mHealth INtervention for Dementia PRevention through lifestyle Optimisation

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Ethical review	Approved WMO
Status	Pending
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON56583

Source
ToetsingOnline

Brief title
MIND-PRO

Condition

- Dementia and amnestic conditions
- Lifestyle issues

Synonym
unhealthy behavior, unhealthy lifestyle

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Dementia, lifestyle intervention, mHealth, risk reduction

Outcome measures

Primary outcome

This is a type 2 hybrid implementation-effectiveness randomised controlled clinical trial. There is a primary effectiveness outcome and there are several implementation outcomes.

- Effectiveness: composite score of systolic blood pressure, LDL-cholesterol and BMI. We will use the z-score of the difference between baseline and 12 months follow-up values to be analyzed as continuous variables, as previously done in the HATICE trial.

- Implementation of the mHealth application: Since the different implementation outcomes will have to be weighed against each other, we will measure multiple aspects of implementation using mixed methods.

o Acceptability: user-friendliness and credibility (qualitative research methods).

o Adoption: quantitative analysis of the utilisation, usage and uptake of the mHealth intervention.

o Appropriateness: qualitative analysis of the perceived fit or relevance of the mHealth intervention in the target population.

o Feasibility: qualitative analysis to what extent the mHealth application can be carried out in a low socio-economic setting and in a population with a migration background.

o Fidelity: qualitative evaluation of the degree to which the mHealth

application is implemented compared to the original design.

o Implementation cost: analysis of the implementation costs will be part of a health economic analysis.

o Sustainability: quantitative evaluation of the extent to which the mHealth application is being used during the 12 months of the implementation trial.

Secondary outcome

- Change in CAIDE and LIBRA dementia risk score
- Change in individual modifiable components of the CAIDE and LIBRA risk score (i.e. blood pressure, BMI, total cholesterol, physical activity)
- Disability (questionnaire: WHO Disability Assessment Schedule 2.0 (WHODAS 2.0, 12-item))
- Depressive symptoms (questionnaire: Geriatric Depression Scale 15-item (GDS-15))
- Self-efficacy (questionnaire: Partners In Health (PIH))
- Cost-effectiveness
- Intervention costs
- Cognitive functioning, assessed with culturally-sensitive short cognitive test battery
- Digital measures for social daily functioning measured by BeHapp (remote behavioural monitoring app). Only in a subgroup of participants willing to install the BeHapp app; separate consent will be asked on the informed consent form.

Study description

Background summary

Dementia is a growing public health problem as its prevalence is expected to rise the coming decades, particularly among people of lower socio-economic status (SES) and/or migration background. Given the absence of curative treatment, there has been a growing interest in interventions aimed at dementia prevention to mitigate the rising demand for dementia care. Dementia is associated with up to 40% modifiable risk factors which may pose an additive or even synergetic effect on dementia risk. Even a modest reduction of 10% in these risk factors can significantly decrease the incidence of dementia, especially in vulnerable communities with lower socioeconomic status and/or a migration background, where these risk factors are more prevalent. This prompted the development of a mHealth multidomain intervention, targeting several risk factors simultaneously. The widespread use of mobile phones, coupled with increasing access to the internet via mobile devices, presents a unique opportunity for leveraging mHealth to reach these underserved populations. Development of this platform is based on the experiences of the Prevention of Dementia by Mobile Phone Applications (PRODEMOS) project and the Healthy Aging through Internet Counselling of the Elderly (HATICE) study. The aim of these studies was to improve healthy lifestyle for the prevention of dementia and cardiovascular disease in a middle-aged to elderly population, delivered through a coach-supported app. In the MIND-PRO project we will built on the lessons learned from PRODEMOS and HATICE to further adapt a mobile phone application and tailor it to a population with a migration background and/or low-SES in the Netherlands.

