

**MAGNETIC RESONANCE IMAGING (MRI) STUDY TO  
INVESTIGATE POSSIBLE NERVE INFLAMMATION IN PATIENTS  
WITH CHRONIC WHIPLASH ASSOCIATED DISORDER  
PARTICIPANT INFORMATION SHEET**

23<sup>rd</sup> September 2013, version 2

**Dear Participant**

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you if you took part. We ask you to have a read through the information sheet. If you have any questions and would like to discuss the study, please do not hesitate to contact the study team. Contact details can be found at the end of this information sheet.

Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

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

Following a whiplash injury to the neck, many people experience arm and neck pain that does not go away. This is called chronic whiplash. Current treatments for chronic whiplash are not very effective. This is partly because we do not understand what is causing the pain. However, our previous studies suggest that in some patients with chronic pain, the nerves in the neck and arm may be inflamed (which is the body's response to an injury) and that this inflammation may be causing painful symptoms. In this study, we want to find out whether this is the case for chronic whiplash. Therefore, we will use magnetic resonance imaging to look for inflammation of the nerves in the neck and arm in patients with chronic whiplash and determine whether this is a cause of pain. If this study is successful, then it would hopefully lead to better targeted treatments.

We would therefore like you to consider taking part in this study.

**2. Who is organising and funding the research?**

This is a one year study funded by the University of Brighton.

### **3. Why have I been invited?**

We will be recruiting 40 research volunteers aged 18-60 to take part in this study: Twenty with chronic whiplash and 20 healthy individuals who will act as control subjects. You have been invited because you have chronic whiplash associated disorder.

You will not be able to take part in this study if you are under the age of 18, have had a recent upper limb trauma, or you suffer from rheumatoid arthritis, a systemic connective tissue or neurological disease, or diabetes. You will also not be able to take part in this study if you are pregnant or deemed unsuitable to have Magnetic Resonance Imaging (MRI).

### **4. Do I have to take part?**

No, you do not have to take part; it is up to you to decide. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You are free to withdraw at any time without giving a reason.

### **5. What will happen to me if I take part?**

Your treatment and monitoring will continue as normal with the only addition being a magnetic resonance imaging scan and a clinical examination. You will also be asked to complete two questionnaires.

### **6. What will I have to do?**

- With this information sheet you should have received a leaflet explaining the magnetic resonance imaging (MRI) procedure as well as an MRI screening questionnaire.
- If you are interested in participating in this study we would be grateful if you could complete the MRI screening questionnaire and return it to the study team in the pre-paid envelope. By signing the screening questionnaire, you will be giving consent for this information to be made available to the study team. The MRI screening questionnaire will only be used to determine whether you are suitable for imaging.
- When we have received your completed MRI screening questionnaire, a member of the study team will contact you to let you know whether you are suitable for the study. If you are suitable, and you are still interested in participating, we will arrange a time for you to attend the Clinical Imaging Sciences Centre, at the Brighton and Sussex Medical School, on the University of Sussex Campus at Falmer.
- During this visit you will be given an opportunity to discuss the study with a member of the study team. If you agree to take part, you will be asked to sign a consent form.
- You will then be assessed by a qualified physiotherapist. This assessment will involve checking your clinical history and diagnosis, drawing pain maps and performing some standard clinical tests. These clinical tests will involve the physiotherapist moving your arm and neck into different positions and also

using their fingers to palpate over parts of the limb to assess for nerve tenderness. This assessment will take approximately 30 minutes.

