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**Participant Information Sheet - Participant**

**Active prevention in people with memory problems (APPLE-Tree Pilot study)**

We are inviting you to take part in a research project that is part of the APPLE-Tree programme led by University College London (UCL). APPLE-Tree stands for the active prevention in people at risk of dementia through lifestyle, behaviour change and technology to build resilience. We want to try out a new programme to support people with memory problems to make changes to their lifestyle and daily habits that may help prevent their memory problems worsening. Before you decide whether to take part it is important that you understand why the research is being done and what this study will involve. Please take time to read the following information carefully and discuss it with relatives, friends, and colleagues if you wish.

* Part 1 tells you the purpose of this study and what will happen to you if you take part.
* Part 2 gives you more detailed information about the conduct of this study.

Ask us if anything is not clear or you would like more information. Take time to decide whether or not you wish to take part.

**Part 1**

**What is the purpose of the study?**

We want to try out a new programme to support people with memory problems to make changes to their lifestyle and daily habits that may help prevent their memory problems worsening. We will do this by randomly allocating people to one of two groups: participants will either receive the new programme alongside any usual care they receive, or they will continue to only receive their usual care from their GP or any other health service. This group will also receive written information about dementia prevention and information for services. We will then compare the outcomes of participants from the two groups to see if the programme is successful. We also want to learn more about how and why people with memory concerns or cognitive impairment take part in health intervention sessions; how they use and understand the information delivered and how attending sessions affects their thoughts about memory impairment.

**Why have I been invited?**

You have been identified as having some problems with memory (that trouble you and/or that have been detected on a memory test), that are not dementia.

**Do I have to take part?**

No. It is completely up to you. Please read this information sheet carefully and think about any concerns you may have. If you agree to see us or want to talk on the phone, we can discuss the study in more detail with you and answer any questions or concerns you may have. We will then ask you to sign a consent form to show you have agreed to take part and you will be given a signed copy to keep. You do not have to give any reason for not wanting to take part.

**What will happen if I do not want to carry on with the study?**

You are free to withdraw from the study at any time, without giving a reason. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways 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, however we will not collect any further information from you. To safeguard your rights, we will use as little information as possible which can be linked to you personally. If you withdraw this will not affect any care that you receive in any way.

**What will happen to me if I take part?**

If you agree to take part in this study, you will be invited to talk to a researcher in a place you choose (by video call, or we can come to your home or meet you at our centre) and you will be asked to sign a consent form. This visit will take around 1 hour and a half. The researcher will ask you questions about your age, gender, marital status, ethnicity, education, first language and living arrangements. These questions are because we want to include people from different backgrounds in the research study. The researcher will then ask you to complete some questionnaires: to assess your memory, service use, quality of life, daily activity levels and mental health. If you agree, we would also like to take a blood sample, 34ml (about two tablespoons), but this is optional. We will use the blood samples to look at the effect of diet on the body, and to measure cholesterol and other tests that help assess wellbeing. If any values are outside the normal range we would send these results to your GP, and send you a copy of the letter, unless you have asked us not to do this. We will use some of the blood sample to measure DNA to see how genetics might affect how people respond to the intervention. We will not pass on any details about this to you or your GP.

Your blood will be stored at UCL or University of East Anglia Laboratories, and disposed of at the end of the study, unless you have consented for it to be used for future studies, in which case it will be retained pending ethics approval for subsequent studies. For these studies it may be transferred to other public or private research teams, national or international, to use in projects related to the wellbeing of people with memory concerns.

The researcher will then contact you again to tell you if you and your relative/friend have been randomly allocated to receive the new programme or to receive written information only. People who are in the group without the new programme are just as important to this study, as we want to find out if it provides any benefit beyond what is already currently provided.

If you and your relative/friend are allocated to receive the new programme, you will be invited to attend ten group sessions over a 6 month period. If you are unable to attend the group session, or would not like to attend for any reason, a researcher can arrange some (up to 4) individual sessions with you. These can be over the telephone or video-call, at the site of the group session or at your home. The researcher will meet you again at 12 months and 24 months to repeat the assessments undertaken at the beginning of the study, including the blood test if you agree to this.

If you are allocated to receive the new programme, we may also invite you to take part in one separate, qualitative interview. This will be to learn about your experience of the sessions, and of making and keeping some of the lifestyle changes suggested in the sessions. We would like to audiotape the interview, which will then be transcribed by an external company (WayWithWords). All identifiable information will be removed and it will be totally anonymised.

You may also be asked whether you agree to a researcher observing some of the sessions. The researcher would observe all aspects of the group including the facilitators and other members in the sessions. As part of the observations the researcher may talk to you from time to time about the session, either before the session begins or after it finishes. Information recorded from these conversations and observations will be anonymised.

