

# (Essex) REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (rTMS) PROCEDURAL GUIDELINES

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<b>PROCEDURE SUMMARY</b>	
This Procedure details how the Essex rTMS service functions, the clinical services offered to clients and the processes involved.	
<b>The Trust monitors the implementation of and compliance with this procedure in the following ways:</b>	
Monitored through audit and team meetings	

## SCOPE-

Services	Applicable	Comments
Trustwide		
Essex MH&LD		
CHS		
Privately funded patients	✓	

**The Executive Director responsible for monitoring and reviewing this procedure is Executive Medical Director**

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PROCEDURAL GUIDELINES**

**ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST**

**(ESSEX) REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (rTMS)  
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# CLPG82 - REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (rTMS) PROCEDURAL GUIDELINES

## REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION PROCEDURAL (rTMS) GUIDELINES

### Assurance Statement

The purpose of this procedural guideline is to ensure that the guidelines set out in the rTMS policy are detailed in a way that is understood by all staff, thereby, the policy can be fully implemented, monitored and reviewed within the organisation.

## 1.0 INTRODUCTION

### 1.1 Background information on rTMS

rTMS stands for Repetitive Transcranial Magnetic Stimulation. It is a non-invasive, non-convulsive form of neuromodulation used for treatment of psychiatric illnesses. It is based on the principle of electromagnetic induction. Magnetic fields are generated by passing rapidly alternating electrical currents through a coil with a ferromagnetic core. The magnetic field generated by the TMS machine varies from 1.5 to 3 Tesla comparable to that of an MRI machine.

The magnetic pulse is applied to a small focused area of the brain to result in cortical stimulation. The common area of stimulation is the left dorso-lateral pre-frontal cortex (LDLPFC). The pulses can be delivered in a rapid (1-20Hz) repetitive fashion, increasing the cortical activity or in a slow (<1Hz) repetitive fashion, inhibiting cortical activity.

rTMS has been shown to be a well-tolerated procedure with minimal side effects and an effective treatment option for patients with depression who have not benefitted from antidepressant treatment.

It received FDA approval in 2008 and since then has been used widely in the USA. NICE renewed its guidance for use of rTMS recommending its use as treatment for depression in 2015.

The strongest evidence base is in the treatment for depression but there is emerging evidence base for its use in other psychiatric disorders such as anorexia nervosa and PTSD.

### 1.2 About Essex rTMS Service

Essex rTMS Service is part of EPUT but is currently only able to accept patients who are funded either through their insurance providers, self-funded or funded by NHS Commissioners.

The Essex rTMS Service is situated at Brentwood Resource Centre, Greenwich Avenue, Brentwood, Essex, CM14 4SW. Contact details for the department are: Tel: [REDACTED], Fax: [REDACTED], email [REDACTED]. The service is available 5 days a week (Mon-Fri) and sessions are scheduled 5 days a week for approximately 4 to 6 weeks. Provision for rTMS is limited during bank holidays. The clinic uses the Magstim Rapid Plus machine.

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This policy has been developed by the core rTMS team and will be periodically updated in order to take into account emerging new evidence. It takes into consideration the current available evidence for the safety and efficacy of the use of rTMS therapy in routine clinical practice. It has been informed by the FDA Protocol for rTMS, the NICE Interventional Procedural Guidance update IPG542 (2015), CG 90 Depression in Adults, the Clinical TMS Society Consensus Review and Treatment Recommendation for TMS Therapy for Major Depression (2016) and guidelines for use of Magstim Rapid Plus.

### **2.0 MANAGEMENT STRUCTURE AND STAFFING**

#### **2.1 Lead Consultant Psychiatrist**

There is a Lead Consultant Psychiatrist who has overall responsibility for the service. The responsibilities of the post involve initial consultation at the time of referral taking note of the history, decision regarding suitability of the patient to receive rTMS, prescribing of rTMS, attending the rTMS clinic as required, arranging for weekly follow up and monitoring of clinical progress.

He/she will also liaise with referring GPs or Consultant Psychiatrists and assist by offering second opinion on suitability of rTMS treatment. The Lead Consultant will also be responsible to have an overview of the training and CPD of the staff and credentialing of the staff involved in the rTMS service. They will attend team meetings held at the treatment centre to discuss management and clinical governance issues.

It will be the Lead Consultant's remit to look into developing training for interested Senior Trainees and conduct special interest sessions.

