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## **Can Theta Burst stimulation accelerate re-learning of impaired wrist and hand movements early after stroke?**

Information Sheet for Patients with stroke

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You are being invited to take part in a research study. Before you decide if you want to participate, 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 in this study.

### ***What is the purpose of this study?***

The main purpose of this study is to investigate whether a type of brain stimulation (TBS) can speed up the natural processes of recovery from stroke. At this stage we are focusing on hand weakness, which is a very common problem after a stroke. In particular, we are testing whether brain stimulation can improve the effectiveness of training for the wrist and the fingers.

### ***Why have I been chosen?***

We are looking to study approximately 25 people who had a recent stroke affecting the hand but have recovered enough so there is some movement in their wrist and fingers. Your doctor has therefore identified you as a good candidate for this study.

### ***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 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.

### ***What is involved in the study?***

#### What will happen to me if I take part?

There are 3 parts to this study which will take place on 5 consecutive days, Monday to Friday. On the first day, we will measure how fast you can move your wrist and fingers on the affected side. We will also use a technique called Transcranial Magnetic Stimulation (TMS), to measure how fast the nerve impulses travel from your brain to the muscles of the hand. These tests will take approximately three hours. On the next three days we will teach you to perform a simple movement with your affected hand and we will ask you to practice this movement for approximately half an hour. Each day you will practice a different movement. Before you start practicing we will apply a slightly different form of magnetic stimulation called Theta Burst

Stimulation (TBS). This particular form of stimulation takes about 2 minutes. On the fifth day, we will repeat all the measures we made in the beginning to look for improvements in the function of your hand.

In order to prove that these interventions are really helpful, some of the participants will have what we call “placebo” stimulation, which means that the brain will not be really stimulated. There are equal chances to receive real or placebo stimulation, but you will not know which until the end of the study.

If you decide to take part in the study, we will ask you not to have any other form of physical therapy for your hand for the 5 days your participation lasts. There are no other restrictions associated with this study and the rest of your medical treatment will not be affected.

We will need to inform your GP or any specialist involved in your care about it. In some cases, we might ask them to provide some additional information about your medical history. If you have any objections, you must discuss it with the researchers.

We will reimburse all your travelling expenses.

#### What kind of personal information is needed and how is it going to be used?

Your medical records may be inspected by competent authorities and properly authorised persons, but the information obtained will be in coded form so that confidentiality is strictly maintained. We will collect basic data from you about your age, sex, and diagnosis, and we will also make a detail evaluation of your disability status after the stroke. These data, along with the test results, will be safely stored on a University computer with all personal identifiers removed. Professor John Rothwell will be responsible for security and access to these data. After the completion of the study, approximately two years from its onset, the results will be published in scientific journals or presented in medical conferences, but identification of the participants will not be possible. We will inform you about these publications and how to access them.

#### ***What is the drug or procedure that is being tested?***

The magnetic stimulator that we use to activate the brain works by producing a brief strong magnetic impulse that activates the part of the brain under the stimulating probe. In these tests, this part is the motor cortex, the area that controls the movements of the opposite side of your body. The stimuli are painless and the procedure has been used in this hospital and other centres throughout the world for 20 years. For the past 4 years, it is being used in patients at different time intervals after their stroke, to test whether it can improve some of their symptoms.

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

We hope that these interventions will help you, but this cannot be guaranteed. However, the information we get from this study may help us to improve recovery from stroke in the future.

#### ***Are there any risks or side-effects involved?***

Because TMS works by a magnetic field, it cannot be performed on people who have implants as cardiac pacemakers, aneurysm clips in their brain, ear implants, permanent eye lining, or have been exposed to metallic flakes or splinters travelling at high speed. Please inform the investigators if you might fall into any of these categories. TMS can theoretically cause seizures, which have been rare in practice and difficult to produce on purpose, even in epileptic patients. Please note that since the introduction of agreed safety guidelines (which we will implement), there have been no reports of seizures. If you ever had any kind of seizures (fits) prior or after the stroke or you were on anticonvulsant medication at any time, please inform the investigators. In the unlikely event of a seizure, we will have to end your participation in the study. The driving license authority (DVLA) has told us that they would not disqualify you from driving. Besides seizures, the only known risk of TMS is mild headache, which has always gone away promptly with non-prescription medication.

### ***What is something goes wrong?***

If you are harmed by taking part in this study, because of someone's negligence or because something happened that could not be foreseen, you can make legal claims, but you may have to pay for it. Should something happen, the normal National Health Service complaints mechanisms will be available to you.

### ***What if new information about risks or side effects becomes available during the study?***

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

### ***Withdrawal from the study***

Your participation in the trial 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 regarding your medical records will be treated as strictly confidential and will only be used for medical purposes. Your medical records may be inspected by competent authorities and properly authorized persons, but if any information is released this will be done in a coded form so that confidentiality is strictly maintained. Participation in this study will in no way affect your legal rights.

### ***Organization and funding***

This study is organised by the Institute of Neurology and funded by the Stroke Association. Prof John Rothwell is the principal investigator. Below is the list of all researchers involved in this study. Ulrike Hammerbeck is the study-coordinator and can be contacted in case of queries.

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