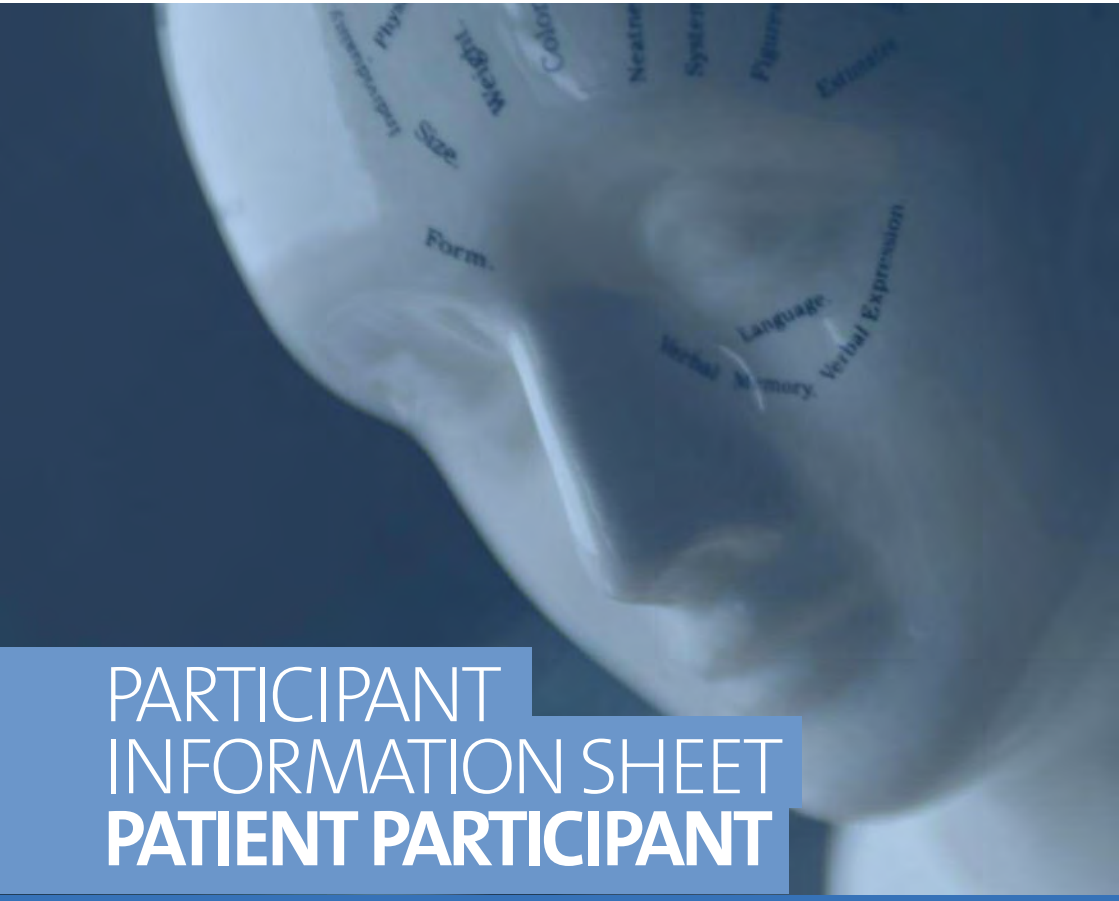
MANCHESTER 1824
The University of Manchester

Institute of Psychiatry
at The Maudsley

KING'S College LONDON



PARTICIPANT INFORMATION SHEET
PATIENT PARTICIPANT

The role of the medial temporal lobes in memory

Supported by
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YOUR INVITATION

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you.

Part 1 tells you the purpose of this study and what you will be asked to do if you take part.

Part 2 gives you more detailed information about how the study is conducted.

Please take time to read the following information carefully and discuss it if you wish with friends, relatives or your GP. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART ONE

What is the purpose of the study?

