ISRCTN92928122 https://doi.org/10.1186/ISRCTN92928122

Mobile health intervention for dementia prevention through lifestyle optimisation

Submission date
28/12/2023

Recruitment status
No longer recruiting

Registration date
04/03/2024

Overall study status
Ongoing

Last Edited
04/02/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Reducing risk factors for dementia is increasingly important in light of its rising prevalence in the coming decades, particularly among lower socioeconomic status (SES) and migrant populations. The aim of this study is to evaluate the effectiveness and implementation of an mHealth lifestyle intervention to optimize brain health and reduce dementia risk factors through self-management with remote coaching.

Who can participate?
People aged 50-75 years who are of low socio-economic status and/or have a migration background (Turkish or South-Asian Surinamese), and have one or more dementia risk factors or cardiovascular (heart) disease

What does the study involve?
Participants are randomly allocated to a coach-supported, interactive app facilitating self-management of dementia risk factors (including hypertension, dyslipidemia, physical inactivity, smoking, and overweight) or to a control app with static health information. Blood pressure, total cholesterol, and BMI are measured, as well as the coverage, acceptability, adoption, appropriateness, feasibility, fidelity, and sustainability of the intervention, and dementia risk score, individual risk factors, and cost-effectiveness.

Where is the study run from?
Amsterdam UMC (Netherlands)

When is the study starting and how long is it expected to run for?
January 2023 to December 2026

Who is funding the study?
ZonMw (Netherlands)

Main contact:
Edo Richard, e.richard@amsterdamumc.nl

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Edo Richard

ORCID ID
https://orcid.org/0000-0002-7250-3390

Contact details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 9111
e.richard@amsterdamumc.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
mHealth Intervention for Dementia Prevention through lifestyle Optimisation (MIND-PRO): a hybrid effectiveness-implementation randomized controlled trial in middle-aged persons with low SES and/or migration background

Acronym
MIND-PRO

Study objectives
The intervention is effective in reducing dementia risk factors and can be implemented to reduce dementia risk factors.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 30/01/2024, METC Amsterdam UMC (Meibergdreef 9, Amsterdam, 1105AZ, Netherlands; +31 (0)20 444 55 85; metc@vumc.nl), ref: 2023.0770

Study design
Single-center investigator initiated prospective randomized open-label blinded endpoint (PROBE) trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Lowering dementia risk factors in people with elevated dementia risk

Interventions
Current interventions as of 19/06/2024:
Randomization will take place in the app using a computer algorithm in a 1:1 manner. Participants will be informed that random allocation will be to one of two different smartphone apps and that the study is on improving lifestyle to reduce dementia risk factors. Partners who also participate in MIND-PRO will automatically be allocated to the same treatment arm, to avoid contamination.

The intervention is aimed at lifestyle behavioural change using a mHealth intervention (app), supported by a coach. Participants randomized to the intervention arm will have access to an interactive mobile app that facilitates self-management of dementia risk factors (hypertension, dyslipidaemia, active smoking, overweight, lack of physical exercise). After secure login, the app shows the participants' dementia risk profile, based on baseline assessment. Participants can set goals for lifestyle change, monitor these goals, and enter self-measurements of for example weight, blood pressure and physical exercise. Furthermore, the app contains 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 coaches will use motivational interviewing to help participants to formulate simple, measurable, achievable, realistic and time-bound (SMART) goals and guide the process to achieve the goals.

Participants randomized to the control condition will have access to an app which is similar in appearance but lacks any interactive features and does not provide coach support. It will contain general information on how to live a healthy lifestyle.

The intervention and follow-up are 12 months for the intervention and control group.

Previous interventions:
Randomization will take place in the app using a computer algorithm in a 1:1 manner, stratified by ethnicity. Participants will be informed that random allocation will be to one of two different smartphone apps and that the study is on improving lifestyle to reduce dementia risk factors. Partners who also participate in MIND-PRO will automatically be allocated to the same treatment arm, to avoid contamination.

The intervention is aimed at lifestyle behavioural change using a mHealth intervention (app), supported by a coach. Participants randomized to the intervention arm will have access to an interactive mobile app that facilitates self-management of dementia risk factors (hypertension, dyslipidaemia, active smoking, overweight, lack of physical exercise). After secure login, the app shows the participants' dementia risk profile, based on baseline assessment. Participants can set goals for lifestyle change, monitor these goals, and enter self-measurements of for example weight, blood pressure and physical exercise. Furthermore, the app contains 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 coaches will use motivational interviewing to help participants to formulate simple, measurable, achievable, realistic and time-bound (SMART) goals and guide the process to achieve the goals.

Participants randomized to the control condition will have access to an app which is similar in appearance but lacks any interactive features and does not provide coach support. It will contain general information on how to live a healthy lifestyle.

The intervention and follow-up are 12 months for the intervention and control group.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 05/06/2024:

All effectiveness outcomes are measured at baseline and at the study end after 12 months.

