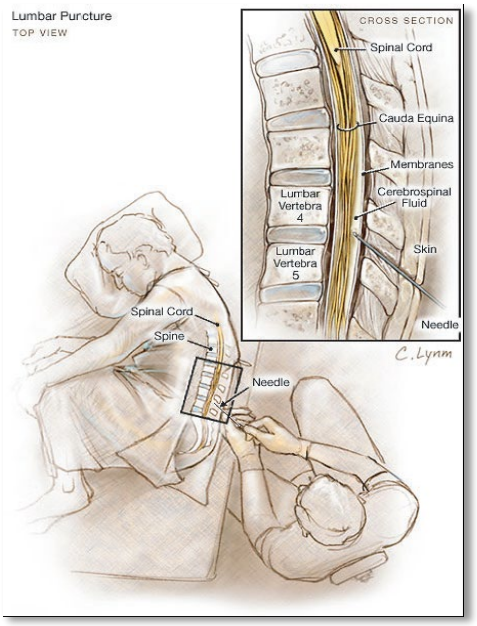
- We will give you a letter to inform your primary doctor of your participation in the EXERT study.

Baseline (Visit 2)

Baseline procedures may be completed over multiple days, and before you can be assigned to one of the 2 exercise groups. The Baseline procedures include:

- We will measure your weight and vital signs.
- We will review your medications.
- We will collect about 3 tablespoons of blood from your arm. You will be required to fast for 12 hours overnight prior to blood collection.
- We will review any changes in health that you may have experienced since the last clinic visit.
- You will complete tests of memory and thinking, and questionnaires about your memory, daily activities, and mood.
- Your study partner will be asked questions about your memory and thinking skills, and will be asked to complete a questionnaire about his/her own overall health and quality of life.
- You will be asked to undergo a lumbar puncture (LP). This procedure will allow us to examine the fluid that surrounds your spinal cord and brain that contains important proteins and hormones to help us better understand the impact of exercise on the health of your brain. The LP is an optional procedure. Prior to the LP, you will be asked to avoid food and drinks except water. At the start of the procedure, you will be positioned sitting up and bent forward, or lying on your side with your knees bent (see picture). The lower part of your back will be cleaned with antiseptic. The study doctor will inject local anesthetic (lidocaine, 1%) into the skin of your lower back. When the area is numb, a very thin needle will be inserted into the spinal canal in the lower back, well below the level where the spinal cord ends. A little over 2 tablespoons of spinal fluid will be removed for analysis and storage. Your body replaces this spinal fluid within 1-2 hours. After the LP is completed, we will ask you to remain in the clinic for about 60 minutes, where you will rest comfortably in a bed. You should not do any strenuous physical activity for 24 hours, which includes lifting, bending, housework and gardening, or your study exercises.



- You will have an equal chance of being assigned to 1 of 2 exercise groups. The study staff will provide information about your group assignment and your study responsibilities. You will receive contact information for your personal Trainer at the YMCA, and a 6-month supply of activity diaries (called "Physical Activity Logs") to record information about your exercise.
- You will be asked to sign a document indicating your willingness to complete the clinic visits and the assigned exercise program as instructed for the duration of the 18-month trial.
- Your first appointment at the YMCA will take place within 2 weeks of your last Baseline procedure. During your first appointment at the YMCA, you will receive a tour of the facility, review the study exercise goals with your Trainer and other YMCA staff, receive a heart rate monitor and instructions about how to use the device, and your personal training appointments will be scheduled.

