Professional Practice Guideline 16

# Administration of repetitive transcranial magnetic stimulation (rTMS)

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The Royal Australian & New Zealand College of Psychiatrists

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## Purpose

This Professional Practice Guideline developed by the Royal Australian and New Zealand College of Psychiatrists (RANZCP) provides guidance on key professional practice issues that psychiatrists should consider when prescribing and administering repetitive transcranial magnetic stimulation (rTMS). This is not intended as a directive about clinical practice, or instructions as to what must be done for a given patient[1].

In reading this guideline it is important to recognise that the circumstances of each individual can vary. As a consequence each patient's assessment to undergo rTMS and their rTMS treatment plan may differ. Consideration should be given to each patient's presentation so treatment is individually and clinically tailored. For further information about efficacy, benefits and side-effects, please refer to Position Statement 79: Repetitive transcranial magnetic stimulation (rTMS).

## What is rTMS?

rTMS involves the focal application of a localised, pulsed magnetic field to the cerebral cortex, inducing small electrical currents which stimulate nerve cells in the region of the brain involved in mood regulation and depression. The precise mechanism of action is not yet fully understood although studies suggest that the nerve cells, when stimulated, cause neurons to fire with the aim of altering brain function for therapeutic purposes (Anderson et al., 2016). Magnetic fields are passed through the skull to the brain using a coil placed on the patient's head. The treatment is non-invasive and does not involve seizure induction or loss of consciousness. The patient is completely alert during the procedure and an anaesthetic is not required. When appropriate procedures are followed for patient selection and treatment, there are minimal risks with rTMS and any side effects are usually mild, transient and/or can be easily managed.

## When can rTMS be used?

In clinical practice rTMS should only be administered for an illness where there is adequate evidence of clinical indication and effectiveness. It should be considered as a therapeutic option alongside other treatments after detailed psychiatric assessment.

- Depression: The primary clinical indication for rTMS at this time is in the treatment of depression. An evidence base of over 30 randomised controlled trials involving a placebo-control (sham stimulation) has demonstrated that rTMS has efficacy in the treatment of depression that place response rates in the order of 50% (effect size from a recent meta-analysis of the active-sham comparison was 0.55) (Brunoni et al., 2017). This evidence base includes several large-scale multi-site trials (Slotema et al., 2010). Thus, rTMS should be considered an effective treatment for depression with level I evidence as has been reflected in multiple clinical practice guidelines (Malhi et al., 2015)

[1] The term patient is used through this document for clarity and consistency although it is recognised that individuals may prefer alternative terms, for example person, consumer, client or service user.

- Schizophrenia: The evidence base for the use of rTMS in schizophrenia is less substantive than that for depression (Galletly et al., 2016). Clinical trials have examined the use of rTMS to treat symptoms of schizophrenia, particularly auditory hallucinations, negative symptoms and cognitive deficits. The majority, but not all, randomised controlled trials involving a sham control comparison, have found rTMS to have beneficial effects in reducing the severity and/or frequency of auditory hallucinations. A meta-analysis and review of these studies concluded there is evidence of efficacy for rTMS as a treatment for auditory hallucinations (Matheson et al., 2010). There remains a lack of large multi-site trials in this area. However, given the lack of therapeutic options for patients who have persistent auditory hallucinations despite optimal medication treatment, it would seem reasonable to offer rTMS therapy in centres with specialist training and where data on outcomes is collected for analysis and reporting. There is insufficient evidence supporting efficacy of rTMS in treating other symptoms in schizophrenia.

- Obsessive-compulsive disorder (OCD): There is accumulating evidence supporting the use of rTMS in OCD with recent meta-analyses reporting positive findings (Zhou et al., 2017; Rehn et al., 2018). However, there is a the wide variety of treatment targets and paradigms used in studies to date and pooling of paradigms in some meta-analyses making firm conclusions difficult to make. Clearly, the optimal stimulation targets and parameters remain undefined. Of note, in 2018 the FDA in the US approved marketing of a Deep TMS device for the treatment of OCD based on a trial of 100 medication resistant patients. This device uses a 'deep TMS' coil, i.e. a technology that is different to standard rTMS. The use of standard rTMS should continue to be provided in research contexts until an adequate evidence base is established from large multisite randomised controlled trials.