- Prior to clinical assessment, you will be given two questionnaires to complete. These will be used to determine the severity and pattern of your symptoms. The questionnaires should take 15 minutes to complete. They can be completed during your visit or alternatively you may wish to complete them at home and return by post. If you prefer, we can email you an electronic version of the questionnaires to complete.
- After the clinical assessment, suitable participants will undergo a series of MRI scans to look at the nerves in your wrist, elbow and neck. The total scanning time should be 45 minutes. You will be given a short break between each set of scans.
- You will be asked to lie on your back in the MRI scanner and to keep as still as possible for the duration of each set of scans.
- When scanning your wrist, your forearm and wrist will be secured in a wrist coil at your side. This is like a large bracelet. It is padded on the inside and fits firmly round your wrist, but not too tight, and should not cause any discomfort. When scanning your elbow, a similar coil will be placed around the elbow. When scanning your neck there is no need to use a coil and you will simply be asked to lie comfortably on your back with your head supported on a pillow.
- The MRI scanner makes a variety of loud noises, and you will be given ear protectors to wear to filter out the majority of this noise.
- You will be given a call button to press if at any time you wish the scan to stop.

## **7. What are the possible benefits of taking part?**

There will not be any direct benefits to you from taking part in this study. It is important to understand that the results from this study will not provide a diagnosis. Furthermore, we will be unable to provide feedback on your individual MRI results. If you would like feedback of the overall research findings, then this can be provided.

You will not receive payment for participating in this study. However, we will normally reimburse all travel expenses.

## **8. Are there any possible disadvantages or risks of taking part?**

There are no disadvantages to taking part in the study, if you decide not to take part your current treatment will not be affected in any way.

Magnetic Resonance Imaging (MRI) is a very safe procedure. During your initial assessment you will have been screened for any known problems.

The images that will be acquired are not for diagnostic purposes and that the examination should not be considered an alternative to a proper medical consultation. However, very rarely something may be found in the images and an expert opinion sought. If there are any unexpected findings that need further tests, your GP will be contacted in the first instance. The GP will then contact

you if further tests are required. If you have any concerns about this please contact a member of staff.

During clinical assessment of your arm and neck, you may sometimes feel slight pain or discomfort. However, this should not last long and we will stop if you ask us to.

## **9. What about confidentiality?**

All the information about you having taken part in this study and all information collected during the course of the research will be kept strictly confidential. Any information about you which leaves the Clinical Imaging Sciences Centre will have your name and address removed so you cannot be recognised from it. All data will be stored securely for a maximum of 10 years, after which it will be destroyed.

Some parts of the data collected for the study will be looked at by authorized radiologists that are not directly involved with the research. They may also be looked at by representatives of regulatory authorities to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that would reveal your identity will be disclosed outside the research site.

## **10. What will happen if I don't want to carry on with the study?**

You are free to withdraw at any time and without giving a reason. If you decide to withdraw or not join the study, this will not affect the standard of care you receive. We will also be happy to discuss with you what will happen to any data that has been collected up to the point of your withdrawal from the study.

## **11. What if there is a problem?**

If you have any concerns about any aspect of this study or complaints about the way you have been treated during the study or possible harm you might suffer, you should ask to speak with the researchers who will do their best to answer your questions. The researchers contact details are provided at the end of this information sheet. However, as you are not being asked to do anything above and beyond the routine treatment that you would receive normally, it is not expected that any problems will occur.

## **12. Harm**

The University of Sussex has insurance in place to cover their legal liabilities in the unlikely event harm should arise from this study.

## **13. What will happen to the results of the research study?**

The results of the study will be written up and published in a scientific journal.

#### **14. Who has approved this study?**

This study has received ethical approval from *the Brighton and Sussex Medical School Research Governance and Ethics Committee (BSMS RGEC)* and the *National Research Ethics Committee (South East Coast)*.

Thank you for taking the time to read this information sheet.

