PARTICIPANT INFORMATION SHEET (mTBI case-control)

mTBI-Predict

Mild Traumatic Brain Injury Biomarker Study, a prospective cohort biomarker study of military and civilian participants with mTBI

What is this research for?

- Mild traumatic brain injury (or mTBI), commonly called concussion
- We don't always know how a brain injury will affect people's health
- This study will test members of the public, service personnel and sports people to find ways to help us predict how a brain injury will affect people's health
- This will help us treat people better, getting them back to work, duty or play quicker

Do I have to take part?

- No! Joining the study is voluntary. If you decide not to take part, your usual care will not be affected
- Please take the time to read this information sheet fully and talk to others about the study if you wish
- You will be able to discuss the study with a member of the research team and ask any questions you might have

Will I be paid for taking part?

We will help with travel and parking costs and offer compensation for your time

Where can I get more information?

- Part 1 tells you what will happen to you if you choose to take part
- Part 2 gives more detailed information about the conduct of the study

For questions about the study please contact:

Animesh Ghose / Karen Tester; mtbiclinicalresearch@uhb.nhs.uk

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Part 1 – about the mTBI-Predict study

What is this research for?

There are nearly a million hospital visits each year in the UK for mild traumatic brain injury, or mTBI. This is sometimes called concussion. We call it "mild" but a third of people can't work a year after their injury. Problems can include headaches, poor memory, and poor mental health.

We can't always tell which patients might have long-term problems so we can't always give people the right early treatment.

Biomarkers are things like blood samples or brain scans. We are going to test many different biomarkers to see which can show who is at risk of long-term health problems after mTBI. We want to find biomarkers that are accurate and practical for civilians, soldiers and sports people.

Why have I been invited?

We are asking you because you have had an mTBI in the last 3 weeks and are over 18.

Do I have to take part?

No, this is entirely up to you. Taking part is voluntary. You don't have to take part if you don't want to. This will not affect your standard of care. We are giving this information for you to consider carefully before you decide. You can discuss it with family or friends. If there is anything unclear, please speak to a member of your care team or the research team.

What would taking part involve?

If you decide to take part, the research team will ask you to do the following over the next 24 months. **This will vary depending on how soon after your injury you enter the study:**

- If you join within one week of your injury you will do all study visits
- If you join 3 weeks after your injury you will skip the first visit and do the green and blue boxes

Within one week of your injury (visit 1)
• Complete an Informed Consent Form • Give a blood sample • Give a saliva sample 12 times between now and visit 2 • Use an app and smart watch to collect some information about you until visit 2 • Use the app and smart watch to do a 6-minute walk test before visit 2

Three weeks after your injury (visits 2, 3 and 4)
• Complete an Informed Consent Form if you haven't already

• Have 3 main research visits:
  ○ a remote test visit, using an app, including a 6-minute walk
  ○ a clinical assessment day at a hospital including samples of blood, hair, saliva and tears, with a phone call the day before
  ○ a brain scan day at an imaging centre

• Complete some memory and brain health tests for 5 minutes a day for 2 weeks after your visits, using the study app
• Complete a headache and sleep diary daily until visit 6 (nearly 3 months) • Give weekly saliva samples until visit 6

Two months after your injury (visit 5)
• Complete some memory and brain health tests for 5 minutes a day for 2 weeks, using the study app
• Remote tests using the study app

Three months after your injury (visits 6, 7 and 8)

• Have 3 research visits:
  ○ a remote test visit, using the study app, including a 6-minute walk
  ○ a clinical assessment day at a hospital including samples of blood, hair, saliva and tears, with a phone call the day before
  ○ a brain scan day at a university

• Complete some memory and brain health tests for 5 minutes a day for 2 weeks after your visit, using the study app

