University of Washington Alzheimer's Disease Research Center (ADRC) Clinical Trials Update

THERESA KEHNE, RESEARCH COORDINATOR

UW ALZHEIMER'S DISEASE RESEARCH CENTER

UW MEDICINE MEMORY AND BRAIN WELLNESS CENTER

JANUARY 10TH, 2025





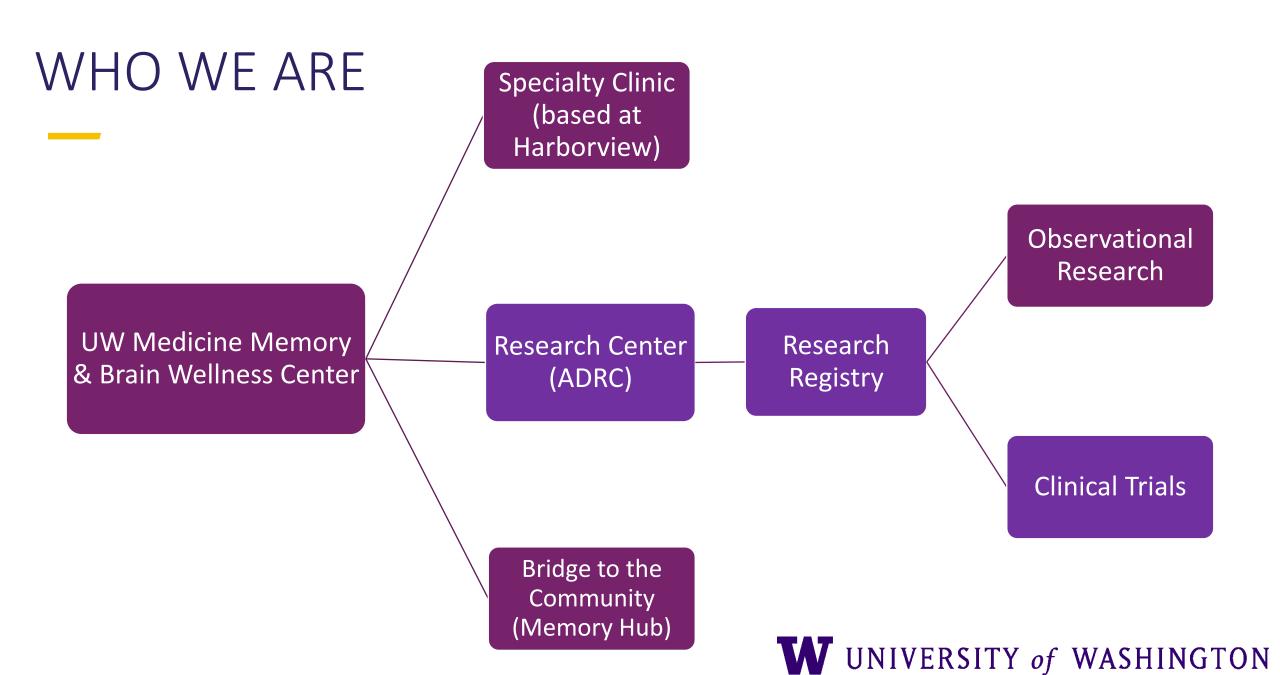
WELLNESS CENTER

LEARNING OBJECTIVES

Learn about:

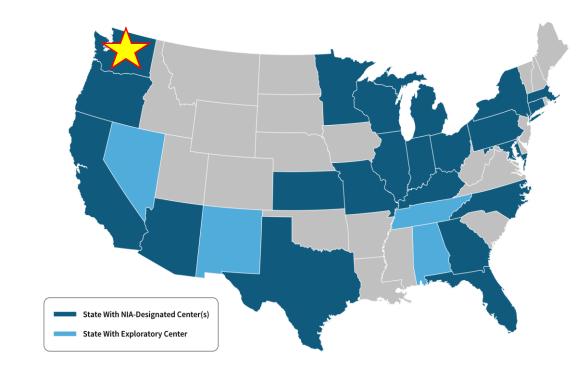
- The UW ADRC's structure, mission, and aims.
- Currently enrolling UW ADRC clinical trials and studies.
- How to refer patients to the UW ADRC that are interested in research participation.
- Frequently asked questions and answers about research and research involvement.