1. The primary effectiveness outcome will be a composite score of the objectively measurable dementia risk factors:
1.1. Systolic blood pressure measured twice with a calibrated automated blood pressure device
1.2. non-HDL cholesterol measured using a capillary blood sample
1.3. BMI (kg/m2) calculated using weight and height measured with a calibrated scale

Implementation outcomes:
Quantitative:
2.1. Coverage: (non)response rates, comparison characteristics participants with eligible/source population measured at baseline
2.2. Adoption: quantitative analysis of the utilisation, usage and uptake, e.g. logins, goals setting, sending messages measured after 1 month (data features)
2.3. Appropriateness measured using a short questionnaire of perceived fit or relevance after 6 months and at study end
2.4. Acceptability measured using a short questionnaire of agreeability, user-friendliness, credibility, complexity, content* after 6 months and at study end
2.5. Sustainability: adherence, dropout measured after 6 months and at the end of the study, data features throughout the study
2.6. Implementation cost estimated by platform price and coach full-time equivalent at the end of the study

Qualitative:
2.7. Feasibility: the extent to which the mHealth intervention can be carried out, practical and

social barriers/facilitators measured after 6 months
2.8. Appropriateness: perceived fit or relevance in the target population measured after 6 months
2.9. Acceptability: agreeability, user-friendliness, credibility, complexity, content measured after 6 months
2.10. Fidelity: the degree to which the mHealth application is implemented compared to the original protocol, measured after 6 months
2.11. Adoption: initial utilisation, usage and uptake measured after 6 months
2.12. Sustainability: adherence, dropout measured after 6 months

_____

Previous primary outcome measure:

All effectiveness outcomes are measured at baseline and at the study end after 12 months.

1. The primary effectiveness outcome will be a composite score of the objectively measurable dementia risk factors:
1.1. Systolic blood pressure measured twice with a calibrated automated blood pressure device
1.2. Total cholesterol measured using a capillary blood sample
1.3. BMI (kg/m2) calculated using weight and height measured with a calibrated scale

Implementation outcomes:
Quantitative:
2.1. Coverage: (non)response rates, comparison characteristics participants with eligible/source population measured at baseline
2.2. Adoption: quantitative analysis of the utilisation, usage and uptake, e.g. logins, goals setting, sending messages measured after 1 month (data features)
2.3. Appropriateness measured using a short questionnaire of perceived fit or relevance after 6 months and at study end
2.4. Acceptability measured using a short questionnaire of agreeability, user-friendliness, credibility, complexity, content* after 6 months and at study end
2.5. Sustainability: adherence, dropout measured after 6 months and at the end of the study, data features throughout the study
2.6. Implementation cost estimated by platform price and coach full-time equivalent at the end of the study

Qualitative:
2.7. Feasibility: the extent to which the mHealth intervention can be carried out, practical and social barriers/facilitators measured after 6 months
2.8. Appropriateness: perceived fit or relevance in the target population measured after 6 months
2.9. Acceptability: agreeability, user-friendliness, credibility, complexity, content measured after 6 months
2.10. Fidelity: the degree to which the mHealth application is implemented compared to the original protocol, measured after 6 months
2.11. Adoption: initial utilisation, usage and uptake measured after 6 months
2.12. Sustainability: adherence, dropout measured after 6 months

Key secondary outcome(s))

Current secondary outcome measures as of 05/06/2024:

All effectiveness outcomes are measured at baseline and at study end after 12 months:
1. Physical exercise measured using the self-administered short International Physical Activity Questionnaire - Short Form (IPAQ-SF)
2. Disability measured using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0, 12-item)
3. Depressive symptoms measured using the Geriatric Depression Scale 15-item (GDS-15)
5. Dementia risk score measured using Cardiovascular Risk Factors, Aging and Dementia (CAIDE)
6. Individual modifiable components of the CAIDE risk score
7. Intervention costs measured using costs of coaches and intervention development by Interactive Studios
8. Cost-effectiveness analyses using health-economic decision-analytic model
9. Cognitive functioning measured using the Rowland Universal Dementia Assessment Scale (RUDAS) and Box task
10. Daily distance moved, measured usingBehapp, a remote behavioural monitoring app, in a subgroup of participants willing to install the BeHapp app

_____

Previous secondary outcome measures:

All effectiveness outcomes are measured at baseline and at study end after 12 months:
1. Physical exercise measured using the self-administered short International Physical Activity Questionnaire - Short Form (IPAQ-SF)
2. Disability measured using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0, 12-item)
3. Depressive symptoms measured using the Geriatric Depression Scale 15-item (GDS-15)
5. Dementia risk score measured using Cardiovascular Risk Factors, Aging and Dementia (CAIDE)
6. Individual modifiable components of the CAIDE risk score
7. Intervention costs measured using costs of coaches and intervention development by Interactive Studios
8. Cost-effectiveness analyses using health-economic decision-analytic model
9. Cognitive functioning measured using the Rowland Universal Dementia Assessment Scale (RUDAS)
10. Daily distance moved, measured usingBehapp, a remote behavioural monitoring app, in a subgroup of participants willing to install the BeHapp app

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/06/2024:

1. Age ≥50 years ≤75 years
2. Basic level of literacy in Dutch
3. Possession of a smartphone
4. Turkish or South-Asian Surinamese background; OR Dutch background with low SES, operationalised using educational level and occupational status
5. Increased risk of dementia based on ≥ one dementia risk factor defined as:
5.1. Hypertension, defined by any of the following:
5.1.1. Diagnosis by specialist or general practitioner.
5.1.2. Currently on anti-hypertensive drugs.

