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The feasibility and practicality of dementia risk reduction

Submission date
09/07/2018

Recruitment status
No longer recruiting

Registration date
16/07/2018

Overall study status
Completed

Last Edited
11/12/2019

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Thirty percent of Alzheimer's disease cases have been linked to modifiable lifestyle behaviours such as smoking and lack of physical activity. However, to date, much focus for prevention has focused on the younger old age groups rather than those who are at highest immediate risk of developing dementia (i.e. persons aged 75 years and older). Internet counselling, targeting lifestyle behaviours, is being developed as a possible way to reduce risk but it is not known if such an intervention would be acceptable, feasible or appropriate for people aged over 75 years in the UK. The aim of this study is to test an internet counselling intervention targeting cardiovascular (heart disease) risk factors that has been successfully trialed in continental Europe (Netherlands, France and Finland) in the Cognitive Function and Ageing Study II (CFAS II). The aim is to investigate the feasibility and acceptability of the intervention to UK populations and whether outcome measures are suitable for launching a full-scale trial.

Who can participate?
Past participants in the CFAS II study who have at least one of the following: hypertension (high blood pressure), angina (chest pain), intermittent claudication (cramping pain in the leg) or heart attack, stroke or transient ischaemic attacks (mini stroke), current or recent smoker (within last five years), diabetes, physically inactive

What does the study involve?
Participants are randomly allocated to receive either internet counselling with support from a coach over 12 weeks or to receive information on cardiovascular risk factors. Information is collected about participant's memory and thinking skills and risks of heart and other health problems at the start and end of the study. In addition, a random group in each centre receive no intervention at all to test whether the trial recruitment itself changes behaviour.

What are the possible benefits and risks of participating?
The results will show whether a larger trial is feasible. Participants who receive the intervention may feel some benefit to their health following the trial – giving up smoking, eating a more balanced diet and reduction of cholesterol levels and blood pressure will be potential long-term benefits if adhered to. Participants may find it difficult to reduce or stop smoking, increase their level of activity or eat a balanced diet. The researchers will work with participants to achieve

Specific Measurable Achievable Realistic Targets (SMART) which should reduce potential burden and risk.

Where is the study run from?
1. Cambridge University (UK)
2. Nottingham University (UK)
3. Newcastle University (UK)

When is the study starting and how long is it expected to run for?
January 2018 to June 2020

Who is funding the study?
Alzheimer's Research UK

Who is the main contact?
Linda Barnes
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Study website
http://www.cfas.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37290

Study information

Scientific Title
The feasibility and practicality of dementia risk reduction in the older population: a pilot trial

Study objectives
Thirty percent of Alzheimer's disease cases have been linked to modifiable lifestyle behaviours such as smoking and lack of physical activity. However, to date, much focus for prevention has focused on the younger old age groups rather than those who are at highest immediate risk of developing dementia (i.e. persons aged 75 years and older). Internet counselling, targeting lifestyle behaviours, is being developed as a possible way to reduce risk but it is not known if such an intervention would be acceptable, feasible or appropriate for people aged over 75 years in the UK.

The trialists propose to pilot an internet counselling intervention targeting cardiovascular risk factors that has been successfully trialed in continental Europe (Netherlands, France and Finland) in an existing cohort study (Cognitive Function and Ageing Study II (CFAS II)). The aim is to investigate feasibility and acceptability to UK populations and whether outcome measures are suitable for launching a full-scale trial. If effective these interventions can then be translated and scaled up for the benefit of older populations.

Aim: to conduct the preparatory work necessary to design a feasible, large scale, randomised controlled trial of an internet based intervention in the older population by resolving key uncertainties for trials in this neglected age group. Specific objectives include: trialling administration procedures for randomisation, ascertaining the numbers of eligible participants and the number who accept randomisation, estimating rate of recruitment, short term retention and adherence/fidelity; as well as assessing the variability of primary outcomes, changes in outcome in the intervention and control groups and the safety and comprehensiveness of the data collection. The trialists will also assess the impact of engagement in such a trial on a sample typical of people aged 75 years and older in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 7, 30/04/2018, ref: 18/WA/0120

Study design
Randomised; Both; Design type: Prevention, Education or Self-Management, Validation of outcome measures

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dementia

Interventions
Timetable: Training of interviewers will be conducted in April 2018. Once governance processes (DBS, Research letters of access etc), are in place the trialists will begin approaching participants in May 2018. They will conduct the interviews and 12 week follow up interviews over a period of 15 months. Qualitative interviewing will begin July 2018 until August 2019 with focus groups being held between January and July 2019. The study will end in June 2020.

