**INFORMATION SHEET FOR YOUNG PEOPLE**

*Ethical Clearance Reference Number:* HR-18/19-9033

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

**Title of study**

**E-BRAIN: Early experiences and BRAIN maturation**

**Invitation Paragraph**

I would like to invite you to participate in this research project which forms part of my research program. 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 me if there is anything that is not clear or if you would like more information.

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

The purpose of the study is to understand how the way in which the brain grows, and the body responds to stress may lead to better or worse mental health in young people.

Mental health includes our emotional, psychological and social wellbeing. It affects how we think, feel and act as we cope with life. It also helps determine how we handle stress, relate to others, and make choices. It includes: How you feel about yourself and your life; How you respond to stress; How you cope with things that come up in your life; and Your self-esteem and confidence.

Most mental health problems begin when people are still at school, and around 1 in 10 young people experience a mental health problem each year. This is a time when the body goes through a lot of changes, particularly in the brain and in how we cope with the stressors of life. This study will help us understand what in the body may make some young people more or less likely to maintain good mental health and cope with stress. Since physical exercise and diet are important for both brain development and maintaining good mental health, we aim to also study their role at this young age.

This study will focus on what promotes better mental health and could help many young people in the future.

**Why have I been invited to take part?**

You are being invited to participate in this study because we are approaching young people in schools in South London, to see whether the way in which the brain grows, and the body responds to stress influence young people’s mental health.

Almost everybody can take part. However, you may not be able to take part in the study if you have metal in your body, for example: metal clips, pins, braces, metal or shrapnel wounds, metal joint replacements or heart valve replacements. This is because to look at how the brain grows you will have to lay in an MRI (Magnetic Resonance Imaging) scanner that contains a powerful magnet. People with metal in their body cannot have an MRI scan and should not even be in the same room as an MRI scanner. We will carry out a detailed MRI check questionnaire during the consenting process and before we allow you to enter the MRI scanner.

Also, some young people have a fear of needles, and if this is the case, just let us know and we will not ask you to have blood drawn. Do let us know if you prefer the possibility of a finger-prick.

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

If you choose to take part in the study, you will be asked to:

1. Complete a questionnaire at school or in a place of your preference about how you feel, your life experiences and circumstances, and how you handle difficult situations, and to do some computer-based tasks which will measure thinking processes, such as how we make judgements about things and how we understand different emotions. Also, physical exercise and food may affect how the brain develops, how we respond to stress and maintain good mental health. For example, eating lots of fish, fruits and vegetables helps have better mental health, particularly in young people. We will ask you how much physical exercise you do, which food you prefer and how often you eat it. We will visit you again, one and two years from now, and ask you to complete the questionnaire again. On your final visit with us, we would also like to ask you about your experiences with any non-prescribed substance, such as alcohol, tobacco or others as we know that these may affect your wellbeing.
2. We will then ask you to have an MRI (Magnetic Resonance Imaging) scan at King’s College London, which gives detailed pictures of the brain that cannot be obtained in any other way. It is safe and it does not use X-rays or radiation. This will last around 45 minutes, during which time you will need to lie still. While this takes place, you may also have your parent or guardian present in the room next door, or watching you through a video link to a screen in a private waiting room. The scanner will record information about your brain. In order to get clear pictures of your brain, it is very important that you keep still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so you can keep still. The scanner is very noisy and so we will give you earphones to reduce the noise, and a movie to watch if you like.

For part of the scan, you will be asked to perform one task, which will be displayed on a computer screen. During this task, you will be shown faces showing different emotions and you will be asked to match them to the correct emotion and remember the images for a short period of time.

You will have the chance to do a ‘practice’ MRI scan to familiarize yourself with the scanner and the scanning process. Our team is very experienced at preparing young people for MRI scans, but we will stop the scan if during the practice session or the real scan you become anxious or uncomfortable with this. You may find it helpful to use our video App, developed for young people and their families, called “My MRI at King's” (available on YouTube www.youtube.com/watch?v=5WaY-ia\_mX0), which shows 360° videos of the process from arrival through to scan.

We will ask you, one and two years from now, to complete an MRI scan again.

1. On the same day we would also like to collect a sample of your blood to examine markers that indicate how the body responds to stress. If you are willing to do this, you will be seated, and a nurse will take a small amount of blood, like 1-2 teaspoons (which is 7.5ml) by putting a thin needle in your arm. If you prefer not to do this, you can have what is called a “finger-prick”, similarly to what people do to check blood sugar. In this way, after your finger is sterilised with an alcohol swab, the finger is quickly pierced and 5-6 drops of blood (each drop contains 50ul of blood) are collected onto a special card for reading the stress markers. We will also ask you to collect some urine in a cup, which you will do alone in the toilet. This is to measure nutritional substances in your body, that come from the food you have eaten. Finally, we would like to ask you to collect a small amount of your saliva, by simply allowing saliva to pool in your mouth, and then letting it drool into a small tube. From your saliva, we will be able to have another measure the stress and immune markers.

