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Reducing cognitive decline and dementia by lowering blood pressure pilot I study

Submission date
27/09/2019

Recruitment status
No longer recruiting

Registration date
07/10/2019

Overall study status
Completed

Last Edited
31/03/2023

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
Ahead of a large online clinical trial to determine whether reducing blood pressure can prevent dementia, this pilot study will determine the feasibility of recruiting participants aged ≥60 years into an online study. Participants will be recruited via general practice. This study will determine whether participants can complete online registration and consent, measure and enter their home blood pressure online and complete an online cognitive function (thinking and reasoning) questionnaire. This information will inform the design of the larger study. The feasibility of using a portable device to perform study blood tests will be determined by asking participants to attend their GP practice for a blood test using the device (iSTAT).

Who can participate?
Individuals over 60 years old, with a valid email address and access to the internet

What does the study involve?
This is a pilot study to determine the feasibility of performing a large secure online study of blood pressure lowering to prevent dementia, by testing several aspects of trial methodology (including recruitment and baseline data collection).

What are the possible benefits and risks of participating?
Risks- Blood sampling may cause bruising and discomfort. There may be inconvenience to participants attending GP/MEMO research/Community Hubs for blood sampling. Online cognitive function questionnaires can take up to 45 minutes to complete. Participants may find asking the alternative contacts to act in this capacity for them in the study uncomfortable.
Benefits- There are no direct benefits however, participants will be able to keep the OMRON home blood pressure monitor.

Where is the study run from?
MEMO Research, Ninewells Hospital, Dundee, UK

When is the study starting and how long is it expected to run for?
November 2019 to June 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Thomas MacDonald (scientific),
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Study website
https://www.recallstudy.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1-020-18

Study information

Scientific Title
RECALL – REducing Cognitive decline and dementiA by Lowering bLood pressure - Pilot I

Acronym
RECALL

Study objectives
Complex interventions aiming to slow cognitive decline have been disappointing, are time-consuming and labour intensive and require extensive commitment on behalf of the health services, individual therapist, and participant. Mounting evidence supports the beneficial effects of reducing blood pressure to ameliorate cognitive decline and to prevent dementia. We intend to conduct a large online study of blood pressure-lowering medication to lower blood pressure and prevent dementia. Although elements of the proposed study methodology have been used in other studies, they have not yet been tested in the target population. We therefore plan a pilot study to assess the feasibility of several aspects of the proposed method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/05/2019, NHS HRA North East- York Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0) 207 104 8079; nrescommittee.northeast-york@nhs.net), ref: 19/NE/0172

Study design
Feasibility study

Primary study design
Other

Secondary study design

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cognitive decline

Interventions
Potential participants will be invited to visit a study web page by letter of invitation. On this study webpage they can read the participant information documentation and then complete an electronic informed consent form. Participants will then be asked to complete questions on their demographics, medical history, and lifestyle. Consenting participants will be supplied with a home blood pressure monitor (HBPM) and detailed instructions on how to use it. They will then be asked to submit a set of readings (modified version of NICE guidance) to the website. Following consent participants will be asked to complete an online cognitive function assessment hosted by Cambridge Brain Sciences (CANADA) and attend either their GP, the MEMO Research Unit in Dundee or Community Hubs to have a blood sample taken. They will also be asked to provide two alternative contact details. The participant will be asked to get the permission of their alternative contacts before entering their details into the RECALL secure website. The alternative contacts will be asked by email if they are willing to act in this capacity. Once this information has been submitted the participants will be asked to complete feedback questionnaires on the study/website. All aspects of the study are voluntary and so the participants may still proceed to the next section whether they have completed the previous section of the study or not. Once the participant has submitted their information then their participation is the study is complete. Participants will be asked to complete the tasks within 4 weeks if possible. There will be no follow up.

Intervention Type
Other

Primary outcome measure
1. Recruitment numbers
2. Protocol adherence
Timepoint: End of pilot

Secondary outcome measures
1. Assess suitability of online cognitive testing for study cohort
Outcome measures: Proportion of participants who complete a baseline test
2. Assess baseline cognitive function
Outcomes measures: Proportion of study population completing online screening cognitive function test, and scores obtained
3. Assess feasibility of requiring each participant to identify two individuals who agree to act as alternative contacts
Outcome measures: Proportion of participants who have two consenting alternative contacts
4. Assess feasibility of home blood pressure monitoring using study supplied HBPM machine
Outcome measures: Proportion of participants submitting a complete set of home BP measurements
5. Assess baseline blood pressure suitability of study cohort
Outcome measures: Proportion of participants with a home BP submission averaging 140mmHg or below systolic

6. Assess feasibility of using portable i-STAT Alinity device for providing blood results
Outcome measures: Proportion of blood results obtained using portable system
7. Assess the likely number of eligible patients signing up
Outcome measures: Proportion of those invited who meet proposed formal study entry criteria

Overall study start date
14/10/2019

Completion date
18/06/2021

Eligibility

Key inclusion criteria
1. Over 60 years old
2. Valid email address (per participant)
3. Able to access the internet

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
110

Total final enrolment
251

Key exclusion criteria
1. GPs may exclude participants who they deem unsuitable to participate
2. Clinical diagnosis of dementia, treatment with medication for dementia or cognitively unable to follow the protocol (investigator opinion)

Date of first enrolment
01/11/2019

Date of final enrolment
20/05/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
MEMO Research
Level 7
Mailbox 2
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Sponsor information

Organisation
University of Dundee/NHS Tayside

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Sponsor type
University/education

Website
http://www.ahspartnership.org.uk/ahsp

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Protocol to be published in BMJ Open. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5	26/04/2021	12/08/2022	No	No
Statistical Analysis Plan	version 1	14/07/2021	12/08/2022	No	No
HRA research summary			28/06/2023	No	No