Month 6 (Visit 3)

This visit will be completed 6 months from the time you start your exercise program at the YMCA, and may be completed over multiple days. You will be asked to fast for 12 hours prior to the visit, to avoid exercise for 24 hours prior to the visit, and to bring your heart rate monitor to the clinic. The following tests and procedures will be conducted at Month 6:

- We will review your medications.
- You will receive brief physical and neurological exams.
- Your weight and vital signs will be measured.
- We will collect about 3 tablespoons of blood from your arm.
- You will be asked about any adverse events (changes in health or any side effects) that you may have experienced since the Baseline clinic visit.
- We will ask you to complete tests of memory and thinking, and complete questionnaires about your memory and other daily activities, and about your mood. Some of your responses will be recorded with a digital recorder so that we can accurately document your exact words.
- You will be asked to complete a timed walk test using our walking course.
- We will replace the battery in your heart rate monitor.
- We will review your Physical Activity Logs that you completed over the past 6 months, and we will give you another 6-month supply of these diaries.
- Your study partner will be asked questions about your memory and thinking skills, and will complete questionnaires about his/her own overall health and quality of life.
- You will wear the wristwatch-like ActiGraph device continuously for 10 days. We will provide you with an addressed and stamped envelope so that you can return the device to the clinic at the end of this period.

Month 12 (Visit 4)

This visit is completed 12 months from the time you started your exercise program at the YMCA. This visit may be completed over multiple days. You will be asked to fast for 12 hours prior to your appointment, to avoid exercise for 24 hours prior to your appointment, and to bring your heart rate

monitor to the clinic for battery replacement. The Month 12 tests and procedures are the same as those described for Month 6 with the addition of an MRI (see Visit 1 description) and a lumbar puncture if you previously agreed to complete this procedure (see Visit 2 description). About 3 tablespoons of blood will be collected from your arm at this visit.

Month 18 (Visit 5)

This visit is completed 18 months from the time you started your exercise program at the YMCA. This visit may be completed over multiple days. You will be asked to fast for 12 hours prior to each appointment, to avoid exercise for 24 hours prior to each appointment, and to bring your Physical Activity Logs and heart rate monitor for battery replacement. The Month 18 tests and procedures are the same as those described for Month 6 (no MRI, no LP), however you will receive the watch-like ActiGraph device 14 days prior to your Month 18 visit so that we can record your total activity, day and night, before you return to the clinic for your last appointment. We will remove the device at that time. About 3 tablespoons of blood will be collected from your arm at this visit. At Month 18, we will also provide you with additional information about how to continue your exercises if you desire to do so.

Summary of Study Visit Activities

Visit	Screen I	Screen II	Baseline	Month 6	Month 12	Month 18
Obtain Informed Consent	X					
Obtain Medical History	X	X				
Medication Review	X	X	X	X	X	X
Brief Physical & Neurological Exams		X		X	X	X
Measure Vital Signs, Weight		X	X	X	X	X
Measure Height		X				
Fasting Blood Collection		X	X	X	X	X
Blood Collection for Genetic Testing & DNA Banking		X				
Adverse Event Monitoring			X	X	X	X
EKG		X				
Memory Testing, Questionnaires about Memory, Mood, & Everyday Function		X	X	X	X	X
Complete Research Satisfaction Survey			X	X	X	X
Study Partner to Complete Self-Assessment Questionnaire			X	X	X	X
400 m Walk Test		X		X	X	X
Magnetic Resonance Imaging (MRI)		X			X	
Lumbar Puncture (LP)			X		X	
Dispense/Review Physical Activity Logs			X	X	X	X
Actigraphy Recording using ActiGraph		X		X	X	X

How Long Will I Be In The Study?

You will be in the study for up to 22 months (including screening).

Early Discontinuation

Participation in this research study is voluntary. You can stop participating at any time without jeopardy to your current medical care. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

If you stop participating in the study for any reason, you will be asked to return to the clinic for a final evaluation visit. This final evaluation will include all of the procedures normally performed at Month 12 (Visit 4). It is important for the research, and for your health and safety to have these final procedures completed. Your participation in the study may be stopped by the study doctor or sponsor if you experience a medical condition that makes it unsafe for you to continue in the study.

If you choose to withdraw your permission, you must notify Dr. [Insert Site PI Name] in writing. Dr. [Insert Site PI Name]'s mailing address is:

[Insert Site Address]
[Insert Site Address]
[Insert Site Address]

Dr. [Insert Site PI Name] will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been sent to the sponsor cannot be withdrawn.

Genetic & Biomarker Research

During this study, blood and cerebrospinal fluid (CSF) samples will be collected from you for genetic and biomarker research. The samples will be sent to laboratories contracted for the study and to the ADCS Biomarker Core at the UCSD.