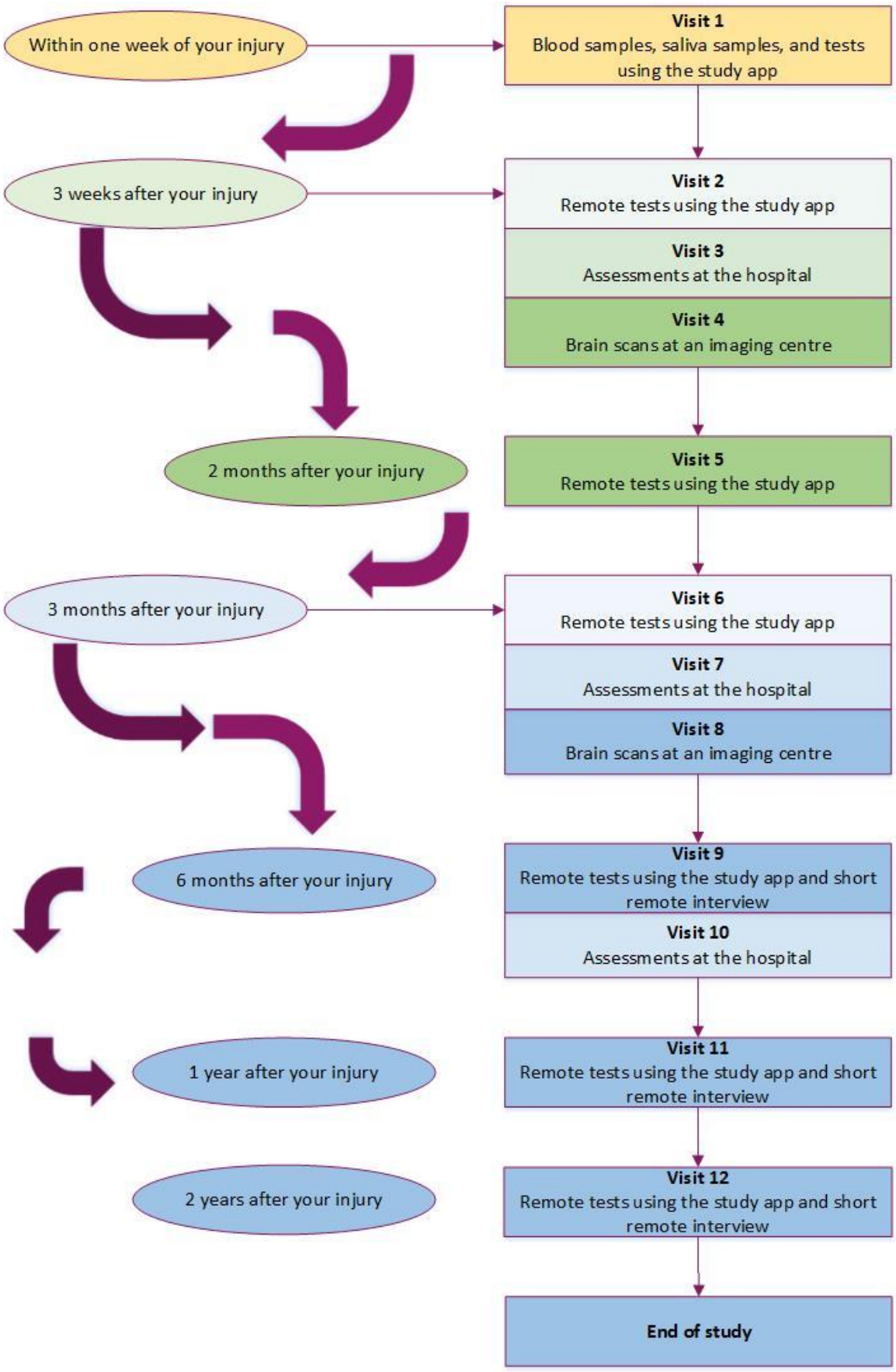
Six months after your injury (visit 9 and 10)
• For the month before your visit, wear the smartwatch and complete a headache and sleep diary daily. Do a weekly memory and brain health test (5 minutes)

• Have 2 research visits:
  ○ Remote interview by a researcher, and a remote test visit, using the study app, including a 6-minute walk
  ○ a clinical assessment day at a hospital, with a phone call the day before

One year after your injury (visit 11)
• For the month before your visit, wear the smartwatch and complete a headache and sleep diary daily. Do a weekly memory and brain health test (5 minutes)
• Once: Remote interview by a researcher, and remote tests using the study app, including a 6-minute walk

Two years after your injury (visit 12)
• For the month before your visit, wear the smartwatch and complete a headache and sleep diary daily. Do a weekly memory and brain health test (5 minutes)
• Once: Remote interview by a researcher, and remote tests using the study app, including a 6-minute walk

Figure 1 – The different visits depending on when you start in the study



What will I be asked to do if I agree to take part?