#### **2.2 Lead Nurse Manager**

The service is operationally led by a Nurse Manager who has clinical and management experience to take overall responsibility to ensure the smooth running of the service. He/she will also work towards future development of the service and explore potential service level agreements with different organisations.

The Nurse Manager will also have the responsibility to liaise with the Finance Department for budgetary management of the service and to report at rTMS Management Meetings.

The Nurse Manager along with the Lead Consultant will be responsible for arrangements of clinical governance, audit and quality assurance of the rTMS service. He/she will also be in charge of ensuring that staff meet all the required training competencies.

The Lead Nurse will appropriately delegate responsibilities for the day to day running of the service and manage the staff rota, sickness and absences as necessary. He/she will also be responsible for staff recruitment, training and induction of new staff.

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Other duties will include direct supervision of staff responsibilities for:

- Ensuring rTMS consultation and treatment rooms are properly prepared, organised and maintained.
- Making sure the rTMS machine is functioning, maintenance checked, and appropriate contact is maintained with the manufacturers.
- Appropriate ordering and stocking of all replacements, disposable items and stationery etc.
- Periodically reviewing staff training and competencies and provide appropriate supervision.

### **2.3 Nursing Staff**

The rTMS service has a team of staff running the service with a minimum set number present during treatment sessions to meet the safety and needs of the patient. There will be at least one qualified registered nurse and one competent health care assistant present during the treatment.

The qualified staff will be competent in assessing the capacity of the patient, assisting and making the patient comfortable on the chair, setting up the rTMS machine and adjusting the parameters. They will also be competent in management of seizure activity and also dealing with any minor side effects reported by the patient. The rTMS Consultant will be contactable by telephone. The service will have back up staff easily available in case of emergency sickness or in circumstances of an emergency situation.

All staff within the rTMS service will adhere to the EPUT Mandatory Training requirements. This will be along with specific in house training for rTMS. The training and competency for qualified staff will also include Immediate Life Support (ILS) and training in management of seizures. There is an expectation that staff will attend external courses to continue with CPD specific to rTMS. They will participate in periodic competency checks and supervision pertaining to both the treatment and practical use of rTMS machine.

For each session the rTMS Nurse has responsibility to:

- Welcome the patient and answer any doubts or questions.
- Carry out a capacity check and seek verbal consent, making note of this in the nursing records.
- Ensuring that rTMS machine and coils are checked.
- Ensuring that electrical activity of the machine is checked and recorded as per manufacturer's recommendations.
- Dosage parameters are appropriately set and delivered.
- The recording of each session is maintained in the appropriate nursing records.
- Ensure that post treatment any complaints or side effects is looked into and recorded.
- Patient is given the next appointment time and date in the appointment card.
- Any adverse incidents are recorded in accordance with the Trust's incident reporting system.
- All documents are scanned on to Trust's electronic records.

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### 2.4 Training

All staff are expected to undergo specific training and regular supervision for periodic competency checks for rTMS. This will be along with maintaining regular training requirements within the Trust.

The rTMS teaching will include:

- Theoretical knowledge of rTMS and the basic principles behind the treatment.
- Knowledge and understanding of different rTMS protocols.
- Understanding of indications for rTMS, patient eligibility and exclusion criteria.
- Familiarisation with rTMS safety screening questionnaire.
- Familiarisation with detecting any possible adverse effects.
- Familiarisation with procedures for determining the MT and dosing.
- Proficiency in use of the rTMS machine, parameters and controls, coil placement and cooling with practical demonstration and hands on training by the Lead Consultant or Lead Nurse.

There will be opportunity for senior psychiatric trainees to do special interest sessions in rTMS. Patients' consent will be sought prior to treatment if a psychiatric trainee or any other staff member were to observe the treatment. The patient is under no obligation to agree and their wishes will be respected at all times.

### 3.0 REFERRAL PROCESS

The Essex rTMS Service will accept referrals from Consultant Psychiatrists, GPs or CCGs. The patients have to either self-fund or have funding arranged through their insurance or by their referring CCG.

Any queries regarding the service can be made by contacting at- Tel: [REDACTED], email: [REDACTED]. Patients are welcome to visit the department prior to making any decisions about having the treatment.

