

A Multidomain Two-Year Randomized Controlled Trial to Prevent Cognitive Impairment - the FINGER study

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Background: Observational studies have identified multiple modifiable risk factors associated with increased risk of late-life cognitive impairment and Alzheimer's disease (AD). However, previous smaller and shorter term prevention trials with single-factor interventions have had disappointing or at best modest results. The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER) investigated the effects of a 2-year multidomain intervention targeting several lifestyle and vascular risk factors simultaneously.

Methods: FINGER is a 2-year multicenter randomized controlled trial with 1260 participants aged 60-77 years recruited from previous population-based survey cohorts. Inclusion criteria were: CAIDE Dementia Risk Score > 6 points, indicating the presence of modifiable risk factors; and cognitive performance at the mean level or slightly lower than expected for age. Participants were randomized (1:1) into either the multidomain intervention group or the control group. The intervention included nutritional guidance, physical exercise, cognitive training and social activities, and management of vascular risk factors. The control group received regular health advice. Primary outcome after 2 years is cognitive performance measured by a comprehensive neuropsychological test battery (NTB) composite Z score. An extended follow-up (7 years) with a sustenance intervention is planned to evaluate longer-term effects on dementia/AD incidence, and secondary and exploratory outcomes including biomarkers and neuroimaging with MRI and PET. The 2-year intervention was finalized in February 2014. Here we report the main intention-to-treat (ITT) results on cognition after 2 years of intervention. Linear mixed-model statistical analyses were used.

Results: We found a significant beneficial intervention effect on overall cognitive performance (NTB) ($p < 0.001$ for time*group interaction). The beneficial effect was seen on each cognitive domain: memory ($p < 0.05$); executive function ($p < 0.05$), and psychomotor speed ($p < 0.05$). Drop-out rate was only 11%, and participants' experiences were very positive.

Conclusions: This is the first large RCT showing that it is possible to prevent cognitive decline using a multidomain intervention among older at-risk individuals. These results highlight the value of the feasible and novel multidomain approach that is effective for several cognitive domains.

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**RESEARCH ADVANCES FROM 2014 ALZHEIMER'S ASSOCIATION
INTERNATIONAL CONFERENCE**

***Two-Year Clinical Trial of Multifaceted Lifestyle-Based Intervention Provides
Cognitive Benefits for Older Adults at Risk of Dementia***

COPENHAGEN, July 13, 2014 – Positive results presented at the Alzheimer's Association International Conference® 2014 (AAIC® 2014) in Copenhagen include data from a two-year clinical trial in Finland of a multi-component lifestyle intervention, known as the Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER Study).

The study with 1,260 older adults at risk for cognitive impairment and Alzheimer's showed that physical activity, nutritional guidance, cognitive training, social activities and management of heart health risk factors improved cognitive performance, both overall and in separate measures of executive function, such as planning abilities, and the relationship between cognitive functions and physical movement.

“AAIC is the premiere Alzheimer's and dementia research conference, and this year's topics are exciting both in their scope and findings,” said Keith Fargo, Ph.D., Alzheimer's Association director of Scientific Programs & Outreach. “Regarding the FINGER Study, researchers have previously observed a number of modifiable factors associated with increased risk of late-life cognitive impairment and Alzheimer's, but short-term studies focusing on single, isolated risk factors have had modest results, at best. Longer, larger, better controlled trials looking at modifying multiple risk factors – like the FINGER Study – have been needed. This new data is very encouraging, and we look forward to further studies to confirm and extend these findings.”

With the support of the Alzheimer's Association and the Alzheimer's community, the United States created its first National Plan to Address Alzheimer's Disease in 2012. The plan includes the critical goal, which was adopted by the G8 at the Dementia Summit in 2013, of preventing and effectively treating Alzheimer's by 2025. It is only through strong implementation and adequate funding of the Plan, including an additional \$200 million in fiscal year 2015 for Alzheimer's research, that we'll meet that goal. For more information and to get involved, visit www.alz.org.

Lifestyle Changes Improve Memory and Thinking in At-Risk Older Adults in Two-Year Clinical Trial

At AAIC 2014, Miia Kivipelto, M.D., Ph.D., Professor at the Karolinska Institutet, Sweden and the National Institute for Health and Welfare, Helsinki, Finland, and colleagues reported on the results of the FINGER Study, a two-year randomized controlled trial of 1,260 participants age 60 to 77 with modifiable risk factors for cognitive impairment and Alzheimer's. Randomized controlled clinical trials are considered the "gold standard" for demonstrating treatment efficacy and safety.

Participants were divided into two groups; one received an intervention that included nutritional guidance, physical exercise, cognitive training, social activities, and management of heart health risk factors, while the control group received regular health advice. After two years, the intervention group performed significantly better on a comprehensive cognitive examination. In addition to performing better overall, the intervention group did significantly better on specific tests of memory, executive function (complex aspects of thought such as planning, judgment, and problem-solving), and speed of cognitive processing.

"This is the first randomized control trial showing that it is possible to prevent cognitive decline using a multi-domain intervention among older at-risk individuals. These results highlight the value of addressing multiple risk factors in improving performance in several cognitive domains," said Kivipelto. "Participants told us their experience was very positive, and dropout rate only 11 percent after two years."

The researchers say an extended, 7-year follow up study is planned, and will include measures of dementia/Alzheimer's incidence and biomarkers including brain imaging with MRI and PET.

About AAIC

The Alzheimer's Association International Conference (AAIC) is the world's largest gathering of leading researchers from around the world focused on Alzheimer's and other dementias. As a part of the Alzheimer's Association's research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community. Scientists leading the advancement of research gather to report and discuss the most current data on the cause, diagnosis, treatment and prevention of Alzheimer's disease and related disorders.

About the Alzheimer's Association

The Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer's. Visit www.alz.org or call 800.272.3900.

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