Oxford Centre for Functional MRI of the Brain
(FMRIB-WIN),
University of Oxford
John Radcliffe Hospital, Headington,
Oxford, OX3 9DU

Principal Investigator:
Mr Tim Lawrence
Tim.lawrence@ndcn.ox.ac.uk
Primary researcher:
Izabelle Lövgren (DPhil Student)
Izabelle.lovgren@ndcn.ox.ac.uk

Imaging Study of 11-18 Year Olds with Head Injuries

HEALTHY VOLUNTEER - PARENT/GUARDIAN INFORMATION SHEET

South Central - Berkshire Research Ethics Committee Approval Reference: 24/SC/0155

Your child is being invited to take part in a study at the University of Oxford. Before you decide if you would like them to take part, it is important that you understand why we are doing this research and what it would involve for you both. Please take time to read the following information carefully and discuss it with others if you wish. Do feel free to ask us if there is anything that is not clear, or if you would like more information.

Why are we doing this research?

Head injuries are very common in young people. Most recover well afterwards. However, some feel worse than others after a similar injury. At the moment, we don't know why this happens.

In this study, we will use a scan called magnetic resonance imaging (MRI) to take pictures of your child's brain. We hope that the MRI scans will give us useful information about head injuries. In the future, this could help us identify children who have had a worse injury than expected.

Why has my child been invited to take part?

Your child has been identified by their school, sports club, or via local advertisements as someone who might be interested in taking part in our study. This is because they are an individual who is fit and healthy, aged between 11-18 years, who takes part in sport. They are also someone who we understand **has not had a head injury before**.

We are hoping to generate MRI scans of 60 young people with recent head injuries, as well as 30 with old injuries and another 30 without any head injuries. This is so that we can compare their brain scans.

Unfortunately, not everyone can take part. Your child will **not** be able to take part if any of the following apply:

- Currently having treatment for / recovering from a head injury.
- Currently or previously diagnosed with a neurological or psychiatric condition
- Previous head surgery
- Have previously had a brain scan which led to a diagnosis
- Unsafe to be around a strong magnet (e.g. have metal implant in the body)

What will happen if my child takes part in the research?

1. **MRI Safety Check**
   To make sure your child is safe to enter the scanner, we will **ask you some questions** before the first visit. This may be over the phone.

2. **Attend Two Research Visits**
   We will ask you to attend **two visits** around **6 months apart**. The sessions will take place at the **FMRIB-WIN Centre at John Radcliffe Hospital**.

   Each visit will last around **2 hours**, and will involve:
   - **Height and weight** measurements
   - A 30-40 min **MRI scan**
   - **Questionnaires for you and your child**. These will ask about your child's symptoms, behaviour, brain function, sleep, pubertal development and medical history.
   - **Short tasks** such as a line-drawing task
   - **Optional:** Wear an **EEG headband** to record your child's brain activity (less than 15 minutes). Your child can choose if they want to take part in this assessment or not.

What will the MRI scan involve?

Before the scan

At both visits, we will start by **reminding you about what the study involves.** We will also **ask if you still want to take part**.

At the first visit, we will ask you and your child to **sign a consent and assent form.** The forms confirm that you both understand what your child is being asked to do, and that you would like to take part. However, **you can stop taking part at any time.**

Next, you will be **seen by a Radiographer.** This is a person who is trained in taking pictures of the brain. They will **ask questions** to make sure that your child will be safe in the scanner.

Safety Guidance

The scanner uses a strong magnet, so it is important to not bring any metal objects in with you. To make this easier, **we will give your child a set of "pyjama-style" top and trousers** that are **safe to wear in the scanner**.

However, please be **mindful of the following guidance:**

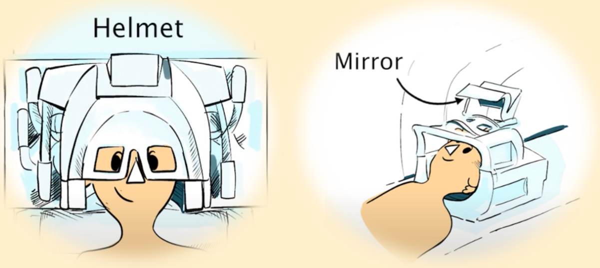
- ✓ Underwear and socks can be kept on.
- ✗ **Remove** underwired bra or wear non-wired bra.
- ✗ **Remove** metal jewellery, body piercings, and hair clips.
- ✗ **Remove** any anti-odour fabrics, such as sports or therapeutic fabrics.
- ✗ **Avoid** eye makeup. If worn to the visit, we can provide removal wipes.

