

Short Patient Information Sheet

BRIGHtMIND

BRAIN IMAGE GUIDED TRANSCRANIAL MAGNETIC in DEPRESSION

A study looking at the effectiveness of a new approach to treat treatment resistant depression (TRD) using pulses of magnetic stimulation applied to the scalp.

Would you be interested in taking part in a research study looking at the effectiveness of a new approach to treat treatment resistant depression (TRD) using pulses of magnetic stimulation applied to the scalp.

The treatment we are testing is called Transcranial Magnetic Stimulation (TMS) and has been recommended for use in the NHS in the UK by the National Institute for Health and Care Excellence (NICE) as a treatment for treatment resistant depression.

There are uncertainties about how to achieve the best results from this procedure, in terms of where it needs to be targeted on the scalp and the pattern of the magnetic pulses. Recent developments in magnetic resonance brain imaging means that we can locate a part of the brain in each person where three different brain systems involved in producing depression symptoms meet. If we target the magnetic pulses at this site, which varies slightly in its position in each person, those who respond to TMS and the length of time they remain well afterwards might be increased. If so then it may be worth people having these brain scans before receiving TMS.

Who can take part in this study?

You need to be over the age of 18 and have been diagnosed with Major Depressive Disorder, that has not improved with at least two previous antidepressant treatments (Treatment resistant depression). You must be willing to undergo Transcranial Magnetic Stimulation treatment.

Is TMS treatment like Electroconvulsive Therapy (ECT)?

TMS is not ECT and they are two completely different procedures. When you have TMS treatment you will sit in a comfortable chair, and we would like you to relax, although you will be awake the whole time. You can leave as soon as you finish and you can drive if you want. Patients who receive TMS treatment you will not suffer memory loss or confusion as can sometimes be seen in ECT treatment.

What are the possible disadvantages and risks of taking part?

Current evidence suggests that 1 in 20 people who receive TMS will experience an adverse effect. In most cases this is in the form of headache, neck pain or scalp discomfort. While others report light-headedness, watering eyes, tinnitus, muscle tightness and nausea. If any of adverse events happen, you will be advised how to manage these problems. A small proportion (estimated as 1 in 1000) may experience a seizure upon receiving TMS. If you have a seizure you will be medically reviewed before any further treatment is offered.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help us to determine the most effective method for administering TMS for the treatment of treatment resistant depression in the future.

What will happen to me if I take part?

The first appointment consists of a 2-hour visit to one of our four study centres (Nottingham, Northampton, Camden and Islington or Newcastle). During this visit, a member of our team will explain the procedure and provide answers to your queries. Following this visit you will be invited to

have a Magnetic Resonance Imaging (MRI) scan of your brain, this will take a maximum of 60 minutes.

Sometimes we don't know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is allocated to a group by chance (randomly).

The next step:-

You will be given a daily TMS treatment (Monday to Friday) over 4 – 6 weeks (20 in total). Each visit will last for about 1 hour, except the first one that will last for 2 hours.

- You will be asked to attend follow up assessments at 8 and 16 weeks after your first treatment session.
- Following your 16 week follow up assessment you will be asked to attend for a repeat MRI Magnetic Resonance Imaging (MRI) scan of your brain.
- Your final follow up assessment will be at 26 weeks after your first treatment session.

When should I expect a response to the TMS treatment?

It is not clear when the treatment will start working for you, as it varies depending on an individual's response to treatment.

Do I have to take part?

Participation is entirely voluntary. If you do not wish to take part you may do so without justifying your reason and your future care and treatment will not be affected. If you decide to join the study, you will still be free to change your mind at any time during the study.

Would I be paid for taking part?

Travel and parking expenses will be offered for use of a private car at standard National Health Service rates or public transport (but not taxis), for all the TMS treatment and assessment sessions. If required, a carer, friend or relative are welcome to attend with you and reimbursements will also apply. We will provide each participant with a £10 shopping voucher as a thank you for completing follow up assessments at 16 and 26 weeks

What should I do if I am interested in taking part?

If you are interested in finding out more, please complete the reply slip and return it to the research team or contact the team directly using the contact details at the end of this leaflet. A member of the team will contact you to tell you about the study, answer any questions you may have and check you are eligible to take part.

If you are eligible and wish to take part you will be sent a full Patient Information Leaflet which describes exactly what the study involves.

If you decide to take part, the study team will ask you to provide written informed consent. If you have anything you would like to ask the study team, please contact us and we will be happy to help.

Thank you for reading this.

For more information or to volunteer, please complete the enclosed reply slip and post in the freepost envelope provided or post to:

BRIGHtMIND Study, 1st Floor Bloomsbury Building, St Pancras Hospital, 4 St Pancras Way, NW1 0PE

Or please contact:

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