Previous studies have shown that a gene called apolipoprotein E ("APOE") may influence the rate of disease progression or a subject'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 maintained in scientific databases for this research study. 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 biomarker research will be entered into your regular medical record. Data from your tests will not be revealed to other sites that are participating in the clinical study, family members, insurance companies, employers, or other individuals or organizations.

Although the study researchers and the study sponsor will have access to coded individual data, any information gained from this research will be reported in publications in an anonymous summary form. Data will be stored in a locked file, and in a computer with restricted access. Any information that could be used to potentially identify you in the computer will be stored in a separate file and encrypted. Only the researchers and their research assistants will have access to the original research data.

Your samples will be stored for up to 20 years. More research may be performed on your samples at a future date. You will not be notified at the time this additional research is conducted, nor will any additional informed consent be obtained. You will not be contacted in the future to provide any further information.

DNA, Blood, and Cerebrospinal Fluid Storage & Future Use

With your consent, we would like to store your DNA sample for future research studies related to Alzheimer's disease and other neurodegenerative disorders. If you decide you do not want to have your DNA sample stored for future research, you may still participate in this study.

Storage of your remaining blood samples and CSF (if a lumbar puncture was completed) are required for this study. If you decide that you do not want your blood or CSF samples stored for future research, you may not participate in this study.

Your samples will be stored by code number and no identifying information will be included with them. Samples will be stored indefinitely at the ADCS Biomarker Core and may be shared with other researchers studying AD or aging.

By signing this consent form, you give the Sponsor and other commercial or academic third parties that collaborate with the Sponsor, permission to use the material obtained from your sample for research. At any time for any reason, you may withdraw consent for this genetic testing and request that your sample be destroyed with no further testing being performed.
If your samples are sent to other researchers, they will be identified only by a code number and descriptive data (such as your age and gender). No other personal identifying information will be attached to your samples, so it will not be possible to identify you from any of the samples.

MRI Image Storage & Future Use

Your MRI images will be sent to the ADCS and will be analyzed by researchers at other institutions. ADCS investigators will maintain your imaging data and be responsible for deciding how it will be used for future research.

Study investigators may make some of this data available to investigators at other scientific institutions for research purposes. Your name and all links to your identity will be removed from the data before it is shared. Your imaging data will be labeled with a coded research identifier to protect your identity.

Will This Research Data Be Shared?

Data from this research will be shared with other researchers. Data sharing is important for further translation of research results into knowledge, products and procedures to improve human health. All links with your identity will be removed from the data before it is shared.

What Are The Risks Of The Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to your participation in this study are outlined below.

Risks of Blood Collection

Removal of blood by a needle and syringe poses a small risk of pain or bruising at the site of the needle stick, but this is temporary. Some people may experience fainting or dizziness, and there is also a slight risk of infection at the site of the needle stick. To minimize these risks, experienced medical personnel will collect all blood, and sterile conditions will be maintained. About 15 tablespoons of blood will be taken over the 18-month study and your body will readily produce new blood to make up for the loss.

Risks of Cognitive Testing

Repeated evaluations of mood and mental status may be slightly frustrating or produce fatigue and boredom.

Risks of EKG

There is no pain or discomfort during an EKG; however, removing the pads may cause some irritation to your skin.

Risks of Brain Scans using MRI

An MRI may cause possible discomfort for people due to the loud banging made by the machine and the confined space of the testing area. You will be given earplugs or headphones to reduce the noise. If you experience a fear of the confined space while in the scanner, you can stop the test and trained medical personnel will help you out of the scanner.

People with pacemakers, aneurysm clips, artificial heart valves, ear implants or metal/foreign objects in their eyes are not permitted to have an MRI.

Risks of Lumbar Puncture

During and after the procedure, you may have temporary pain and discomfort in your neck and back pain due to the positioning required for the procedure. Lightheadedness or feeling faint may also occur. Headache may occur in people who receive an LP. Occasionally, a mild headache may develop, presumably due to leakage of spinal fluid. If this headache persists it may require additional treatment. Uncommonly a blood patch (injection of some of your blood into the puncture site to patch the spinal fluid leak) may be required. This often relieves the headache immediately.

