

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

Submission date 27/09/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 07/10/2019	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 26/05/2026	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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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Additional identifiers

Protocol serial number
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

Study type(s)

Other

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 in 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(s)

1. Recruitment numbers

2. Protocol adherence

Timepoint: End of pilot

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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**

United Kingdom

Scotland

Study participating centre

MEMO Research

Level 7

Mailbox 2

Ninewells Hospital

Dundee

Scotland

DD1 9SY

Sponsor information**Organisation**

University of Dundee/NHS Tayside

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

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?
HRA research summary			28/06/2023	No	No
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes
Thesis results			26/05/2026	No	No