Damage to certain parts of the brain, even if very minor, can cause memory problems, but there is a lot of variation between people. We are interested in finding out more about the role of a particular part of the brain called the medial temporal lobes, in memory. These parts of the brain are quite deep and close to the centre, at about the level of your ears. We want to learn more about people's memory problems and whether they are linked to any changes in the brain in these areas. Volunteers will have a brain scan using magnetic resonance imaging (MRI), and will take part in interviews, fill in questionnaires and complete some memory tests.

Why have I been invited?

A doctor may have invited you to take part in this study because you have previously been diagnosed as having a medical event that may have involved damage to the medial temporal lobes and you may also have reported a change in your memory. We are looking for 90 people who have had such a medical event, and 80 people who have not (40 people who are of a similar age and 40 healthy older adults).

Also, in order to participate in this study you need to be between the ages of 24 and 65 and fluent speaker of English (if English is not your native language).

You will not be able to take part in the study if you have:

- History of alcohol or substance dependence within the last 6 months
- History or presence of psychiatric conditions (eg schizophrenia, major depression, generalised anxiety disorder)
- Diagnosed with any degenerative condition such as dementia or Alzheimer's
- History of seizures
- Undergone neurosurgery
- Significant hearing impairment
- Significant visual impairment including colour blindness
- Non-MR compatible pacemakers, mechanical heart valves or any other non-MR compatible metal implants in your body.

If you have any questions or doubts regarding any of these points and you want to discuss them with a member of the research team please call us on the telephone number provided below. You will also be able to discuss all points regarding Phase 2 again during the first telephone contact after you have completed Phase 1 of the study.

Do I have to take part?

It is completely up to you whether you decide to join the study. First, please take some time and read through this information sheet carefully. If you agree to take part, we would like to ask you to complete and sign the consent form and send it back to us. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will I expected to do if I take part?

If you are interested in taking part please take time to read this Participant Information Sheet and then sign the accompanying consent form. Following this, please complete the memory questionnaire included in this pack. Please also fill in your contact details on the Contact detail form that is enclosed. These three documents (questionnaire, signed consent form and contact details form) can then be posted using the pre-paid stamped envelope included in this pack. Please note that your contact details will only be used by the research team to inform you about the second phase of the study. A member of the research team will call you after we have received your returned

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documents and will talk to you about the rest of the project and ask a few questions to check that you are eligible for the second phase. The researcher will also be able to answer any questions you may have about the study. If you agree to take part, your participation in the research study will not span more than one year, although usually very much less and during this time we will only require your input a small number of times. If you have any doubts or you want to ask any questions before you return your signed documents to the research team please call the research centre on the number provided below.

The study is divided into two phases:

Phase One: If you are eligible and happy to proceed you will, in the first instance, be admitted to the first phase of the study. At this stage, you will simply be asked to carefully read, complete and sign the consent form accompanying this leaflet and return it to the research team in the stamped, addressed envelope provided. As part of the first phase we may need to check your medical notes so we ask consent to do this. After signing the consent form we would like you to complete the short questionnaire (also included in this pack) about any medical or memory problems you may have experienced. This questionnaire is the main component of the first phase of the study and your participation in it will be of value to the overall study.

Phase Two: After finishing this first phase you may be invited to participate in the second phase as well. However, a limited number of people will be admitted to the second phase of the study. If you move on to Phase 2 you will be invited to contribute to the research over several sessions. The first visit is a Screening Visit, the second visit is a Brain Scanning Visit and the third visit is a Testing Visit.

Phase 2 of the study includes several testing sessions which will be completed in 3 to 5 visits. These are described below:

Screening Visit (allow approx 3 hours)

During this session the researcher will discuss with you what the second phase of the research project involves and you will be asked to sign an informed consent form confirming that you would like to participate in phase 2 of the research. We will then complete some tests of memory and attention, as well as some questionnaires which focus on your memory for events in your past. For some of these tests we would like to record your responses with a digital voice recorder. All recordings will be deleted immediately after they are transcribed and/or scored. This visit will take place locally to you.