Although very rare, it is possible that you may have an allergic reaction to the local anesthetic (lidocaine l%) used for the LP. This would cause swelling and a rash on your skin where the anesthetic was injected. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist). Potential but rare risks of lumbar puncture include infection, damage to nerves in your back and bleeding into the spinal fluid space. The risk of these is very small. To minimize these risks, the LP procedure will be performed by experienced medical professionals who are specifically trained to carry out this procedure.

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

Risks of Physical Activity

As with any form of exercise, there is a possibility of injury and/or bodily discomfort. It is possible that during or after exercise, you will experience muscle soreness, joint pain, stiffness, swelling or muscular fatigue. Additional risks could include, headache, abnormal blood pressure, fainting and in rare instances – heart attack, stroke, or death. Every effort will be made to minimize potential risks by gradually increasing exercise intensity, and by providing you with education about the proper way to exercise. Emergency equipment and trained personnel will be available at the YMCA to deal with unusual situations that may arise during exercise.

Risks of Genetic Testing

Under some circumstances, it can be a risk for genetic information to be known by others. Variation in some genes is known to be directly related to risk of certain illnesses. In some cases, knowledge of genetic information could have negative psychological consequences or could affect access to or retention of certain benefits or entitlements. For example, the information could potentially be used against subjects if it were revealed to insurance companies or potential employers.

A U.S. Federal law called the “Genetic Information Nondiscrimination Act” generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

You will not get the results of the genetic portion of the study nor will the results be made available in your medical record. Furthermore, the researchers have adopted strict privacy and confidentiality procedures for maintaining your genetic information as described in this consent form.

Risk of Rejection for YMCA Membership

As part of the membership process at the YMCA, all potential participants will be checked against a National Sex Offender Registry. If a potential participant is found to be a registered sex offender, they will not be eligible for membership at the YMCA, and will not be permitted to continue in EXERT. This may result in causing you embarrassment or frustration. The results of this check will be kept completely confidential, and as explained in the confidentiality statement of this consent, we do not intend to disclose this information outside of this study.

Are There Benefits To Taking Part In The Study?

You will receive an 18-month membership to a participating YMCA for exercise. You will also receive a personal trainer who will oversee your exercise in the first 12 months of the study. You may experience improvements in your physical fitness as a result of your participation in either exercise program. Your blood test results will be provided to your primary care provider upon your request. Your participation will also help us understand how exercise affects memory and thinking skills in people with mild memory loss.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

Will My Medical Information Be Kept Private/Confidential?

Research records will be kept as confidential as possible within the limitations of state and federal law. The study staff and sponsors will handle your personal health information in a confidential manner.

Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. This includes information in your existing medical records needed for this study and new information created or collected during the study.

The persons and entities that you are authorizing to use or disclose your personal health information may include the:

- Study doctor
- Study staff
- The institution where this research is conducted
- The institution's Internal Review Board (IRB)
- The Alzheimer's Disease Cooperative Study (ADCS)
- Other ADCS research sites participating in this study
- Wake Forest School of Medicine (helps to coordinate this study)
- Laboratories used for this study

In order to analyze the data collected during this research study, all of the health information generated or collected about you during this study may be inspected by the study Sponsor and its authorized agents, the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies and the Institutional Review Board (IRB).

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. Once your personal health information is released it may be re-disclosed, at which point your health information will no longer be protected by federal privacy regulations.

To help us protect your privacy, a Certificate of Confidentiality has been provided for this study by the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below). The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is used for auditing or evaluation of Federally-funded projects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an

insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state or local authorities of [INSERT STATE REQUIRED REPORTINGs; list what will be reported, such as child abuse and neglect, or harm to self or others for example].

This authorization will have no expiration.

What Are The Costs Of Taking Part In This Research Study?

There will be no costs to you for participation in this study.

Will I Be Paid For Taking Part In This Research Study?