5.1.3. Baseline blood pressure: ≥140/90 mmHg;
5.2. Dyslipidaemia, defined by any of the following:
5.2.1. Diagnosis by specialist or general practitioner
5.2.2. Use of lipid-lowering drugs
5.2.3. Baseline total cholesterol ≥5.0 mmol/L
5.3. Diabetes mellitus, defined by any of the following:
5.3.1. Diagnosis by specialist or general practitioner
5.3.2. Use of any blood glucose-lowering medication
5.4. Active smoking (use of any sort of tobacco in any quantity)
5.5. Overweight, defined by any of the following:
5.5.1. Body mass index (BMI) ≥30 kg/m²
5.5.2. Waist circumference men ≥102 cm, women ≥88 cm
5.6. Lack of physical exercise, defined as below the World Health Organization (WHO) norm (five times a week 30 minutes or a total of 150 minutes per week of intermediate exercise)
5.7. Depression
5.7.1. Currently on anti-depressive medication or receiving psychotherapy for depression
5.7.2. History of treatment (i.e. drug therapy or psychotherapy) for depression OR Manifest cardiovascular disease, as diagnosed by specialist or general practitioner

———

Previous inclusion criteria:

1. Age ≥50 years ≤75 years
2. Basic level of literacy in Dutch
3. Possession of a smartphone
4. Turkish or South-Asian Surinamese background; OR Dutch background with low SES, operationalised using educational level and occupational status
5. Increased risk of dementia based on ≥ one dementia risk factor defined as:
5.1. Hypertension, defined by any of the following:
5.1.1. Diagnosis by specialist or general practitioner.
5.1.2. Currently on anti-hypertensive drugs.
5.1.3. Baseline blood pressure: ≥140/90 mmHg;
5.2. Dyslipidaemia, defined by any of the following:
5.2.1. Diagnosis by specialist or general practitioner
5.2.2. Use of lipid-lowering drugs
5.2.3. Baseline total cholesterol ≥5.0 mmol/L
5.3. Diabetes mellitus, defined by any of the following:
5.3.1. Diagnosis by specialist or general practitioner
5.3.2. Use of any blood glucose-lowering medication
5.4. Active smoking (use of any sort of tobacco in any quantity)
5.5. Overweight, defined by any of the following:
5.5.1. Body mass index (BMI) ≥25 kg/m²
5.5.2. Waist circumference men ≥102 cm, women ≥88 cm
5.6. Lack of physical exercise, defined as below the World Health Organization (WHO) norm (five times a week 30 minutes or a total of 150 minutes per week of intermediate exercise)
5.7. Depression
5.7.1. Current depression
5.7.2. Currently on anti-depressive medication or receiving psychotherapy for depression
5.7.3. History of treatment (i.e. drug therapy or psychotherapy) for depression OR Manifest cardiovascular disease, as diagnosed by specialist or general practitioner

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Diagnosed with dementia by a specialist or general practitioner
2. A score below 21 on the Rowland Universal Dementia Assessment Scale (RUDAS) validated dementia screening method specifically developed to be less susceptible to cultural, linguistic, and educational biases
3. Any condition expected to limit 12 months of compliance and follow-up, including metastasised malignancy or other terminal illness
4. Any impairment interfering with the operation of a smartphone
5. Participating in another RCT on lifestyle behavioural change
6. Present alcohol or illicit drug abuse impairing study participation

Date of first enrolment
01/07/2024

Date of final enrolment
01/07/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC
Meibergdreef 9
Amsterdam
Netherlands
1105AZ

Sponsor information

Organisation
Amsterdam University Medical Centers

ROR
https://ror.org/05grdyy37

Funder(s)

Funder type
Government

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon reasonable request in anonymised .csv format after publication of the main results for at least 5 years after publication. The request can be sent to the data manager, currently Dr M. Hoevenaar-Blom (m.p. hoevenaarblom@amsterdamumc.nl), upon which the study steering committee will judge the suitability of the data for the research question. In the informed consent form, explicit consent will be asked for future data use for research questions related to the original research question.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article		03/02/2025	04/02/2025	Yes	No
Participant information sheet	Participant information sheet version 3.1	11/11/2025	11/11/2025	No	Yes
Protocol file		30/05/2024	05/06/2024	No	No
Protocol file		14/06/2024	19/06/2024	No	No
Statistical Analysis Plan		05/06/2024	05/06/2024	No	No
Statistical Analysis Plan		14/06/2024	19/06/2024	No	No