We will ask you who you would like to make decisions about whether you should continue with the study on your behalf, if you ever became unable to decide this for yourself.

**Expenses and payments**

We will give you one £20 voucher as a token of our appreciation for your time and involvement at the first appointment, 12 month and 24 month appointments (a total of £60). A further £20 voucher will be offered to participants who received the programme and who take part in an additional interview. We can also reimburse any travel costs upon submission of valid receipts.

**What are the possible disadvantages and risks of taking part?**

We do not foresee there being risks associated with the study. It is possible that you could find some sessions emotionally difficult. If during any of the sessions you find a topic sensitive or upsetting you can leave the session or take a break. At each session, there will be a designated space for you to go should you need to take a break.

**What are the possible benefits of taking part?**

We cannot promise that there will be any direct benefits to you from attending these groups. As the sessions are aimed at promoting a healthier lifestyle, this could be of benefit to your health.

**What happens when the research stops?**

You will no longer be required to attend the new programme, if you were allocated to this group, however you will receive information on support services that you can keep after the research stops.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information on this is in Part 2.

**Will my taking part in the study be kept confidential?**

UCL is the sponsor 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.

You can find out more about how we use your information by contacting [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk) or by going online and accessing the UCL research privacy notice: <https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice>

[NHS site] will collect information from you or your medical records for this research study in accordance with our instructions.

[Third party partner] will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded, and to oversee the quality of the study. Individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [Third party partner] will pass these details to UCL along with the information collected from you. The only people in UCL who will have access to information that identifies you will be people who need to contact you to arrange the research appointments or audit the data collection process.

We respect confidentiality but cannot keep it a secret if anyone is being harmed or is at risk of any harm. If this arises, you will be informed that confidentiality cannot be maintained in that particular regard, and the appropriate personnel will be informed.

Your confidentiality will be partially maintained. Personal data, such as your name, contact details and date of birth will be kept separate from the information we collect. We will keep your contact details separately for the duration of the study so we can contact you again when we need to for the study. Your anonymity will be maintained in the data analysis as you will be assigned an anonymised code which will be used throughout the analysis. You will not be identified in any reports or academic papers coming from the work. The information that you give will be stored securely, to enable researchers to continue analysis of the study data in future projects.

The audio recordings will be transcribed by a UK based professional transcription company (WayWithWords) that is a preferred supplier of UCL. WayWithWords has strong data protection, confidential storage and removal from the transcription service database when transcription is complete. Any identifiable information will be removed from the transcripts. The information we collect will be stored on computers at UCL, in a form in which you cannot be identified. Only study staff will have access to the data. We will delete the recording after it has been transcribed, checked and the data has been analysed. The transcript will be stored securely in accordance with UCL’s archiving policy.

We will need to use information from you and from your medical records for this research project. This information will include your initials, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. The information that you give will be stored securely, to enable researchers to continue analysis of the study data in future projects.

UCL will keep identifiable information about you for up to three years after the study has finished for the purpose of contacting you about future research.

**Contact**

Please contact the researcher [Programme Manager, Michaela Poppe: Tel: 020 7679 9311. Email: [m.poppe@ucl.ac.uk/](mailto:m.poppe@ucl.ac.uk/) research assistant?] for further information. This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please read Part 2 before making any decision.

**Part 2**

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak with the Programme Manager, Michaela Poppe: Tel: 020 7679 9311. Email: [m.poppe@ucl.ac.uk](mailto:m.poppe@ucl.ac.uk).

If you remain unhappy, or wish to make a complaint about the conduct of the project, you can contact Professor Claudia Cooper (Study Principal Investigator on 0203 549 5875) who will do her best to answer your questions. If you remain unhappy and wish to complain formally about any aspect of the way you have been approached or treated during the course of this study, please write to Professor Claudia Cooper, UCL Division of Psychiatry, 6th Floor, Maple House, 149 Tottenham Court Road, London, W1T 7NF quoting study 274277. She will then send the complaint to the Research Governance Sponsor: University College London. In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for a legal action for compensation against UCL but you may have to pay your legal costs.

You can also contact [local independent site contact] for support if you would like to complain about the study.

**What will happen to the results of the research study?**

We will publish results in relevant conference proceedings and publications. Please tell the researchers if you would like a summary of the research findings.

**Who is organising and funding the research?**

The Economic and Social Research Council and National Institute of Health Research are funding it, and University College London are sponsoring it.

**Who has reviewed the study?**

All proposals for research using human subjects are reviewed by the Health Research Authority (HRA) and an Ethics Committee before they can proceed. This proposal was reviewed by London - Camden & Kings Cross Research Ethics Committee.

You will be given a copy of the information sheet and a signed consent form to keep. Thank you for taking time to read this sheet.