MRI Scanning Visit (allow approx 2 hours for scan)

This visit will take place in Manchester and we will arrange and pay for any travel expenses. In addition, in the case of travelling long distances, we will also arrange and pay for an evening meal and overnight accommodation in a hotel in Manchester. If you feel more comfortable travelling with a spouse, family member or close friend we will be happy to arrange for their travel and accommodation as well. Before you have your brain scan you will be asked to sign an MRI consent form. You will lie flat on the scanner bed for the scan and will not have to do any tasks. The scan should last about one hour (with short breaks in between scans).

Testing Visits (allow approx 2 to 3 hours for each)

There will be three further testing sessions, but we expect the first one to take place on the same day as your scanning visit, if that is convenient. We will also try to combine the remaining two sessions into the same visit if that is easier, with a break for lunch in the middle. In these sessions we will ask you to complete a variety of memory tests, some with pen and paper and some on the computer. We will ask you to study things like words, pictures, faces and scenes and then test your memory in a variety of ways. None of the materials we use are upsetting or threatening in any way.

You will be telephoned within 2 weeks after the final visit to follow-up on your well-being and to check whether there are any issues concerning your memory that you would like to discuss further with us.

Expenses and payments

We will cover all travel and accommodation expenses incurred through the study. These include standard train/bus tickets and hotel accommodation. All the necessary arrangements (train tickets, hotels etc.) will be made by us in accordance with your schedule and the requirements of your visit.

What are the possible disadvantages and risks of taking part?

There are no obvious risks associated with this research study. However, if any aspect of the study concerns or upsets you, please notify the researcher and we will interrupt the session immediately.

Also, please, notify a member of the research team if you experience any significant changes in your health during the study so that we do not disturb you unduly.

MRI Scan

There are no known risks of MRI for most people. However, as this type of scan uses magnets, the scan procedure is not suitable for people with non-MR compatible pacemakers, mechanical heart valves or with any other non-MR compatible metal implants in their body. Also, if you have ever sustained an eye injury involving metal or have any history of seizures you should not take part. If you suffer from claustrophobia or if you have suffered previously from anxiety in narrow spaces, you may find lying still in the scanner unpleasant and it may be better not to take part. Please note that the MRI scan is not a diagnostic scan and it is not a substitute for a scan that a clinician would request. However, all scans are reviewed by a radiologist and if they identify an abnormality, they will contact your GP with your permission.

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What are the possible benefits of taking part?

There will not be any direct benefits for you from taking part in this study although you will have the opportunity to discuss any memory problems and strategies with the research team. The information learned from this study may help other patients in the future.

What happens when the research study stops?

By agreeing to participate in this study, you understand that, although very unlikely, the researchers in charge of the study or the study sponsor may stop the study or your participation at any time, without your consent for the following reasons:

- The researchers decide that it is in the best interests of your health and welfare to discontinue
- The sponsor may stop the study for safety, ethical or administrative reasons

This study is independent of any medical care so when the study ends, there will be no impact on your continuing clinical care.

What if there is a problem?

If you have any complaint about the way you have been dealt with during the study or any possible harm you might have suffered, these will be addressed. The detailed information on this procedure is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART TWO

What if relevant new information becomes available?

Sometimes we get new information as the study progresses. If this happens, a member of the research team will tell you and discuss whether you should continue in the study. If you decide to continue in the study we may ask you to sign an updated consent form. Stopping your participation will not affect your care.

What will happen if I don't want to carry on with the study?

If you withdraw once the study has started, you do not need to give a reason. This will not prevent you from participation in future studies. If you agree, we would like to keep data already collected, however it is up to you to decide whether we are allowed to do that, or not.