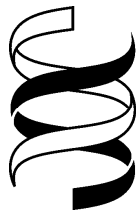
#### **15. Contact Details:**

Dr Andrew Dilley PhD and Dr Jane Greening PhD

Address: Division of Clinical and Laboratory Investigation  
Brighton and Sussex Medical School  
Medical Research Building  
University of Sussex  
Falmer  
Brighton BN1 9PS

Telephone: 01273 877094

Email: [a.dilley@bsms.ac.uk](mailto:a.dilley@bsms.ac.uk)



brighton and sussex  
medical school

**Clinical Imaging Science Centre (CISC)**

## **A VOLUNTEER'S GUIDE TO MRI**

This document provides information about magnetic resonance imaging (MRI) for people interested in volunteering for the study to investigate possible nerve inflammation in patients with non-specific arm pain, complex regional pain syndrome and chronic arm pain following whiplash injury. This study is being conducted at the CISC – Brighton and Sussex Medical School's new Clinical Imaging Sciences Centre.

### **What is MRI?**

MRI is short for Magnetic Resonance Imaging, MRI is a very safe and sensitive form of scanning that can be used to look at any part of the body.

### **How does MRI work?**

MRI works mainly by producing maps of the water concentration in the body. The scanner uses radio frequency waves (not radioactivity) in a magnetic field to focus on water in different tissues. The scanner itself is a large magnet that is continuously on. The person being scanned is moved on a bed into this magnetic field. A device called a coil is secured around the wrist or elbow. This is like a large padded bracelet. It receives radio frequency waves that are used to produce detailed images of your nerves. Scanning always start with a short localizer scan to check that the limb is positioned in the correctly. Once this has been performed, scans of your nerves can be obtained.

When it is active, the scanner makes different machine-like knocking or ringing noises that are caused by the apparatus rapidly switching 'radio frequency pulses' and 'magnetic field gradients' on and off to produce the scans. Since it is noisy, we participants are offered headphones or earplugs to wear in the scanner.

### **Who cannot have MRI scans?**

MRI uses the combination of a large magnetic field and radio waves. People with metal implants or devices, such as cardiac pacemakers, aneurysm clips in their brain, old style hip replacements or cochlear implants will not generally be able to have research MRI scans at CISC, unless the implant or device is specifically listed as 'MRI safe'. People with permanent eye liner (which may contain tiny metal fragments) and anyone who has an eye injury involving metal splinters (e.g. lathe working) also cannot be scanned. Magnetic metal may move or heat in the scanner, hence everyone entering the scanning room must remove all loose metal items and complete a safety metal check form. If you suffer from severe claustrophobia you should not volunteer for this study.

**What will I have to do?**

Everyone will be required to empty their pockets and remove all metal or magnetic items (coins, keys, train tickets, credit cards). You will be required to answer questions about your health and to complete a 'metal check' to ensure that you do not bring any metal into the scanning room.

The researcher or radiographer will log your details on the MR scanner and then take you into the scanning room. There, you will be given earplugs or headphones to wear and be given a demonstration of the alarm bell that will allow you to signal if you want to stop the scanner. Next, you will be positioned on the scanner bed and the coil will be secured around your wrist or elbow. The coil is padded on the inside so that it can be fitted firmly against the skin but not too tight that it may cause pain or discomfort. Once the radiographer has checked your position and is sure that you are comfortable, you will be moved into the scanner and the localizer scan performed (a few seconds).

We will perform a number of different scans to look at your nerves. Each individual scans will take between 3 to 10 minutes to perform. The researcher or radiographer can hear and speak to you between scans. During the scans, you will be required to keep very still; this is easiest if you relax.

**What risks are there?**

For healthy individuals who have no contraindications to MRI (see above), there are no risks from MRI scanning. Some people may feel nervous at the start of scanning if they have not previously had a scan, but even people with mild claustrophobia adapt quickly to the MRI. Our MRI scans have no side-effects.

It is extremely important not to bring any loose metal near the scanner as it may fly into the magnetic field to damage the machine, or anyone inside!

**Will the scans be seen by a radiologist?**

As this is a research study, we will not be performing the types of scans used to diagnose clinical conditions, and scans will not be routinely seen by clinical neuroradiologists who are trained to read and interpret clinical scans. If unexpectedly an abnormality is noted by the researcher or radiographer, the opinion of a neuroradiologist will be sought, and the participant and his/her GP will be notified.