You may receive up to [INSERT AMOUNT] for participation in this the study. This money covers the costs for time spent at the clinic and travel expenses to and from the clinic. [Sites to insert when payment will be received; after each visit or at the end of the study] In addition, at the completion of the Month 12 visit, you will receive a hand-crafted quilt, donated to the ADCS for study participants.

If you choose to leave or are withdrawn by the study staff before finishing all study procedures, you will be paid a lesser amount that is based on the number of completed visits or procedures.

What Happens If I Experience An Injury Or Illness As A Result Of Participating In This Study?

All forms of medical findings and treatments – whether routine or experimental – involve some risk of injury. In spite of all safety measures, you might develop medical problems from participating in this study.

You must report any suspected illness or injury to the study doctor immediately. If such problems take place, the YMCA or the [SITE INVESTIGATOR'S INSTITUTION] will provide emergency medical treatment and will assist you in getting proper follow-up medical treatment. Neither financial compensation nor reimbursement for such things as pre-existing conditions, illness or disease unrelated to study participation, lost wages, property damage, disability, or discomfort is available.

The National Institute on Aging and the Alzheimer's Disease Cooperative Study do not provide compensation for research-related injury. [SITES TO ADD INSTITUTION'S SUBJECT INJURY CLAUSE HERE (you will / will not pay for subject injury, etc)] By signing this consent form you do not give up any of your legal rights.

Who Do I Contact If I Have Questions Or Concerns About This Research?

If you have any questions regarding this research or if you believe that you may have experienced a research related injury, you should contact Dr. **[Insert Site PI Name]** (study doctor) at **[TELEPHONE]** to report this or other research-related problems.

STATEMENT OF CONSENT

You have read (or have had read to you) the description of EXERT. You have been informed of the risks and benefits involved, and all of your questions have been answered to your satisfaction. By signing this form, you voluntarily consent to participate in the research study and you authorize the use of your data, including bodily fluid samples, for the research described above.

Unless you authorize the use and disclosure of your personal health information, you cannot participate in EXERT. If you refuse to give your authorization, your medical care will not be affected.

You will receive a copy of this consent form.

	YES	NO	Participant Initials
You voluntarily agree to participate:	☐	☐	_____

Lumbar Puncture (optional)	YES	NO	Participant Initials
You agree to undergo a lumber puncture at Baseline, and at Month 12:	☐	☐	_____

Sample Storage	YES	NO	Participant Initials
You agree that your **DNA samples** may be stored and used for future research (optional):	☐	☐	_____
You agree that your **blood samples** may be stored and used for future research (NOT optional):	☐	☐	_____
You agree that your **CSF samples** may be stored and used for future research (NOT optional if lumbar puncture performed):	☐	☐	_____

Participant's Name (print)	**Signature**	**Date**
Person Obtaining Consent (print)	**Signature**	**Date**

Witness Name (print)	**Signature**	**Date**

STUDY PARTNER INFORMATION & CONSENT

As the participant's Study Partner, you have important tasks that need to be carried out in order for the study to be conducted in the safest and best manner possible. These responsibilities include:

- You must have regular weekly contact with the participant.
- You must be able to accompany the participant to most clinic visits.
- You are an important source of information about the participant. You must agree to be asked questions about your relationship with the participant, as well as his/her health, memory, daily functioning and behavior in order to find out whether there are any changes in the participant.
- You must be willing to complete questionnaires about your own general well-being, mood, and quality of life.
- You will not receive a YMCA membership for your participation as a Study Partner.

If for some reason you become unable to carry out your responsibilities, please tell the study team immediately. You may be asked to help select a substitute who can take over your duties.

You have read all the preceding information that describes both the participant's involvement and your role as Study Partner in EXERT. The study has been explained to you in detail, and all of your questions have been answered to your satisfaction.

	YES	NO	Study Partner Initials
You voluntarily agree to participate as a Study Partner:	☐	☐	_____

Study Partner's Name (print)	**Signature**	**Date**
Person Obtaining Consent (print)	**Signature**	**Date**

California Site Only: Insert the Experimental Bill of Rights