University of HUDDERSFIELD

CeBioR

INFORMATION SHEET FOR PARTICIPANTS

This is an information sheet about research into chronic lower back pain, which may be specific- or non-specific, as well as individuals who are pain free, we are looking for participants to take part in the study. We are also looking for other pain groups including trigeminal neuralgia, post-herpetic neuralgia and osteoarthritis. So if you fall into any of the following groups below, please contact us:

1. ***No pain (pain-free)***
2. ***Non-specific chronic lower back pain (no specific diagnosis or cause)***
3. ***Specific chronic lower back pain (specific diagnosis or cause)***
4. ***Trigeminal neuralgia***
5. ***Post-herpetic neuralgia***
6. ***Rheumatoid Arthritis***

To try to understand this more, we are asking participants to donate a blood sample and to help us identify biomarkers in the blood that can be useful to diagnose the condition more efficiently. A subset of participants will also be asked to compete several sensory tests (optional), these will be used to determine individual pain sensitivity. You will be given time to talk with the researcher, who will explain everything and answer your questions.

STUDY TITLE: THE IDENTIFICATION AND VALIDATION OF TRANSLATIONAL BIOMARKERS OF CHRONIC LOWER BACK PAIN

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

SCREENING QUESTIONNAIRE lets us know if you are eligible to take part in the study.

PART 1 tells you the purpose of this study and what will happen to you if you take part.

PART 2 gives you more detailed information about the conduct of the study.

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.

Screening questionnaire

For each of the following questions, please answer yes/no

Have you ever been diagnosed with cognitive impairment?
(e.g. a learning disability or dementia including Alzheimer's disease)

Have you ever suffered a traumatic head injury?

Do you regularly abuse alcohol, prescription drugs or other substances?

Do you suffer from:

Any major psychiatric illness? (e.g. Schizophrenia, Autism Spectrum Disorder)
Please note that major depressive disorder (depression) and generalised anxiety disorder are not excluded from the study

Diabetes or cancer? (current)

Epilepsy or seizures? (current)

Multiple sclerosis or chronic regional pain syndrome?

To the best of your knowledge, do you currently have a blood-borne disease?
(e.g. Hepatitis, HIV, malaria)

If you answered **YES** to any of the above, you are not eligible to take part in this study. Thank you for your time.

PART 1: The purpose of this study and what will happen to you if you take part.

What is the purpose of the study?

This study is looking at determining biomarkers of chronic lower back pain from blood samples. We will compare what we see in people with specific chronic lower back pain, non-specific chronic lower back pain, those who are healthy, and those who have the inflammatory pain condition osteoarthritis.

A biomarker is a medical term used for a well-defined feature that is a sign of a particular condition. The biomarkers we are looking at could help improve diagnosis and treatment of pain, as well as possibly improving the understanding of the causes of chronic pain.

Why have I been chosen?

You have been invited to take part in this study because you have been diagnosed with a type of pain called chronic lower back pain which has persisted for more than 3 months.

Do I have to take part?

No, it's up to you to decide whether or not to take part. If you decide to take part you will be asked to sign a consent form to confirm that you would like to be contacted by a member of the research team.

If you decide to take part you are free to leave the study at any time and without giving a reason. A decision to withdraw from the study, or a decision not to take part, will not affect your rights in any way and will not affect the care you are receiving. By completing the consent form, you are consenting to be involved in the study.

What will happen to me if I take part?

If you are suitable for the study and decide to take part, you will be invited to attend the University of Huddersfield and meet a member of the research team who will explain your participation to you in detail. You will also be asked to complete a series of short questionnaires about your lifestyle and how you feel. We will also ask to take blood samples for the biomarkers test.

What do I have to do?

The study involves a single visit. The visit will include completing the questionnaires, blood test and sensory testing, and is expected to last around 90 minutes. All participants will be asked to sign and date a consent form before enrolment in the study.

Firstly, we will need some blood samples for the biomarker tests. We will take several tubes of blood, equating to 40ml in total. For comparison, during a normal blood donation, a volume of 470mL is taken with little adverse effects. Following this, you will be asked to complete several short questionnaires about your lifestyle, medical history, current pain and your current mental health. The questionnaire will take no longer than 15 minutes to complete. Next, the optional quantitative sensory testing will be carried out, details of this can be found in section 2.

What are the possible disadvantages to taking part?

There are 2 possible disadvantages to taking part in this study. Firstly, the time taken to complete the study participation, secondly you may experience discomfort and slight bruising from the needle puncture site for the blood test.

What are the possible advantages to taking part?

There will be no immediate benefit to you from taking part in this study but the findings may help us to better understand chronic pain, enable patients to get a more accurate diagnosis as early as possible. The study may also enable research into more effective treatments for patients with chronic pain.

