ELSEVIER

Alzheimer's & Dementia ■ (2017) 1-8

Alzheimer's & Dementia

Featured Article

Multidomain lifestyle intervention benefits a large elderly population at risk for cognitive decline and dementia regardless of baseline characteristics: The FINGER trial

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Abstract

Introduction: The 2-year Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER) multidomain lifestyle intervention trial (NCT01041989) demonstrated beneficial effects on cognition. We investigated whether sociodemographics, socioeconomic status, baseline cognition, or cardiovascular factors influenced intervention effects on cognition.

Methods: The FINGER recruited 1260 people from the general Finnish population (60–77 years, at risk for dementia). Participants were randomized 1:1 to multidomain intervention (diet, exercise, cognition, and vascular risk management) and regular health advice. Primary outcome was change in cognition (Neuropsychological Test Battery z-score). Prespecified analyses to investigate whether participants' characteristics modified response to intervention were carried out using mixed-model repeated-measures analyses.

Results: Sociodemographics (sex, age, and education), socioeconomic status (income), cognition (Mini–Mental State Examination), cardiovascular factors (body mass index, blood pressure, cholesterol, fasting glucose, and overall cardiovascular risk), and cardiovascular comorbidity did not modify response to intervention (*P*-values for interaction > .05).

The authors have no conflicts of interest to report.

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https://doi.org/10.1016/j.jalz.2017.09.006

Conclusions: The FINGER intervention was beneficial regardless of participants' characteristics and can thus be implemented in a large elderly population at increased risk for dementia.

Keywords: Prevention; Cognitive impairment; Dementia; Alzheimer's disease; Multidomain; Lifestyle; Intervention; Randomized controlled trial

1. Introduction

Alzheimer's disease (AD) and dementia are a global public health priority [1], and prevention has been highlighted as a pivotal component to reduce the burden of AD and dementia [2,3]. It has been estimated that up to a third of all AD cases can be attributed to common modifiable risk factors, including midlife hypertension and obesity, low educational level, diabetes, low physical activity, depression, and smoking [4], and a reduction of these risk factors would have a significant impact on the disease prevalence [4]. The current generation of randomized controlled prevention trials recognizes this multifactorial nature of AD and dementia and focuses thus on multidomain interventions. Targeting several risk factors of AD and dementia simultaneously will likely lead to better preventive effects [2,5]. Recently, several large multidomain lifestyle-based trials aiming to prevent cognitive decline and dementia have been initiated [5–9], and some have already been completed [10–14]. The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGER) is the first large, long-term randomized controlled trial demonstrating that a multidomain lifestyle intervention consisting of nutritional guidance, exercise, cognitive training, and management of vascular risk factors has beneficial effects on cognition [10].

As recently emphasized by The Lancet Neurology Commission, immediate actions in dementia prevention need to be taken and up-to-date research knowledge as well as effective prevention programs must be put into practice promptly [2]. To facilitate the effective and feasible implementation of successful prevention programs, such as the FINGER trial, into clinical practice, it is of great importance to identify individuals most likely to benefit from the interventions and potentially tailor the interventions to different target populations with different characteristics [2,5]. However, considering the limited number of completed, large long-term dementia prevention trials, it is largely unknown, whether certain subgroups of trial participants are more or less prone to benefit from these types of interventions. The FINGER trial provides the first opportunity to explore whether the positive response to a multidomain lifestyle intervention is modified by characteristics of the trial participants. In this study, prespecified subgroup analyses were carried out to investigate specifically whether participants' sociodemographic characteristics, socioeconomic status, cognitive performance, and level of cardiovascular risk at baseline influenced the intervention effects on cognition.

2. Methods

2.1. Trial design and participants

FINGER is a 24-month multicenter randomized controlled trial (ClinicalTrials.gov identifier NCT01041989), which was completed in February 2014. The FINGER trial included 1260 individuals aged 60–77 years. Participants were screened from Finnish observational population-based studies and had a CAIDE Dementia Risk Score [15] of $\geq$6, indicating increased risk for dementia later in life. In addition, participants were required to meet at least one of the following criteria: Consortium to Establish a Registry for Alzheimer's Disease (CERAD) [16], word list memory task result $\leq$ 19 words (maximum score 30), CERAD word list recall $\leq$ 75% (maximum 100%), or Mini–Mental State Examination (MMSE) [17] score of 20–26 (maximum score 30). These selection criteria identified cognitively healthy older individuals whose cognitive abilities were at the mean level or slightly lower than expected based on age [18]. Exclusion criteria included diagnosed dementia, suspected dementia at screening visit, conditions affecting participation in the intervention including impaired vision, hearing or ability to communicate, other conditions as judged by the physician, and participation in another trial. The design of the trial and selection of trial participants have been described in detail elsewhere [19,20].

2.2. Trial protocol

Participants were randomized in a 1:1 ratio into the multidomain lifestyle intervention group or the control group receiving general health advice. Informed consent was obtained from all participants. To maintain double-blinding as much as possible, the randomization status was not disclosed to participants, participants were instructed not to discuss the intervention with each other, and the outcome evaluators were blinded. Both the intervention and the control group participants visited the study nurse at the screening and baseline visits and at 6, 12, and 24 months. In addition, all participants met the study physician at the screening visit and at 24 months. At baseline, both groups received information and advice on healthy diet and activities that support management of vascular risk factors. During the trial, the intervention group engaged additionally in a multidomain lifestyle intervention program focusing on four components: nutrition, exercise, cognitive training, and management of vascular risk factors. Nutritional guidance