**INFORMATION SHEET FOR PARENTS AND CARERS**

*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**

We are a group of researchers from King’s College London. Your child’s head teacher and the school governors have given us permission to undertake a research study in your child’s school. I would like to invite your child to participate in this research project, which forms part of my research program. Before you decide whether you want your child to take part, it is important for you to understand why the research is being done and what your child 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 what biological mechanisms (like for example the way in which the brain grows or the way in which we respond to stress) may lead to better mental health and what leads to worse mental health in young people from all backgrounds.

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. The overall aim of the study is to see if information from the brain scans and the blood can be used to understand what makes children 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 provide information on how and when to intervene to improve mental health and well-being among young people. Doing this study could help many young people in the future and spare their families a great deal of distress.

**Why has my child been invited to take part?**

Your child is being invited to participate in this study because he/she is attending one of the schools in South London that we are approaching for the study.

Almost every young person can take part. However, your child may not be able to take part in the study if they have metal in their 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, they 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 establish their suitability by carrying out a detailed MRI check questionnaire during the consenting process and before we allow your child to enter the MRI scanner.

Also, some young people have a fear of needles, and if this is the case for your child, we will not ask them 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 your child chooses to take part, he/she will be asked to:

1. Complete a questionnaire at school or in a place of their preference, about how they feel, their life experiences and circumstances, and how they handle difficult situations, and some computer-based tasks which will measure thinking processes, such as how we make judgements about things and how we understand different emotions. Also, it is well known that 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 is associated with better mental health, particularly in children and adolescents. We will ask your child some questions about how much physical exercise they do, which food they prefer and how often they eat it. On their final visit with us we will also ask your child questions about use of substances, for example if they drink alcohol, smoke, or use non-prescribed substances, as we know that these can affect wellbeing.  We will visit the school again, one and two years from now, and ask your child to complete the questionnaire again. We will contact you again before we do this.
2. Attend King’s College London (in Camberwell, SE5) for a visit. Transport can be arranged for you and/or your child. If you prefer, one of our researchers could pick up and accompany your child, or you can make your own way and upon presentation of receipts you will be reimbursed for your travel expenses. We will ask some questions to make sure they do not have any contraindication to have an MRI or a blood test. Your child will then undergo practice in a mock MRI scanner to make sure that they are comfortable in a scanning environment and understand the task they will be asked to complete in the scanner. Following this your child will undergo the MRI scan, have a blood test and give a urine sample. They will receive a £40.00 voucher for their time.

The visit will consist of:

**MRI scan**: MRI (Magnetic Resonance Imaging) 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. We would like your child to have an MRI scan of the brain. This will last around 45 minutes, during which time your child will need to lie still. You may be present in the control room during the scan, or you may prefer to watch your child through a video link to a screen in a private waiting room while the scan is done.

We will ask your child to lie on a table inside the MRI scanner. The scanner will record information about your child’s brain. In order to get clear pictures of your child’s brain, it is very important that your child keeps still during the scanning. When your child lies on the table, we will make sure they are in a comfortable position so they can keep still. The scanner is very noisy and so we will give your child earphones to reduce the noise, and a movie to watch if they like. For part of the scan, your child will be asked to perform one task, which will be displayed to him/her on a computer screen. During this task, your child will be presented with faces showing different emotions and he/she will be asked to match them to the correct emotion and remember the images for a short period of time.

Your child will have the chance to undergo a ‘practice’ MRI scan to familiarize him/herself with the scanner and the scanning process. Our team is very experienced at preparing young children for MRI scans, but the scan would be cancelled if during the practice session or the real scan you or your child becomes anxious or uncomfortable with the process. You may find it helpful to also use our video App, developed for young individuals and their families, called “My MRI at King's” (available on YouTube), which shows 360° videos of the process from arrival through to scan.