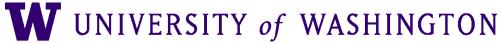


The Research Center – UW ADRC

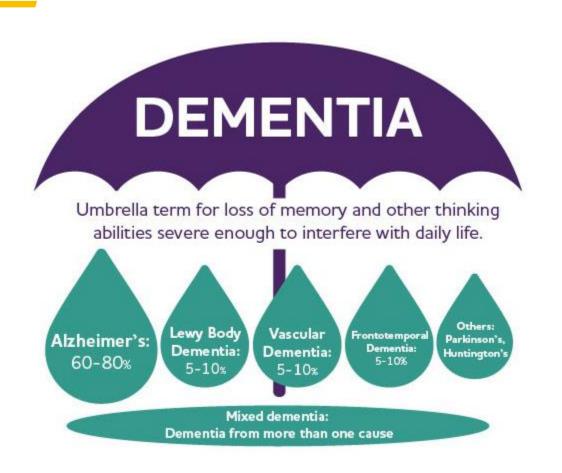
- The UW Alzheimer's Disease Research Center (ADRC) is one of the 37 centers sponsored by the National Institutes of Health (NIH).
- It is part of the UW Memory and Brain Wellness Center.
- The aim of the ADRC is to accumulate scientific knowledge to create treatments and prevention for Alzheimer's disease and related dementias (ADRD).

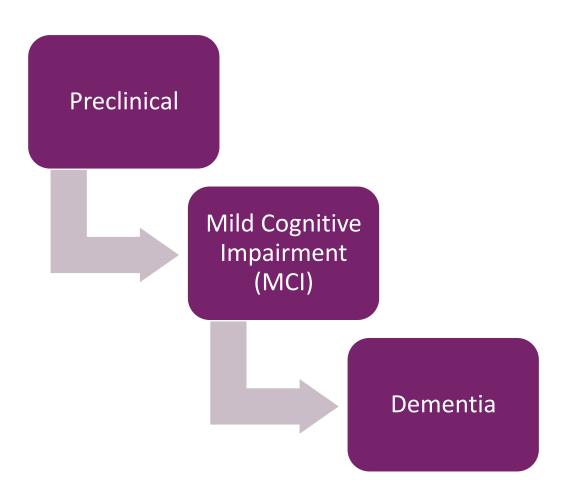






Studies by Disease and Disease Stage







Clinical Research Observational **Clinical Trial** Study Longitudinal follow-up Evaluate treatment of drug Looks at risk and protective or device factors for AD Most address early-stage AD

Preclinical AD MCI due to AD Mild AD dementia

Moderate AD dementia

Severe AD dementia



Why Participate in Clinical Research?

- Sense of meaning and purpose
- Contribution to science
- Better education about disease and treatment
- Access to novel treatment approaches



Common Participant Concerns about Clinical Research

"I will be receiving a new drug that treats and possibly cures dementia."

> Most clinical trials are testing an intervention that may or may not be effective in treating disease.

"They want me to be a guinea pig."

Research studies range from just involving surveys to taking medications. Participant safety is prioritized, and all participants may withdraw from the study if issues arise.

"I will be exposed to an unsafe medicine that causes lots of side effects."

➤ Most drugs have been vetted through phase I/II clinical trials to assure relative safety.

"The treatments and tests that I receive will be very expensive."

> Participation in clinical research means that study activities are covered by the study or a sponsor.

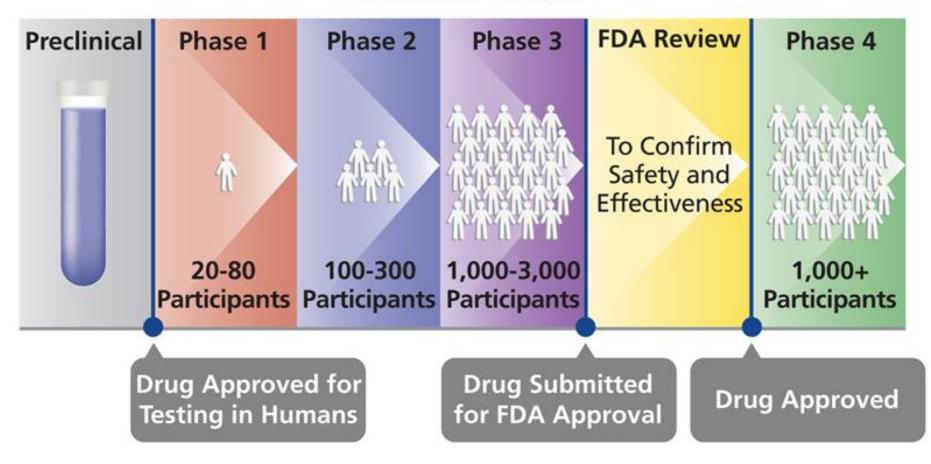
"I live too far away to participate."

> Depending on the study, remote participation may be an option or visits may be infrequent enough that study enrollment is still possible.

