Why Participate in Research?

Right now, several thousand clinical trials are being conducted in the United States. Every day, data are collected and analyzed—the results of these efforts could one day improve the quality of life for you or a loved one.

What exactly is meant when “research” is involved? Put simply, the purpose of research is to answer a question. Scientists conduct research in situations where they are unsure about what works best to help someone—in the medical field, this research process is vital in order for patients to receive the highest quality of care. Clinical trials are among the fastest and safest ways to find treatments that work in people. For example, which drug treatment for Alzheimer’s disease is the most effective? How do the drugs work? Are there any side effects? What changes can we expect to see in a person after they begin these drug treatments? Answers to these questions would be impossible without the help of people who are willing to participate in these clinical trials.

Discoveries in the Making

Research participants play a very important part in the search for answers about some of the most serious diseases. Medical research has led to several discoveries which have improved quality of life and standards of medical care. It is because of past research that we are able to use x-ray machines, MRI scanners, vaccines for various illnesses, and many new drugs for the treatment of cancer, diabetes, and other serious diseases.

Before you decide to participate, it is important to ask certain questions and consider certain issues. One of the most frustrating aspects of research participation is “the unknown.” Scientists cannot guarantee that a research study will help you, specifically. The study findings may benefit people in the future—however, it may not benefit the participant while the study is ongoing. It is hard to do something when there’s no immediate payoff—if you give your time and energy to research, it is only natural to expect something in return. If the research does not end up helping you, it may help your children or your grandchildren. In any case, you have contributed to a very worthy cause, and your efforts contributed to the body of knowledge regarding the best way to treat patients. Above all, participation in a research project is voluntary—the decision to participate is up to you.

Participants in clinical trials have the advantage of taking a very active role in their own health care; in addition, it could be advantageous to have access to new research treatments before they are widely available to the public. Another benefit of clinical research is the exposure to medical care at leading health facilities during the trial. Many participants enjoy the opportunity to have consistent contact with medical practitioners who are leaders in their field at some of the world’s premier centers.
There are issues unique to individuals with memory changes and to their family members. We are trying to learn how to better address these issues by developing new services and providing support groups that meet the needs of individuals with memory problems and their families. We are involved in ongoing development of support groups to achieve these goals. Currently the following groups are available at our center:

**Caregivers Support Groups**
This small group is designed to provide answers to individual questions and concerns of caregivers as well as educational information. It also provides a network to offer support and guidance.

**Mild Cognitive Impairment Group**
This group is for individuals with a diagnosis of mild cognitive impairment (symptoms not meeting criteria for dementia) and their family members or friends. The main focus is on education, communication, management, and psychosocial concerns.

**Early-Stage Alzheimer’s Patient and Caregiver**
This group is for early-stage Alzheimer’s patients and their caregivers. It is designed to provide a forum for participants to discuss their concerns and ask questions about the illness. Sessions combine education, psychotherapeutic principles, and support to enhance understanding and coping mechanisms. Patients and caregivers meet simultaneously but separately.

**Alzheimer’s Treatment Consultation Group**
This group is designed for research participants and their caregivers. Dr. Shamala Kanchar answers questions about medical issues and medications. This is a drop-in group that meets every Wednesday from 10:00am - 11:00am.

Some of our basic goals include helping participants to:
- Develop new connections with fellow participants.
- Lessen feelings of isolation and being alone.
- Gain a better understanding of Alzheimer’s Disease and Mild Cognitive Impairment.
- Keep abreast of new research and possible treatments.
- Keep current with legal, financial, long term planning issues and community resources.
- Learn about opportunities for participation in research and community activities.
- Acknowledge personal strengths and positive aspects.
- Share information about what works and what does not work.

All groups meet at the Palo Alto VA Health Care System
3801 Miranda Ave., Bldg. 4, conference room A101
(650) 858-3915 or 493-5000, x 65051
http://arcc.stanford.edu/family.html

learning and research. The study team is also available to suggest a wide variety of resources to help with any concerns that the participant and caregiver are facing.

**Deciding to Volunteer**
What questions should you ask when you are considering participating in research? Before beginning the study, you should ask: What exactly will happen to me in this study? Are there any risks? Will there be any side effects? Will the research help me personally? What other options do I have? Can I leave the study at any time? Will it cost me anything? These and other guidelines for research participation can be found at http://humansubjects.stanford.edu/general/participants.html.