- Other: rTMS has also been investigated for use in a range of other disorders such as post-traumatic stress disorder, autism spectrum disorders, substance dependence, tinnitus and chronic pain conditions. A variety of these other potential uses have been explored in clincial trials of varying number and size. The preliminary therapeutic evidence in these other disorders varies but in no area have large scale multi-site trials or meta-analyses to date established efficacy. However, there are multi-site trials underway in a number of other conditions and it is likely that the range of approved applications for rTMS could change rapidly.

- A full review of evidence can be accessed through the suggested further reading at the end of this statement.

A summary of available evidence of efficacy for rTMS and its recommended use is provided in the RANZCP Clinical Practice Guidelines for mood disorders (2015, pp.43-46) and the RANZCP Clinical Practice Guidelines for the management of schizophrenia and other related disorders (2016, pp.48).

## Patient selection

- rTMS is indicated for the treatment of major depressive disorder. This includes the management of a depressive episode that has inadequately responded to initial treatment with one or more adequate medication trials (defined as treatment resistant depression).

- The screening and selection of patients appropriate for rTMS treatment is essential and should be conducted by a psychiatrist. All psychiatrists undertaking assessment and prescription of rTMS should be adequately trained and have a detailed understanding of when rTMS is clinically indicated and contra-indicated.

- When psychiatrists are considering rTMS treatment for their patients but do not have detailed knowledge of rTMS, it is recommended that the psychiatrist seek advice from a psychiatrist with current and appropriate rTMS experience to determine a patient's suitability to undergo rTMS.

- Research to date indicates that rTMS is well tolerated and safe when patients are carefully screened and treatment is given within recommended safety parameters and evidence-based guidelines. There are common side effects including headache. More serious side effects (including risk of seizure and inducing a manic or hypomanic episode) are rare and these risks diminish when safety precautions are followed (Taylor et al., 2018). A summary of side effects is available in Position Statement 79: rTMS. Monitoring and assessment prior to and during the treatment and treatment course, in line with these guidelines, will help to minimise risks. Psychiatrists should be aware of the contra-indications by familiarising themselves with guidelines relevant to safety.

- The risk/benefit ratio should be carefully considered before recommending a treatment course in certain groups:

    - There is little safety data on the use of rTMS in pregnant women. Though current evidence is limited to case series, the theoretical risk of rTMS is thought to be low due to the rapidly dissipating magnetic field from the stimulation coil and the distance of the foetus from the coil (Taylor et al., 2018). Nonetheless, the use of rTMS in this group requires a careful assessment of the patient's situation and detailed informed consent. Careful discussion of known and potential risks of rTMS compared to alternative modalities of treatment is warranted. It is advisable for these discussions to include other family members as appropriate. Outcomes in this group should be closely monitored and where possible, employed to inform an empirical evidence base.

    - There is little safety and efficacy data on the use of rTMS in children and adolescents. rTMS should only be given to those aged under 18 within an approved research protocol or under circumstances where there are limited other treatment options and potential clinical benefit is considered to outweigh the known and unknown risks of treatment in this group. This would require a careful assessment of the patient's circumstances, family situation, developmental stage and maturity, capacity to provide informed consent, including an understanding of known and potential risks. The opinion of a specialist child and adolescent psychiatrist should be sought. Outcomes in this group should be closely monitored and where possible employed to inform an empirical evidence base. A service using a specific TMS device should check the intended use that has been formally approved by the Therapeutic Goods Administration (TGA) in Australia or the New Zealand Medicines and Medical Devices Safety Authority as the age group specifications can differ between devices.

    - Whilst the overall incidence of seizures induced by rTMS is very low, attention needs to be directed to the assessment of seizure risk factors, such as pre-existing neurological conditions, past seizures, comorbid alcohol / substance use and changes in concurrent medications during the rTMS course, some of which may reduce seizure threshold (Taylor et al., 2018).

    - Caution should be exercised when considering treatment for patients with implanted metal implants or electronic devices, with a safe distance between the rTMS coil and the metal/electronic device considered (Taylor et al., 2018).

    - The efficacy of TMS in treating major depression with psychotic symptoms is unclear.

- rTMS is an appropriate treatment for both non-treatment resistant and treatment resistant depression. For patients with depression that is very severe, associated with psychotic features, highly treatment resistant, or requires a rapid response due to acute risk, clinicians should consider whether treatment with ECT is required.

- Although rTMS studies specifically in older populations are scarce, current evidence suggests that the antidepressant efficacy of rTMS is not necessarily reduced in older patients, and there are no additional safety concerns (Gálvez et al., 2015).

