

# KU Alzheimer's Disease Center Studies at a Glance

## Studies for those with memory loss

### **Therapeutic Effect of Exercise in Adults with Amnesic Mild Cognitive Impairment (EXERT)**

A study to test whether physical exercise can slow the progression of early Alzheimer's disease memory problems in older adults

Type of Study: Low or moderate intensity exercise at local YMCA with personal trainer

Who: Underactive individuals with Mild Cognitive Impairment

Procedures: Physical exam, pen and paper tests, questionnaires, blood draws, fitness tests, ECG, MRI and optional lumbar puncture

Duration: 18 months of intervention with about 4 visits a week to the YMCA

Compensation: Yes -YMCA membership and personal trainer fees paid

### **Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)**

A study designed to help caregivers manage everyday situations associated with dementia care with technology

Type of Study: Caregiver support

Who: Individuals with dementia residing with family caregiver

Procedures: In home visit to set up home monitoring unit, weekly calls

Duration: 3 months, 3 home visits

Compensation: Yes

### **Trial of Oxaloacetate in Alzheimer's disease (TOAD)**

A study to test the safety and tolerability of oxaloacetate (a natural compound/supplement) and to assess the best dose for future studies

Type of Study: Investigational medicine (no placebo)

Who: Individuals with Alzheimer's disease, ages 50-85

Procedures: Blood draws, PET and MRS scans (similar to MRI), pen and paper tests, vital signs

Duration: Approximately 10 visits over 10 weeks

Compensation: Yes

### **Intervention to Reduce Sitting Time in Mild Cognitive Impairment (ReST-MCI)**

A study to reduce the amount of time spent sitting.

Type of Study: Activity monitor study

Who: Individuals with Mild Cognitive Impairment and their study partner

Procedures: Wear an activity monitor

Duration: 15 weeks with 2 clinic visits, 3 home visits, 2 telephone calls

Compensation: Yes-Will receive wrist worn activity monitor (\$100 value)

### **A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Aducanumab (BIIB037) in Subjects with Early Alzheimer's disease (ENGAGE)**

A study to evaluate the safety and effectiveness of an investigational medicine (aducanumab) in individuals with mild cognitive impairment.

Type of Study: Investigational medicine (chance of placebo)

Who: Individuals with Mild Cognitive Impairment / early Alzheimer's disease, ages 50-85

Procedures: MRI's, PET scans, pen and paper tests, questionnaires, blood draws, infusions, physical exams

Duration: 23 months (18 months on study drug), about 30 visits

Compensation: Yes

## Studies for those with memory loss (cont.)

### **S-Equol in Alzheimer's disease 2 (SEAD2)**

A study to test if S-Equol, a compound that acts like estrogen in the body, can improve a particular energy metabolism deficit that is found in persons with Alzheimer's disease (AD)

Type of Study: Investigational medicine (on placebo for half treatment duration and investigational medication the other half)

Who: Individuals with Alzheimer's disease (APOE4 non-carriers)

Procedures: Genetic counseling, physical and neurological exams, blood draws, pen and paper thinking tests, vital signs

Duration: 4 months, 4 visits & 1 phone call

Compensation: Yes

### **A Phase 2 Multiple Dose, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ABBV-8E12 in Subjects with Early Alzheimer's disease (AWARE)**

A study to evaluate a drug that may slow Alzheimer's progression in those with early AD. The drug is designed to target tau tangles in the brain and will be delivered via IV.

Type of Study: Investigational medicine (chance of placebo)

Who: Individuals with Mild Cognitive Impairment or probable AD

Procedures: PET brain imaging, MRI brain imaging, 2-3 lumbar punctures, study drug infusion, ECG's, blood draws, physical and neurological exams, memory and thinking tests, and questionnaires/interviews

Duration: ~2 ½ years, about 45 visits

Compensation: Yes

### **Protocol I8D-MC-AZET, A Randomized, Double-Blind, Placebo-Controlled and Delayed-Start Study of LY3314814 in Mild Alzheimer's Disease Dementia (DAYBREAK)**

A Phase 3 study designed to test whether an investigational medicine (LY3314814) will slow disease progression in patients with mild dementia of the Alzheimer's type

Type of Study: Investigational oral medicine (chance of placebo for first 78 weeks; no chance of placebo for second 78 weeks)

Who: Individuals with mild Alzheimer's disease, ages 55-85

Procedures: MRI scans, Amyloid PET scans, ECGs, lab draws, physical exams, skin exams, eye exams, optional Tau PET scans

Duration: 3 years, with 30 visits

Compensation: Yes

## Studies for those without memory loss

### **Alzheimer's Prevention Program (APP)**

A study to evaluate risk for development of Alzheimer's disease in those without any symptoms. The program also offers strategies to improve health and reduce your risk for chronic diseases, including Alzheimer's disease

Type of Study: Observational (no treatment)

Who: Individuals with normal cognition, age 65 and older, who are interested in participating in the APEX study

Procedures: pen and paper tests, amyloid PET scan, health screen, questionnaires

Duration: Approx. 7 months, 3 visits and 2 follow up surveys by phone or email

Compensation: No

### **Alzheimer's Prevention through Exercise (APEX)**

A study to evaluate the effects of aerobic exercise in individuals who have completed the APP study and were determined to be at risk for developing Alzheimer's disease

Type of Study: Treadmill walking at a local YMCA with a personal trainer (chance of control group)

Who: APP participants (see above) who were determined to be at risk for Alzheimer's disease

Procedures: physical function tests, DEXA, MRI, PET scan, pen and paper tests, questionnaires, blood draws

Duration: 52 weeks of intervention, with about 4 visits a week

Compensation: Yes –YMCA membership paid

## Studies for those without memory loss (cont.)

### **Risk Reduction for Alzheimer's disease (rrAD)**

A study to test whether aggressive blood pressure and cholesterol lowering through medication and physical exercise can slow the cognitive decline and risk for developing dementia.

