Participant Information Sheet

RECALL – REducing Cognitive decline and dementiA by Lowering bLood pressure- PILOT

Researcher: Prof T M MacDonald, University of Dundee

Invitation to participate

We would like to invite you to take part in a pilot research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read this information sheet carefully and ask any questions you have. You can also discuss this study with other people such as your family or your family doctor (GP). If you decide to participate in this study, you will be asked to complete an electronic consent form.

The RECALL Pilot Study is sponsored by the University of Dundee and NHS Tayside. The study has been organised by Professor Thomas MacDonald and will be carried out in Tayside by MEMO Research (www.memoresearch.com), at the University of Dundee.

Background to the pilot study

Dementia is a leading cause of disability in the UK and the biggest health and social care challenge of the 21st century. At present there is no effective treatment for the two leading causes of dementia, Alzheimer's disease and vascular dementia. There is, however, increasing scientific evidence that there are beneficial effects of reducing blood pressure to prevent cognitive decline and ultimately prevent dementia of either type. Based on this, we are planning to carry out a large study of blood pressure lowering medication to prevent dementia. Before the main study can take place, we must run a smaller pilot (test) study. This is so that we can understand how to best run the study with participants using a study-specific website. Since the main study needs to be very large to be feasible, we need to complete it using modern methods.

What is the purpose of the pilot study?

This pilot study is open to people aged 60 years or over from GP practices within Tayside. Our aim is to see how many people will be willing to sign up to the study, and how many of these can carry out our web-based recruitment and screening processes. We can then learn whether these procedures will work in the main RECALL study.

Why have I been contacted?

We are currently writing to all patients aged 60 years and over from various GP practices in Tayside (at least 5). You have been contacted because you are within this age group. In total we hope to recruit at least 100 participants.

If I take part what will it involve?

The study is in 2 parts, as detailed below. Part 1 involves online enrolment, entering information onto our website and doing cognitive games. Part 2 involves having a blood test and taking your blood pressure. You need to be willing to complete both part 1 and part 2 to take part in this study.

Part 1

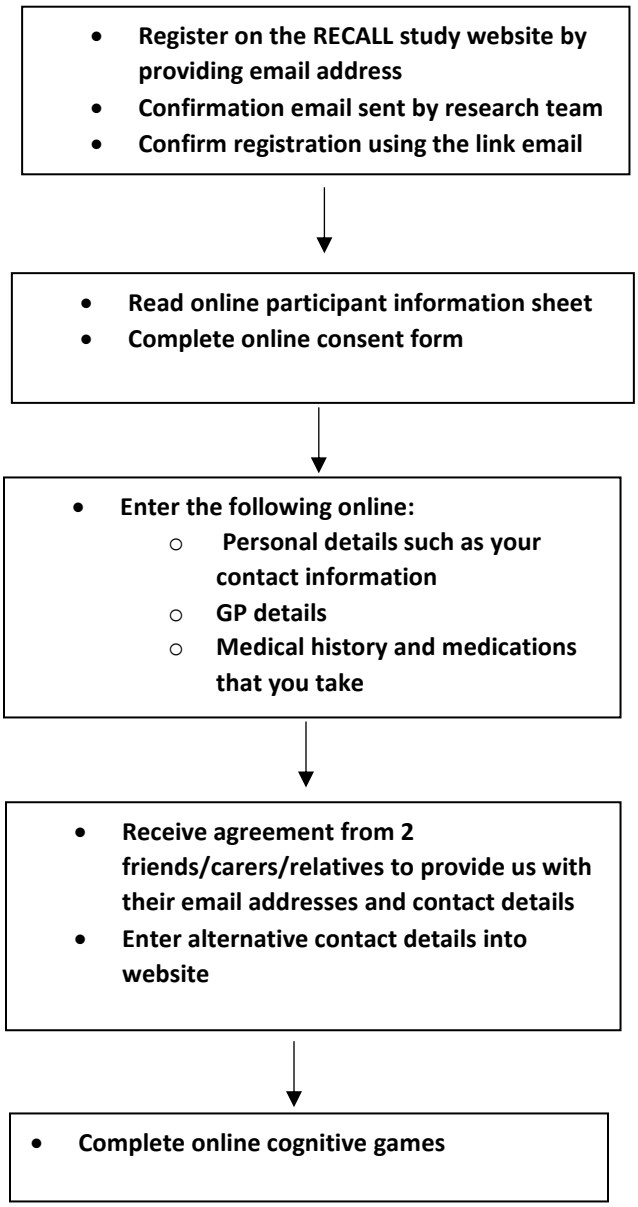
If you are interested in taking part in this pilot study, the first step would be to register on the study website <<website address>> Here, you can find out more information and register with your email address (this needs to be personal to you, rather than an email address you share with others). You will then receive an email with a validation link that you can click on and this will take you to a study consent form. Once you have completed the study consent form you will be asked to enter details about yourself, including your medical history, family history and any medications that you are currently taking. You will be requested to enter your height and weight on the website. We will also ask you some lifestyle questions, for example smoking history.