If you would like to enter the scanner room with your child, you will also need to follow the safety screening and procedures.

During the scan

The scanner makes loud banging noises during the scanning process, similar to those from a construction site. This is completely normal but can be uncomfortable, so **we will give your child earplugs**.

Before going inside the scanner, your child will be asked to **lie on the scanner table** while we **put some equipment around their head**, like a helmet. The helmet will have a mirror, so that they can see the outside of the scanner.



Images by Alice Haskell

We will then slowly move them into the scanner. They will be asked to **lie still on the table inside the scanner for 30-40 minutes.**

To make the scanning more comfortable for them, we will provide them with **cushions and videos to watch**. If they have their own DVDs, they can bring one to the visit.

To make sure that they are still comfortable, **we will check in with them several times** during the scanning. They will also be given a call button. They can **use this call button at any time** if they would like to talk to us, or to stop the scan.

If you would like to know more about what a research MRI scan is like, follow this link to our website for videos and frequently asked questions: https://www.win.ox.ac.uk/research/take-part/what-to-expect

Do they have to take part?

No - it is up to you and the child to decide if you want to take part. **They can stop taking part at any time during the study**, **without giving a reason.** Their future medical care will not be affected in any way.

What are the possible risks in taking part?

MRI scans are painless and safe. However, because MRI uses a very strong magnet, not everyone can go into the scanner. To make sure that your child will be safe, we will ask you both questions and provide them with clothes to wear.

Some people feel panicked when they enter small spaces. This is known as claustrophobia. The Radiographers have been trained to support people who feel scared in small spaces. If your child feels worried about this but still wants to take part, let us know and we can talk about the options available.

Will I get medical information from my child's scan?

Your child's scan will **not** be used to diagnose any condition or illness. It is only used to collect information for research. Because of this, it will not be shown to you. It is also not normally looked at by a doctor.

What if you find something unexpected?

On very rare occasions, the scan shows something unusual. If this happens, we will ask a doctor to look at the scan. It is important to know that the doctor will only contact you about the finding if they think you need to know about it. A hospital scan may then be arranged for your child instead. If the doctor does not think you need to know about it, you will not be contacted.

Are there any benefits in taking part?

There are no personal benefits to you or your child. However, we hope that this research will benefit other children in the future. For example, by helping us identify which children may need extra care after a head injury.

Will we be paid?

Any reasonable costs incurred by taking part in our study will be reimbursed (for example, travel costs, extra childcare) - please note that **this can take a few weeks**. Additionally, as a token of appreciation, you and your child will be offered a **£10 gift card each at both visits.** This may be for Amazon or other providers.

Will anyone else know that my child is doing this?

We will keep your child's information private. This means we will only tell those who have a need, or right to know, such as the research team **and your child's GP/Doctor**. Your child's GP/Doctor will be informed about their participation upfront in case something medically important is identified on their study MRI scan.

To help keep your child's information confidential, their MRI scans and any information recorded about them in this study will be assigned a study code that is used instead of their name or other identifiers. Any personally identifiable data will be kept in a secure location as described below in "*What will happen to my child's data?".*

Responsible members of the University of Oxford, regulatory authorities and the Oxford University Hospitals NHS Trust may be given access to data for monitoring and/or audit of the study. This is to ensure that the research is complying with applicable regulations.

Data from this study may also be used in other research studies in the department, or by colleagues working on related topics (at institutions both inside and outside of the UK/Europe). Importantly, **all of your child's personal information would be removed** so that it cannot be traced back to them. The unidentifiable data may also be deposited in a data repository/trusted research environment.

What information will be collected and what happens to the results of the research?

