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Towards independence: to research the use of upper limb movements to improve trunk motor control after spinal cord injury.

Patient Information Sheet

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Invitation

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. Please 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. Thank you for reading this.

What is the purpose of the study?

A significant proportion of people with spinal cord injury (SCI) have difficulties controlling the muscles of their torso/trunk which results in problems with sitting upright and stabilizing the upper body. The detrimental effects of this include limiting the use of the arms to aid with a number of activities of daily living such as feeding, dressing, weight-shifting, transferring between wheelchairs and bed/toilet and using wheelchairs.

We know that muscles of the trunk become active with almost any movement of the body and our research in healthy people has shown that movements of the arms can "excite" the brain pathways involved in controlling the trunk muscles. These movements can be as simple as bending the elbow, or lifting the arms up to the shoulder.

In this study was want to know:

Is this effect observed in people with SCI and, if so, is it possible to improve the functioning of the trunk by using simple exercise of the arms?

Why have I been chosen?

You are someone who has a stable, incomplete cervical or mid-thoracic spinal cord injury, can voluntarily contract selected arm muscles as well as have some residual trunk muscle function.

Do I have to take part?

No. It is entirely up to you. If you would like to take part, you will be asked to sign a consent form. Even after you have signed this consent form and agreed to take part in the study, you are free to withdraw from the study at any time.

What will happen to me if I take part?

Once you have decided to take part in this study, you will be asked to come to the Nick Davey laboratory, located in Charing Cross hospital, where a member of our research team will discuss the study with you and answer any questions you may have. If you are still happy to take part, we will ask you to sign the consent form.

You will be required to attend up to 2 sessions in the Nick Davey Laboratory, depending on the result of the first set of neurophysiological assessments. The test sessions should last approximately take 2-3 hours.

We will undertake a number of assessments while you are in the lab. **N.B.** You will need to wear clothing that will allow us to carry out the standard clinical assessment according to the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI).

Clinical Assessment – this assessment will approximately take 20 minutes

The clinical assessment will be performed by the research investigator, which involves testing the sensitivity of your skin over various parts of your body and testing the power of your muscles. You will also be asked your demographic information including date of birth, height and weight. We will use this information to calculate your age and body mass index (BMI).

Neurophysiological Assessment - this assessment will take approximately 90 minutes

We will then use brain stimulation and recording of muscle activity to assess how excitable the pathways controlling the trunk muscles are when you contract muscles of the arms (e.g. by bending your elbow or raising the arms). To do this we will use an investigative procedure called transcranial magnetic stimulation (TMS). This is used to activate the nerves in your brain which control your trunk muscles and involves placing a plastic coil in a specific position over your head, this is connected to a machine which delivers a

small magnetic stimulus to the nerves in the brain, this is not painful and does not involve any needles. A number of pulses will be given while you contract your arm muscles. We will record the electrical activity from the muscles under study in response to these stimuli using sticky self-adhesive electrodes (like those used to record ECGs) stuck to the skin overlying the muscles.

Please note you will only be asked to attend the additional session depending on the findings of the first neurophysiological assessment.

Functional Assessment – this will approximately take 40 minutes

You will be asked to transfer to a custom-made chair mounted on a force plate (measuring instrument) and undertake three tests:

1. Trunk impairment scale and sitting functional reach tests - for the first task you will be asked to sit upright, bend sideways and rotate your trunk. For the functional reach test, you will be asked to lift up your arm and reach forward as far as possible without losing balance and the distance reached beyond the staring position is recorded.
2. Pegboard test – this test is used to assess gross movement of the arm, hand and fingers as well as dexterity. The task involves participants picking up small plastic rods from a receptacle, inserting them into individual holes and then removing them and placing them back into the receptacle. This is carried out as fast as possible the time is recorded.
3. Shoulder flexion – for this task you will be asked to lift your arms up as fast as you can in response to a cue (light or a sound).