If you take part, there will be up to 12 study visits over the next 2 years. This depends on how soon after your injury you join the study. Some of these will be a day at a hospital or university, and some will be much shorter, done at your home on your phone or tablet.

Visit 1

You will do this if you join **within one week of your injury.** There will be symptom questionnaires for balance and hearing. We will take blood, saliva, and tears samples. We'll need to take around 30ml (volume of around 5 teaspoons) of blood. We will give you kits (with prepaid postage packaging) to collect saliva samples for the next 21 days (12 times).

We'll also help you to install the study app on your personal device. This is free and doesn't take up much space or data. We'll also give you a Garmin smartwatch to use with the app to collect data about yourself between now and the next visit. To help us set up the smartwatch, we will make a record of your height and weight. The smartwatch can be taken off when you are not performing study visits. **You will be able to keep this smartwatch after completing the study.**

What do we want to collect between visit 1 and visit 2?
• Saliva samples – 12 times over 21 days
• Smartwatch data – daily movement data over 21 days
• Daily headache and sleep diary using the study app

Remote tests using the study app (visits 2, 5, 6, 9, 11 and 12)

The next "visit" will be at home using the study app. You will get a notification to do your tests.

There will be a set of tests looking at how your brain functions doing different tasks. Everyone will do a practice run before any proper tests, to get used to them. These tests are on a database called Cognitron which is already used in brain research across the country. These memory and brain health tests should take about 30 minutes to complete.

The app also has questionnaires about your headache, vision, balance, mental health and sleep. These questionnaires should take about 30 minutes to complete.

Remote test visits will be done at 3 weeks, 2 months, 3 months, 6 months, 1 year and 2 years after your injury. Except at 2 months, this remote test also involves a 6-minute walk test. This is a walk in the street or park, wearing the Garmin smartwatch. You should try to do it in the same place each time. **After the 2 year tests you finish the study**.

There is also a symptom diary. This is to record any headache and sleep symptoms daily for 3 months – this should take a couple of minutes to do each day. You'll also do a 5 minute memory tests 5 times a week for 2 weeks.

What do we want to collect between visit 4 and visit 6?
• Complete some memory and brain health tests for 5 minutes daily for 2 weeks
• Smartwatch data – daily movement data over 3 months
• Daily headache and sleep diary using the study app
What do we want to collect just before visit 9, 11 and 12?
• For the month before your visit, wear the smartwatch and complete a headache and sleep diary daily. Do a weekly memory and brain health test (5 minutes)
• Remote tests using the study app, including a 6-minute walk test.

Assessments at the hospital (visits 3, 7 and 10)

Before the hospital assessment day, the study doctor will call you to ask you questions about yourself including personal details, your injury and past medical problems. We also want to know detailed questions about your headaches (if you have them), any balance or hearing problems, and mental health. This phone call could take at least an hour.

These assessment days take place at The NIHR/Wellcome Trust Clinical Research Facility (WTCRF), based at the Queen Elizabeth Hospital Birmingham.

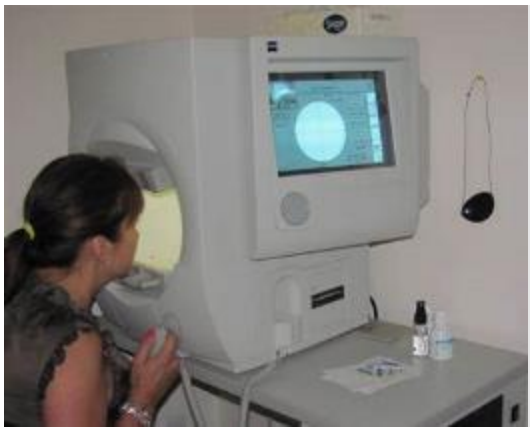
The visit will start early. You will be provided with a light breakfast and lunch. We will also provide you with a voucher if you wish to buy your own lunch at the hospital canteen.

First, a researcher will measure your weight and blood pressure. You will then give a saliva sample by placing a small absorbent pad in your mouth before transferring it into a sample pot. The researcher will then collect a small sample of your tears by holding a small tube to the corner of your eye. Next they will take some blood samples (around 5 teaspoons, or 30mls). At visit 3 only, the researcher will use scissors to take a small sample of hair from the crown of your head.

A doctor and a physiologist will then do various tests looking at balance, hearing, vision and cerebral physiology (how the brain works). These tests are split into categories below.