Recruitment: All potential participants were recruited into the Cognitive Function and Ageing Study II (CFAS II) between 2008 and 2011. Over 7700 people were initially recruited to the study from three centres of the UK – Cambridge, Newcastle and Nottingham. All participants have conducted a baseline and two year follow-up interview. All participants have given their consent for the study to approach them in the future for further interviews. Interviews will take place in participants own homes or a place of their choosing which provides a level of privacy.

The trialists will approach 336 CFAS II participants aged over 75 years in each centre and invite them to take part in a further wave of interviewing. The interview is administered using assisted computer direct entry and has the following sections: demographics (marital status, education, residential status and intellectual activity) Lifestyle (smoking and alcohol), brief measure of physical activity. Health status including self-perceived health, self-reported chronic diseases including heart disease, angina, diabetes, stroke, Parkinson's disease, epilepsy and meningitis. Rose angina questionnaire, medication history, activities of daily living and cognition. We will also include new proposed outcome measures: Australian National University Alzheimer Disease Risk Index (ANU ADRI), EQ-5D - a health related quality of life questionnaire, blood pressure, cholesterol measurement and body mass index.

At the end of the computer based interview participants will be randomly selected into groups, 72 will remain in the epidemiological investigation per site, this will be split into two arms. The first arm (EC) will include the existing CFAS interview and new measurements. The result of the cholesterol measurement will be fed back to participants.

The second arm (EO) will include the existing CFAS interview, and the new outcome measures, however this group will not be given their cholesterol result at the end of the first interview, this will enable us to see if knowledge of cholesterol measurement itself changes behaviour. For both these groups (EC and EO) there is no change to their participation in CFAS II and they will continue, as originally consented, to be part of the ongoing epidemiological study. The trialists

will request a follow up interview to record the new measures, inclusive of cholesterol. At the end of the 12 weeks interview both the EC and EO participants will receive the results of their cholesterol measurement.

Intervention component: 72 individuals per site will be split into two arms. The first arm, intervention control (IC) will consist of individuals who have been informed of the randomised control trial for risk reduction and have consented to take part but have been randomised to the control group, this will allow participants access to a static area of the HATICE internet platform where they can read information on cardiovascular risk factors. This platform will lack the interactive features and coach support seen by those in the active treatment group.

The second arm will consist of individuals who have been informed of the randomised control trial for risk reduction, have consented to take part and have been randomised to the active trial intervention (AT). The intervention is interactive allowing participants to set personal goals for lifestyle change, making a corresponding action plan and monitor goals by entering data (e.g. blood pressure and weight) supported by a coach trained in motivational interviewing. Equipment for the measurement of blood pressure and weight will be left with participants for the 12 week trial and collected at the 12 week interview. Guided by the preferences of the participant, the coach provides remote support by assisting in realistic goal-setting according to Specific, Measurable, Attainable, Realistic, and Time bound (SMART) principles. Communication between the participant and coach is through the HATICE platform's messaging system. Participants are advised to log in every week although this is not compulsory. The coach receives automatic alerts when participants enter measurements or when a participant has not been active on the platform for 3 weeks.

A final group, not in trial (NT) will consist of individuals who were asked to take part in the intervention trial, but did not wish to participate. These individuals will continue to be included in the epidemiological study and will complete any subsequent follow-up interviews if they consent to do so.

Qualitative component: The qualitative work will focus on the acceptability of the intervention to key stakeholders (older people and their carers; intervention coaches and clinicians), the fidelity of the intervention and the feasibility of conducting a large-scale trial of the intervention in England including recruitment through the CFAS study.

The trialists will sample 30 dyads to ensure maximum variation on the basis of location, age, gender and frequency of engagement with the intervention platform, all participants will be interviewed within 2 weeks of the end of the intervention period. Participants will be asked to evaluate the intervention platform materials, and interaction with the coaches. A smaller number, 10 dyads from the control arm will be recruited to assess the control website interactions.

In the second year participants from the different trial arms will be brought together including the EO and EC groups to allow full discussion on the changes participants have seen in their own participation in CFAS and their thoughts on the change from epidemiology to intervention and their ideas for future trials.

Intervention Type
Behavioural

Primary outcome measure

From 25/06/2018:
This trial is not powered to investigate health outcomes. The primary aim of the study is to conduct the preparatory work necessary to design a large-scale randomised controlled trial of an internet based intervention in the older population by resolving key uncertainties for trials in this population of older age adults (75-90 years) with an increased cardiovascular risk.