## Consent

Valid consent is essential for patients considering rTMS and should be sought in line with Principle 5 of the RANZCP Code of Ethics. Details should be provided about the treatment methodology, process, possible adverse events and what to expect before, during and after the administration of the treatment. During the consent process, psychiatrists should ensure patients understand that therapeutic outcomes of rTMS cannot be guaranteed.

It would usually be appropriate for families and carers to be involved in this process depending on the patient's preference. The provision of rTMS to a patient lacking capacity to provide informed consent should only occur with appropriate substituted approval / consent as per local regulations.

## rTMS administration

### Clinical settings for rTMS

- rTMS treatment can be conducted safely as an outpatient procedure and is predominantly provided in this context internationally. rTMS treatment does not require sedation or general anaesthesia.
- All services providing rTMS should have in place appropriate protocols, training and equipment to allow for the safe and effective administration of treatment. This should include protocols for patient assessment, monitoring during treatment, monitoring of the quality of the provision of treatment, protocols for response to adverse events and monitoring of outcomes
- Where rTMS is conducted as an outpatient the outpatient rTMS clinic should be suitably accredited by an accepted accreditation agency such as International Standards Organisation (ISO) or Australian Council of Healthcare Standards (ACHS)
- Devices used for rTMS should be approved by the Therapeutic Goods Administration (TGA) for use in Australia or the New Zealand Medicines and Medical Devices Safety Authority for use in New Zealand. A service using a specific TMS device should check the intended use that has been formally approved by these organisations, as these can differ between devices.

### rTMS treatment variables

- There is a wide range of variables which can be modified in the delivery of rTMS (e.g. stimulation site, stimulation frequency, stimulation intensity, frequency of treatment sessions, number of stimulation pulses or trains applied per session and total duration of rTMS course). These are determined by the treating psychiatrist as part of the prescription procedure. All psychiatrists prescribing rTMS should have undertaken training and have sufficient expertise to allow for the appropriate choice of rTMS stimulation parameters.
- There are several rTMS protocols for which there is Level I evidence of efficacy in the acute treatment of depression:
    - High frequency stimulation applied to the left dorsolateral prefrontal cortex (DLPFC). This is the form of rTMS treatment for which there is the largest evidence base and is the most commonly used. The evidence base includes over 30 independent clinical trials including two large multisite studies. The FDA approval of rTMS in 2008 was based on a trial with stimulation applied to the left DLPFC at an intensity of 120% of the patient's resting motor

threshold (RMT), total of 3000 pulses for each session, lasting 37.5 minutes (high frequency, 10 pulses/second in a 4 second train with a 26 second pause between trains).

- Low-frequency stimulation applied to the right DLPFC. This form of treatment has been evaluated in more than 10 clinical trials and there are multiple studies demonstrating therapeutic equivalence between low-frequency right-sided rTMS and high-frequency left-sided rTMS. Right-sided treatment is usually applied in a single 20-30 minute train to the right DLPFC at 120% of the RMT.
- Sequential bilateral rTMS. This involves a combination of the two approaches described above applied at each stimulation session. The majority of research suggests that sequential bilateral TMS is more effective than sham but no more effective than unilateral stimulation protocols.
- Deep rTMS: this refers to stimulation that is applied with a proprietary 'H-coil' produced by one rTMS device manufacturer. Deep rTMS is usually applied at a high frequency to the left DLPFC but with a deeper and less focussed magnetic field. Research is underway to compare the efficacy of deep and standard rTMS in the treatment of depression.

- Theta burst stimulation (TBS) for depression was approved by US FDA in August 2018 based on large multisite RCT finding no difference in efficacy between TBS and rTMS for treating depression (Blumberger et al., 2018). However, TBS treatment has not been evaluated in multi-site sham-controlled trials and as such is not supported by the same quality of evidence as other forms of rTMS treatment.

- The intensity, or magnetic field strength, of rTMS is usually set as a percentage of the patient's motor threshold (MT), defined as the minimum stimulus strength required to induce a small involuntary muscle contraction (usually in the thumb of the contralateral upper limb) assessed visually or with the aid of electromyography.

- rTMS coil placement in the treatment of depression is usually determined using one of three approaches: 1) A modified 6cm rule (research has shown that the earlier 5 cm approach is inadequate in targeting the appropriate region in the prefrontal cortex and is not recommended), 2) Targeting based on the 10-20 EEG system (for example at the F3/F4 EEG electrode, such as the F3 Bean method) or 3) Neuronavigation technique(s).