Your personal physician can also play a role in the clinical trial process. He or she may be a great source of information and advice – you can ask the doctor’s opinion when you are considering participating in a clinical trial, and his/her detailed medical knowledge can be helpful when making the decision to participate. Involvement in a clinical study does not substitute for continuing a course of medical care with your personal physician – you can and should continue to see your physician throughout the course of the study.

**Protection and Well-Being**
Participant safety is extremely important during clinical trials. The same ethical and legal codes that apply to medical practice also apply to clinical trials. Results of the research are reported as the study is ongoing, and the risks and benefits are constantly assessed. In addition, researchers take many precautions and are guided by several strict sets of rules regarding the protection of participant confidentiality.

It is important to realize that participation in a research trial is different from a treatment course that you may follow with your primary care physician. When you are a patient with your personal physician, you have a great deal of freedom in making choices together about your

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Spotlight: Leah Friedman, Ph.D.
Senior Research Scholar, Stanford University School of Medicine
Department of Psychiatry and Behavioral Sciences

On a typical day, you can find Dr. Leah Friedman in her office, with her research assistants, working intensely on various projects with a humor and enthusiasm that are contagious. Those who work closely with Dr. Friedman know that she is deeply invested in her research, not only for intellectual reasons, but out of her genuine concern for the welfare of her study participants, in particular, and older adults, in general. Her lively conversation, human warmth and keen awareness of modern culture defy the stereotype of the isolated research scientist.

Dr. Friedman earned her Masters degree in Counseling Psychology from Stanford University and her doctorate in Human Development and Aging from the University of California at San Francisco. Her research work has focused on understanding the causes and treatments for memory problems and sleep disturbances in older adults with and without Alzheimer's disease. Over the years, Dr. Friedman has conducted several studies on behavioral (non-drug) treatments for insomnia in older adults, investigating the effectiveness of therapies like sleep hygiene (that discourages behaviors that hinder sleep and encourages behaviors that promote sleep), sleep restriction and light therapy.

For the past four years, she has been serving on the standards of practice committee of the American Academy of Sleep Medicine. The charge of this committee is to use current research to derive standards of practice for diagnosing and treating various sleep disorders. In her work with this committee, she has been a co-author of several articles that make evidence-based recommendations to standardize the developing field of sleep medicine and to incorporate the latest research findings into clinical practice.

In addition to her interest in sleep, Dr. Friedman has devoted many years to the study of cognition and memory impairment in older adults. She has coordinated several projects studying memory training for older adults with memory complaints associated with normal aging. Dr. Friedman is especially interested in Mild Cognitive Impairment (MCI), a transitional type of cognitive and memory deficit that may be a precursor to the development of more severe problems like Alzheimer's disease. Some adults with MCI never go on to develop dementia. Along with Dr. Yesavage and other researchers at our Center, Dr. Friedman hopes to uncover the distinguishing biological and cognitive characteristics of individuals who eventually progress from the moderate memory complaints of MCI to a diagnosis of Alzheimer's disease, in order to develop interventions that may slow or stop this process altogether.

Currently, Dr. Friedman is coordinating a 5-year study investigating the effectiveness of light treatment on the sleep, cognition and quality of life in older adults with moderate to severe memory impairments, also focusing on their primary caregivers. Dr. Friedman works closely with each patient and caregiver encouraging them to learn and practice daily behaviors that should lead to less fragmented, more satisfying sleep.

This year we celebrate Dr. Leah Friedman's 20th year of involvement with our team at the Stanford/VA Aging Clinical Research Center! Through her strong work ethic and dedication to research, Dr. Friedman has been essential to our Center as we strive to come closer to a better understanding of the aging process. We hope she continues to be part of our team for many years to come. ✮
Memantine and Alzheimer's Disease Study

Is memantine effective in delaying, weakening, or preventing the progression of early Alzheimer's disease? Memantine or Namenda™, an anti-dementia drug, has been shown to be an effective treatment for some symptoms of moderate to severe Alzheimer's disease. Study participants are randomly assigned to receive memantine or placebo (inactive pill). Participants receive two MRI scans and are regularly monitored by physicians and qualified health care professionals who specialize in dementia during the 1-year research study.
Participants should:
- be aged 50-95
- have been diagnosed with probable Alzheimer's disease
- have someone who can be a study partner