Vision tests (about 60 minutes):

Our ophthalmologist will perform a series of tests on your vision and eye health. These are similar to an eye test you would have at the optician. We will examine how well your eyes can detect colours, light, and distance. We will also measure your field of vision, using a Humphrey's Visual Field Analyzer, and look at the nerves and blood vessels in the back of your eye with a scanning laser call Optical Coherence Tomography, or OCT.

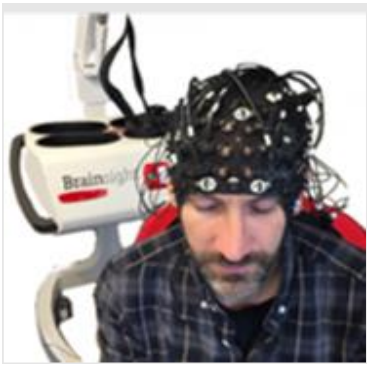


A Humphrey's Visual Field Analyzer

An Optical Coherence Tomography scanner

Balance, eye movement and hearing tests (about 90 minutes):

Our researchers will also examine your balance, eye movement and hearing. This will involve tests where you are sitting, lying, and standing in the dark and light. A computer screen will be used for some tests where you will respond by pressing a button or answering verbally. You will be asked to stand up and sit down and do a very short walk across the room. Somebody will be available to assist if you have any mobility issues. We may ask you to wear some goggles for some of the tests and will place some electrodes on your neck and face to detect electrical activity from your muscles in response to a stimulus, known as vestibular evoked myogenic potential testing (VEMP).



The NIRS-EEG headset

Cerebral physiology tests (about 180 minutes, with a break):

Our researcher will fit you with two headsets: a NIRS (near-infrared spectroscopy) and EEG cap which will measure oxygen in your blood and electrical conductivity in your brain, and a transcranial doppler (TCD) which will measure blood flow in your brain. You will be asked to do some simple tasks whilst sitting, standing, and squatting. A researcher will be available to assist with any mobility issues. You will also be fitted with a mouthpiece where you will breathe normal room air and a carbon dioxide enriched air mixture. You will do this breathing test twice and each should last around 10 minutes but you can stop at any time. Finally, the researcher will hold a coil over your head to activate nerves in your brain, called Transcranial Magnetic Stimulation (TMS). This will make the muscle twitch in your finger but is not painful.

The whole hospital visit:

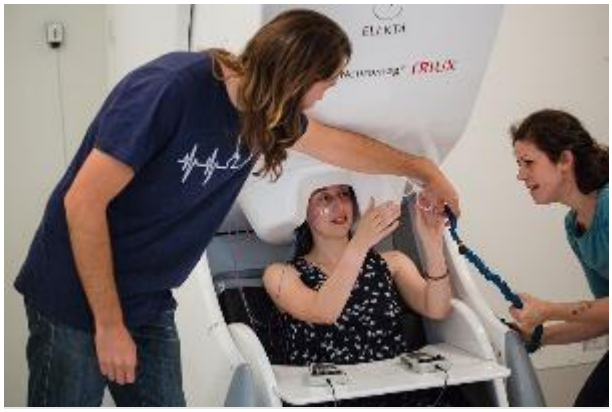
The whole visit starts at 8 or 10 am and finishes around 4 or 6 pm. We know it's a long day and there will be complimentary morning hot drinks and biscuits, with a break for lunch which will be provided and an afternoon hot drink and biscuit break. Some of the assessments are very sensitive so we kindly ask you to avoid drinking caffeinated drinks such as tea or coffee in the morning. We also ask you to avoid alcohol the evening before, and vigorous exercise the day before and morning of each clinical visit. If this is not possible you will be able to discuss with the nurse.

Figure 2 – Clinical day at the hospital

Brain scan days (visits 4 and 8)

What happens on the imaging assessment day?

Visits 4 and 8 will take place in Stamford Hall, Birmingham, Aston or Nottingham. On your visit day, you will have one MEG session and then two MRI scan sessions in the MRI suite (detailed below).