- Almost all rTMS clinical trials have evaluated treatment applied as single sessions on a daily basis, five days per week for between 4 and 6 weeks but the largest multisite trials have provided treatment for up to six weeks and several have also included a tapering schedule following this. This treatment schedule should be used in routine clinical applications.

- Research studies are beginning to explore 'accelerated' treatment approaches but they should not be considered standard treatment at this point in time.

- In clinical practice, rTMS should follow protocols derived from (and proven effective by) substantive clinical trials. If rTMS is prescribed in a manner that deviates from the standard stimulation parameters derived from clinical trials, patients receiving the treatment should be informed and the reasons for this clearly documented. rTMS services consistently using non-standard stimulation protocols should only do this within a research protocol approved by the local research ethics committee. This includes significant variations in rTMS scheduling, stimulation frequency, intensity and site.

**Assessment prior to procedure**

- No specific pre-treatment preparation is required prior to a treatment session. Patients sit in a comfortable chair during the treatment sessions. Ear plugs or other hearing protection should be provided to minimise potential discomfort caused by noise generated by the coil.

- Psychiatrists must ensure that a pre-rTMS evaluation is undertaken that includes a full psychiatric assessment, as well as consideration of relevant investigations if indicated. A medication review must also be completed prior to the administration of rTMS. The use of a structured safety screen is highly recommended (Keel et al., 2001; Taylor et al., 2018)

- Before prescription of rTMS, patients should be assessed for factors which place them at greater risk of rTMS related complications, especially seizures.

- rTMS is associated with a small risk of treatment-emergent affective switching. This should be discussed with all patients, particularly those with a history of bipolar affective disorder in whom the risk may be increased. The use of mood-stabilising medication in patients with bipolar affective disorder, particularly those with a history of manic switching, would seem likely to reduce this risk but has not been formally evaluated.

**Monitoring during treatment sessions and the treatment course**

- During each course of therapy, patients should be monitored by appropriately trained and supervised clinicians[2] including ongoing assessment of mental state, treatment response and any side effects should be reviewed as well as any unusual experiences.

- Appropriate facilities to manage any complications from rTMS, including seizures, should be available.

- Daily monitoring of patients by clinicians should include assessment of factors that may alter the seizure threshold. This includes any changes in medication prescribed, alcohol or other substance use, and evidence of acute neurological symptoms or a decline in physical health.

- Protocols should be in place to allow for the timely management of the common side-effects of rTMS including scalp discomfort and headache. Pain can improve over the course of the treatment, and headache may be eased with the use of analgesia. A switch from high-frequency to low-frequency stimulation protocols may be warranted if these side-effects continue to be a barrier to treatment continuation.

- Clinicians supervising rTMS therapy should have the capacity to identify signs of an emergent manic switch and have protocols in place to respond appropriately.

## rTMS use with other treatments

- rTMS should be considered as part of the spectrum of treatment options currently available. Treatment with rTMS can occur in combination with psychological therapies or medications. This depends on the care needs and symptom profile of the individual patient.

- The current state of understanding of rTMS and ECT indicate these treatment modalities have distinct mechanisms of action and side effect profiles, and therefore are best considered distinct therapeutic modalities in their own right. Patients with depression who have not responded to one modality may well respond to the other. Only very limited research has explored the concurrent combination of both treatments to date.

## Maintenance and further rTMS

A period of continuation rTMS treatment may be appropriate at the end of an acute course of therapy: this is a tapering process where the patient gradually transitions from treatment occurring five days per week. This should be distinguished from ongoing maintenance rTMS.

[2] Clinicians in the context of these guidelines include psychiatrists or appropriately trained healthcare professionals, such as a psychiatric nurse, who are administering rTMS or involved in delivering the rTMS treatment under the supervision of a psychiatrist.

Maintenance rTMS is the provision of regular treatment sessions to patients who are in remission or who have minimal ongoing depressive symptoms, in order to prevent depressive relapse. Two approaches to maintenance rTMS have been evaluated in the literature or tried in clinical practice. In the first, single rTMS sessions are applied at a frequency that might vary between two per week and one per month depending on clinical need. In the second approach, a cluster of four – six treatments are provided over several days at a frequency of once every 3 to 6 weeks (Wang et al., 2017).

Further acute courses of rTMS may be offered to patients who have experienced a partial or full relapse of depressive symptoms during a course of maintenance rTMS.