Participation to complete the questionnaires will take place at school or in a place of your preference, while the MRI (Magnetic Resonance Imaging) scan, the blood test, and urine and saliva collection will take place at King’s College London.

**Do I have to take part?**

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in anyway. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part, we will ask you to sign an assent form and you will be given a copy of this form to keep.

**Incentives**

We will arrange transport for you to come to King’s College London when you need to attend, or cover the costs of the transport. If you decide to take part in the study, you will receive a certificate of participation and a £40 voucher for your time.

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

After the questionnaires, you will have a chance to discuss your thoughts and feelings one to one with either a member of the research team or somebody of your preference at school the school counsellor or safeguarding lead. There are no known risks involved in MRI scans providing the appropriate safety procedures are followed. In fact, because MRI scanners use very powerful magnets to acquire their images, care must be taken to ensure that metallic objects are kept away. Also, some people feel uncomfortable in small spaces like the MRI scanner, so you will have a chance to practice this before the real scan. It is also possible that the blood tests cause some discomfort, which usually is like a bruise.

Also, if the MRI shows that there is anything for which you may need to see a doctor, we will contact a specialist from our institution who will provide you and your parent/guardian with advice and further assistance. We will also contact your GP to inform them of findings and arrange for you to be referred to appropriate clinical team.

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

There are no direct benefits for taking part.

**Data handling and confidentiality**

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR).

* We will ensure anonymity by giving you an ID number if you take part. We’ll put that ID number in the questionnaires, MRI and on the blood sample we collect from you. We will never put your name or other personal information on any blood samples, MRI or questionnaires.
* The samples will be held at the Wohl Clinical Neuroscience Institute, part of King’s College London. Only the research team will have access to the data. The samples will only be used for medical and scientific research and the research team will not be able to identify you in any way. The samples will not be transferred outside the UK. This will only be performed if ethically approved. We will ask you, one and two years from now, to repeat the questionnaires, the MRI and to give a blood sample again.
* I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs. I understand that confidentiality and anonymity will be maintained, and it will not be possible to identify me in any research outputs. Your answers to our questionnaires and interview will remain confidential. Should you tell us something that might cause concern for your wellbeing, we will discuss with you the best way to pass this information on to a family member or a member of staff at your school.
* We will retain the data for at least 10 years after publication, as requested by the body funding this study.
* The data will only be shared within the research team. The data will only be used for medical and scientific research and the research team will not be able to identify you in any way.
* The data will only be shared with other studies with your consent and only if they have ethical approval. In this case, a data transfer agreement will be in place which will ensure that data continues to be held in compliance with UK data protection standards (GDPR).

**Data Protection Statement**

The data controller for this project will be King’s College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a ‘task in the public interest’ You can provide your assent for the use of your personal data in this study by completing the assent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King’s College London Data Protection Officer Mr Albert Chan [info-compliance@kcl.ac.uk](file:///\\kclad.ds.kcl.ac.uk\anywhere\UserData\PSStore02\k1217397\My%20Documents\2018\info-compliance@kcl.ac.uk). If you wish to lodge a complaint with the Information Commissioner’s Office, please visit [www.ico.org.uk](http://www.ico.org.uk).

**What if I change my mind about taking part?**

You are free withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. You are able to withdraw your data from the study up until **February 2023**,after which withdrawal of your data will no longer be possible as the **data will have been anonymised and entered in the final reports for publication.** If you choose to withdraw from the study, we will not retain the information you have given thus far.

**How is the project being funded?**

This study is being funded by the Medical Research Council, UK.

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

The results of the study will be summarised in reports for the funder and conferences, papers to be published in scientific journals, students’ theses or newsletters.

**Who should I contact for further information?**

If you have any questions or require more information about this study, please contact me using the following contact details:

E-BRAIN (Principal Investigator: Professor Paola Dazzan)

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Institute of Psychiatry, Psychology and Neuroscience

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Telephone: 020 7848 0029.

This research study has been approved by an independent group of people called King’s College London Research Ethics Committee (reference HR-18/19-9033).

**What if I have further questions, or if something goes wrong?**

If you believe this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

**The Chair, PNM Research Ethics Subcommittee**

[**rec@kcl.ac.uk**](mailto:rec@kcl.ac.uk)

**Thank you for reading this information sheet and for considering taking part in this research.**