Prior to 25/06/2018:
The proportion of people with pre-existing eligibility criteria from the CFAS II cohort who remain eligible for approach

From 25/06/2018:
1. The acceptability of the intervention to the target population of people aged 75-90 years, measured at baseline
2. The proportion of the older population who have access to and use the internet, measured at baseline
3. A primary health outcome measure of treatment will be a change in the Australian National University - Alzheimer Disease Risk Index (ANU-ADRI) score conducted at baseline and 12-week follow-up interviews
4. The number of those randomised to the 'active intervention' group who agree to accept the intervention
5. The proportion of those randomised to the 'control intervention' group who agree to take part
6. The retention rate post randomisation at baseline for all groups
7. The adherence rate during the internet intervention period of 12 weeks

Secondary outcome measures
From 25/06/2018:
1. The variability between baseline and 12 weeks in the main outcome measure (ANU-ADRI), a validated self-reported tool to identify those at risk of Alzheimer's disease (AD) and dementia in later life
2. Composite scores of systolic blood pressure, total cholesterol, body mass index and MMSE at baseline and 12-week follow-up interviews
3. The EuroQol 5-Dimension (EQ-5D), a health-related quality of life questionnaire, will be measured and tested for suitability as an assessment of cost-effectiveness for the main trial
4. Alternative health outcome measures such as brief dementia screening index, and the UK based dementia risk score, will be measured for comparison purposes at 12 weeks
5. At baseline the trialists will determine the impact of the trial discussion on study retention
6. The extent to which informed consent has modified behaviour at 12 weeks
7. The potential for changes in outcomes in intervention and control groups at 12 weeks

Overall study start date
01/01/2018

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Past participants in the Cognitive Function and Ageing Study II who have not refused further contact with the study
2. Must report at least 1 of the following:

2.1. Hypertension, angina, intermittent claudication or heart attack
2.2. Stroke or transient ischaemic attacks
2.3. Current or recent smoker (within last five years)
2.4. Diabetes
2.5. Physically inactive
3. Participants must have capacity to provide informed consent
4. Must have access to a computer (library if not at home)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 765; UK Sample Size: 765

Total final enrolment
756

Key exclusion criteria
1. Non participants of the Cognitive Function and Ageing Study II or those study participants who have refused further contact from the study
2. Dementia or cognitive impairment (study diagnosis using CFAS algorithm) or MMSE< 21
3. Computer illiteracy (defined as unable to send email)
4. Severe visual impairment (interferes with computer operation)

Date of first enrolment
25/06/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University (lead centre)
CFAS, Institute of Public Health
Forvie Site, University of Cambridge
School of Clinical Medicine
Cambridge Biomedical Campus

Cambridge
United Kingdom
CB2 0SR

Study participating centre
Nottingham University
Institute of Mental Health
Triumph Road
Nottingham
United Kingdom
NG7 2TU

Study participating centre
Newcastle University
Institute for Ageing and Health & Society
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Sponsor type
University/education

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Charity

Funder Name
Alzheimer’s Research UK; Grant Codes: ARUK-PRRF2017-008

Alternative Name(s)
Alzheimer's Research Trust, AlzheimersResearch UK, AlzResearchUK, ARUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol will be submitted for publication and when available will be uploaded. Planned publications in peer review scientific journals, internal reports and conference presentations. Results will also be displayed in a report on the participant area of the study website www.cfas.ac.uk and on department websites of the study centres in Cambridge, Newcastle and Nottingham Universities. Results will be shared with the GP surgeries of the participants.

Intention to publish date
30/06/2021

Individual participant data (IPD) sharing plan
Once the final datasets have been cleaned and ready for release, they will be accessible to researchers via a data request. Researchers wishing to request the data would be encouraged to use the CFAS website (www.cfas.ac.uk) to explore the applicable questionnaires to formulate research questions and ideas. The data request application form must be filled in and submitted in the first instance to the National Coordinator (Mrs Linda Barnes, leb22@medschl.cam.ac.uk). Data applications are then reviewed by the Co-operative Management Committee (CMC) of CFAS before the Data Managers create the requested datasets which are encrypted (using VeraCrypt) and sent to researchers. The data is stored within STATA format, is anonymised (use of study ID number) and datasets are created specifically on the questions that are required for the research question to be answered rather than the full datasets being issued. Participants receive the audit trail of all individuals over each wave which indicates their level of involvement along with summary variables such as indicating if the person is deceased. Participants are

consented before the interview takes place. The results of this wave of CFAS II interviewing will be included in the longitudinal analysis of the CFAS II cohort which began in 2008. The trialists plan to publish any longitudinal results of interest that are found.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1.3	11/05/2018	16/07/2018	No	Yes
HRA research summary			28/06/2023	No	No