Type: FDA-approved medications, moderate intensity exercise or both

Who: Underactive individuals age 60+ with high blood pressure, and family history of dementia or concern about memory

Procedures: physical exam, pen and paper tests, questionnaires, blood draws, fitness tests, ECG, MRI, and vascular measures

Duration: 24 months of intervention

Compensation: Yes

### **Investigating Gains in Neurocognition in an Intervention Trial of Exercise (IGNITE)**

A study to explore the idea that physical activity may help maintain and improve brain health in older adults.

Type of Study: Treadmill walking or stretching and toning exercise at a local YMCA

Who: Individuals 65-80 who are not exercising regularly

Procedures: physical function tests, body composition measurements, MRI & PET scans, pen and paper tests, questionnaires, blood draws

Duration: 12 months of intervention, with about 4 visits a week

Compensation: Yes –YMCA membership paid

### **A randomized, double-blind, placebo-controlled, two-cohort parallel group study to evaluate the efficacy of CAD106 and CNP520 in participants at risk for the onset of clinical symptoms of Alzheimer's disease (GENERATION)**

Study of efficacy of CAD106 and CNP520 in comparison to respective placebo in participants at the risk for the onset of clinical symptoms of Alzheimer's disease

Type of Study: Investigational medicine (chance of placebo)

Who: Individuals with normal cognition, ages 60-75

Procedures: PET scans, MRI scans, blood draws, physical exams, memory testing, memory evaluations, questionnaires, other optional procedures

Duration: 5-8 years of study treatment with quarterly study visits, 25-37 visits total

Compensation: Yes

### **A Phase 2b/3 Randomized, Double-blind, Placebo-Controlled, Parallel Group, Multicenter Study Investigating the Efficacy and Safety of JNJ-54861911 in Subjects who are Asymptomatic At Risk for Developing Alzheimer's Dementia (EARLY)**

To determine whether treatment with JNJ-54861911 slows cognitive decline compared with placebo treatment, in amyloid-positive subjects who are asymptomatic at risk for developing Alzheimer's dementia.

Type of Study: Investigational medicine (chance of placebo)

Who: Individuals with normal cognition, ages 60-85

Procedures: PET scan and/or Lumbar Puncture, MRI scan, blood draw, ECG, physical exam, dermatology exam, memory testing, memory evaluation, questionnaires

Duration: 4.5 years of study treatment with about 30 visits total

Compensation: Yes

## Studies for those with or without memory loss

### **KU Alzheimer's Disease Center Clinical Cohort**

A National Institute of Health (NIH) grant funded study to develop and maintain a well characterized group of individual to support further research on memory and aging

Type of Study: Observational (no treatment)

Who: Individuals with memory loss of any age and individuals without memory loss 65 and older

Procedures: Clinical memory assessment, pen and paper test, blood draw

Duration: 3 annual visits

Compensation: No

## Studies for those with or without memory loss (cont.)

### Relationship of Energetics and Cognitive Trajectory (REACT)

A study to characterize the relationship between metabolic hormone secretion, energy production, and memory

Type of Study: Observational (no treatment)

Who: Clinical Cohort participants with and without memory loss, age 60 and older

Procedures: Mixed meal tolerance test, blood draws, MRI

Duration: 2 visits

Compensation: Yes

### Alzheimer's Disease Neuroimaging Initiative 3 (ADNI 3)

A public/private collaboration between academia and industry to study biomarkers and progression of Alzheimer's disease.

Type of Study: Observational (no treatment)

Who: Individuals with normal cognition ages 65-90 and individuals with Mild Cognitive Impairment or mild Alzheimer's disease ages 55-90

Procedures: Participants will undergo longitudinal clinical and cognitive assessments, computerized cognitive batteries, biomarker and genetic tests, PET (FDG, amyloid and tau) and MRI scans and cerebral spinal fluid (CSF) collection

Duration: Up to five years, with annual visits

Compensation: Yes

### Aging and Disease Mitochondria (ADMIT)

A study to test the relationship between energy production in cells, genetics, and fitness.

Type of Study: Observational (no treatment)

Who: Individuals with memory loss of any age and individuals without memory loss age 65 and older

Procedures: Blood draw, fitness test, muscle biopsy

Duration: 2 visits

Compensation: Yes



If you have already started your research journey and have received your Potential Participant Information Form, please complete your survey and identify on the last page which of the studies would be of interest to you.



To learn how you or a loved one can participate in any of these studies, please visit our website at [KUAlzheimer.org](http://KUAlzheimer.org), click on "Join a Study," and then click "Complete this form" to get started. Or call our mainline at 913-588-0555 for more information.



If you are a medical provider and would like more information about any of these studies or information to share with your patients, please call our mainline at 913-588-0555 and ask for Recruitment.