To sign up for the Memantine and Alzheimer's Disease study
Contact: Aimee Stepp
(650) 849-1225

Alzheimer's Disease Neuroimaging Initiative (ADNI)

Do you want to help us learn how to stop the progression of Alzheimer's disease in future generations? The goal of ADNI is to help predict and monitor the onset and progression of Alzheimer's disease through regular brain imaging (MRI and PET scans). In addition, the study will collect and test blood, and, for some participants, cerebrospinal fluid to determine if biomarkers found in blood or spinal fluid can predict and/or monitor Alzheimer's disease.
You may be eligible to participate if:
- you are 76 or older, in good general health with no memory problems, OR
- you are between 55-90, in good general health with some memory problems or concerns, OR
- you are between 55-90 and have a diagnosis of early Alzheimer’s disease

You will need a study partner to accompany you to all visits.
Participants will be assessed regularly by physicians and other qualified health care professionals.

To sign up for the Alzheimer’s Disease Neuroimaging Initiative study
Contact: Kelly Landy
(650) 849-0491

Light Study

This study is testing light treatment to improve daytime alertness and nighttime sleep. It is designed to benefit both the individual with memory impairment and their caregiver.
A Stanford research team will set up light equipment for the treatment in your home and assist in making your participation in the study as convenient as possible.
Participants should:
- be 55 years or older
- have memory impairment or dementia
- live at home with a caregiver/study partner

To sign up for the Light study
Contact: Ellen Kim
(650) 496-2578
RESEARCH OPPORTUNITIES

Valproate In Dementia
(The VALID Study)

To sign up for the VALID study
Contact: Emily Gere
(650) 852-3287

In November 2006, we will begin recruitment for a pilot study that combines memory training with a medication (donepezil). Donepezil has been proven to be safe and effective in Alzheimer’s patients. This study represents a novel application of the drug in normal elderly with memory complaints and will include our well-tested memory training program. The training program teaches specific memory, organization, concentration, and attitude techniques designed to help you improve your memory performance. The classes will meet every weekday in the morning for two weeks. Study participation will last a total of 16 weeks.

You may be eligible to participate if you are:
- Aged 55 – 90 years
- Experiencing memory problems
- Free of dementia (such as Alzheimer’s disease)
- Willing to take an FDA approved medication (donepezil)

Memory Training

To sign up for the Memory Training study
Contact: Beatriz Hernandez
(650) 849-0494

Memory Screening

To sign up for the Free Memory Screening
contact: (650) 852-3287

This project is developing an approach to screen for memory problems in group sessions.

Each screening session:
- begins with a brief talk on memory & aging
- involves simple memory games many enjoy
- reviews your results and concerns with staff

The VALID Study is a nationwide clinical research study designed to evaluate if Valproate is effective in delaying, weakening or preventing difficult behaviors in individuals with Alzheimer’s disease, or if it can slow the progression of Alzheimer’s disease overall. Participants will be assessed regularly by physicians and other qualified health care professionals.

Participants should:
- be aged 50-90
- have been diagnosed with probable Alzheimer’s disease
- have someone who can be a study partner
- have not experienced agitation or psychosis since the onset of Alzheimer’s disease
Alzheimer’s Disease Neuroimaging Initiative (ADNI)

Would you like to be part of a national effort in the fight to end Alzheimer’s Disease? Researchers across the country have begun an exciting new research project called the Alzheimer’s Disease Neuroimaging Initiative (ADNI). ADNI is a major clinical study seeking a total of 800 older adults to participate. The project was begun by the National Institute on Aging (NIA) and is supported by more than a dozen other federal agencies and private-sector companies and organizations.

The aim of the study is to identify markers of memory decline that signal the onset of Alzheimer’s Disease. In addition, the study seeks to discover whether imaging the brain every six months can help predict the onset and monitor the progression of Alzheimer’s Disease. MRI and PET scans are the imaging methods used in the studies. In addition to imaging, the study will test blood, urine, and, for some participants, cerebrospinal fluid. Researchers will examine whether these biomarkers can predict and monitor the disease.

Scientists hope that gradual biological changes in the brain can be detected; this could help them evaluate the effectiveness of drugs at the earliest possible time. Investigators across the U.S. and Canada are asking people ages 55 to 90 to become a part of this ground-breaking research.