Following the acceptance of a referral the patient will be offered a pre-assessment appointment with the Consultant Psychiatrist at the treatment centre. This appointment is likely to last one and half hours. In this appointment the Consultant will take the appropriate history to determine the indication and suitability for rTMS treatment. The patient will be required to fill in an rTMS safety screening questionnaire.

A baseline clinical outcomes score will be recorded using both self-scoring inventories as well as clinician administered scales. Presence of capacity to consent will be recorded and consent to receiving rTMS treatment will be recorded in the consent form. In this appointment, the patient will also be provided with a patient information pack.

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The patient has the choice of opting to do the initial measurements on the same day as the pre-assessment. This will determine the motor threshold (MT), which will then inform the treatment dosage. The treatment sessions will commence on Mondays, and run Monday to Friday i.e. patient receiving 5 sessions a week. If the patient opts to have the measurements and MT determination on some other day, they will be given an appointment on a separate date to the pre-assessment. It will be done on any day prior to the Monday commencing the treatment.

Outcomes scales for monitoring the clinical improvements will be done at weekly reviews. The referrer and the patient's GP will receive all relevant communication regarding the progress made from the treatment.

### **4.0 CONSENT AND PATIENT ELIGIBILITY**

#### **4.1 Process of Obtaining Consent**

##### **4.1.1 Person Obtaining the Consent**

A patient is accepted for rTMS only if he or she has the capacity to make a decision to undertake the treatment, following which a written consent is taken from the patient using the Essex rTMS Service consent form. The written informed consent is obtained by the Consultant Psychiatrist who has understanding and knowledge of the nature and effects of rTMS therapy.

##### **4.1.2 Consenting Process**

The initial written consent is obtained for the course of treatment with a stipulated number of treatments. In order to assist the patient to make an informed decision the rTMS treatment should be explained properly, all potential side effects explained along with expected benefits. It must also be explained to the patient that in some cases the expected benefits may not be attained. Alternate treatment options should also be explained to the patient. The patient is provided with an information pack containing written information about the treatment. The patient will also be given adequate time to consider the pros and cons before making an informed decision.

Consent should never be obtained through any form of coercion. It should be clearly explained to the patient that even though they have signed a consent form they can withdraw their consent at any time.

##### **4.1.3 Consent Forms**

Patients consenting to rTMS treatment will be asked to sign the consent form.

The consent form will have the following information:

- The consent form will stipulate the proposed number of treatments; usual course of treatment will be 20.
- If the number is exceeded, further consent is sought and a fresh form signed and recorded.

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- If there is a break in treatment for more than 2 weeks, continuation should be regarded as a new treatment.
- The consent form will have details of the clinician having explained the procedure, expected benefits, and side effects.
- Statement from the patient, signed by the patient.

Before each treatment session, verbal consent will be taken by the nurse and recorded in the appropriate form.

### **4.1.4 Patient Information**

For the patient to be able to make an informed choice regarding the treatment, appropriate information should be provided both verbally and in written format.

The patient information pack will contain a description of the process of rTMS, the anticipated benefits, risks and likelihood, alternate therapies that are available along with information on patients' rights and the advocacy service.

The information can be translated to other languages if needed. There will also be provision of an interpreter service if required.

## **4.2 Patient Selection and Eligibility**

### **4.2.1 Eligibility Criteria**

rTMS is FDA and NICE approved for treatment of major depressive disorder. The clinical TMS society has developed consensus recommendations for rTMS therapy for major depressive disorder. Recommendations are for use of rTMS as an acute treatment; for use as a subsequent option in the patient group who have previously benefitted from rTMS and experiencing recurrence of symptoms; to be used as continuous or maintenance treatment for patients who benefit from acute treatment; and it can be reintroduced in patients who are relapsing after initially responding.

Patients should have capacity and be able to give a valid consent for the treatment. The service currently offers rTMS only to adult patients over 18 years of age, but consideration can be given to treatment being offered to suitable young persons based on their clinical presentation and capacity to consent when agreed by second opinion CAMHS Consultant.

### **4.2.2 Criteria That Might Exclude Patients from the Treatment Option**

- Patients who do not have capacity to consent.
- Patients under the age of 18 (see above for exceptions)
- Patients with previous or current history of seizures or epilepsy.
- Patients who are actively suicidal
- Those with an on-going dependence with alcohol or stimulant drugs which might lower the seizure threshold.
- Concurrent major medical disorder
- Patients with neurological co-morbidities such as space occupying lesions, CVA, aneurysms etc.

