

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21543

Bron

Nationaal Trial Register

Verkorte titel

FINGER-NL

Aandoening

Cognitively normal adults with risk factors for cognitive decline

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VU Medical Center (VUmc)

Overige ondersteuning: NWO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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):

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 (TICS_m score < 23);
3. Conditions affecting safe and continuous engagement in the intervention

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	09-02-2022
Aantal proefpersonen:	1206
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	28-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9634
Ander register	METc VUmc : METc 2021.0220

Resultaten