You will also be asked to discuss the study with two alternative contacts, and check they are happy for you to provide us with their names and email addresses. Your alternative contacts need to be people who know you and see you on a reasonably regular basis. For example, friends, carers or relatives. This is a common request with online studies and is a backup just in case for some reason we cannot contact you directly. We will send the people you have asked, and agreed this with, an email asking them to confirm their details and that they are happy to be contacted. (Please remember that you should discuss the study with them and get their agreement **before** you send us their contact details).

You will also be asked to complete a set of online cognitive function games to assess your thinking and memory. These games will be provided by a company called Cambridge Brain Sciences. These will take approximately 30 - 45 minutes to complete. We would appreciate if they could be completed in one sitting, although you can finish them anytime within 48 hours after starting them if you need to. The games are research assessments designed to measure changes in cognitive function over several repeated assessments. As you are only completing them on one occasion, we are unable to demonstrate changes and therefore we won't be able to share any results with you. By completing the games, we will however, be able to gather useful information about how many people were willing to complete them, and how many were able to answer all the questions.

It would be helpful to us if these could be finished within **4 weeks** of completing the consent form on the website.

The flowchart below explains what you are asked to do in Part 1 of the study



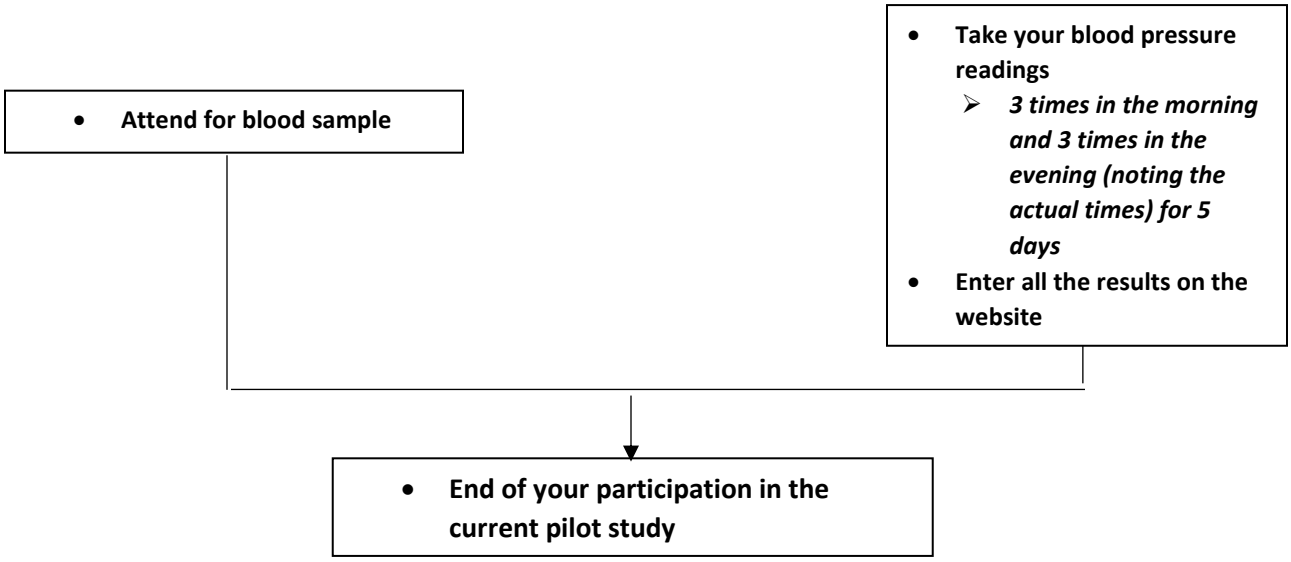
Part 2

You will be asked to attend your GP practice or MEMO Research at Ninewells Hospital, whichever is most convenient to you, for a blood test. A member of the study team will contact you by email to arrange this visit. The blood test will involve one draw of venous blood (approximately 5ml or 1 teaspoon full) and will provide results for: Sodium, Potassium, Chloride, TCO2 (how acidic or alkaline your blood is), Anion Group, Ionized Calcium, Glucose, Urea Nitrogen (BUN), Creatinine, calculated eGFR (kidney function), Haematocrit and Haemoglobin.

