

Fit to Study – Brain imaging sub-study

PARENT/GUARDIAN INFORMATION SHEET

Ethics Approval Reference: R51313

We would like to invite your child to take part in the **‘Fit to Study’ – Brain imaging sub-study**. This research study is part of the ‘Fit to Study’ trial, a project that your child’s school has agreed to take part in and that aims to link physical education to academic performance.

This sheet provides information to help you and your child decide whether to participate in the Brain imaging sub-study. Please take time to read this carefully and discuss it with your child, friends, family or your child’s GP if you wish. If there is anything that you do not understand, or if you would like more information, please contact us.

What is the purpose of the research?

We are interested in understanding **whether the content of school Physical Education (PE) lessons affects brain organisation and function**. This knowledge might help future efforts to optimise PE lessons to improve brain function.

We can investigate the brain using Magnetic Resonance Imaging (MRI) brain scans, which are safe and non-invasive. We will use MRI to image the structure and function of your child’s brain and relate this to the content of their school PE lessons.

Why has my child been invited?

Your child has been invited to take part in this research because your child’s school is participating in the Fit to Study main trial (CUREC: R48879). We will be recruiting up to 100 pupils from a range of different schools for this study.

Does my child have to take part?

No. It is up to you to decide if you want your child to take part in this study. We will describe the study and go through this information sheet with you and your child to answer any questions you may have. If you agree for your child to take part, we will ask you to sign a consent form and your child will be asked to sign a form agreeing to take part. We will give you a copy of these to keep. However, your child would still be free to withdraw from the study at any time, without needing to give a reason. This would not affect legal rights you would receive.

What will the study involve?

Before the day of testing

Please make sure you and your child read these information sheets carefully. If you have any questions please contact us. We are happy to answer any questions that you may have so that you and your child can decide if you want to take part in the study.

Please also ensure your child fills out the short questionnaire contained in this information pack prior to the testing session. The research team will collect the questionnaire on the day of testing.

To check whether it is safe for your child to have an MRI scan, a first MRI screening will be carried out over the telephone. This screening is compulsory in order to make sure that it is safe for your child to participate in the study (see additional information below).

On the testing days

Your child would participate in two assessment days. These will take place at the **Oxford Centre for Functional MRI of the Brain (FMRIB), John Radcliffe Hospital**, once in **July/August 2017** and once in **July/August 2018**.



On arrival, one of our research team would meet you and your child to describe what participation will involve and to answer any questions you or your child may have. If you and your child are happy to continue they will then ask you to sign a consent form. Your child will be asked to sign an assent form.

Each testing session will take up one morning or afternoon.

Each session will include:

- Paper and pencil or computer-based tasks to measure memory and attention. The tasks will take up to 60 minutes and will be followed by a 30 minute break.
- A repeat of the MRI Safety Screening assessment (previously conducted by telephone) with your child to make sure that it is safe for your child to participate in the study. This screening form will include questions about your child's medical history and about possible pregnancy.
- Up to 60 minutes of lying inside the MRI scanner for a series of brain scans. Your child may be asked to make particular movements, to respond to specific stimuli (e.g. a sound, something presented on a screen, or a touch) or to perform simple thinking tests. This will be followed by a 30 minute break.
- Up to 30 minutes of filling-out questionnaires asking, for example, about your child's lifestyle, experiences, or mood.
- A fitness test (VO2 max test) lasting about 20 minutes. This involves your child cycling on a stationary exercise bike while wearing a face mask, in order to measure the maximum volume of oxygen that he or she can use in order to get an objective measure of her/his fitness. (For your child's comfort during the fitness test, please bring along some sports clothes or comfortable clothes).

We will also ask your child to wear a wristwatch-style activity monitor for seven days following the assessment, in order to record their level of physical activity. (You will be provided with an envelope to return it).

Please let us know beforehand if your child has braces or wears contact lenses or glasses.

Will my travel costs be reimbursed?

Yes. We will compensate you for your parking and travel costs for every visit. In addition you will receive an Amazon Gift Voucher of £20, whilst your child will receive a children's book introducing neuroscience.

If you and your child are interested in your child taking part in the study, or would like to express an interest in participating, then please contact us via e-mail at fittostudy@fmrib.ox.ac.uk or via telephone at 07864 800761 or visit www.fit-to-study.org. A researcher will then contact you to answer any questions you might have and to arrange a visit.

With best wishes,

The Fit to Study Team



Additional information

Are there any risks in taking part in this study?

MRI is safe and non-invasive and does not involve any ionizing radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. Because of this, your child will be asked pre-screening safety questions to help determine if your child is able to take part. For example, if your child suffers from claustrophobia, she/he could not be scanned. Normally, MRI scanning for research purposes would not be performed without further investigation if your child has a heart pacemaker, mechanical heart valve, mechanical implant such as an aneurysm clip, hip replacement, or if your child carries other pieces of metal that have accidentally entered their body.



