

Healthy Ageing Through Internet Counselling in the Elderly

Published: 26-06-2014

Last updated: 20-04-2024

To investigate whether an interactive internet-based intervention strategy targeting vascular and lifestyle-related risk factors can lead to improvement of cardiovascular risk profile and prevention of cardiovascular disease and whether this in turn...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON44453

Source

ToetsingOnline

Brief title

HATICE

Condition

- Cardiac disorders, signs and symptoms NEC
- Central nervous system vascular disorders
- Vascular hypertensive disorders

Synonym

cardiovascular disease, cardiovascular risk

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Europese Commissie

Intervention

Keyword: cardiovascular risk, Healthy Aging, internetplatform, lifestyle

Outcome measures

Primary outcome

The primary endpoint of the study is a weighted composite score based on z-scores of the difference between baseline and 18 months follow-up values of systolic blood pressure, cholesterol and BMI.

Secondary outcome

Main secondary endpoints are z-scores of the individual risk factors, 10-year risk of cardiovascular disease (Framingham risk score), number of risk factors on target, incident cardiovascular disease, CAIDE dementia risk-score, disability, depression, cognitive decline and mortality.

Study description

Background summary

Older persons with multiple cardiovascular risk factors and/or cardiovascular disease are at increased risk of poor clinical outcome: myocardial infarction, stroke, cognitive decline, dementia and death. Adherence to effective and evidence-based interventions is thought to play an important role in prevention. Improved patient engagement has considerable potential to improve management of individuals at risk. In HATICE an innovative Internet platform to optimise management of cardiovascular risk factors in older persons is developed and will be tested for efficacy in a randomised controlled clinical trial.

Study objective

To investigate whether an interactive internet-based intervention strategy targeting vascular and lifestyle-related risk factors can lead to improvement of cardiovascular risk profile and prevention of cardiovascular disease and whether this in turn may prevent or delay the onset of cognitive decline and

dementia.

Study design

European, multi-centre, investigator initiated, open-label blinded endpoint (PROBE), parallel group, randomised controlled trial.

Intervention

The intervention group gets access to an interactive internet platform supported by a coach to facilitate and encourage self-management of risk factors and lifestyle change. The control group receives care as usual and access to an internet platform similar in appearance, but only providing general information on a healthy lifestyle, without the interactive features.

Study burden and risks

All participants have two site visits (baseline and 18 months). At both visits a venous blood sample will be taken. During the site visits the participants get a physical examination and are requested to fill out questionnaires on disability, depression, physical activity, diet, quality of life and self-management. A short neuropsychological test battery will be applied. Participants in the intervention group are recommended to visit the internet platform at least once a week for 20 minutes and monitor their lifestyle, although intensity of use can be adapted according to participant's wishes. If participants manage to improve their risk profile they might benefit from this, since this might reduce their risk for cardiovascular disease.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age \geq 65 years
- Available informant
- * two cardiovascular risk factors and/or manifest cardiovascular disease defined as:
cardiovascular risk factors;
 - * hypertension, defined by either:
 - o diagnosis by specialist or a general practitioner
 - o currently on anti-hypertensive drugs
 - o if < 80 years: $\geq 140/90$; if ≥ 80 years: Systolic BP ≥ 160
 - * dyslipidemia, defined by either:
 - o diagnosis of dyslipidemia by specialist or GP
 - o use of lipid-lowering drug (this will include persons who have no dyslipidemia, but use it after a previous cardiovascular disease; this is acceptable, since these people automatically fulfil inclusion criteria as well)
 - o baseline cholesterol or TC/HDL ratio or LDL above or below cut-offs according to European guidelines
 - * overweight, defined by either:
 - o BMI > 30
 - o Waist circumference men > 102 cm, women > 88 cm
 - * active smoking (self-reported, any tobacco use)
 - * lack of physical exercise (self-reported) defined as below the WHO norm of 5 times a week 30 minutes (or a total of 150 minutes per week) of intermediate exercise.
- OR
- * History of cardiovascular disease: stroke/TIA, myocardial infarction, angina pectoris, peripheral arterial disease and/or diabetes mellitus (DM)

Exclusion criteria

- Previously diagnosed dementia as diagnosed by a GP or specialist
- Mini Mental State Examination score <24
- Any condition expected to limit 18-months compliance and follow-up
- Computer illiteracy, defined as unable to send an email
- Severe visual impairment interfering with operating a computer
- Participating in another randomised controlled trial

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2015
Enrollment:	1450
Type:	Actual

Ethics review

Approved WMO	
Date:	26-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-10-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-05-2016
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	NL48261.018.14