Dutch multidomain lifestyle intervention in older adults at risk of cognitive decline

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21543

Source
Nationaal Trial Register

Brief title
FINGER-NL

Health condition

Cognitively normal adults with risk factors for cognitive decline

Sponsors and support

Primary sponsor: Amsterdam UMC, location VU Medical Center (VUmc)
Source(s) of monetary or material Support: NWO

Intervention

Outcome measures

Primary outcome

2-year change from baseline in global cognitive composite score derived from subtest scores from the Neuropsychological Test Battery (NTB) that includes 15-Word Verbal Learning Test delayed recall, DDST 90 seconds, WAIS digit span backwards, and animal fluency.

Secondary outcome

2-year change from baseline in:
a) individual cognitive test performances, representing memory, processing speed and attention and executive functioning;
b) Instrumental activities of daily living;
c) Quality of life;
d) Modifiable dementia risk;
e) Intervention specific outcomes
f) Blood-based biomarkers for Alzheimer's disease (Aβ42/40, p-tau), axonal damage (NfL), astrocytes activity/injury or stress (GFAP) and brain plasticity (BDNF).

Study description

Background summary

Findings from previous observational studies have linked several vascular and lifestyle-related risk factors with increased risk of late-lifecognitive impairment. Up till 40% of dementia cases worldwide is estimated to be attributable to twelve modifiable factors (including e.g.midlife hypertension, midlife obesity, physical inactivity, and low social contact), providing prevention opportunities (1, 2). Randomisedcontrolled trials are needed to confirm whether intervention strategies targeting modifiable risk factors indeed help to maintain cognitivefunctioning (3, 4). Intervention studies targeting lifestyle factors to prevent cognitive decline and dementia have yielded mainly negativeresults, although some positive effects on cognition have been reported for dietary intervention, physical activity and cognitive training(5-12).

Successful prevention of cardiovascular disease and type 2 diabetes have emphasized the importance of a multidomain lifestyleapproach, as different aspects of lifestyle and vascular risk are thought to exert their influence in synergy (13, 14). FINGER was the firstintervention study to evaluate a multi-modal lifestyle intervention to prevent cognitive decline (15). FINGER simultaneously targeted fourlifestyle domains (physical activity, cognitive training, dietary counselling and cardiovascular risk management) and showed a positiveeffect on the cognitive composite primary outcome measure (NTB), particularly on executive functioning and processing speed. Othermulti-domain intervention studies showed a beneficial effect on cognition in specific subgroups that were at highest risk (16, 17),illustrating that for lifestyle interventions to be successful, participants should be selected for 'prevention potential' – i.e. there should beroom for improvement in modifiable risk factors.

Inspired by the positive results in FINGER, World-Wide FINGERS (WW-FINGERS, wwfingers.com) is a global effort to replicate theoriginal findings around the globe, while simultaneously optimizing the intervention under local circumstances. Additional lifestyledomains which may benefit cognition are sleep, mindfulness and social activities. Sleep problems increase with ageing and may beassociated with cognitive decline in older people (18). Internet-delivered cognitive behavioral strategies are promising to improve sleepefficiency and decrease insomnia (19). Second, cultivation of mindfulness has been

shown to be beneficial in stress management,coping with daily events, and promotes mental resilience. Recent studies have shown that long-term mindfulness meditation practicecan help maintain brain health, by beneficially influencing inflammatory processes or vascular damage (20-23). Last, social participation can help maintain cognitive health as a result of cognitive stimulation, stress buffering or enhancement of healthy behavior (24). In thecontext of a lifestyle intervention, the latter is of particular interest, since participants can help each other adhere to the lifestyle changes.

In addition, recent developments have shown promise of medical food, specifically designed to promote synapse growth and preventcognitive decline (25, 26). Souvenaid is a medical food which has been shown to prevent cognitive decline in mild cognitive impairment(27, 28). It is conceivable that daily consumption of Souvenaid could help maintain cognitive function in elderly at risk of cognitivedecline as well.

The COVID19 pandemic has boosted the application of online delivery of interventions. Online applications have great potential forpromoting interaction with and between participants. A former review has shown that web-based lifestyle programs can positivelyinfluence brain health outcomes and have the potential to help maintain brain health (29). Particularly in the Netherlands, where internetaccess is remarkably high, also among elderly (30). Taking the original FINGER study as a starting point, and embedded in the WW-Finger network, FINGER-NL is designed as a multidomain lifestyle intervention targeting eight lifestyle aspects to improve cognitivefunctioning, with a hybrid approach including both online and on site intervention sessions.

Study objective

The primary objective is to investigate the effectiveness of a personalized 2-year multidomain lifestyle intervention on cognitive performance in older adults at risk of cognitive decline.

Study design

Outcome:
Both groups visit the study site 3 times (at baseline, follow-up 1 (12 months) and follow-up 2 (24 months)) for outcome assessments including neuropsychological testing, clinical measures, blood sampling and questionnaires (duration ~3 hours).

Intervention:
The high-intensity intervention takes on average 3 hours per week for 24 months. The high-intensity group is supervised by an educated lifestyle coach to oversee and if necessary mitigate putative risks associated with the intervention. The low-intensity group gets online access to general lifestyle-related health information which takes on average ~30 minutes per month for 24 months.

Intervention

Participants are randomized in a 1:1 ratio to participate in either the high-intensity group or

the low-intensity group for a duration of 24 months. The high-intensity multidomain lifestyle intervention comprises 8 domains, namely (1) physical activity, (2) cognitive training, (3) cardiovascular risk factor management, (4) dietary counselling, (5) Souvenaid, (6) sleep counselling, (7) stress management, and (8) social activities. The high-intensity group receives a personalized, supervised intervention consisting of group meetings and individual sessions (hybrid; both online and at study site). The low-intensity intervention group gets online access to general lifestyle-related health information covering all domains except Souvenaid.

Contacts

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Eligibility criteria

Inclusion criteria

1. 60-79 years of age at pre-screening;
2. Adequate fluency in Dutch to understand the informed consent and complete questionnaires;
3. Providing informed consent to all study procedures;
4. Internet access at home;
5. Presence of ≥3 self-reported risk factors for cognitive decline (must contain at least 2 modifiable risk factors and 1 non-modifiable riskfactor):

Exclusion criteria

1. Diagnosis of dementia or mild cognitive impairment at baseline (self-reported);
2. Significant cognitive impairment assessed using the Modified Telephone Interview for Cognitive Status battery (TICSm score<23);

3. Conditions affecting safe and continuous engagement in the intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-02-2022
Enrollment:	1206
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9634
Other	METc VUmc : METc 2021.0220

Study results