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- Cochlear implants
- Cardiac pacemaker, implanted medication pumps
- Pregnancy

### **5.0 PREPARATION OF PATIENT FOR rTMS**

#### **5.1 Initial Assessment**

The patient will have an initial appointment with the Consultant Psychiatrist in order to note the details of the history, clarify the diagnosis, recommend investigations if needed and to note the current medications. In this appointment any risk factors or past history that might increase the risk or exclude the patient from having rTMS will be clarified. The patient will be given all relevant information both verbally and in written format. A screening questionnaire handed over to the patient will be checked to explore any risk factors. Base line outcome scales will also be done on that initial appointment.

The patient will have the choice to see the treatment room and decide if they want to consent and have the measurements for MT done on the same appointment or schedule another appointment for determining the MT.

#### **5.2 Introduction to the rTMS Treatment Room.**

Patients will be given the opportunity to see the rTMS treatment room and the machine to familiarise themselves with the process. Any questions or doubts regarding the treatment process will be answered.

#### **5.3 Arranging Subsequent Sessions**

If the patient agrees for the treatment and consents, subsequent appointments for the treatment will be arranged. The patient can choose to have the measurements for MT done at the assessment appointment or book a further appointment. The main treatment sessions will commence on Mondays and will proceed Monday to Friday.

#### **5.4 Patient Preparation Prior to rTMS Treatment.**

The patient will be given an information pack with all relevant information. Guidance will be issued for the preparation before the treatment. They will be asked to wash their hair and refrain from using hair gels or hair sprays. They will be informed that during the treatment they would be asked to remove jewellery, glasses, and hearing aids. The patient will also be asked to wear ear plugs during the treatment.

They are welcome to bring someone along to support them but children will not be allowed in the treatment room. Patients are encouraged to use informal mood diaries to determine any changes.

## **6.0 TREATMENT**

### **6.1 Administration of rTMS**

rTMS treatment is delivered by the TMS machine which gives repetitive pulsed magnetic fields through coils applied to a small area over the patients head. This results in changes in the cortical activity of the brain without inducing seizures.

The frequency and dosage of the treatment follows the FDA protocol. The treatment is normally given five days a week for 4-6 weeks.

The treatment does not require anaesthesia and the patient is usually able to drive immediately after the treatment. It is a relatively safe treatment with only minor side effects.

The main adverse effects to be aware of is risk of seizures, the risk being 1 in 30,000. Other side effects might be discomfort at the site of the coil, headache, mild muscle pain or twitching. In some rare cases the patient may experience syncope. Hearing loss is unlikely as earplugs are used during the treatment.

### **6.2 Determining the Motor Threshold (MT)**

The first step in order to determine the dosage is to measure the MT. As this involves some measurements, this will be done in the week prior to actual start of the treatment. It also gives the patients the opportunity to acclimatise with the rTMS chair and the machine on a lower dosage.

MT is the intensity of the magnetic field required to activate the skeletal muscles when the coil is placed over the primary motor cortex. It is the minimal TMS intensity required to evoke a motor response in 50% of trials. This is the basic neurophysiological parameter which enables the determination of optimum dosage for individual patients.

For the purpose of determining the MT for rTMS the abductor pollicis brevis muscle is observed for twitching after application of stimulation. MT is patient specific and though it remains relatively stable, it can vary with time. Due to anatomical variation, measurements are required to find the optimal site of the motor cortex to elicit the skeletal muscle twitch.

In order to find the MT, measurements are taken from nasion toinion and halfway point marked. Then measurement is taken from tragus to tragus and the point where it crosses the first point is marked. This is the vertex- Cz. Next step is to measure 20% of the tragus to tragus distance from Cz vertically towards the ear on left side. This is the C3.

Next step is to find the motor hot spot on the left side. The output is set at 50% and coil placed on C3 flat against the head at a 45 degree angle to midline. The coil is moved anteroposteriorly and mediolaterally in relation to the starting point in steps of 0.5-1 cm. the point at which the strongest twitch is elicited is the motor cortex hot spot.

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The stimulation intensity is gradually decreased in gradients of 1-2%, noting the weakening of the muscle twitch. The dose setting at which there is minimal muscle twitch is noted as the MT.

### **6.3 Prescribing the Dosage and Protocols**

Once the MT is established and the motor cortex hot spot is identified, the treatment is given at 120% of the MT. The site of the treatment coil will be at the LDLPFC. The site of DLPFC can be identified either using the 5/6/7cm rule or marking the F3 on the 10/20 EEG system.

