

# Apathy in Alzheimers Disease Methyphenidate Trial II (ADMET II)

<https://neurodegenerationresearch.eu/survey/apathy-in-alzheimers-disease-methyphenidate-trial-ii-admet-ii/>

## Principal Investigators

MINTZER, JACOBO E.

## Institution

MEDICAL UNIVERSITY OF SOUTH CAROLINA

## Contact information of lead PI

### Country

USA

## Title of project or programme

Apathy in Alzheimers Disease Methyphenidate Trial II (ADMET II)

## Source of funding information

NIH (NIA)

## Total sum awarded (Euro)

€ 6,717,857.80

## Start date of award

15/09/2014

## Total duration of award in years

3

## The project/programme is most relevant to:

Alzheimer's disease & other dementias

## Keywords

Acquired Cognitive Impairment... Aging... Alzheimer's Disease... Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)... Basic Behavioral and Social Science... Behavioral and Social Science... Brain Disorders... Clinical Research... Clinical Research - Extramural... Clinical Trials and Supportive Activities... Dementia... Mental Health... Neurodegenerative... Neurosciences... Translational Research

## Research Abstract

**DESCRIPTION** (provided by applicant): Apathy is defined as a loss of will and initiative, lack of interest in activities, lack of productivity, as well as limited affective response to positive and negative elements. Apathy is one of the most common neuropsychiatric symptoms (NPS) of Alzheimer's disease (AD), affecting approximately 70% of AD patients and resulting in serious adverse consequences for patients and caregivers. Apathetic patients are also more likely to require institutionalization, the largest single driver of direct costs in AD. Despite the high prevalence of apathy in AD and its serious consequences, there are no proven treatments for this condition. Nonpharmacologic strategies appear to have limited effects on apathy in AD, as do current FDA-approved medications for AD such as cholinesterase inhibitors. Recently, new research has suggested the involvement of dopamine pathways in the biology of apathy in AD and the potential value of dopamine enhancers, such as methylphenidate, for the treatment of this condition. Moreover, we have recently reported the results of two six-week randomized controlled trials showing a clear benefit of methylphenidate over placebo in treating apathy in AD, as well as potential cognitive benefits of methylphenidate and a favorable safety/tolerability profile. [However, a number of key questions relevant for clinical practice were not answered by these studies. For example, is the treatment effective and safe beyond six weeks in a larger sample? Can the potential cognitive benefit of methylphenidate be reproduced and remain clinically significant in this population? Can the combination of a decrease in apathy and an improvement in cognition be translated to clinically significant functional change? Does the treatment of apathy in AD have an impact on subject quality of life and pharmacoeconomics? We propose to address these questions by conducting a multi-site, parallel, randomized, double-blind, placebo-controlled study evaluating methylphenidate for the treatment of apathy in AD patients (Apathy in Dementia Methylphenidate Trial-II (ADMET II)) in a larger sample, over a more extensive period of time and employing a concise battery of neuropsychological tests optimized for apathetic AD patients. The ultimate goal is to collect evidence strong enough to support a change in clinical practice. This trial will bring together a team of investigators who have collaborated successfully in the execution of the first ADMET study as well as other clinical trials exploring treatments for neuropsychiatric symptoms of dementia.]

### **Lay Summary**

**PUBLIC HEALTH RELEVANCE:** Apathy affects over 70% of patients suffering from Alzheimer's disease (AD) resulting in excess disability for the patient, caregiver burden, and high emotional and economic costs to society. Today, there is no current approved treatment for apathy in AD. This application aims to provide information that will allow methylphenidate, a widely available generic drug, to become the first treatment for apathy in AD.

**Further information available at:**

### **Types:**

Investments > €500k

### **Member States:**

United States of America

### **Diseases:**

Alzheimer's disease & other dementias

### **Years:**

2016

**Database Categories:**

N/A

**Database Tags:**

N/A