What happens at the end of the study?

Your participation in the study will be complete once the questionnaires, blood test, and sensory testing are completed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with a member of the research team who will do his/her best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the University of Huddersfield complaints procedure. Details can be obtained from the research team.

Will my taking part in this study be kept confidential?

Yes, all the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact details

Dr Patrick McHugh,
Director, Centre for Biomarker Research
University of Huddersfield
Tel: 0758711468
Email: painresearchteam@hud.ac.uk

This completes Part 1 of the information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making a decision**.**

Part 2: More Detailed Information

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

You are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will keep the information you provided on the questionnaires, sensory testing data and blood results as this information is valuable to the study. A decision to withdraw at any time will not affect the quality of care you receive.

Will my part in this study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team. You will be allocated a unique study number, which will be used as a code to identify you on all study forms.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the research sponsor (University of Huddersfield), which is the organisation responsible for ensuring that the study is carried out correctly. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant. If you withdraw consent from study treatment, unless you object, your data will remain on file and will be included in the final study analysis. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Do I need to bring anything with me?

Although not essential, it would be helpful if you could bring a list of all prescription medication and medications purchased from a pharmacy or shop, along with the dosage, that you are currently taking, or have taken in the past 2 weeks. This may include one-off medications such as paracetamol or ibuprofen. If you require reading glasses, it would also be helpful if these were brought along too.

What will happen to my blood samples?

On the day, several different types of blood tubes will be taken, these will be used for analysis of DNA, proteins and other molecules found in the blood. Following consent, two of the tubes will be taken straight to the lab for extraction of white blood cells, these will be cultured in the lab in order for us to study the

different types of white blood cells, and to find out if these cells react differently in a healthy participant when compared to that of a person with chronic pain.

Will any genetic tests be done?

The blood sample that you provide will be used for genetic analysis for the purpose of this research study, or if you give your consent, your sample will be stored securely at the University of Huddersfield, for use in other future studies that have been granted ethical approval from an appropriate committee. The research data we collect will be anonymous and kept confidential. Your legal rights are not affected by participating in this study and you may withdraw from the study at any point and withdraw your consent for your sample to be stored, at which point it will be destroyed.

What is quantitative sensory testing and how will it be performed?

Nerves are like wires and sensory nerves pass messages from the surface of the skin to the brain. Quantitative sensory testing, or QST, is used to determine how well these sensory nerves relay messages to the brain. QST is made up of several different methods in order to determine an individual's sensitivity to pain. The tests are carried out on the hand or forearm and are used to measure a person's ability to detect, and feel pain, following stimulation from a range of parameters including touch, heat, cold, vibration and pressure. Upon testing, you will be seated in a comfortable chair and the researcher will describe, in detail, what tests will occur and what sensations you are to expect from each test. You will have plenty of time to ask the researcher any questions you may have about the tests. All tests are safe, non-invasive and will take around 45 minutes to complete in total.

Informing your General Practitioner (GP)

Your GP will not be informed of your participation in the study.

What will happen to the results of the research study?

The results of the study will be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the study will be identified in any report or publication. Should you wish to see the results, or the publication, please ask your study doctor.

Who is organising and funding the research?

This study is funded through the Centre for Biomarker Research.

Who has reviewed the study?

To make sure the study is being conducted safely and ethically, it has been reviewed and approved by the Leeds/Bradford ethics committee. This committee comprises of medically qualified people and laypersons from the local community.

Contact for further information:

