

Cocoa Supplement and Multivitamin Outcomes Study in the Mind (COSMOS-Mind)

<https://neurodegenerationresearch.eu/survey/cocoa-supplement-and-multivitamin-outcomes-study-in-the-mind-cosmos-mind/>

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Country

USA

Title of project or programme

Cocoa Supplement and Multivitamin Outcomes Study in the Mind (COSMOS-Mind)

Source of funding information

NIH (NIA)

Total sum awarded (Euro)

€ 3,530,468.81

Start date of award

01/06/2016

Total duration of award in years

1

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)... Behavioral and Social Science... Brain Disorders... Clinical Research... Clinical Research - Extramural... Clinical Trials and Supportive Activities... Complementary and Alternative Medicine... Dementia... Dietary Supplements... Mental Health... Neurodegenerative... Neurosciences... Nutrition... Prevention... Translational

Research Abstract

? DESCRIPTION (provided by applicant): Identifying a safe, affordable, and well-tolerated intervention that prevents cognitive decline in older adults is of critical public health importance. There is compelling evidence from basic science, and small clinical studies that cocoa flavanols may protect cognitive function in older adults and reduce risk of Alzheimer's disease (AD) and related dementia. Thus, this intervention could have important downstream benefits for health care utilization and cost, caregiver burden, and overall quality of life for older adults. Cocoa flavanol effects on cognition, however, need to be assessed in a definitive clinical trial. We propose to leverage the unique and timely opportunity provided by the funded COcoa Supplement and Multivitamin Outcomes Study (COSMOS) to conduct an ancillary cognitive study, referred to as "COSMOS-Mind." COSMOS is a randomized, double-blind, placebo-controlled clinical trial that will begin randomization in early 2016. It will enroll 18,000 women and men nationwide, drawn from the Women's Health Initiative (WHI) participant cohort and the VITamin D and Omega-3 Trial (VITAL) non-randomized respondent cohort, and will be conducted primarily by mail. COSMOS will assess whether high-potency cocoa flavanol extract (capsules containing 750 mg/d flavanols, including 75 mg (-)-epicatechin, and 90 mg theobromine; Mars Symbioscience) and a multivitamin (Pfizer Centrum(r) Silver(r)) – alone or in combination – will reduce risk of cardiovascular disease and cancer over 4 years of follow-up. The COSMOS leadership invited us to conduct an ancillary study to examine the cognitive effects of their interventions, given our extensive and successful experience collecting cognitive data using cost-effective and validated telephone-administered assessments in the geographically diverse WHI cohort. COSMOS-Mind will enroll 2,000 participants from COSMOS (50% men, aged ≥65 years), and conduct standardized telephone cognitive assessments pre-randomization and annually for 3 years to examine longitudinal effects of cocoa flavanols on a cognitive composite outcome. We will also establish whether administration of a multivitamin benefits cognition, explore whether cocoa flavanols reduce risk of dementia including AD, and examine intervention effects on key cognitive domains (e.g., executive function, short-term memory). Our assessments will yield reliable and sensitive measures of memory, executive function, language, and global cognitive function. We will use our previously successful techniques to promote high retention and longitudinal reliability. Our proposed cohort will provide >90% statistical power to establish whether cocoa flavanols protect cognitive function. We will share our data with the COSMOS study groups, WHI, and VITAL to facilitate other investigations and expand the scientific footprint of our study. COSMOS-Mind is an unprecedented, cost-efficient, and timely opportunity to test whether cocoa flavanols – a promising and widely translatable intervention – can protect against normal and pathological cognitive decline.

Lay Summary

PUBLIC HEALTH RELEVANCE: Identifying a safe, affordable, and well-tolerated intervention that prevents or delays cognitive decline in older adults is of critical importance, and there is growing evidence from basic science, uncontrolled studies, and small trials that cocoa flavanols could provide protection against this decline. We propose to add a novel and cost-efficient cognitive ancillary study to the funded large, simple, 2x2 factorial, randomized double-blind, placebo-controlled COcoa Supplement and Multivitamin Outcomes Study (COSMOS). The proposed study, COSMOS-Mind, will enroll 2,000 women and men from the parent trial (>65 years old), and conduct standardized and validated cognitive assessments via telephone at

baseline (before randomization) and annually over 3 years of follow-up to establish whether daily use of cocoa flavanols with or without a multivitamin can protect cognitive function and reduce incidence of cognitive impairment, including Alzheimer's disease.

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:

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