Clinical Trials Overview

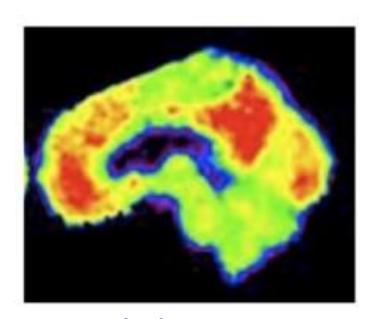
Lifecycle of a Clinical Trial

Clinical Trials





Common Procedures in Alzheimer's Research



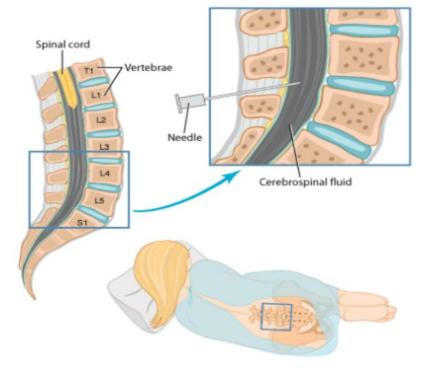
Amyloid PET Scan

- Detects brain amyloid plaques
- Radioactive agent binds to plaques
- In this image, amyloid plaques seen as red and orange spots



Brain MRI Scan

- Detects brain shrinkage and vascular disease
- Can be contraindicated if patient has a metal implant (e.g. pacemaker)



Lumbar Puncture

- Measures levels of amyloid and tau in the brain
- May be contraindicated if patient takes a blood thinner or has extensive arthritis



Enrolling ADRC Clinical Trials January 10th 2025

Mild to
Moderate
AD

A Randomized, Double-Blinded Study to Evaluate the Efficacy and Safety of Mevidalen in Patients with Alzheimer's Disease (Eli Lilly) UW site PI: Michael Rosenbloom, MD



Daily oral pill of placebo or mevidalen (dopamine D1R receptor agonist in the prefrontal cortex) for individuals with mild to moderate stage Alzheimer's disease.

- Phase II, double-blind, placebo-controlled, parallel, 3-arm study to evaluate safety and efficacy (25mg, 50mg, placebo); n=300
- Age range: 50-80 years old, MMSE 13-24 (~MoCA 6-18)
- If taking any psychiatric or antihypertension meds, must be on stable dose for 30+ days
- Requires a study partner, no significant neurological conditions other than AD
- 14 study appointments (12 in-person) over 8 months (6-month dosing period)
- Study Coordinator: Madina Akhmedova, madina03@uw.edu



Mild Cognitive Impairment /Mild AD

Transcranial Magnetic Stimulation (TMS) Study (UW ADRC)

PI's: Michael Rosenbloom, MD and Andrea Stocco, PhD



TMS for individuals with evidence of heightened brain amyloid, prior MRI imaging and clinical diagnosis of MCI or mild stage AD.

- Ages 18+, MoCA > or = 17, evidence for CNS amyloidosis, *open to ADRC participants and MBWC patients*
- Involves five, 5-to-7-hour long TMS treatments, over course of one week (12-weeks total involvement)
- fMRI imaging (3T) pre and post treatment (NO pacemakers)
- 8-minute memory games pre and post treatment
- Study Coordinator: Siqi Mao, smao2@uw.edu



Mild
Cognitive
Impairment

"COGIT-2" Cognitive Training and Neuroplasticity in Mild Cognitive Impairment (Columbia University)



Evaluate if systemic cognitive training in the form of crossword puzzles, compared to health education, can improve performance and everyday functional abilities in participants experiencing memory loss and meet the criteria for MCI.

• 55-89y.o., English-speaking, study partner and computer access required

UW site PI: Angela Hanson, MD

- MoCA > or = 20/30
- Weekly crosswords and/or educational health reading assignments for up to 18 months total); additional cognitive testing, brain MRI, and blood draws includes 6 clinic visits
- Cannot have a diagnosis of dementia or other significant neurological or psychiatric conditions
- Study Coordinator: Kristen Gonzalez-Farris, 206-897-6797, kmfarris@uw.edu

Observational Research Studies Overview

Why participate in observational research?

- A path to help us understand how to better diagnose Alzheimer's disease (e.g. biomarkers)
- Identify ways to prevent disease and potential risk factors
- Ensure that understanding of disease is equal across all demographics



Current UW ADRC-Affiliated Research Studies

No Memory Concerns,

MCI,

OR AD/FTLD/DLB/Other

Dementia

- UW ADRC Clinical Core Study
- Lipid MRI Study
- Pathological Mechanisms of White Matter Hyperintensities
- AD Family-Based Study (VA)
- DLB Consortium (VA)
- Technology for Early Dementia Diagnosis (VA)

Care Partners/Caregivers
of People Living With
Dementia (PLWD)

ImPACT-AD



Highlight #1 - UW ADRC Clinical Core (NIA) PI: Suman Jayadev, MD



ADRC Clinical Core Research Study – NIA-funded, multi-site, longitudinal cohort study involving annual neurological evaluations, biomarker collection, and cognitive testing

- Currently seeking to enroll:
 - People with Mild Cognitive Impairment
 - Racial & ethnic underrepresented groups (URG's), including Spanish speaking individuals
 - People with familial AD or frontotemporal dementia-spectrum disorders
 - 85+ y.o. cognitively well

• To learn more, please call the ADRC research line: 206-616-3973 OR email us at

uwadrc.org.









