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NHS Foundation Trust

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## 1. Study title

**Multimodal recording of chronic pain**

## 2. Invitation paragraph

You are being invited to take part in a research study. Before you decide 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. 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.

## 3. What is the purpose of the study?

The influence of pain on everyday life can be considerable. Pain is a complex and intense experience affecting the way we feel, move and approach different situations. This project aims to better understand how pain affects the way you move and your posture. To do this we need to represent on a computer the differences in movement and posture between someone with back pain and someone without. The best way to do this is to electronically record your movements, using a special motion capture device, and then combine these data with information about your pain.

## 4. Why have I been invited?

We are asking patients with chronic low back pain to volunteer for this study, except those who are or might be pregnant, and those who use mobility aids such as crutches and wheelchair. We can also not record if you have metal inside you, such as in replacement joints, spinal cord stimulator, or pacemaker.

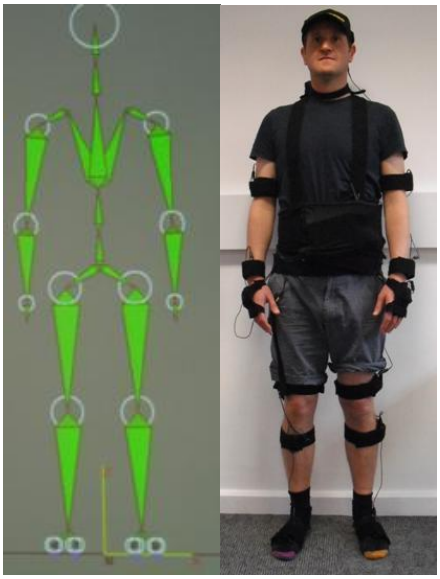
## 5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care you receive.

## 6. What is involved in the study?

You will be asked to wear a motion capture device (IGS190: www.animazoo.com) for up to 45 minutes while you perform movements or stay still. During this time you will be videoed. Plastic self adhesive stickers sensors placed on your skin will also be used to record your low back muscle activity. Other sensors will monitor your heartbeat and breathing rate. If you feel that you cannot go ahead with this study once you have the equipment on, you are free to withdraw the consent you gave. You can also stop at any time and ask for any device to be removed and/or to rest. You will also be asked some questions about your pain and asked to complete some questionnaires about your mood and your activity level. Altogether, this may take between one hour and one and a half hours.

The motion capture device weighs about 2kgs (approximately 4.5 lb), distributed over the body, and may constrain your movement to some extent. The equipment is a commercial product and is licensed for safe use. It consists of bands worn round arms, legs, and body, over your clothes, plus a cap on the head, and a battery and transmission pack worn on your waist (see picture below).



The wearing of the “IGS190” motion capture device is done in two steps. In the first step we need to set the system to your dimensions, and this means that we will take a picture of you which will be kept securely and is confidential to this research study. Once the system has been set, we will help you to put on the motion capture device. It is advisable to wear comfortable clothes but not too baggy and comfortable shoes, such as trainers. We will make available different sizes sets of sport clothes for you if you wish to change.

We will also place 2 sensors on your skin on your lower back to record muscle activity there (EMG sensors). These sensors are very small and lightweight. A further sensor will be attached to your skin to monitor your breathing rate and heartbeat.

Once the suit is on, you will be asked to perform simple everyday movements such as walking, standing up from sitting, standing on one leg, and picking up and lifting lightweight objects (e.g. a shopping bag). We will guide you through the movements we would like you to do and if you do not feel able to perform a particular movement, you can decide not to. While moving, a set of video cameras (with microphones) will be recording your movements and your face.

A physiotherapist and/or a sport scientist will be present during the recordings and can discuss the movements further if you like.

## 7. What are the known risks of the study or the side effects of the procedure?

There are no known risks for using this system; use of these systems is widespread and no adverse effects have ever been reported. If you have any concerns about your health as a result of taking part in the study, either during the study or after, you can contact Dr Nadia Berthouze on 020 7679 0690. We will not ask you to take part if the added load of the motion sensor device might put you at risk of injury or strain. If you find that it causes you increased pain you are free to stop, rest temporarily or to leave the study.

## 8. What are the possible benefits of taking part?

There is no direct benefit to you from taking part in this study: we are asking you to do it to help research in chronic pain.

## 9. How will Information be kept?

We will collect the following information:

- Your full body picture, clothed, for calibration of the motion capture system.
- Body measurements.
- Information about your pain problem, treatment history and medication.
- Questionnaires which cover pain and mood ratings, your level of activity, and impairment caused by pain. For these questionnaires there are no right answers: we just need to know about you.
- Videotape record. There is a separate item on the consent form asking your permission to use videotapes for teaching purposes. The videotape is the only data recorded which may enable anyone to recognise you.
- Motion data; used to create a unique “computer character” or avatar. Each avatar is a faceless computer model which will not be identifiable as you.
- Biosensor data containing information on your muscular and physiological response to movements. It is not possible to identify you from this information.

A unique research ID number will be assigned to the information we collect from you, and any personal identifiable information, such as your name and data of birth, will be in a separate file and not linked directly with the rest of the information.

All the information collected will be treated according with the Data Protection Act 1998 and UCL Data Protection Act Policy 2000 (http://www.ucl.ac.uk/efd/recordsoffice/data-protection/). Paper records will be stored in locked filing cabinets. Digital information (e.g.

your movement data and the videotape) will be stored in password protected and secure computers to be used by researchers involved in the project. If consent is granted we would also like to share your video recordings with other research groups, as this can help research progress in this field. However we want you to think about this before giving consent because there is a small possibility when video recordings are shared there is no longer full control over how widely they are distributed and they could become accessible in the public domain (e.g. on the internet). This is why there is a separate consent form concerned with video recordings.

## 10. What if something goes wrong?

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with the researcher, please make the claim in writing to *Dr. Nadia Berthouze,* who is the Chief Investigator for this study and is based at UCL Interaction Centre University College London, Malet Place Engineering Building, London, WC1E 6BT UK. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study, the normal National Health Service complaints mechanisms are available to you. Please ask to a member of the research team if you would like more information on this. Details can also be obtained from the Department of Health website: http://www.dh.gov.uk

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

This research project is 4 years long, and we would hope to publish and disseminate the results, or to present them at conferences, during and after the project. During the dissemination process no patients' names will be disclosed either in publications or in conferences. If you would like us to send you a summary of our findings, please give us a mailing or e-mail address so that we can do so.

## 12. Who is organising and funding the research?

The research is funded by The Engineering and Physical Sciences Research Council (EPSRC) grant to Dr Berthouze at UCL.

## 13. Withdrawal from the project

Your participation in this study is entirely voluntary. You are free to decline to enter or to withdraw from the study any time without having to give a reason. If you choose not to enter the trial, or to withdraw once entered, this will in no way affect your future medical care. All information provided will be treated as strictly confidential and will only be used for medical purposes. Participation in this study will in no way affect your legal rights.

## 14. Who has reviewed the study?

The study has been reviewed and passed by the UCLH Research Ethics Committee and the Engineering and Physical Sciences Research Council (EPSRC).

## 15. Contact for further information

If you want any further information about the study, please contact:

Dr Nadia Berthouze 020 7679 0690 n.berthouze@ucl.ac.uk

Dr Amanda Williams 020 7679 1608 amanda.williams@ucl.ac.uk

Dr Matteo Cella 020 7679 5682 m.cella@ucl.ac.uk

Or visit the project website: http://www.emo-pain.ac.uk

***Thank you for taking the time to read this information sheet and considering taking part in the study.***