Right: MEG scanner

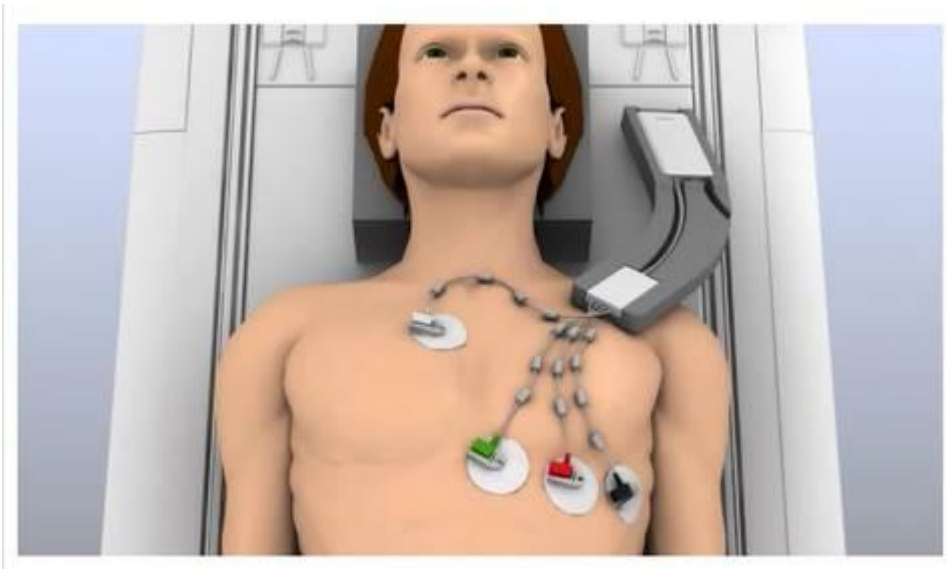
Before your scan sessions

Before each session you will have some time (15-30 minutes) to get changed into scrubs. What you will do in the scanner will be explained. You will complete a safety questionnaire before your scan to make sure you are safe to be scanned. This is done every time MEG or MRI scans are done and it is important you answer all the questions as accurately as possible. It will ask about things like whether you have any metal in your body.

What is a MEG scan and what will happen?

A MEG scan measures the magnetic fields generated by your brain. There will be one MEG session per visit. At the beginning of this session we will take 30 minutes to prepare the MEG. You will be able to get familiar with the equipment and tests. The researcher will put some electrodes on your body that will track heart rate and the position of your head and eyes in the MEG system.

If you have a hairy chest you may be asked to shave, or trim, an area on your chest for the electrodes to adequately stick to your skin better. The image below demonstrates how the electrodes will be attached to your chest.



After the preparation you will do some tasks while the researcher records your brain activity in the MEG. You will be presented with things like a visual display or tones. You will be told how to respond to these, for example by pressing a button. Throughout the tasks you will

need to keep your eyes focused, but there will be some sections where you will be able to freely move your eyes and relax. In total, the MEG session will last about 90-120 minutes.

What is an MRI scan and what will happen?

An MRI scan creates images of the brain or other parts of your body.

You lie on a table inside a cylindrical machine which uses magnetic fields and radio waves (not x-rays) to take pictures of your brain. To get good pictures, it is very important to stay still during the scan. Positioning aids will keep your head from moving and you should try to relax.

The scan itself is a harmless, non-invasive procedure but it is noisy. Some people can feel uncomfortable whilst lying in the scanner tube. There will be two MRI scan sessions on the visit day and will each take about an hour.

For each MRI session, you will have some time (30-60 minutes) before going into the scanner to get changed and the details of what you will need to do in the scanner will be explained.

Any equipment which is needed for the scan sessions will be set up on you. The researcher will record your heart rate and breathing with a belt around your chest, and a set of sticky pads on your chest will also monitor your heart rate. The 2 sessions will be separated by at least 30 minutes so you have a good break and can walk around. You will be able to talk to the researcher during the scans by using the scanner's intercom.

What are the MRI tasks?

In the first MRI session we will take measurements of your brain structure while resting. You will then be asked to carry out a cognitive task whilst in the scanner. This allows us to take measurements of your brain structure whilst active.

The second MRI session will again mostly be you lying still and relaxed. We will take some measurements of the blood flow in your brain. Then we will give you a mouthpiece to breathe through. We will give you a carbon dioxide enriched air mixture through this mouthpiece and you'll be asked to breathe normal room air then the carbon dioxide air mixture and back to room air. You will be asked to breathe normally throughout, but you might breathe slightly faster when breathing the carbon dioxide mixture. You will be able to remove the mouthpiece during the test if you need to.