Information	Why this information is relevant
MRI scans	• Using MRI, we will take several types of scans of your child's brain. Each scan generally lasts around 5-6 minutes, and tells us different things. In this study, we will look at the structure of the brain on both large and small scales. We will also look at its activity and natural chemical levels.
Questionnaires, Tasks Data	• We will use this data to investigate relationships between the brain scans and o different symptoms & the body's environment. o your child's sleep, behaviour, and brain function. • Your child's medical history and pubertal stage will help us spot and account for other things that may be responsible for brain changes.
Height and Weight	• Your child's weight must be reported before being scanned. This is to make sure they will be safe in the scanner. • Both your child's weight and height are collected so that the dataset can be re-used by others in the future (see above).
Demographics	• Age, gender, and ethnicity data will help us understand the diversity of our study cohort.
Medical Records	• Where required, and with your permission, we may request access to relevant medical records to help us ensure that your child is safe to enter the scanner.
EEG (optional)	• If your child chooses to take part in this assessment, we will record their brain activity while they are at rest for less than 15 minutes using an EEG headband. This data will be used to study the electrical activity of your child's brain.

Optional – Does your child use the SportSmart app or wearable devices?

If they do, and are happy for us to analyse their data, please let us know at the start of the study. Examples of data include: performance on baseline tests, information about previous injuries, blood oxygen levels, and data about movements of their head. The child will decide how much or how little of this data they share with us.

What will happen to my child's data?

Data protection regulation requires that we state the legal basis for processing information about you/your child. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

We will be using information from You/your child and, if applicable, your child's hospital/GP records in order to undertake this study and will use the minimum personally-identifiable information possible.

We will store any research documents with **personal information**, such as consent forms, securely at the FMRIB-WIN Centre, University of Oxford (on-site, or on secure, password-protected servers) **for the duration of the study only** as part of the research record.

If you agree to your details being held to be contacted regarding future research (see "Participation in future research on page 8) or to receive a copy of any publications from this research, a copy of your consent form will be retained securely until your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.

Unidentifiable research and imaging data will be retained on secure, password-protected servers and/or on archive tapes at the University of Oxford **indefinitely after the end of the study** period (up 30+ years).

Bank details used for reimbursements will be stored for 7 years in accordance with University of Oxford financial policy. We will keep any other identifiable information about you until the study has finished.

With your permission, research members with appropriate contracts in place may use your child's personal details (name, date of birth, NHS number) to access relevant medical records as described above in "*What information will be collected and why?".*

Jisc Online Surveys will be used as a third-party processor in this study. Jisc has been approved by the University of Oxford for collection of confidential data and will be used for questionnaires. Questionnaire data will be stored in Jisc for the duration of the study period only.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Izabelle.lovgren@ndcn.ox.ac.uk

How will the findings of this research study be used?

Some of the research being undertaken will contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis). They will also be used in academic publications, conference presentations, and reports. If we want to use the information for anything else, we will ask your permission. If you would like access to any publications that result from this study, you can choose to opt in on the consent/assent form.

What if we change our minds during the study and don't want to take part anymore?

Your child can stop taking part at any point, without having to give a reason. If your child withdraws or is withdrawn from the study, the data collected up to the point of stopping may still be used.

Who has reviewed the research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by South Central - Berkshire Research Ethics Committee.

How have patients and the public been involved in this study?

To make our information sheets as clear and straightforward as possible, we reached out for feedback from a group of 8 young individuals via GenerationR's Young Person Advisory Group alliance.

What do I do now?

If you would like to take part, **please contact us** via email (Izabelle.lovgren@ndcn.ox.ac.uk) or by phone (01865 610 471), so that we can discuss things further.

What if there is a problem or something goes wrong?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of their participation in this study.

Please tell us if you are worried about any part of this research, by contacting Izabelle (Izabelle.lovgren@ndcn.ox.ac.uk) or Mr Tim Lawrence (Tim.lawrence@ndcn.ox.ac.uk).

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Izabelle Lövgren (Izabelle.lovgren@ndcn.ox.ac.uk ; 01865 610 471) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) on 01865 616480, or the director of RGEA at rgea.complaints@admin.ox.ac.uk.

Participation in future research

If you would like to be approached for participation in future research studies, you can express this on the consent / assent form. Any contact about future research would come from a member of the research team in the first instance. Importantly, agreeing to be contacted does not mean you have to take part in future research.

You can be removed from the register at any time by contacting us using the details below. Your contact details would be held on secure, password-protected hospital or University of Oxford servers, accessible only by authorised members of the research team.

Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Izabelle Lövgren
Izabelle.lovgren@ndcn.ox.ac.uk
01865 610 471

FMRIB-WIN Centre,
University of Oxford,
John Radcliffe Hospital, Headington,
Oxford OX3 9DU

Thank you for reading – please ask us any questions.