## Privacy and professional practice issues

Administration of rTMS should be conducted in a respectful manner and privacy should be maintained throughout the procedure. It is not appropriate for a patient to be receiving rTMS when another patient is waiting for treatment in the same room or having two patients being treated in the same space without some form of isolating barrier in place.

## Skills required for delivering rTMS

### rTMS by Psychiatrists

All psychiatrists who are administering rTMS should be credentialed by their institution for rTMS treatment. Every service offering rTMS should have a process for the assessment and subsequent credentialing and re-credentialing of psychiatrists who administer rTMS to ensure that they meet required professional standards. This should be undertaken and monitored in accordance with local governance systems. Institutions that deliver rTMS should detail their credentialing requirements in a local policy document.

The capacity to undertake rTMS management should take into consideration:

a) competence in performing assessments of suitability to undergo rTMS and ability to conduct rTMS treatments across a range of clinical situations

b) demonstration of maintenance of knowledge and practical skills through continuing education and practice improvement activities in rTMS (including recognised rTMS courses, conferences, peer review groups, quality improvement activities). Appropriate training for psychiatrists is likely to require participation in a relevant course that features a certification process. Basic practical knowledge from a device manufacturer is unlikely to provide adequate depth and breadth of knowledge needed for clinical applications of rTMS.

To be credentialed to prescribe or administer rTMS, a formal assessment of the psychiatrist's practical skills in rTMS administration should also be conducted by a site director or equivalent, e.g. an rTMS-credentialled psychiatrist. The determination is then made that the required standard has been met as a means of practice review and quality assurance. The psychiatrist peforming the credentialing should have expertise and detailed knowledge of current rTMS practice.

### rTMS by psychiatry trainees or other health care professionals

When rTMS is administered as a treatment for psychiatric disorders by a psychiatry trainee or other clinician (e.g. psychiatric nurse), this should be done under the direct supervision of a psychiatrist who has professional training in rTMS and is credentialed as detailed above.

### Ongoing education

It is acknowledged that rTMS is a specialised and evolving practice. It is important to ensure clinical and technical application is carried out optimally for each individual patient. There should be continuing professional education to ensure all clinicians involved in the provision of rTMS treatment keep up to date on clinical indications and treatment advances. Where required, psychiatrists may need to engage in peer review or primary/secondary consultation processes to determine the appropriateness of rTMS for a given patient. Collaboration, peer review and sharing of knowledge and experience across psychiatrists practising rTMS are recommended.

## Outcome based measures

It is essential for all services delivering rTMS to have systems in place for monitoring of efficacy, outcomes and treatment-related adverse effects of treatment. Clinical and psychometric assessment of symptom severity before, during and at the end of treatment is highly recommended. These measures should be incorporated into routine clinical practice to guide treatment planning. A regular clinical audit process, conducted at least annually, should also be in place to ensure high quality, patient-focused treatment is always delivered.

## Governance

Each clinical setting that conducts rTMS treatment should have in place formal policies and procedures which govern:

- the clinical assessment of patients considered for rTMS and its prescription, incorporating evidence-based stimulation parameters and consideration of appropriate clinical indications
- the qualifications, training and credentialing of clinicians involved in rTMS provision
- the process for monitoring outcomes, including both efficacy outcomes and adverse events
- maintenance and servicing of rTMS machines and ancillary equipment.

Each service that conducts clinical rTMS treatment should have a process for ensuring adequate training of clinicians delivering rTMS and a process of credentialing, such that practitioners have appropriate levels of both theoretical knowledge and practical experience. All clinicians who administer rTMS should be properly trained in the theory, technique and safe operation of rTMS. Each service should have a formal time period for re-credentialing of personnel involved with rTMS.

## Research

Psychiatrists should contribute to continued service development, quality improvement and research by monitoring treatment outcomes. This is important for both established and evolving rTMS techniques to contribute to a more complete understanding and improvement in clinical practice.

Further optimisation of treatment protocols, and efficacy in different patient groups, and other psychiatric conditions are important foci of ongoing research.

## Further reading

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**Disclaimer**

This information is intended to provide general guidance to practitioners, and should not be relied on as a substitute for proper assessment with respect to the merits of each case and the needs of the patient. The RANZCP endeavours to ensure that information is accurate and current at the time of preparation, but takes no responsibility for matters arising from changed circumstances, information or material that may have become subsequently available.

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