ISRCTN48151589 https://doi.org/10.1186/ISRCTN48151589

Healthy aging through internet counseling in the elderly

Submission date
18/06/2014

Recruitment status
No longer recruiting

Registration date
05/09/2014

Overall study status
Completed

Last Edited
07/04/2022

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Older people that have cardiovascular disease (for example, heart disease, stroke) or have a number of risk factors that make them more likely to develop cardiovascular disease (for example, high blood pressure, diabetes, high cholesterol levels) are at an increased risk of a heart attack (myocardial infarction), stroke, dementia and death. Effective treatment for cardiovascular disease is available, but may not be enough to prevent serious health problems in cases where the patient has a number of risk factors. Being able to manage these risk factors is therefore thought to have an important preventive role and getting the patients actively involved is also likely to be beneficial. HATICE is an internet programme (intervention) that has been developed to help older people to manage their own health and, in particular, manage their pre-existing cardiovascular risk factors. Here, we want to find out if such an intervention can help prevent cardiovascular disease and also prevent, or at least delay, the onset of dementia.

Who can participate?
Adults that are at least 65 years of age, have two or more cardiovascular risk factors or have a history of cardiovascular disease.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are able to use an interactive internet programme that helps and encourages them to make changes to their lifestyle and manage their own risk factors. Those in group 2 are given their usual care and also access to an internet programme similar in appearance to that used by group 1 participants, but only providing general information on a healthy lifestyle, without the interactive features. Each participants BMI, blood pressure and blood cholesterol levels are taken before the start of the trial and 18 months later. They are also asked to fill out questionnaires on disability, depression, physical activity, diet, quality of life and self-management. They are also tested for dementia.

What are the possible benefits and risks of participating?
All participants have a blood sample taken at before the start of the trial and 18 months later. Participants in group 1 may benefit from the interactive internet programme and find that their risk of cardiovascular disease is reduced.

Where is the study run from?
The HATICE study has been set up by the Academic Medical Centre (AMC) in Amsterdam, the University of Eastern Finland (UEF), Institut National de la Sante et de la Recherche Medicinale (INSERM) in France, the Karolinska Institutet in Sweden and the University of Cambridge in England. Recruitment of participants will take place in three countries (Netherlands, Finland, France).

When is study starting and how long is it expected to run for?
January 2015 to January 2018

Who is funding the study?
European Unions' Seventh Framework Programme

Who is the main contact?
Dr E. Richard
E.richard@amc.nl

Study website
http://www.hatice.eu

Contact information

Type(s)
Scientific

Contact name
Dr Edo Richard

Contact details
Academic Medical Centre Amsterdam
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
305374

Study information

Scientific Title

Healthy aging through internet counseling in the elderly: a European, multi-centre, investigator initiated, open-label blinded endpoint (PROBE), parallel group, randomised controlled trial

Acronym
HATICE

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Northern Savonia Hospital District Research Ethics Committee (Finland), 10/06/2014, ref: 35 /2014
2. Medical committee of the Academic Medical Center (Netherlands), 26/06/2014, ref: METC 2014_126.
3. Comité de Protection des Personnes (CPP) Sud Ouest et Outre Mer (France), 24/09/2014, ref: 2014-A01287-40

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet
Currently not available in web format, please use the contact details below to request a patient information sheet. For each country we will have a website where patient information will be available. These are currently under construction. Dutch website: www.capio-onderzoek.nl Finnish website: www.terveika.fi French website: www.resteractif.fr

Health condition(s) or problem(s) studied
Cardiovascular prevention

Interventions

1. The intervention group is provided with access to an interactive internet platform supported by a coach to facilitate and encourage self-management of risk factors and lifestyle change.
2. 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.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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. The rationale behind this primary outcome is that:
1. 18-months follow-up is too short for a significant number of clinical outcome events even when using this sample size
2. Only measurable risk factors are included (self-reported factors such as physical exercise are sensitive to bias)
3. This will allow for very sensitive and direct assessment of the risk factors we target
This has the potential caveat of making a type I error, but even a very small effect on cardiovascular risk profile could have considerable effect at the population level (prevention paradox).

Secondary outcome measures
Main secondary outcomes are:
1. Z-scores of individual components of the primary outcome only in persons who have this risk score at baseline
2. Improvement in estimated 10-year cardiovascular disease risk based on the Framingham cardiovascular disease risk score (measured at 18 months)
3. Incident cardiovascular disease (stroke/TIA, myocardial infarction, peripheral arterial disease, heart failure)
4. Improvement of the number of measurable risk factors (blood pressure, BMI, cholesterol, glycated haemoglobin)
5. Improvement of the number of self-reported risk factors (physical exercise, diet)
6. Mortality
7. Disability
8. Cognitive decline
9. CAIDE dementia risk-score
10. Physical fitness (short physical performance battery)
11. Depression (15-item Geriatric Depression Scale)
12. Cost-effectiveness

Overall study start date
01/01/2015

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. Age ≥ 65 years
2. Available informant
3. ≥ 2 cardiovascular risk factors and/or manifest cardiovascular disease defined as:
3.1. Cardiovascular risk factors:
3.1.1. Hypertension, defined by any of the following:
3.1.1.1. Diagnosis by specialist or GP
3.1.1.2. Currently on anti-hypertensive drugs
3.1.1.3. Baseline BP: if < 80 years: ≥ 140/90 mmHg; if ≥ 80 years: Systolic BP ≥ 160
3.1.2. Dyslipidemia, defined by any of the following:
3.1.2.1. Diagnosis of dyslipidemia by specialist or GP
3.1.2.2. 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)
3.1.2.3. Baseline total cholesterol ≥ 5 mmol/L and/or LDL ≥ 2.5 mmol/L
3.1.3. Overweight, defined by any of the following:
3.1.3.1. BMI ≥ 30
3.1.3.2. Waist circumference men ≥102 cm, women ≥88 cm
3.1.4. Active smoking (self-reported, any tobacco use)
3.1.5. Lack of physical exercise (self-reported) defined as below the WHO norm of 30 minutes 5 times a week (or a total of 150 minutes per week) of intermediate exercise
or
3.2. History of cardiovascular disease:
3.2.1. Stroke/transient ischemic attack (TIA)
3.2.2. Myocardial infarction
3.2.3. Angina pectoris
3.2.4. Peripheral arterial disease
3.2.5. Diabetes mellitus (DM)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
2600

Total final enrolment
2724

Key exclusion criteria
1. Previously diagnosed dementia as diagnosed by a GP or specialist
2. Mini Mental State Examination score <24
3. Any condition expected to limit 18-months compliance and follow-up

4. Computer illiteracy, defined as unable to send an email and/or do a simple Google search
5. Severe visual impairment interfering with operating a computer
6. Participating in another randomised controlled trial

Date of first enrolment
01/01/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
Finland

France

Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre Amsterdam (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme, grant agreement No 305374

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication of study results in a high-impact peer reviewed journal.

Intention to publish date
15/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. E. Richard (e.richard@amc.uva.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/06/2016		Yes	No
Statistical Analysis Plan		12/06/2017	27/06/2017	No	No
Results article	qualitative sub-study results	21/01/2018		Yes	No
Results article	qualitative sub-study results	06/06/2019	02/06/2020	Yes	No
Results article	qualitative study results	06/08/2020	10/08/2020	Yes	No
Results article	results	01/12/2019	17/12/2020	Yes	No
Other publications	Factors predicting engagement in the intervention	13/12/2021	07/04	Yes	No

/2022