**How long will it take?**

In total, expect to be in CISC for up to about two hours, though the scanning session will only take about one hour at the most. Completing our questionnaires before scanning is particularly important. Please bring a book in case there is some extra waiting.

**When do you want me to arrive at the CISC?**

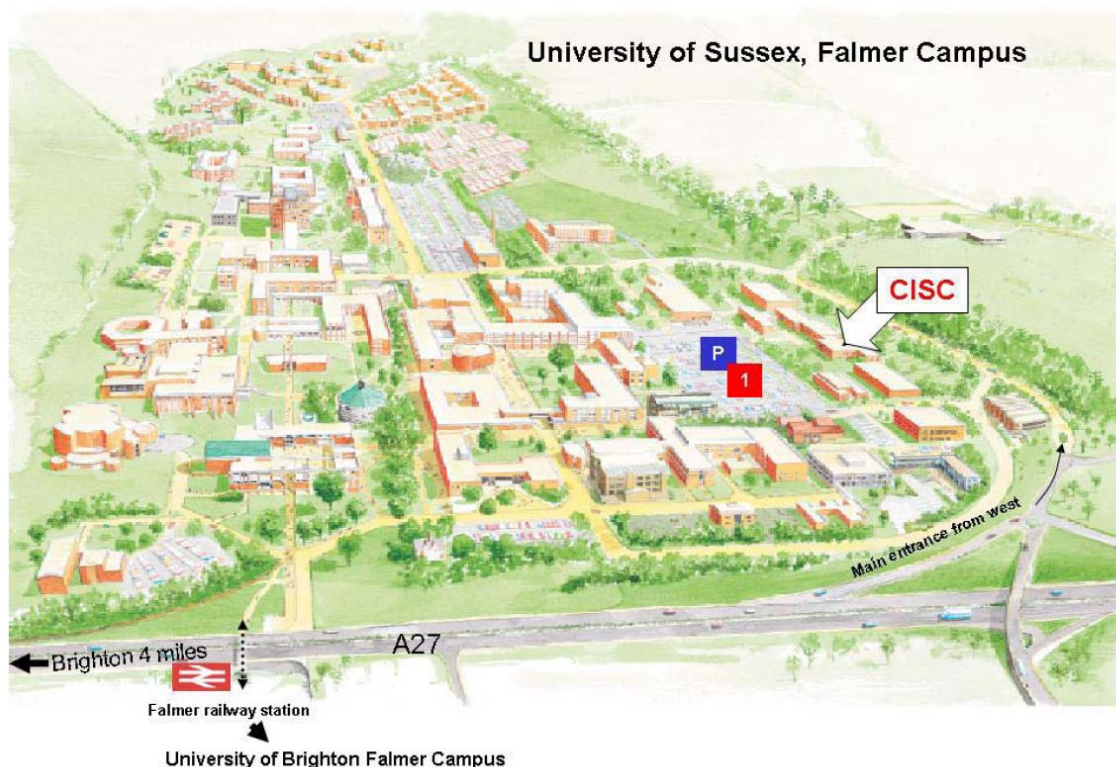
It is very important that you arrive at CISC at or before the exact time given to you by the researcher. If you are going to be late or cannot make the appointment, please give the research as much notice as possible, since it may just be possible to use the scanning time for another volunteer or study.

### What happens when I arrive?

Please report to the reception located inside the main entrance. Please show any appointment letter and give your name and the name of your contact researcher who has asked you to attend. Then she/he will be called and will take you to the scanning waiting area.

### Where is the CISC?

CISC is located in the University of Sussex Falmer Campus at the top part of the Science P1 Car Park.



### Getting there

#### By train

Purchase your ticket through to Falmer Station, which is immediately opposite the University entrance (pedestrian access to campus is through the underpass). Visitors traveling via London and the West need to change trains at Brighton Station for Falmer. Falmer Station is well served by frequent local trains which run between Brighton and Lewes - the journey to Falmer Station from Brighton takes about eight minutes. (You can also travel to Falmer Station from London and the east via Lewes, using the same local train service.) For train times, please consult the Southern Railway timetable.