F3 will be the correct position for administering the treatment.

The prescription will be made by the Consultant Psychiatrist for up to 10 sessions. The nursing records will also record the dosage administered.

Several parameters can be adjusted when delivering rTMS, such as the stimulus pulse intensity, duration of the pulse, interpulse interval, frequency, train duration, intertrain interval and number of pulses per sec.

The FDA protocol for Depression stands as

- 120% of MT
- 10Hz frequency
- 4 sec pulse duration
- 10 pulses per sec
- 75 trains
- total of 3000 pulses
- 26 sec off
- total duration of 37.5 minutes

There is emerging evidence for use of patterned TMS such as Theta Burst TMS (TBS) which has been shown to be comparably safe and effective as the above protocol but considerably reduces the time needed for the treatment.

### **6.4 Setting Up the rTMS Machine**

Ensure all the connections are made as per Magstim Rapid2 Operating Manual, a copy of which is kept in the treatment room cupboard.

To switch on Magstim, turn on the 2 switches on the rear of Magstim which will lead to the green indicator in the front of Magstim blinking. Then, switch on the power switch toggle in front of Magstim which will power up Magstim and this would be indicated by all the green lights on all the 3 components of Magstim lighting up.

Then connect the motor threshold or the stimulating coil as required to the coil output socket in front of the machine.

To find the motor threshold select 'Single Pulse Mode' in the options menu on the touch screen, select the parameters as per protocol and then press the green button on the right hand side of the screen which will then indicate on the screen that the

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machine is ready to use. The motor threshold coil can be switched on by either pressing the yellow button on the right hand side of the screen or using the foot switch and pressing one of the unlock buttons on the coil simultaneously.

To deliver rTMS, after placing the stimulating coil in the appropriate position, select 'Repetitive Mode' on the options menu, set the parameters as per the protocol and select 'Run Session'. Then press the green button on the right hand side of the screen followed by the yellow button which will start the treatment as per the set parameters.

### **6.5 Patient Preparation and Treatment**

The patient would be given prior information and opportunity to see the treatment room before the treatment.

The patient will be fully conscious during the whole course of treatment. There is no requirement to come fasting and they can do their normal day to day activities. He/she will comfortably recline on the chair and the coil will be adjusted to the correct position to begin the treatment. The patient would be asked to stay relatively still whilst having the treatment and they can talk to the nurse/HCA or the person accompanying them.

Before the start of treatment the patient will be asked to remove any magnet sensitive materials such as watches, jewellery, mobile phones, bank cards and for these to be kept at a distance from the machine. Patients are requested to wear ear plugs for hearing protection.

The nurse administering the treatment will give an explanation of what to expect.

Once the MT is determine as detailed above, the treatment coil will be placed in the correct position at a 45 degree angle to the midline. The treatment parameters are pre-loaded. The stimulation dose is given at 120% of the MT at a frequency of 10HZ for 4 sec followed by 26 sec wait. The exact duration of treatment will be 37.5min.

The patient will hear a loud clicking noise and feel a tapping sensation under the coils. Some patients might experience discomfort, scalp tingling and sensitivity especially during the initial treatment. These side effects are easily managed by taking medications such as paracetamol. Headache and tiredness may also be experienced in some cases. Some patients, especially if very anxious, may feel faint.

The nurse/HCA will always be present during the treatment and periodically check the coil is making correct contact with the patient.

Once the treatment is completed the coil is moved away from the patient's head and fixed to the stand.

The patient will be asked to remove the single use ear plugs. The nurse/HCA will assist the patient to stand up and make sure the patient is comfortable. The nurse/HCA will make note of any side effects reported by the patient and recommend appropriate remedies. The observation chart with measurement of P/BP/O<sub>2</sub> Sat will be maintained both pre- and post-treatment.

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### **6.6 Post Treatment**

#### **6.6.1 Patient Care**

Post-treatment the patient will be given sufficient time to settle down and the nurse/HCA will make sure the patient's vital signs are stable and all of the patient's questions are answered. Most of the patients are able to carry on with their normal activities immediately after the treatment.

The nurse/HCA will ensure appointments are in place for subsequent sessions and also ensure the patient has the contact numbers in case of any emergencies.

