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2020 Part the Cloud Gates Partnership (PTC-G) - \$1,936,563

**MET-FINGER-APOE: Multimodal lifestyle intervention + metformin to prevent cognitive decline**

*This Phase IIb clinical trial will evaluate whether a combination of lifestyle intervention approaches along with a drug used to treat diabetes may prevent cognitive decline.*

**PI**

- Ph.D., Medicine/Neurology, University of Kuopio, 2002
- Chair of Neuroepidemiology at the Ageing Epidemiology (AGE) Research Unit, School of Public Health, Imperial College London
- Professor in Clinical Geriatrics, Center for Alzheimer Research, Karolinska Institutet, Stockholm
- Director of Research, Development, Education and Innovation, Theme Aging, Karolinska University Hospital, Stockholm
- Arthur C. Cherkin Memorial Award, USA, 2019
- Swedish Medical Society award for Alzheimer's Research, 2019
- Neuroscientist of the Year, Brain Research Society of Finland

**STUDY**

- CADRO category: Translational Research & Clinical Interventions
- In 2010, Dr. Kivipelto received the Alzheimer's Association Senator Mark Hatfield Award in Clinical Research to identify biomarkers that could be used to evaluate the effectiveness of treatments designed to reduce cognitive decline.

**Background**

Research has shown that there is not a single cause of Alzheimer's and dementia, but rather the disease develops over time as a result of multiple factors such as lifestyle, environment, and genetics. Studies show that a healthy lifestyle may reduce the risk to develop Alzheimer's and other types of dementia, such as vascular dementia (which is a decline in thinking skills caused by conditions that block or reduce brain blood flow).

Recently, a Finnish study known as FINGER (Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability) led by Dr. Miia Kivipelto showed that a two-year combination of lifestyle intervention approaches including physical exercise, a healthy diet, cognitive stimulation, and monitoring of heart health risk factors - improved cognitive abilities (memory and thinking) in older adults at high risk to develop dementia. This approach is currently being tested globally in the World-Wide FINGERS (WW-FINGERS) network of dementia prevention studies through multidomain lifestyle interventions. Building on these results, Dr. Kivipelto and colleagues will test whether a combination of lifestyle changes and a medication called metformin may further reduce the risk to develop cognitive impairment and Alzheimer's. Metformin is a safe and effective drug for treating type 2 diabetes. Studies show that individuals with diabetes may be more likely to develop Alzheimer's and other dementia, and metformin could help prevent the development of these brain diseases through the treatment of diabetes and may have a beneficial impact on the brain. Dr. Kivipelto will test if metformin in combination with healthy lifestyle changes may further help to prevent dementia.

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### **Research Plan**

Dr. Kivipelto and colleagues will conduct a Phase IIb clinical trial with 600 participants from United Kingdom, Sweden, and Finland, aged 60-77 years, who are at high risk of developing Alzheimer's because of their age, genes and lifestyle. This trial, called MET-FINGER-APOE study, will be part of the WW-FINGERS network of dementia prevention studies through lifestyle interventions.

Participants in the study will follow either a lifestyle intervention combination that includes physical exercise, healthy diet, monitoring of heart health risk factors and cognitive training - or usual healthy lifestyle advice recommended by their local health service. The group that receives the combination of lifestyle intervention approaches will be further split into a group that receives metformin and a group that does not. The total trial duration will be for 2 years. The researchers will evaluate the effect of the intervention by administering cognitive tests to the participants. To better understand the potential added effects of metformin, the researchers will perform brain scans as well as evaluate Alzheimer's-related biological markers from blood samples of the participants.

### **Impact**

The study results may provide insights into whether a drug used to treat diabetes can be repurposed along with a combination of lifestyle intervention approaches to reduce the risk of developing dementia. If successful, the study could give rise to larger clinical trials.

***Made possible through the generous funding from the Part the Cloud benefiting the Alzheimer's Association.***