Study objective

The overall aim is to investigate whether a coach-supported mHealth intervention for lifestyle improvement can reduce the risk of dementia in those with low SES and/or a migration background aged 50-75 years.
The specific objectives are to investigate:
- The effectiveness of a coach-supported mHealth intervention for lifestyle improvement to reduce the risk of dementia in those with low SES and/or a migration background aged 50-75 years.
- The implementation of this blended mHealth intervention for dementia prevention, operationalised as the acceptability, adoption, appropriateness, feasibility, fidelity, cost, and sustainability.

Study design

The study is a single-centre, investigator initiated, prospective, open-label blinded endpoint randomized controlled trial with 12 months intervention. The

study will be conducted in the Netherlands. We will test a culturally-sensitive blended mHealth intervention in a mixed population of vulnerable persons with low SES and/or a migration background. We will use a type 2 hybrid implementation-effectiveness design for a proof of concept study on both effectiveness and implementability of a blended mHealth intervention using a composite of three objectively measurable dementia risk factors as a composite effectiveness outcome.

Intervention

Participants randomized to the intervention arm will have access to an app that facilitates self-management of dementia risk factors (obesity, physical inactivity, hypertension, hypercholesterolemia, and active smoking). After secure login, the app shows the participants* own dementia risk profile, created through baseline measurements. Participants can set goals for lifestyle change, monitor these goals and enter self-measurements of for example weight, blood pressure and exercise. Furthermore, the platform facilitates an environment with evidence-based education modules (both static and interactive), educational videos which will be developed within the project and news items that are arranged according to personal risk factors. The participants will be supported by an experienced lifestyle coach trained in motivational interviewing who will be matched to the ethnicity of the participants as much as possible. The control condition will be a static app without coach or interactive features, with general health advice. The mHealth platform will be built in accordance with the highest security requirements in healthcare. It will comply with NEN 7510, the Health Insurance Portability and Accountability Act (HIPAA) and General Data Protection Regulation (GDPR).

Study burden and risks

The risks of participating in this study are negligible as it is a non-invasive and minimally burdensome study which may lead to a healthier lifestyle, potentially reducing the risk of dementia. There will be three site visits in total, including screening, baseline, and final visits. These visits can occur either at the research site or at the participant's home. Participants are required to provide blood samples (finger-prick) on two occasions (at t0 and t12) and will undergo physical examination (blood pressure and weight measurements) during the visits. Additionally, participants will engage with the intervention platform, which may require them to spend variable amounts of time on the app according to their preferences. The use of the intervention platform is expected to not involve any other health risks than the risks that older individuals generally experience with an active lifestyle. The intervention platform aims to support a healthier lifestyle and doesn't replace primary care, with the assigned coach overseeing goal-setting and safety. The intervention focuses on non-therapeutic aspects and does not involve investigational treatments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >= 50 years under 75 years;
- Basic level of literacy in Dutch;
- Possession of a smartphone;
- Turkish or South-Asian Surinamese background; OR Dutch background with low SES background, operationalised using educational level and occupational status.
- Increased risk of dementia based on:
1. >= 1 dementia risk factors defined as: hypertension, dyslipidaemia, Diabetes Mellitus, Active smoking, Overweight, Lack of physical exercise, Depression
2. OR Manifest cardiovascular disease, as diagnosed by specialist or general practitioner

Exclusion criteria

- Previously diagnosed with dementia by a specialist or general practitioner
- A score below the cut-off score of 21 on the Rowland Universal Dementia Assessment Scale (RUDAS), a validated dementia screening method specifically developed to be less susceptible to cultural, linguistic, and educational biases. The RUDAS is available in multiple languages, including Dutch and Turkish.
- Any condition expected to limit 12 months compliance and follow-up, including metastasised malignancy or other terminal illness
- Any impairment interfering with operation of a smartphone
- Participating in another RCT on lifestyle behavioural change

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	692
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-01-2024
Application type:	First submission

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	NL84958.018.23