These will be reviewed by a research nurse, who will obtain the blood sample from you. If any results are abnormal we will, with your permission, report these to your GP. Once the blood results have been obtained the rest of the blood sample will be discarded.

At this visit we will also provide you with a home blood pressure monitor and you will be given clear instructions on how to measure and record your blood pressure at home. The home blood pressure monitor is an electronic device like that used in your GP surgery or clinic. You will be asked to measure your blood pressure 3 times in the morning and 3 times in the evening for 5 days and enter the results on the study website. If your blood pressure results are abnormal you will be advised by the research team to contact your GP for advice. If your blood pressure is very abnormal/requires urgent treatment, then our Research team may contact your GP or arrange admission for appropriate treatment. You can keep the blood pressure monitor for your own use once the study has finished.

The flowchart below explains what you are asked to do in Part 2 of the study



We will request your feedback with questionnaires about your experience of taking part in aspects of the study after you finish the various sections of this pilot study.

Once you have completed part 2 you will have finished your participation in this pilot study, you will receive a study completion email and you will not be asked to do anything else. However, if you are interested in taking part in the main study once it starts, you can indicate your willingness to do this on your consent form and we will contact you about this later if the main study goes ahead.

What are the possible benefits of taking part?

There are no direct benefits to you for taking part in the study except that you will be given a new home blood pressure monitor that you can keep. However, the information obtained from this pilot study will be extremely useful in allowing us to test the practicalities of carrying out a much larger research study, with the aim of lowering blood pressure with a medication to prevent cognitive decline and dementia.

What are the possible disadvantages and risks of taking part?

We do not think there are any risks in taking part in this pilot study. The disadvantage is that it will take up some of your time to complete the questions online and ask two people close to you to agree to being contacted in the event we are unable to contact you. You are also being asked to travel to either your GP practice or MEMO Research in Ninewells, whichever is most convenient for you. Reasonable travel expenses are available if required, up to £7. You may find giving the blood sample uncomfortable and you may experience pain and bruising at the injection site.

Do I have to take part?

It is up to you to decide. Participation in this study is entirely voluntary. If you do start the process, you are then free to withdraw at any time, without having to give a reason and without this affecting your future medical care or your relationship with medical or nursing staff looking after you. To some extent, knowing how many people start the study but then withdraw is part of the reason for doing a pilot study. If this system does not work, then the main study will not work. We would also value your feedback on any aspect of this pilot study. We will provide opportunities to allow you to give this via questionnaires which you can complete online after each study activity or at the end of your participation in the study. Your feedback may allow us to redesign or improve the website, for example. We are very much interested in public engagement with research and as this pilot study involves a lot of activities carried out by the participants themselves, it is important that we get it right.

What do I do if I want to withdraw once I have agreed to take part?

You are free at any time to withdraw without giving a reason. Your medical care and legal rights will not be affected by this. This can be done by visiting the website to register your withdrawal.

Will my personal information be kept confidential?

Identifiable information about you and the information collected about you during the study will be stored by MEMO Research, University of Dundee. Only specified members of the research team will have access to this information.

Your identifiable information and coded study information will be stored securely on a password-protected database(s) owned and controlled by MEMO Research. Specified members of the data

management team will also have access to your identifiable information to manage your information and maintain the database. Anonymised test results generated from completing the cognitive games will be stored securely by Cambridge Brain Sciences and sent to MEMO Research for linking to your identifiable record. Cambridge Brain Sciences will never be sent or hold identifiable data, nor will they have the ability to link this data to any identifiable data.

Your identifiable information will be kept securely for five years after the end of the study. After five years it will be destroyed, and the rest of the information will be kept for research purposes. If you would like to be informed about future studies that you might be interested to participate in, we will ask you to provide consent to allow us to hold your contact details.

Information which identifies you will not be published or shared.

Your study information, with any information which identifies you removed from it, may be shared with other researchers in the UK/EU/other regions.