In the unlikely event that you lose capacity to consent during the project, the research team will retain any data already collected and continue to use them confidentially in connection with the purposes of the current study, but no further data will be collected from you.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. **The London (King's College London) contact is Dr Ellen Migo (020 7188 0202 or Ellen.Migo@kcl.ac.uk). The Manchester (University of Manchester) contact is Dr Alex Kafkas (0161 275 7341 or Alexandros.Kafkas@manchester.ac.uk)**. If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of the study, please contact the Principal Investigator, **Professor Daniela Montaldi on 0161 275 7335**. If you remain unhappy and wish to complain formally, you can do this through the University of Manchester procedures by contacting the University Research Practice and Governance Co-ordinator on 0161 275 8093 or by email to research-governance@manchester.ac.uk.

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester, King's College London and/or the NHS Trust but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

All data is handled and stored according to the Data Protection Act 1998. All information which is collected about you will be kept strictly confidential, and any information about you which leaves the research centre will have your name and address removed so that you cannot be recognised. The information collected as part of this study will be used only for the purposes described in this information sheet. Your consent is on the condition that we uphold our duties and obligations under the Data Protection Act 1998 for the storage, use and destruction of data and samples. If you do decide to take part your data will be stored for 10 years from when the study ends.

Who has access to medical and personal information collected during the study?

Members of the research team and the independent ethics committee for the study will have access to this information at the site in order to check that the study is done properly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the research centre will have your name and address removed so that you cannot be recognized.

At any time, you may ask a researcher to let you see your personal information, eg name and address and to correct it if necessary. It is important to understand that the data will be completely anonymised when we report questionnaire responses or other performance scores. For analysis and reporting purposes, all information gathered is anonymised so that nobody outside the research team will be able to identify those who contributed.

Involvement of the General Practitioner

If you decide to participate we will ask your consent to inform your GP of your participation. We will ask you to provide the contact details for your GP. If we find that your brain scan (Phase 2) shows unexpected values we will tell your GP to ensure that you receive appropriate care and treatment.

Involvement of other Clinicians

If you have been told about the study by someone on your clinical care team, it may be helpful for them to know your performance on some of the memory, thinking and attention tests from the screening visit. If you wish for us to do this and give consent, we will send them a summary of your scores.

What will happen to the results of the research study?

In the future, the results of this study will be reported in study reports to the funders of the study. Data will also be published in scientific journals and presented at scientific meetings. In either case you will only be identified by your anonymised participant code. If you would like to receive a results summary at the end of the research study, please let us now.

Who is responsible for the management and funding of the research?

The Principal Investigator for this study is Professor Daniela Montaldi, School of Psychological Sciences, University of Manchester. The research is strictly not for profit. The project is funded by the Wellcome Trust.

Who has reviewed the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is ethical. Your project has been checked by the North West (GM South) Research Ethics Committee (NRES Ethics Approval Number 12/NW/0378).

Further information and contact details

Manchester contact: Dr Alex Kafkas, The University of Manchester, School of Psychological Sciences, Zochonis Building, G32, Manchester, M13 9PL,
tel 0161 275 7341,
email Alexandros.Kafkas@manchester.ac.uk;
Lab website:
www.psych-sci.manchester.ac.uk/humanmemorylab

London contact: Dr Ellen Migo, Institute of Psychiatry, King's College London, Academic Unit of Neuropsychiatry, Department of Psychological Medicine, 3rd Floor, Adamson Centre, South Wing Block D, St Thomas's Hospital, Westminster Bridge Road, London SE1 7EH,
tel 020 7188 0202,
email Ellen.Migo@kcl.ac.uk

Useful general information on research can be found on these websites

- National Electronic Library for Health: www.nelh.nhs.uk
- The National Institute for Health Research - UK database of research projects: www.nihr.ac.uk/databases/Pages
- INVOLVE - Promotes public involvement in the NHS: www.invo.org.uk

You will be given a copy of this information sheet and a signed consent form to keep.

Thank you for taking the time to read this.

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For further information, please contact
a member of the research team:

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