#### **6.6.2 Machine Care**

At start of each session ensure that there are no physical signs of damage to any components of Magstim including any blockage to the cooling vents. Check the coil connector and stimulator coil socket regularly for any tarnishing or burning.

As none of the components of Magstim can be sterilised, do not allow them to become contaminated with body fluids. They may be cleaned using a cloth moistened with isopropyl alcohol, however ensure that all components have dried thoroughly before use.

### **7.0 SUBSEQUENT SESSIONS**

The full course of treatment comprises of 5 days a week sessions for 4-6 weeks hence involves 20-30 sessions in total.

Patients are encouraged not to break the treatment sessions as this could affect the efficacy. After every session the nurse /HCA will ensure that the patient has appointments for next sessions arranged.

### **8.0 TREATMENT RESPONSE TO rTMS**

It is essential to have objective documentation of clinical benefits as a routine practice. This will help to chart the progress made and inform clinical decisions.

The outcome scales used in Essex rTMS Service are both, patient- reported outcome measures and clinician administered scales. This helps to gather the subjective changes as well as have objective scoring of the progress.

At the start of treatment, patients will be asked to complete a PHQ9 and BDI. The clinician will complete the MADRS and CGI rating scales. This will provide base line measurements. These scales will then be repeated weekly after every 5 sessions.

A record will also be maintained of all reported side effects during the treatment and post treatment.

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### **9.0 FOLLOW UP**

The Essex rTMS Service will not be able to hold the patient for future follow up and after care. The Psychiatric input and case management will be the responsibility of the referring team/Consultant Psychiatrist.

If the patient relapses after successful response/remission, they can be re-referred for exploring rescue rTMS or maintenance therapy.

### **10.0 DISCONTINUATION OF TREATMENT**

There might be various reasons for discontinuing the treatment. The most important being if the patient withdraws their consent.

On-going treatment sessions are determined by the objective monitoring of clinical improvements. The conclusion of treatment will also be based on clinical improvements and in context of discussion with the Consultant Psychiatrist.

The treatment may also be stopped if the patient is experiencing intolerable side effects or due to poor efficacy.

### **11.0 RESCUE rTMS**

Studies have shown some relapse rates after successful treatment sessions. Few studies have reported 13% relapse in a 6 months follow up while other 1 year follow up studies have shown 37% relapse rate. Currently there is paucity of data to accurately predict the long term efficacy of rTMS.

Some patients may need rescue rTMS after successful response to initial treatment sessions. This will be determined by the clinical outcome response and after discussion with the Consultant Psychiatrist.

### **12.0 COMMUNICATION WITH REFERRING TEAM AND GP**

The rTMS team will maintain liaison with the patient's GP and referring Psychiatrist. Information will be sent at the beginning of the treatment informing both referring Psychiatrist and GP.

Following the conclusion of treatment, a letter will be sent informing of the number of sessions completed and the outcomes achieved. The normal Trust principles of copying letters to patients will apply.

### **13.0 EMERGENCY AND CRISIS SUPPORT**

All medical emergencies will be dealt with in line with EPUT policies and protocols.

For mental health crisis the CRHT of the relevant area will be contacted

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The referrer will be contacted and informed of any occurring mental health crisis and actions taken. In addition, any other key professionals who are involved in supporting the patient will be contacted to ensure identified risks are handed over and an appropriate care plan can be arranged by them for the patient.

### **14.0 ASSURING QUALITY**

The rTMS Service aims to maintain the highest standards of practice and safety protocols. All relevant and current evidence base is looked into. All efforts are made to incorporate NICE recommendations and Royal College of Psychiatrists position statement and follow FDA approved protocols. The service will be subject to the Trust's clinical governance and incident reporting processes. The service will be monitored by regular audits.

### **15.0 CLINICAL PROTOCOLS RELATED TO rTMS**

Clinical protocols have been developed for anticipated clinical scenarios relevant to rTMS.

The rTMS team will follow these protocols in conjunction with other relevant Trust's protocols.

### **16.0 MENTAL CAPACITY ACT 2005**

The principles of the MCA are that capacity will be presumed unless there is evidence to suggest otherwise. The purpose of the MCA is to ensure that individuals without capacity, or for whom it is suspected may not be equipped to consider complex decisions, are safeguarded and any action taken is in their best interests. Capacity is time specific and decision specific and is based upon four key elements – the ability to understand, consider, and retain the information and the ability to appreciate the consequences of the decision being made.

rTMS will be given only to patients who have capacity to make this decision and are able to give a valid consent.

