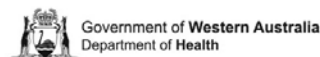


# CENTRE FOR CLINICAL RESEARCH IN NEUROPSYCHIATRY



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## INFORMATION SHEET

### Repetitive Transcranial Magnetic Stimulation in the treatment of depression

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Repetitive transcranial magnetic stimulation (rTMS) is a new technique for activating the brain noninvasively through the scalp and skull. In rTMS, a rapidly changing magnetic field passes through your scalp and skull and generates a small electrical pulses in your brain. It has proven effective in producing localized effects on brain function and has opened many areas of human brain function to direct investigation.

This study is designed to evaluate the therapeutic application of repetitive transcranial magnetic stimulation (rTMS) as a potential treatment for depression. To do this, we plan to apply rTMS using one of two different methods to two groups of participants, and compare the effects. rTMS has helped some people with depression but we do not know what the results will be in your case, or whether you will be randomized to one or other of the rTMS methods. You will be assigned to receive one of these types of rTMS over the left front part of your brain five times per week for four weeks.

Each rTMS treatment session should take about 20 minutes of actual stimulation five days per week, plus once weekly ratings. Appointment times can be made at your convenience, but will involve travelling to Graylands Hospital in Claremont.

Responders to any phase will be offered an additional month of rTMS prior to study termination and recommendations of alternative treatments.

#### **Safety**

rTMS is a new form of treatment, not only in depression, and safety considerations and information are critical in its development. We here provide background to several concerns that have been raised. This information is based on an extensive review of safety issues in the field, published in 2002, as well as our literature searches and discussions.

In early rTMS research, several (7 documented) participants experienced seizures during a session. Since the implementation of parameter and recruitment guidelines (1996) there have been, to the best of our knowledge, no confirmed instances of seizures during rTMS. In addition we will monitor your brain wave activity during the session to provide early warning of possible seizure activity. Several researchers have tested for adverse neuropsychological effects of rTMS, with results unclear and no specific guidelines suggested. No specific effect has been shown within the parameters of this study, and we will be monitoring this aspect with a short task of attention and concentration.



There have been some instances where recorders on your head get hot. This is usually due to poor application, and if you feel any discomfort, then we would be able to alleviate that if you let us know. Some participants consider the clicking noise from rTMS uncomfortable. If you find this so, then we have ear plugs available. Finally some participants develop a mild headache, believed to be due to scalp muscle tension. This can be easily relieved with common headache tablets.

### **What does participation in the study involve?**

If you decide to participate, we will ask you to complete:

A weekly clinical interview before a treatment session.

Daily (5 week days) rTMS stimulation for 20 minutes. This will involve travelling to Ord house, and sitting in a chair with your head resting at a set location. Small recorders will be placed on your head to monitor your brain wave activity as a safety measure. An rTMS stimulus coil will be positioned so as to just touch your head, and will emit a series of clicks during the session.

Once a week, at the same time as the interview, we will ask you to participate in a task of attention and concentration based on verbal responses to questions. This task is recommended as a precaution against unexpected effects of the new treatment, although none have been detected as yet.

All of these activities can be scheduled at times to suit yourself.

### **What we will do**

Information collected from the interviews will be collated and analysed for evidence of an effect of the treatment on depression. Information from the tasks will be analysed for any evidence of unexpected effects of the treatment.

All information will be coded and kept strictly confidential. Information gathered during the course of the project will only be used for research, and no data that will be published in scientific journals will reveal the identity of participants.

We will be happy to share with you whatever results of analyses we can.

### **Your rights**

You may withdraw your consent for this project at any time. In this event, upon receipt of written notification, any information we have collected will be destroyed. If you choose not to participate in the project, this decision will not affect your treatment now, or in the future.

If you have any further questions, please do not hesitate to contact the Chief Investigator, **Dr Joseph Lee** on (08) 9347 6801, or the Coordinator of this project, **Dr Greg Price**, on (08) 9347 6493.