We will only use your personal information to carry out this study or contact you again if you have agreed to this.

The University of Dundee and NHS Tayside are the sponsors for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To protect your rights, we will use the minimum amount of information which is personably identifiable as possible.

University of Dundee/NHS Tayside will use your name, NHS number/CHI/hospital number and contact details to contact you about the study/trial. They will use this information to make sure that relevant information about the study/trial is recorded for your care and to check the quality of the study. Staff from University of Dundee/NHS Tayside and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your GP practice will pass these details to University of Dundee/NHS Tayside along with the information collected from you. The only people in University of Dundee/NHS Tayside who will have access to information that identifies you will be people who need to contact you or to check how the information is collected. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number/CHI/hospital number or contact details.

University of Dundee will keep identifiable information about you from this study for 5 years after the study has finished.

We have contracted Cambridge Brain Sciences to run the cognitive function tests in this pilot. Anonymised results from the online cognitive testing will also be held by Cambridge Brain Sciences (CBS) who provide the tests:

Cambridge Brain Sciences
372 Bay St., Suite 1500
Toronto, Ontario M5H 2W9
CANADA
https://www.cambridgebrainsciences.com

However, there is no ability for CBS to link your test results with your identifiable information held in MEMO Research. CBS are fully compliant with the new GDPR data protection legislation.

Identifiable information about you will not be published or otherwise shared. If you agree in the consent form, we would like to be able to contact you about the main RECALL study, other dementia prevention studies or other studies you may be interested in. Your study data may need to be shared with research regulators or medicines regulators to enable them to audit the study and ensure that it is conducted to the highest possible standard.

What if something goes wrong?

If you have any concerns about your participation in the study, you have the right to raise your concern with a researcher involved in conducting the study or a doctor involved in your care.

If you have a complaint about your participation in the study, you should first talk to a researcher involved in the study. However, you have the right to raise a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside.

Complaints and Feedback Team
NHS Tayside
Ninewells Hospital
Dundee DD1 9SY

If you think you have suffered harm because of your participation in this pilot study, there are no automatic financial compensation arrangements. However, you may have the right to make a claim for compensation. Where you wish to make a claim, you should consider seeking independent legal advice, but you may have to pay for your legal costs.

Insurance

The University of Dundee and Tayside Health Board are Co-Sponsoring the study. The University of Dundee has a policy of public liability insurance which provides legal liability to cover damages, costs and expenses of claims.

Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which provides legal liability cover of NHS Tayside in relation to the study.

As the study involves University of Dundee staff undertaking clinical research on NHS Tayside patients, such staff hold honorary contracts with Tayside Health Board which means they will have cover under Tayside's membership of the CNORIS scheme.

You should be aware that if you apply for health, life, travel or income protection insurance you may be asked questions about your health, including medical history, pre-existing medical conditions, if you have had any genetic test or your participation in this study. It is not anticipated that your involvement in the study will adversely affect your ability to purchase insurance, but some insurers may use this information to limit the offer of cover, apply exclusions or increase any premium. If you have a diagnosed medical condition, even where the condition is diagnosed as part of a research study, the insurer may take this into consideration when deciding whether to offer insurance to you.

Who has reviewed this study?

This study has been reviewed and approved by North East - York Research Ethics Committee who are responsible for reviewing research which is conducted in humans and who has raised no objections.

Contact details for further information.

Thank you for taking time to read this information and for considering participating in this study.
If you would like more information or want to ask questions about this study, please contact the study team using the contact details above.

You can contact us Monday – Friday between 09:00-17:00 on the following number 01382 383119 or freephone 0800 7310241.

Data Protection Privacy Notice

Lawful reason for using your information

It is lawful for the University/NHS Tayside to use your personal data for the purposes of the research/this study. The legal reason for using your information is that using it is necessary for the research which is carried out in the public interest.

It is lawful for the University/NHS Tayside to use your sensitive personal data (if applicable) for the purposes of the research/this study. The reason we use sensitive personal information such as data concerning health is that using it is necessary for scientific research purposes. Legally we must ensure we have technical and organisational processes in place to respect your rights when we use your information.

You can find out more about how we will use your information at:
http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information and
https://www.dundee.ac.uk/information-governance/dataprotection/ and at
http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

or by contacting Research Governance, Tayside Medical Science Centre (TASC), 01382 383900 email tascgovernance@dundee.ac.uk