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

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To investigate the effectiveness of a personalized multi-domain lifestyle intervention compared to online access to general lifestyle-related health information on cognitive performance in older adults at risk of cognitive decline. Cognitive...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52236

Source
ToetsingOnline

Brief title
FINGER-NL

Condition

- Other condition
- Lifestyle issues

Synonym
brain health, cognitive functioning

Health condition

risicofactoren voor verminderd cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NWO,bedrijven (cash and in-kind co-financiering) en Alzheimer's Association,DSM Food Specialties,Nutricia

Intervention

Keyword: cognition, intervention, lifestyle, risk-factors

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 semantic fluency.

Secondary outcome

Secondary endpoints

2-year change from baseline in:

a) individual cognitive test performances, representing memory (15-Word Verbal Learning Test delayed recall), processing speed (Digit Symbol Substitution Test 90 seconds) and attention and executive functioning (WAIS digit span backwards, semantic fluency);

b) Instrumental activities of daily living using the Amsterdam Instrumental Activity of Daily Living Questionnaire (A-IADL-Q);

c) Quality of life using the 5-level EuroQol-5D (EQ-5D-5L);

d) Modifiable dementia risk using LIfestyle for BRAin health (LIBRA);

e) Intervention specific outcomes:

• Physical activity: grip strength, physical activity (SQUASH questionnaire),

sedentary behavior (LASA Sedentary Behavior Questionnaire) and sarcopenia (SARC-F Sarcopenia Questionnaire. For participants at UMCG only: a physical activity diary (Physical Activity Record)

• Cognitive training: cognitive function (semantic fluency test), metamemory (Metamemory in Adulthood Questionnaire);

• Cardiovascular: blood pressure, cholesterol (total, HDL, LDL + triglycerides), blood glucose (HbA1C), medication adherence (Hill-Bone Medication Adherence Scale);

• Dietary counselling: nutritional intake (Traqq app), adherence to Dutch dietary guidelines (Dutch healthy diet index);

• Sleep counselling: sleep behavior (7 day sleep diary), insomnia (Insomnia severity index);

• Stress management: mindfulness (Five Facet Mindfulness Questionnaire), perception of stress (Perceived Stress Scale);

• Social activities: perceived social support (Lubben Social Network Scale), emotional and social loneliness (De Jong Gierveld Loneliness Scale).

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-life cognitive

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). Randomised controlled trials are needed to confirm whether intervention strategies targeting modifiable risk factors indeed help to maintain cognitive functioning (3, 4). Intervention studies targeting lifestyle factors to prevent cognitive decline and dementia have yielded mainly negative results, 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 lifestyle approach, as different aspects of lifestyle and vascular risk are thought to exert their influence in synergy (13, 14). FINGER was the first intervention study to evaluate a multi-modal lifestyle intervention to prevent cognitive decline (15). FINGER simultaneously targeted four lifestyle domains (physical activity, cognitive training, dietary counselling and cardiovascular risk management) and showed a positive effect on the cognitive composite primary outcome measure (NTB), particularly on executive functioning and processing speed. Other multi-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 be room 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 the original findings around the globe, while simultaneously optimizing the intervention under local circumstances. Additional lifestyle domains which may benefit cognition are sleep, mindfulness and social activities. Sleep problems increase with ageing and may be associated with cognitive decline in older people (18). Internet-delivered cognitive behavioral strategies are promising to improve sleep efficiency 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 practice can 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 the context 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 prevent cognitive 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 cognitive decline as well.

The COVID19 pandemic has boosted the application of online delivery of interventions. Online applications have great potential for promoting interaction with and between participants. A former review has shown that web-based lifestyle programs can positively influence brain health outcomes and have the potential to help maintain brain health (29). Particularly in the Netherlands, where internet access 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 cognitive functioning, with a hybrid approach including both online and on site intervention sessions.

Study objective

To investigate the effectiveness of a personalized multi-domain lifestyle intervention compared to online access to general lifestyle-related health information on cognitive performance in older adults at risk of cognitive decline.
Cognitive performance is measured as the global cognitive composite score derived from subtest scores from the Neuropsychological Test Battery (NTB).

Study design

FINGER-NL is a multi-center, randomized, controlled, multidomain lifestyle intervention trial among 1,206 older adults at risk for cognitive decline with a duration of 24 months. Participants are randomized in a 1:1 ratio to a personalized multi-domain lifestyle intervention (high-intensity intervention group) versus online access to general lifestyle-related health information (low-intensity intervention group). After the intervention period, participants are invited for a 2 year (open-label) extension of follow-up to maintain and promote positive and sustainable lifestyle changes.

Intervention

The FINGER-NL multidomain lifestyle intervention comprises eight 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 eight domains are integrated in a hybrid (both online and at study site) fashion. The online dashboard (see 6.2) is a central feature of the intervention, which provides access to the online aspects of the intervention.
Participants are randomized in a 1:1 ratio to either the high-intensity group or the low-intensity group for a duration of 24 months. The high-intensity group receives a structured and personalized intervention consisting of group meetings and individual sessions (see 6.3). The low-intensity group gets online

access to general lifestyle-related health information (see 6.4).

Study burden and risks

The high-intensity intervention group receives a personalized, hybrid intervention including online group meetings, group meetings at the study site, personal lifestyle coach sessions, individual online sessions and free access to Souvenaid®. Former studies have shown that Souvenaid® is safe and well tolerated. 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.
In addition to the intervention activities, both groups visit the study site 3 times (at baseline, follow-up 1 (12 months after start intervention) and follow-up 2 (24 months after start intervention)) for outcome assessments including neuropsychological testing, clinical measures, blood sampling and questionnaires (duration ~3 hours). Study participation might be beneficial, as it can improve (brain) health. Drawing blood samples might cause mild pain and sometimes a bruise.
*

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 60-79 years of age at pre-screening;
- Adequate fluency in Dutch to understand the informed consent and complete (online) questionnaires ;
- Providing informed consent to all study procedures;
- Internet access at home
- >=3 (self-reported) risk factors (must contain at least 2 modifiable risk factors and 1 non-modifiable risk factor):
Modifiable risk factors:
- Physical inactivity (1)
- Unhealthy diet (1)
- Low mental/cognitive activity (1)
- High blood pressure (1)
- High cholesterol (1)
- High body mass index (BMI) (2)
Non-modifiable risk factors:
- First-degree family history of dementia
- Subjective cognitive decline/memory complaints
(1) Measured using LIBRA questionnaire;
(2) Defined as >=25 kg/m2 for 60-69 years old, and >=28 kg/m2 for >=70 years old, based on self-reported height and weight.

Exclusion criteria

1. Diagnosis of dementia or mild cognitive impairment at baseline (self-reported);
2. Significant cognitive impairment assessed using a validated telephone-administered cognitive battery (TICSm score<23).
3. Conditions affecting safe and continuous engagement in the intervention (e.g. under treatment for current malignant diseases, major psychiatric disorders (e.g. major depression, psychosis, bipolar disorder), neurological disorders (e.g. Parkinson*s disease, multiple sclerosis), symptomatic

cardiovascular disease (e.g. stroke, angina pectoris, heart failure, myocardial infarction), re-vascularization within three months, severe loss of vision, hearing or communicative ability, severe mobility impairment, other conditions preventing co-operation) as judged by the local study nurse or consulted physician at the local study site;
4. Coincident participation in any other intervention trial at time of pre-screening.
5. Coincident participation of spouse/partner in the FINGER-NL trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

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

Ethics review

Approved WMO Date:	08-07-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-10-2021
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL77242.029.21
Other	volgt