Below: MRI imaging suites at 3 possible sites: University of Birmingham (left); University of Nottingham (middle), Aston University (right)

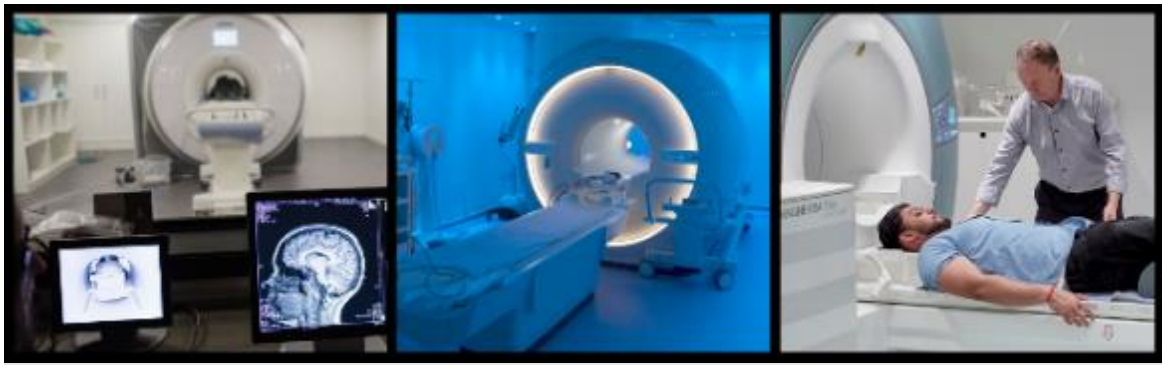


Figure 3 – Brain scan day

Are the tests safe?

All of the tests we will ask you to do are already done in the NHS. The possible risks are:

- Bruising from the needles used to take blood samples
- Feelings of claustrophobia in the MRI scanner
- A very small (less than 1 in 1000) chance of a superficial scratch on your eye resulting from tears collection. This is very unlikely but if it does happen it will heal, usually within 24 hours.

What are the possible disadvantages and risks of taking part?

Apart from the possible risks described above, we know we are asking for a lot of your time, with a lot of tests.

There is a small chance that we may discover something in your brain scans that you were not already aware of, that may require further investigation. If this is the case your scan will be reviewed by a clinical radiologist. If the radiologist believes that there is something in your scan that may require immediate attention, you will be referred for further investigation following standard NHS referral procedures. If your scan shows something that is not immediately urgent, but still may require further investigation, you will be contacted by a member of our clinical team who will discuss the findings with you and direct you to appropriate support. In order to achieve this, a copy of your brain scan will be stored at the imaging centre at which the scan was performed.

There is the possibility of incidental findings being made that would come with career implications. These implications would depend on the nature of the finding, the most likely occurring as a result of brain imaging. However, all military participants with head injury would have brain imaging completed as standard of care, routine imaging would have the same pick-up rate for relevant incidental findings as the study imaging paradigm, as such there is no additional burden. The blood testing is limited to potential biomarkers of brain trauma and hormone testing, as such it is unlikely that there would be incidental findings with clinical and career consequence.

What are the possible benefits of taking part?

There will be no immediate benefit to you for taking part, but our aim is to improve treatment for people with mild traumatic brain injury and concussion in the future.

Will I get paid for taking part?

You will be eligible for Experimental test allowance; the research team will action this via RCDM admin office with payment made via JPA. Clinical days will be eligible for 30 instances of the allowance and imaging days for 45 (visits 3, 4, 7, 8 and 10).

You will be eligible for 15 instances of the allowance each time you complete full remote assessments within the mobile app at visits 2, 5, 6, 9, 11 and 12.

You will also be eligible for 10 instances of the allowance each time you complete daily headache and sleep diaries in the 28 days before your hospital visits, and then before your follow up visits (visits 2, 5, 6, 9, 11 and 12).

You will also be eligible for a further 10 instances of the allowance each time you complete a shorter daily remote assessment for 14 days at visits 1, 2, 5, 6 and 9.

Each month, you will also be eligible for a £10 gift voucher if you are within the top 10 participants with the highest completion of their assessments on the mobile app.

We can also pay for your travel expenses. Please ask one of the researchers for more details.

What will happen to the results of the research study?