We will then see if any effects outlast a short session (30 mins, in sets of 10 mins of gentle arm muscle contraction) of exercise-based repetition.

The practise session will be performed on a subsequent visit to assess the repeatability of any facilitatory effect.

In total we anticipate that you would come to the laboratory for 2 half days, one month apart.

MSk Research Database

We would like your permission for the anonoymised data collected as part of this research study to be stored on our registered MSk Research Database for future research. If you agree to take part, you will be asked to sign the following clause within the consent form "I agree for my anonymised data obtained as part of this research project to be stored on the MSK Research Database for future research projects, including that carried by commercial healthcare companies, or those outside the European Union, where data protection laws are less stringent". This is not a requirement for participation in the main research study. Only your anonoymised data will be stored on this database, you will not be able to be identified.

What are the side effects, and are there any risks in taking part?

The assessment techniques are safe and non-invasive and there are minimal risks from having these test performed under strict safety guidelines which include stringent exclusion criteria (detailed at the end of the form and in the screening questionnaire you will have to complete prior to taking part). You may experience mild muscle ache from repetitive contractions of muscles. All tests will be performed within your limits of tolerance and you will be given as much rest as you need between tests.

What are the possible benefits of taking part?

There are no immediate benefits to you from taking part. However, the results of this work could have wide-ranging implications for SCI subjects. If it is shown that simple exercises of the arms can induce changes in the pathways controlling the trunk muscles and improve trunk function, this could have a positive impact on a number of activities of daily living including improved upright sitting and safer transfers.

Will my taking part in this study be kept confidential?

As per Imperial College policy all data including personal data will be stored by Imperial College London for duration of 10 years. Any information you give us will be kept strictly confidential. If the study is published in a book or scientific journal, no individual will be identified in anyway.

What if something goes wrong?

Imperial College London holds insurance policies, which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr Paul Strutton, 0203 313 8837 or email: p.strutton@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

What will happen to the results of the research study?

The results of the study will be analysed by the research team and presented at health care conferences and published in scientific journals. No individual subject will be identified in any report or presentation arising from the research. If you would like to receive the results of the study when completed, we are happy to send it to you electronically as an email or by post.

Who is organising and funding the research?

This research is being run by a research team based at Imperial College London, Charing Cross Hospital campus and is funded by the INSPIRE foundation (http://www.inspire-foundation.org.uk/)

Will I be paid for taking part in the study?

You will not be paid for your participation in the study, but we will pay for your travel expenses to and from Charing Cross Hospital. Please keep the receipts for your journey as these will be required for your reimbursement.

Who has reviewed the study?

This study has been approved by the West Midlands- South Birmingham Research Ethics Committee, the Health Research Authority and the JRCO at imperial College London.

Contacts for further information:

If you would like to consider this study further before you make your decision, please take your time to do so. You may ask for further information by telephoning 020 3 313 8837, which has a 24-hour answer phone. The person to speak to is the chief investigator, Dr Paul Strutton. Alternatively, you may also send

an email to p.strutton@imperial.ac.uk to request further information. If you would like generic information about taking part in research studies, you can telephone the departmental study coordinator, Miss Hardeep Johal on 020 3311 7326.

Inclusion:

You are eligible to take part in this study if you:

1) Have a stable, incomplete cervical or mid-thoracic spinal cord injury and are able to voluntarily contract selected arm muscles as well as have some residual trunk muscle function.
2) Are aged 18 years or over.

Exclusion:

You **CANNOT** take part in this study if you:

1) Suffer from any neurological condition (except for your spinal cord inury).
2) Are pregnant, breast feeding, or have any chance that you could be pregnant.
3) Have a history of epilepsy (fits or seizures) or a family history of epilepsy.
4) Have any metal implants (other than in your spine) or an artificial cardiac pacemaker.
5) Have had previous brain surgery.
6) Are currently taking antidepressants or other neuromodulatory drugs (for TMS only).