Highlight #2: Lipid MRI Study (UW ADRC) PI: Angela Hanson, MD



Study designed to better understand how the blood flow in the brain directly responds to drinking heavy cream by doing MRI and body composition scans, blood draws and cognitive tests, to help speed up AD discoveries.

- 55+ y.o. normal cognition, healthy controls
- Excludes: non-English speaking, significant neurological or other health issues (e.g., cognitive impairment or dementia, significant lipid abnormalities)
- Two visits (3.5-5 hrs)
- Blood & cheek swabs, memory testing, MRI, DEXA scan, drinking heavy cream, oral glucose tolerance and triglyceride tests
- Study Coordinator: Kristen Gonzalez-Farris, 206-897-6797, kmfarris@uw.edu

How Can I Participate in Research?

How to Participate in Research: Steps 1, 2, 3

UW ADRC scientists want to learn more about the diseases that cause memory loss and dementia. Our center is looking for a variety of people who are willing to partner with us in Alzheimer's research. We think of study participants as our partners in the effort to find a prevention for neurological conditions that lead to dementia. New opportunities for clinical trials and research studies appear over time, and these may involve different groups of patients. This webpage explains how you can learn more about participating in clinical trials or research studies at the ADRC.



We welcome you to explore the list of enrolling clinical trials and research studies through the below pages. Each trial and study description includes the study coordinator to contact directly.



Do you want our help in identifying which studies might be a good fit for you? Please call 206-616-3973 or email us at uwadrc@uw.edu and leave us a message with your name and phone number along with information about your interests.

A staff member will get back to you within several weeks to walk you through some pre-screening questions over the phone.



Check out the following online resources to learn more:

- FAQs About Clinical Studies | En español [NIH]
- Why Should I Participate in a Clinical Trial? [NIH]
- ¿Como decidió participar? [NIH]
- Explore Alzheimers.gov for facts you can trust!



Visit our website uwadrc.org (English)

Join our Research Registry

- Email us at uwadrc@uw.edu
- Call our ADRC research line: (206) 616-3973

 Visit our website, <u>uwadrc.org</u> (English) or <u>memoria.uw.edu</u> (Español) to contact study teams directly

Medical Concerns? Contact the UW Medicine Memory & Brain Wellness Clinic: (206) 744-2458



VELCOME

's Disease Research Center research resource centers ional Institute on Aging. ources of discovery into the er's disease and related o the development of more les to prevention, diagnosis, The UW ADRC contributes to of shared resources that -relevant research, and tch efforts with other NIHand investigators. UW ADRC gned to facilitate and esearch efforts at UW.

e Seattle community with pportunities to participate in tudies of Alzheimer's disease ers. Our outreach team is loting strengths-based eimer's disease and dementiaties, and they organize and nal talks and events and . We support outreach and

CENTER NEWS



Life's Tapestry September 02, 2024



Discoveries Made Possible By You // Fall 2024 September 02, 2024



Dr. Swati Rane Levendovszky's Brain Imaging Approach to Studying the Brain's Blood Vessels and Alzheimer's Disease September 02, 2024



Dementia Friends play a part in building dementia-friendly communities in eastern Washington August 30, 2024



Dimensions Magazine Summer // Fall 2024 August 29, 2024

ANNOUNCEMENTS

Request for Proposals: 2025–2026 Development Projects

September 05, 2024 — The UW ADRC seeks p for Development Projects that advance our understanding, diagnosis, and/or treatment of AD/ADRD. Development Projects that leverag central UW ADRC theme of biological heterogiand/or UW ADRC resources are preferred. Aparewelcome from investigators at levels rang postdoctoral fellows to full professors.

Summer/Fall 2024 Issue of Dimensions

August 28, 2024 — The newest issue of Dime features a spotlight on Dr. Swati Rane Levend work on understanding the role of vascular di: Alzheimer's disease using brain imaging.

Spring/Summer 2024 ADRC Communit Newsletter

June 19, 2024 — We've been busy in your com ¡Hemos estado ocupados en su comunidad!

Announcing the 2024–2025 ADRC Dev Project awardees

February 07, 2024 — Awardees include Jeann PhD, CCC-SLP, Gregory del Zoppo, MD, Nicole



QUESTIONS?

Call our research line, 206-616-3973

OR

Email us at uwadrc@uw.edu