We will publish our results in medical journals and present them at scientific conferences, to help other doctors to learn, and for patients to benefit. When you enter the study you will be asked if you wish to be informed of the trial results, and whether you wish to be informed by email or post. The results will also be made available on the mTBI-Predict trial website (www.birmingham.ac.uk/mtbi-predict).

PART 2 – further details on how this study is run

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

Patients and the public, including civilians, military, and sports people, have been involved in developing this study. We have asked about what is important to test, what seems acceptable from the point of view of how much we are asking people to do, and how the study information is put across.

This study is entirely in the hands of very experienced researchers and no patient group or lay person can influence your treatment or get access to your personal healthcare records.

What if I do not want to carry on?

You can stop being a part of the study at any time, without giving a reason, but we will keep information about you that we already have. You will also be withdrawn from the study if anything happens to you which means you are no longer able to provide informed consent. If you do stop being part of the study, for any reason, we will keep information about you that we already have.

If you stop taking part in the study, we would still like to collect information about your health from the NHS. If you do not want us to do this, please let us know.

What if something goes wrong?

We do not foresee any problems due to taking part in the study. However, all participants are covered for negligent harm according to NHS indemnity guidelines. If you have a concern about any part of this study, you should ask to speak to one of our researchers who will do their best to answer your questions.

The University of Birmingham also arranges clinical trial insurance which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in

relation to the design or management of the study. The insurance may alternatively, and at the University's discretion, provide cover for non-negligent harm to participants.

As this research study will involve both military personnel and civilians, the Ministry of Defence (MoD) maintains the 'No Fault Compensation Scheme' specifically for the payment of no-fault compensation to, or in respect of, a volunteer who suffers illness and/or personal injury as a direct result of participating in research conducted on behalf of the MoD. The no-fault compensation arrangements apply to research participants (Military, Civilian, or non-MoD) who take part in a trial that has been issued with favourable opinion by the MoD Research Ethics Committee.

A research participant wishing to seek no-fault compensation under these arrangements should contact the Directorate of Judicial Engagement Policy, Common Law Claims and Policy (DJEP-CLCP), Ministry of Defence, Level 1, Spine 3, Zone J, Whitehall, London, SW1A 2HB who may need to ask the Claimant to be seen by a MoD medical advisor.

If you wish to complain about any aspect of the way you have been approached or treated during this study, the normal NHS complaints mechanisms will be available to you. Copies of these guidelines are available on request. If you wish to complain about how you have been treated during this study please contact the Patient Advice and Liaison Service (PALS) or the Complaints Team at your local hospital. The contact details are at the end of this Information Sheet.

How will my personal data be kept secure?

Your information passed to the University of Birmingham will be safely and securely stored and kept strictly confidential under the Data Protection Act 2018 in the same way as all of your other medical records. Any electronic data will be stored securely on our password protected University of Birmingham servers. We will not share any data that can identify you with any other third party.

What data will we be collecting and what will we use it for?

We will ask for your consent before collecting your personal data listed in the table below.

When	What data will be collected
Visit 1	• Full name • Email address and/or mobile number • Date of birth, sex at birth, NHS number • Online questionnaires • Smartwatch movement data
Remote visits 2, 5, 6, 9, 11 and 12	• Online questionnaires including cognition, mood, headache, sleep, also some smartwatch movement data
Hospital visits 3, 7 and 10	• The same details as visit 1 if not already collected • Relevant medical history • Physical assessment data collected during this visit
Brain scan visits 4 and 8	• Brain images and assessment task data

Your hospital will collect information from you, your medical records and your GP for this research. Your hospital will use your name, NHS number and contact details to contact you, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Your hospital will pass these details to the University of Birmingham along with the information collected from you and your medical records and will be used exclusively for this research.

Individuals from the University of Birmingham may look at your medical and research records to check the accuracy of the research and that it is being done properly. At the University of Birmingham only people who need it will have access to information that identifies you. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

If you consent to it, the researchers involved in the study may, in future, access data from your central NHS records, for example through NHS Digital. This will give researchers information that is already collected during your GP and hospital visits, and lets researchers find out about your health after the study has ended without needing to contact you again. To do this, we would send your name, gender, date of birth and NHS number with any request for information. If you don't want us to do this, just let the research team know.