While there is no evidence to suggest that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant individuals unless there is a clinical benefit. If your child might be pregnant, they should not take part. For this reason, on the day of testing and in the MR-screening telephone call, girls will be asked whether they may be pregnant.

As some of the scans are noisy, we would give your child ear plugs to make this quieter for her/him. It is important that these are fitted correctly as they are designed to protect your child's ears.

In preparation for your scan and for your child's comfort and safety we may ask your child to change into pocket less and metal free "pyjama-style" top and trousers, which are available in a range of sizes. Your child may keep her/his underwear and socks on but we would ask females to remove underwired bras; if your child has a suitable non-wired bra this may be worn instead. Please avoid your child wearing any fabrics that contain metallic threads or have been silver impregnated (often marketed as anti-microbial/bacterial or anti-odour/stink). Metal jewellery including body piercing must also be removed. Eye shadow and mascara must also be avoided, since some types contain materials that can interact with the magnetic field. If your child wishes to wear eye makeup to the scan we can provide makeup removal wipes but your child is advised to bring her/his own makeup to reapply. Lockers are provided to secure your child's personal belongings and clothing.

It is important to note that we do not carry out scans for diagnostic purposes, only for research. Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor's appointment. Occasionally, however, a possible abnormality may be detected. In this case, we would have the scan checked by a doctor. If the doctor felt that the abnormality was medically important, you would be contacted directly and recommended to have a hospital (NHS) diagnostic scan arranged. You would not be informed unless the doctor considers the finding has clear implications for your child's current or future health. All information is kept strictly confidential.



Will my child be asked any sensitive questions?

On the day of testing pupils will be asked to fill out questionnaires that include questions about their physical development (e.g. boys will be asked whether their voice has broken; girls will be asked whether the period has started), as well as whether they have ever smoked cigarettes or used drugs. Their answers are private and will be anonymised and kept safe. Nobody else will have access to these questionnaires.

As mentioned above, safety screening includes asking girls whether there is any possibility they may be pregnant.

Are there any benefits from taking part in this study?

We hope that participating pupils will find it interesting to be involved in scientific research. There will not be any direct benefits to you or your child from participating in this study. It is hoped that the results from this research will help us understand the effects of physical activity and fitness on brain function, cognitive performance and academic attainment in children.

Who has reviewed this study?

All research studies are checked by an ethics committee to ensure the research is conducted safely and to the best standards. This research has been reviewed by and received favourable opinion through the University of Oxford Central University Research Ethics Committee.

Who is organising and funding the research?

A research team at the University of Oxford and Oxford Brookes University, led by Prof Heidi Johansen-Berg (University of Oxford), is organising this research study. The research is funded by the Education Endowment Foundation (EEF) and the Wellcome Trust.

What will happen to the results of the research?

We hope to publish the results of this study in scientific journals. We may also present the results of this study at scientific conferences, symposia, and seminars in a University or during talks to the general public. The results may also be published on our website. It will *not* be possible to identify your child in any report or publication resulting from this study. We would be happy to provide you and your child with a general summary of our research findings - please contact the researchers if you are interested in such information. Please note that we will only provide you with such a summary after completion of the project and analysis of the data.

Who will know that I am taking part in this research?

Any information collected about you and your child during this study would be kept strictly confidential. Any imaging and electronic data will be anonymised. All such data are kept on firewall and password-protected computers and may be kept indefinitely. Paper information containing study data (such as any paper-based research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building, would only be accessed by the research team and would be destroyed after anonymised data are stored electronically. Study consent forms and MR screening forms will be stored in locked filing cabinets and may be kept indefinitely. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines. Sometimes, new methods to analyse data become available after a study has ended. Therefore, we would ask for your permission to use your child's anonymised data in future studies, and to share data, such as her/his anonymised scan data, with other researchers both inside and outside the European Union. With your consent, we will keep your child's personal information on a secure database in order to contact you for future studies.

***What if something goes wrong?***

If a participant in University research is ever considered to have suffered harm through their participation, the University has arrangements in place to provide for compensation. If you have a concern about any aspect of this project, please speak to the researchers, Dr Piergiorgio Salvan and Mr Thomas Wassenaar, or the Principal Investigator Prof Heidi Johansen-Berg, who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how she/he intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, email ctrq@admin.ox.ac.uk, who will inform the chair of the Research Ethics Committee at the University of Oxford.

What if I have further questions?

If you have any questions or concerns about any aspect of this study, please contact Dr Piergiorgio Salvan or Mr Thomas Wassenaar of the Fit to Study team (fittostudy@fmrib.ox.ac.uk, 07864 800761, Address: FMRIB Centre, Nuffield Department of Clinical Neurosciences, John Radcliffe Hospital, Headington, Oxford, OX3 9DU), who will do their best to answer your questions. The Principal Investigator of the project, Professor Heidi Johansen-Berg can be reached on 1865 222548 and heidi.johansen-berg@ndcn.ox.ac.uk.



Important Contacts

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