The Stanford/VA Aging Clinical Research Center is one of 58 national ADNI sites. Currently, our site is focusing on those individuals with mild cognitive impairment and early Alzheimer’s disease, who are between the ages of 55 and 90 and in good general health. Every study participant needs a friend or family member to accompany them to each visit. For more information about the study, please call Kelly Landy at 650-849-0491.
personal health. When you are a participant in a research trial, the research team will follow the protocol ("rules" of research) as closely as possible without compromising your health. There is less freedom when you are a participant in a research study, but the guidelines are imposed for specific reasons — scientists set certain conditions to keep things standard across all participants, so they can really zero in on the question they’re hoping to answer.

Before you decide to become a research volunteer, you should ask as many questions and learn as much as you can. Know the potential risks and benefits associated with the study, and remember — the decision to participate is up to you. There are so many health questions still left unanswered — with the help of people like you, we can continue to find the best, safest, and most effective medical treatments.  

*Article by Kelly Landy*

Sources:
--- ADNI consent form

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**Make a difference: Help end Alzheimer's Disease!**

A contribution to the Aging Clinical Research Center is a gift to future generations in our quest to cure Alzheimer’s disease. Your generous support ensures that the Center continues to conduct top-quality clinical research to improve treatment options and to provide education and support for patients and families. With your help, our clinical researchers investigate the causes of memory loss and neurodegeneration, develop and test better treatments for Alzheimer’s disease, and share these discoveries with the local community and with scientists around the world.

Tax-deductible contributions can be made by check, payable to:

**Stanford University**

Please indicate **Stanford/VA Aging Clinical Research Center** in the memo line.

Mail your contributions to:

**Jerome Yesavage, MD, Director (151Y)**  
**Stanford/VA Aging Clinical Research Center**  
**3801 Miranda Avenue**  
**Palo Alto, CA 94304**

Gifts may be made in honor of someone’s special occasion or in memory of someone who has passed away. Please provide the name of the person in tribute, as well as the name and address of anyone whom you wish to receive an acknowledgement of the gift.

For additional information about the Aging Clinical Research Center and opportunities to contribute, call (650) 852-3287. All donations are tax-deductible.
UPCOMING EVENTS

Memory Walk 2006
The Alzheimer’s Association
Saturday, October 7 (7:30 am all areas open; 9:30 am walk begins).
Treasure Island, San Francisco Bay
A non-competitive fund-raising walk designed to support the mission of the Alzheimer’s Association. Participants sign up as teams, and collect pledges from their friends, family, coworkers, and others to raise as many dollars as possible. To register, make donations, and to become a Stanford/VA Memory Walkers Team Member, call 800-272-3900, or go online at www.alznorcal.org/MemoryWalk.

Learn How to Remain Independent and Injury Free
Alzheimer’s Disease Educational Series
Wednesday, October 25th, 1 pm to 2:30 pm.
Stanford/VA Alzheimer’s Disease Center, VA Palo Alto Health Care System,
3801 Miranda Avenue, Palo Alto
Join us for an educational workshop by Cesar Arada, a certified occupational therapist with Rosener House, who will discuss how you can reduce your risk of falls and restore function, balance and coordination. The workshop will be held at the Palo Alto VA, in the conference room on the second floor of Building 4. Everyone is welcome to attend. Registration is not necessary. For more information, call Kellie Takagi at (650) 493-5000 extension 64025, at the Stanford/VA Alzheimer’s Center.

Circle of Care 2006
Alzheimer’s Association Annual Conference
Saturday, November 18th, 8:00 am - 3:00 pm
Crowne Plaza Hotel, Foster City
Join some of the nation’s leading experts as we explore together the everyday themes encountered on the Alzheimer’s journey. The circle of care will include an armchair discussion on current research and treatment, and presentations of importance to families interested in early, middle and late stage issues of care. The program is designed for family members and professionals alike. Registration includes continental breakfast, lunch, and all materials. An Exhibitors’ Fair runs continuously throughout the day. Five Continuing Education units are available. To receive conference materials in late September, contact Blanca.vazquez@alznorcal.org or call 800-272-3900.

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Visit us on the web:
Aging Clinical Research Center (ACRC): http://alzheimer.stanford.edu
Stanford/VA Alzheimer’s Center: http://arcc.stanford.edu
MIRECC: http://mirecc.stanford.edu
Older Adult and Family Center: http://oafc.stanford.edu

To add or remove your name from our mailing list, call (650) 852-3287 or visit the ACRC web site.

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