INFORMATION SHEET FOR PARTICIPANTS

REC Reference Number: **PNM/10/11-163 Mapping the relationship between the white matter and executive function across the adult lifespan.**

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study: Mapping the relationship between white matter and executive function across the adult lifespan.

We would like to invite you to participate in this original postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Aims of the research and possible benefits

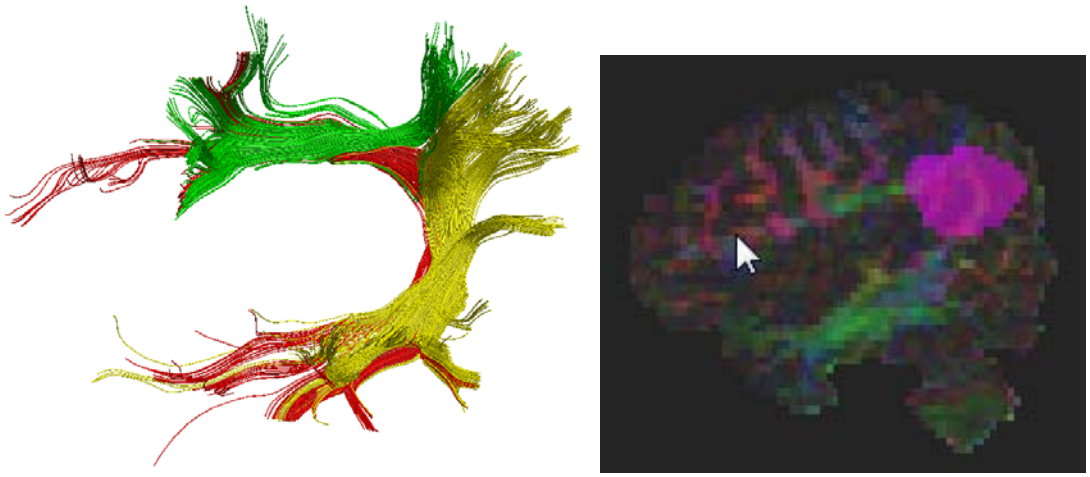
A lot of information is already available showing how cognitive performance changes with age. (cognitive performance means the ability of an individual to perceive and process information; remember and recall information; maintain attention; problem solve; reason or think in abstract ways and to plan). There is also quite a lot of research looking at surface anatomy of the brain and how this changes with age.

Recently, new techniques have been developed to explore the deeper white matter structures within the brain, but there has not been as much research looking into how these structures change with age, and even less that maps such changes to cognitive performance. In this study we aim to build up an atlas of the white matter anatomy of the brain of healthy adult volunteers over the age of 18. We will then map genetic information and cognitive performance information of individuals to their brain anatomy.

The way will gather this information is as follows:

Imaging techniques:
Pictures of the brain will be collected using Magnetic Resonance Imaging techniques. These pictures are extremely valuable to us because here at the Centre for Neuroimaging Sciences, we have special protocols and machines that can take pictures of the brain which cannot be obtained normally in other centres. With these pictures, we hope to be able to understand more about the structure and the function of the brain. By linking information from the images to other factors such as age, we will get a better understanding of how the brain develops throughout the adult lifespan.

Figure 1 Example of images showing some neuronal pathways within the brain [Arcuate fasciculus]



Cognitive tests:
We will also be conducting cognitive tests including those designed to measure general intelligence, memory function and something called Executive function. Executive function is used to describe the way the brain enables an individual to live an independent and purposeful life. It enables people to know what they need to do to look after themselves, and plan and prioritise activities to lead them through their life in a way that is

meaningful, productive and beneficial way. For example, Executive function includes simple every day activities like shopping for weekly groceries, to more complex ones like being able to plan a holiday or long journey.

DNA and RNA analysis
We will also be collecting a small blood sample (20 millilitres / 4 teaspoons) to gather genetic information and link this to brain anatomy. From that blood sample we will extract DNA and RNA information to examine whether or not there are genetic influences related to anatomy and / or cognitive performance changes with age. The blood sample will be taken by a trained phlebotomist or medical professional. There will be a slight risk of bruising as a result of the blood sample being taken.

By providing a detailed picture of how the anatomy of the brain, genetic information and cognitive ability changes with age in normal healthy subjects, we will be providing a baseline from which anomalies in brain anatomy and function in different patient groups can be explored.

Who have we asked to participate?
For this study, we are looking for healthy volunteers over the age of 18.

Who do we have to exclude?
We will not be able to scan anyone who has any history of neurological disorders or of mental illness.
Please note that the MRI scanner consists of a powerful magnet, which may attract metallic objects. You can NOT have a scan if you have received metal injuries to the eye, had metallic or electronically, magnetically or mechanically activated objects (including clips, pacemakers) inserted to your body at an operation, have a fear of enclosed spaces, weigh more than
220 lbs (100kgs), has facial tattoos, extensive dental work, or has received any shrapnel injuries.