Your information may also be accessed for compliance oversight reasons by representatives of the study funding body, the US Department of Defense. This is because it is their responsibility as the study funder to ensure the study is being run correctly and as funded, appropriately and ethically. If this does happen, your information will not leave the United Kingdom and will be accessed from servers within the University of Birmingham and University Hospitals Birmingham NHS Foundation Trust. None of your identifiable records will be copied, removed, or used in any way other than for compliance oversight. Representatives from the US Department of Defense would be on-site to review identifiable records.

What data will be shared?

Research data will be shared between collaborators and researchers working on the study at the institutions who are involved in it.

People who do not need to know who you are will not be able to see your name or contact details. Instead your data will be pseudonymised. This means that an ID code will replace your name. Your brain scans, for example, will be sent to a secure University of Birmingham data server and made available for the investigators and researchers who are working on the project to analyse but none of these people will be able to see who you are.

Data will also be shared with other researchers, whether private, academic or commercial, in the UK or abroad including the US. Data may be made available to other researchers via an open access database. This is good practice so scientific research can be shared and checked. In this case all shared data will be fully anonymised and will never contain any personal details about you (name, address etc.). It will be impossible for anyone to identify you.

If you are ever in the future diagnosed with any brain-related conditions that require further investigation copies of your brain scans will be made available to appropriate NHS services on request.

What will happen to the samples I give?

The blood and tears and hair samples will be stored first in the laboratory at the hospital in which you have been seen, where they will be processed and some sent to the central study laboratory at the University of Birmingham for storage and analysis.

Your saliva samples will be posted directly to the NIHR/Wellcome Trust Clinical Research Facility where they will be transferred to our central study laboratory at the University of Birmingham for storage and analysis.

Your samples will only be identified by your study ID code. They will be kept for 2 years after the end of the study to allow time for the samples to be analysed. After this, excess samples will be stored in the University of Birmingham Human Biomaterials Resource Centre biobank or be destroyed.

How long will my personal data be kept?

Your data will be kept for at least 25 years once the study has finished. Your contact details will be deleted after the study finishes and any central NHS data is collected.

Who is the data controller?

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you. This means that the University is responsible for looking after your information and using it properly.

What is our legal basis for processing your data?

The legal justification we have under data protection law for processing your personal data is that it is necessary for our research, a task we carry out in the public interest. This means that it is a legal requirement that the data we collect about you is only used for research purposes to benefit public health. The data will not be used to make decisions about you.

What are your choices about how your information is used?

We need to manage your data in specific ways for the research to be reliable and accurate. This means that we won't be able to let you see or change the data we hold.

The University of Birmingham takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Staff receive regular data protection training and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law. More information on how the University processes personal data can be found on the University's website on the page 'Data Protection – How the University Uses Your Data' (http://www.birmingham.ac.uk/privacy/index.aspx).

Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- in the leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by contacting the Data Protection Office, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT

Email: dataprotection@contacts.bham.ac.uk Telephone: 0121 414 3916

Who is organising and funding the study?

The study is sponsored by the University of Birmingham (UoB), which means the University of Birmingham has certain legal and ethical responsibilities for the study (reference RG_22-004). It is being coordinated by the Birmingham Clinical Trials Unit (BCTU) and it is jointly funded by the United Kingdom Ministry of Defence (ref: 705737453), and United States Department of Defense (ref: HT942523C0066). The chief investigator for the study is Professor Alex Sinclair, Professor of Neurology, based at the University of Birmingham.

Will my GP be informed of my involvement?

If you agree to it, we will tell your GP that you are taking part and if they need to know of any test results.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people who protect patient interests. This group is called a Research Ethics Committee. This study was reviewed and granted favourable opinion by the Ministry of Defence Research Ethics Committee (ref: 2217MODREC23) before it started.

Who can I contact for further information?

Thank you for taking the time to read this information and for considering taking part in our study. If you need more information or would like to speak to someone please contact:

Name	Animesh Ghose / Karen Tester
Job title	Clinical Trials Coordinator
Contact Details	mtbiclinicalresearch@uhb.nhs.uk

If you would like independent advice about taking part in research you can contact the NHS Patient Advisory and Liaison Service (PALS) for support:

Local PALS contact/Hospital Advisory Service number(s)	0121 424 0808
Local PALS/Hospital Advisory Service e-mail address	pals@uhb.nhs.uk

You can also contact the mTBI-Predict study team:

mTBI-Predict study office
Birmingham Clinical Trials Unit
Public Health Building
University of Birmingham, B15 2TT
Email: mtbi-predict@trials.bham.ac.uk

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