• National Rail enquiries - 08457 484950

#### By car

The University is on the A27 road between Brighton and Lewes, about four miles (six kilometers) from the centre of Brighton. Visitors driving from London and the north should follow the M23/A23 road towards Brighton. Before you reach Brighton town centre, take the A27 eastbound which is signposted to Lewes. Drivers from the east or west should take the A27 direct to the University. (Please note, opposite the University of Sussex campus at Falmer is the University of Brighton's Falmer site. You should follow the signs to 'Sussex University'.)

#### Parking

There are two designated visitor car parks (opposite Sussex House, and in front of the East Slope accommodation); to gain access you need to announce your arrival to University security staff via the intercom system. Car parks are unattended and objects of value should not be left in vehicles. There is a charge for parking (pay-and-display) unless the visitor displays a Visitor Parking Permit sent by the person issuing the invitation.



**By bus**

Bus number 25 runs between the centre of Brighton and the University - stopping at Churchill Square and Old Steine - bringing passengers directly onto the campus. In addition, bus services 28, 29, 728 and 729 operate between Brighton (Old Steine) and destinations east of Falmer. They all stop right outside the University. **local bus services:** Brighton and Hove Bus Co

**By taxi**

Taxis are available at Brighton and Lewes Railway Stations and in central Brighton; it is about four miles (six kilometers) from the centre of Brighton to the University of Sussex. (There is no taxi service at Falmer Station.) Please note that traffic in Brighton can be congested and it is often quicker to take the train to and from Falmer (journey time about eight minutes).

- Streamline Taxis (Brighton) - 01273 747474

**By coach**

Coaches to Brighton leave from London Victoria Coach Station and arrive at Brighton Pool Valley Coach Station. Services depart every hour during the day and the journey takes approximately one hour and 45 minutes. From Pool Valley it is a short walk - approximately 100 meters - to the Old Steine where you can catch a bus (see section on Bus travel) to the University, or alternatively take a taxi.

- National Express Coaches enquiries - 08705 808080

## MRI Safety Questionnaire

**Title of Project: Magnetic resonance imaging study to investigate possible nerve inflammation in patients with chronic whiplash associated disorder**

**Name of Researchers: Dr Andrew Dilley/ Dr Jane Greening**

*The MRI scanner uses a powerful magnetic field so we need to make sure that you are safe to enter the scanning room. Please remove all loose metal objects before your scan eg: keys, coins, credit cards, dentures, hearing aids, mobile phones / pagers, watches, hairclips, metallic body piercings and if you are requested change into the clothes provided.*

Name	Date of Birth	Weight (kg)	Contact Number
Address		Name and Address of GP	

Do you have / ever had any of the following? If yes please include details and dates:			
	No	Yes	Details / Dates
Cardiac pacemaker/defibrillator?			
Heart surgery / valve replacement?			
Head surgery including that to the eye or ears (including a hydrocephalus shunt)?			
Any other surgery?			
Neurological stimulator or any other implanted medical device?			
Epilepsy?			
Skin patches? (HRT, nicotine, pain relief, contraceptive)			
Tattoos or permanent eye makeup?			
Have you ever worked with metal? eg. Mechanics / metal sheet worker			
Have you <b>EVER</b> had metal fragments in your eyes?			
Shrapnel injury?			
Have you had a previous MRI scan at this centre?			

Women of child bearing age		
Is there any chance of you being pregnant?	Yes	No

*Patients / participants with false limbs or callipers please remove them before entering the MRI room. Inform a radiographer if you need assistance*

Please tick box

**I confirm that I have answered and understood the above questions and information, and that the information I have provided is correct to the best of my knowledge**

**I give my consent for this screening information to be made available to the study team so that they can assess my suitability for MRI**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date