### **17.0 HUMAN RIGHTS ACT 1998**

The team will continue to work to the principles of best practice, which involves compliance with and respect for Convention Rights in all aspects of service provision.

The rTMS Team will work to the principles of fairness, respect for human dignity and inclusiveness, whilst adhering to Mental Health Act and Trust Policies, procedures and guidelines.

## **CLPG82 - REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (rTMS) PROCEDURAL GUIDELINES**

### **18.0 GENDER, ETHNICITY, AND DIVERSITY**

The rTMS Team will offer the service in a non-discriminatory way by accepting and being willing to work with an individual's understanding of their own issues.

This involves acknowledging an individual's culture and life experience, taking into account race, religion, gender, disability, sexuality and social class.

Service Users will be assisted in accessing specific services that are relevant to them and their individual needs.

In order to meet the specific needs of people from black and minority ethnic communities, the rTMS service will provide mental health information and health promotion leaflets in the main minority ethnic languages.

The rTMS service will have access to interpreters and the staff will use it when required.

### **19.0 SPIRITUAL GUIDANCE**

The rTMS Team will respect and facilitate the Service User's wishes for obtaining spiritual guidance and support.

### **20.0 CARER'S INVOLVEMENT**

Carers are encouraged (subject to patient's consent) to be involved in the treatment process.

### **21.0 HEALTH AND SAFETY**

There must be at least two staff members in attendance at all times whilst there are patients in the building for treatment. The service may operate outside of normal office hours Monday to Friday and staff are not to be in the building on their own.

There is an intercom facility that has been fitted and this should be used to verify who is at the door before opening to anyone.

Staff will be provided with keys and fobs for the building. Additionally, there is a keypad access to the treatment room. It is the responsibility of the team members to ensure that the treatment and assessment rooms are securely locked at the end of the day and that the building exit is secured appropriately on leaving the building.

Staff and patients will be provided with ear plugs that should be worn during the treatment. This is to protect the individual's hearing as the machine emits a significant amount of noise.

Referrers will be required to provide the rTMS Service with a recent risk history for the patient. A risk assessment will be completed at the time of assessment and any significant risks identified will need a risk management plan. Staff delivering the treatment to the patient will need to be aware of the risks that the patient presents with.

## **CLPG82 - REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (rTMS) PROCEDURAL GUIDELINES**

Staff will be made aware of local fire procedures for the building and will be provided with the appropriate fire keys required. It is expected that staff will adhere to the local procedures for Brentwood Resource Centre in the event of a fire alarm activation or on discovery of a fire. rTMS staff will take responsibility to ensure that patients and their carers are given clear instructions in the event of a fire.

An environmental Risk Assessment will be in place for the service in collaboration with the Trust Risk Department and be kept updated as required.

All equipment will be checked and maintained as per Trust requirements.

### **22.0 INCIDENT REPORTING**

The rTMS team will follow the EPUT policies and procedure for any incident reporting within the Essex rTMS service.

### **23.0 REFERENCE TO OTHER AVAILABLE GUIDELINES AND RESEARCH**

When using the policy reference is made to:

- NICE Interventional procedure guideline IPG 542.
- NICE- CG90 - the treatment and management of depression.
- Royal College of Psychiatrist position statement- CERT03/17
- FDA approved protocol
- Clinical TMS society consensus recommendations
- Mental Capacity Act - Code of Practice

**CLPG82 - REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (rTMS)  
PROCEDURAL GUIDELINES**

**24.0 GLOSSARY OF TERMS**

rTMS	Repetitive Transcranial Magnetic Stimulation
NICE	National Institute of Clinical Excellence
RCPsych	Royal College of Psychiatrists
FDA	Food and Drug Administration
MADRS	Montgomery-Asberg Depression Rating Scale
BDI	Becks Depression Inventory
PHQ9	Patient Health Questionnaire
CGI	Clinical Global Impression
DLPFC	Dorsolateral Prefrontal Cortex
MEP	Motor Evoked Potential
MT	Motor Threshold
ILS	Immediate Life Support
CPD	Continuing Professional Development
CVA	Cerebrovascular Accident
EMG	Electromyography
CRHT	Crisis Resolution and Home Treatment Team
APB	Abductor Pollicis Brevis
MRI	Magnetic Resonance Imaging

**END**