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**Figure 1.** *The MRI scanner. The MRI system is situated at King’s College London. It is a cylinder-shaped tube surrounded by a circular magnet. Your child will be placed onto a moveable examination table and the table will be moved to the centre of a circular magnet. The doctor or nurse looking after your child and the radiographer taking the pictures sit in the adjoining ‘control room’, which has clear views into the scanner and an interface with the monitoring equipment.*

**Blood sample:** We would also like to collect a sample of your child’s blood to examine markers that indicate how the body responds to stress. Your child will be seated, and a nurse will draw blood by putting a thin needle into a vein in their arm. Your child will have a small sample of 7.5ml of blood taken. If your child prefers not to have the blood drawn from their arm, some drops of blood can be taken by doing finger-prick, similarly to what is done to check blood sugar. In this way, the researcher will first sterilise the finger with an alcohol swab, and then use a retractable lancet to get a few drops of blood. The first blood drops are discarded, and the next five subsequent drops of 50ul each are collected onto a special card for reading the stress markers.

**Urine sample:** We would like to collect a sample of your child’s urine to measure nutritional substances in the body, that come from the food eaten by your child. We will give your child a cup, and ask them to collect some urine while alone in the toilet, after allowing the first urine to escape.

**Saliva sample:** We would like to collect a small amount of your child’s saliva, by simply asking them to allow saliva to pool in their mouth, and then letting it drool into a small tube. From the saliva, we will be able to have another measure the stress and immune markers.

**Additional Questionnaires for participant’s mother**

We would like to also offer mothers the option to answer some questions about their health and psychological wellbeing during pregnancy and in the first year of their child’s life, including on any stressful event that may have occurred during that time. These can be completed whilst your child is attending their study visit with us and while you are waiting. This data collection is an optional addition, and we will reimburse you a further £10 Love2Shop voucher to thank you for your time.

**Does my child have to take part?**

Participation is completely voluntary. You should only consent to your child taking part if you want to and choosing not to have them involved 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. If you decide to consent to your child taking part, we will ask you to sign a consent form and you will be given a copy of this form to keep.

**Incentives**

Transport can be arranged for you and/or your child to attend King’s College London on the day of the MRI scan. If you prefer, one of our researchers could pick up and accompany your child, or you can make your own way and upon presentation of receipts you will be reimbursed for your travel expenses. Your child will receive a certificate of participation and a £40 Amazon voucher for their time.

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

After the questionnaires, if your child wishes, he/she will have a chance to discuss their thoughts and feelings one to one with either a member of the research team or somebody of their preference at school the school counsellor or safeguarding lead. If, while taking part, your child tells us something that makes us concerned for his/her welfare, we may inform the school’s safeguarding lead.

MRI scans are safe, and do not involve radiation (unlike X-rays). 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. Because of the possibility of feeling uncomfortable or distressed in the scanner, please remember that the scan can be stopped at any time. It is possible that the blood test may cause some discomfort, or a little bruise, but these are usually very temporary.

During the course of a research project, previously unsuspected clinical findings about your child could be revealed by the MRI. If clinical findings are revealed, we will contact a specialist from our institution who will be able to provide you 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**

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

* We will ensure anonymity by giving your child an ID number if they take part. We’ll put that ID number in the questionnaires, MRI and on the blood sample we collect from your child. We will never put their name or other personal information on any blood samples, MRI or questionnaires.
* Your child’s answers to our questionnaires and interview will remain confidential. Should they tell us something that might cause concern for their wellbeing, we will discuss with them the best way to pass this information on to a family member or a member of staff at their school.
* 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 your child 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, if you would like your child to repeat the questionnaires, the MRI and to give a blood sample again.
* 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 your child. 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 your child at any point of the study, without having to give a reason. Withdrawing your child from the study will not affect them in any way. You are able to withdraw their data from the study up until February 2023, after which withdrawal of the 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 papers to be published in scientific journals and presented at conferences or in 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)

Department of Psychosis Studies

Institute of Psychiatry, Psychology and Neuroscience

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email: ebrain@kcl.ac.uk

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 your child 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.**