When and where will the study take place?
The study is made up of two sessions. These sessions will normally be conducted Mon-Fri during working hours (between the hours of 9.00am – 5.00pm). The study will take place at:

Centre for Neuroimaging Sciences,
Box 089, Institute of Psychiatry,
De Crespigny Park, London SE5 8AF, UK.

What will you be asked to do?

Screening call: We will call you and ask you to answer some MRI safety and study screening questions before we schedule the scans. This is to ensure that it is safe for you to take the MRI, and that you fulfil the specific criteria for this research study. If you do not meet the eligibility criteria at this stage, we will destroy the data collected during the call. All information provided during the call will treated confidentially.

First session:

1. We will ask you to complete some questionnaires.
2. Will take a small blood sample.
3. We will then ask you to take part in the first scan. There will be one functional task where you have to read and remember some letters during the scan.

Second session:

1. The first part will involve being interviewed, filling out some questionnaires and taking part in some computer and pen and paper based tests.
2. The second part will involve another scan, where you can relax or sleep until the end of the exam.

How long will the study last?
If you wish to take part in all of the study this will take roughly one and a half days overall. We will schedule both sessions at a date convenient to you.
The first scan will take no more than 1 hour. The session overall will last no more than 2.5 hours.
The second session will take less than a day to complete (no more than 5.5 hours in total). In the morning, you will spend approximately 3 hours completing the cognitive tests with breaks provided as required. You will have a break for lunch and then in the afternoon, the second scan will take approximately 1 hour.

What are the risks?

These can be a minor risk of some bruising when the blood sample is taken.
MRI scanners can be very loud but we will provide ear protectors to reduce the sound. When taking the scan, you will be asked to lie down in the scanner for an hour without moving which could cause some discomfort.

The neuropsychological tests will mainly involve being interviewed, filling out questionnaires, using a pen and paper or conducting tests using a computer. We will have breaks during the testing and you can ask to take a break at any point. If you find any of the questions awkward, or wish to stop any of the tests, we will stop the test and only continue when you give us permission.

Are there any benefits in being involved in the study?
Participants will be reimbursed travel expenses and paid £20 at the end of the first session and a further £30 at the end of the second session. During the second visit we will provide an additional £6 to cover lunch costs. (A total reimbursement of £56 plus recovery of travel costs). On request, participants will be sent a copy of the final project report.

How will we maintain your privacy and confidentiality?
Once you have agreed to take part in the study, any personal information (such as your name, date of birth and contact details) will be encrypted and stored securely. All your records will be identified using a barcode number rather than your name. Only the study team or MindSearch will have access to your information. All information, including research data and consent form and administrative records will be kept securely. Any of your data used in the study will be anonymised which this means that there will be no way that information can be used in a way to identify you in the report.
If any information we gain from the study may warrant further investigation, we will contact your GP. Check wording.

Who is organising and funding the research?
Dr Andy Simmons is the overall organiser of this project. The principal investigators are Dr Flavio Del Aqua and Anoushka Leslie. The study is being funded by the Biomedical Research Centre for Mental Health.

What if I want to withdraw from the study?
Participation in this research is voluntary. It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason.
In addition to withdrawing yourself from the study, you may also withdraw any data/information you have already provided up until it is transcribed for use in the final report or a paper has been submitted for publication.

What if I have questions about the study?
If you have any further questions about this study, please e-mail brain-atlas@kcl.ac.uk. If this study has harmed you in any way you can contact King's College London using the details below for further advice and information:

NAME AND CONTACT DETAILS OF RESEARCHERS
If you have any general queries about the study, please contact either Anoushka Leslie or Flavio Dell' Acqua.
Anoushka Leslie
e-mail: anoushka.leslie@kcl.ac.uk
Telephone: to be confirmed

Flavio Dell Acqua
e-mail: flavio.dellacqua@kcl.ac.uk
Telephone: to be confirmed

Researcher Supervisor:
Dr. Andy Simmons
e-mail: andy.simmons@kcl.ac.uk
Telephone: 020 3228 3060

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Mapping the relationship between white matter and executive function across the adult lifespan.

This study is affiliated with the programme:

King's College Research Ethics Committee Ref: PNM 10/11-163

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Please tick or initial

- I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw any data/information you have already provided up until it is transcribed for use in the final report or a paper has been submitted for publication. ☐
- I give my consent for my blood to be genotyped for this study. ☐
- I understand that I will not receive any results about my own genotype. ☐
- I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998. ☐
- The information I have submitted will be published as a report and I can be sent a copy. I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me from any publications. ☐
- I agree that the research team may use my data for future research and understand that any such use of identifiable data would be reviewed and approved by a research ethics committee. (In such cases, as with this project, data would not be identifiable in any report). ☐
- I agree that my GP may be contacted if any unexpected results are found in relation to my health. ☐

I would/would not like to receive information on the outcome of the study (delete whichever does not apply).

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed **Date**

Investigator's Statement:

I _____

Confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed **Date**