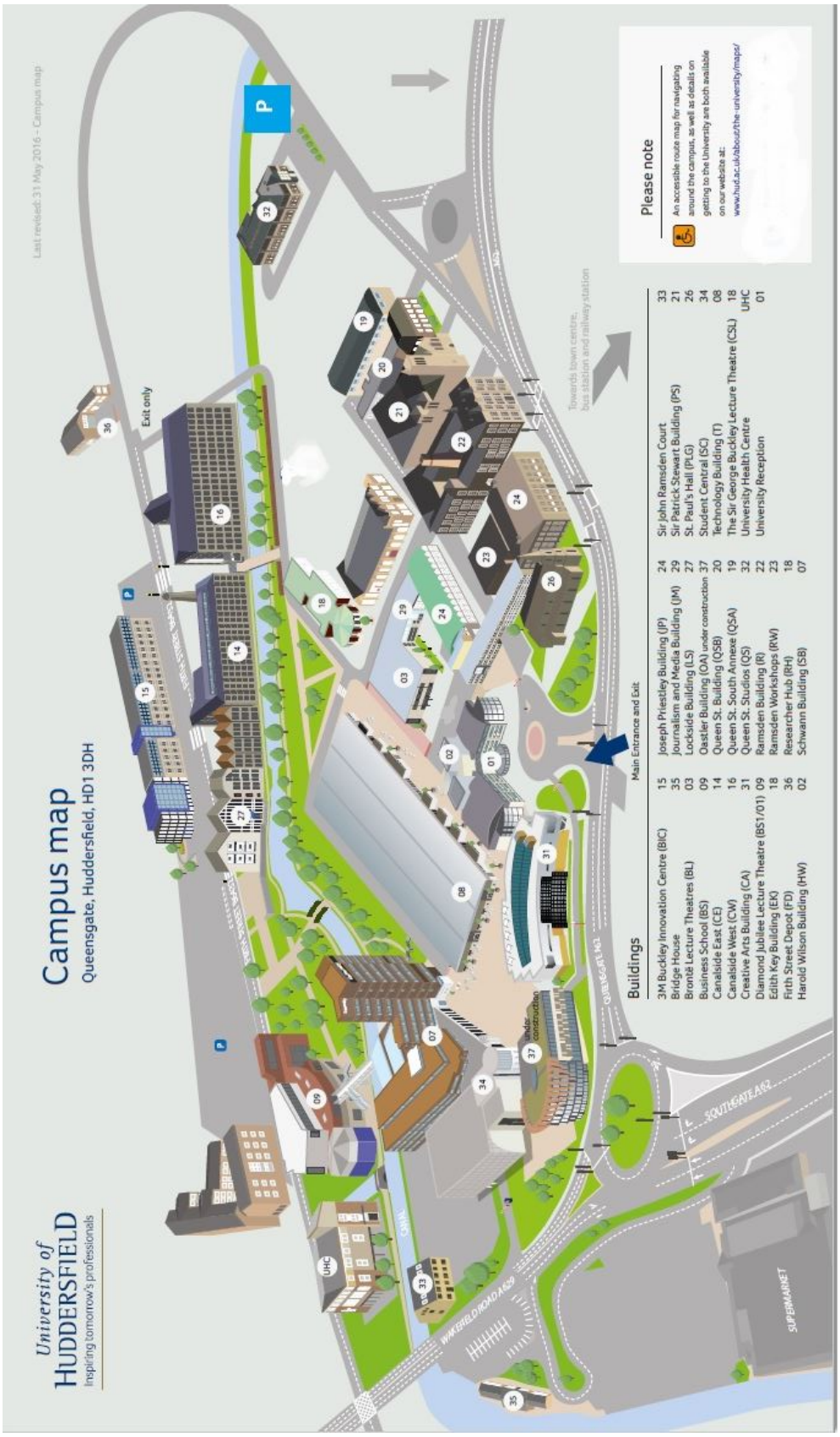
You are encouraged to ask any questions you wish, before, during or after your treatment. If you require any further information or have any concerns while taking part in the study, please contact Dr McHugh at the University of Huddersfield:

Dr Patrick McHugh,
Director, Centre for Biomarker Research
University of Huddersfield
Tel: 07598711468
Email: painresearchteam@hud.ac.uk

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes; one will be filed with the study records. You can have more time to think this over if you are at all unsure.

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

A map of campus is provided on the next sheet for convenience, parking is located at Number 32 (Queen Street, HD1 3DU).


Campus map
Queensgate, Huddersfield, HD1 3DH
University of HUDDERSFIELD
Inspiring tomorrow's professionals
Last revised: 31 May 2016 – Campus map
Exit only
Towards town centre, bus station and railway station
Main Entrance and Exit
Please note
An accessible route map for navigating around the campus, as well as details on getting to the University are both available on our website at:
www.hud.ac.uk/about/the-university/maps/
Buildings
3M Buckley Innovation Centre (BIC) 15
Bridge House 35
Brontë Lecture Theatres (BL) 03
Business School (BS) 09
Canalside East (CE) 14
Canalside West (CW) 16
Creative Arts Building (CA) 31
Diamond Jubilee Lecture Theatre (BS1/01) 09
Edith Key Building (EK) 18
Firth Street Depot (FD) 36
Harold Wilson Building (HW) 02
Joseph Priestley Building (JP) 24
Journalism and Media Building (JM) 29
Lockside Building (LS) 27
Oastler Building (OA) under construction 37
Queen St. Building (QSB) 20
Queen St. South Annexe (QSA) 19
Queen St. Studios (QS) 32
Ramsden Building (R) 22
Ramsden Workshops (RW) 23
Researcher Hub (RH) 18
Schwann Building (SB) 07
Sir John Ramsden Court 33
Sir Patrick Stewart Building (PS) 21
St. Paul's Hall (PLG) 26
Student Central (SC) 34
Technology Building (T) 08
The Sir George Buckley Lecture Theatre (CSL) 18
University Health Centre UHC
University Reception 01
WAKEFIELD ROAD A629
SOUTHGATE A62
SUPERMARKET
under construction