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BRIGhTMIND: brain imaging guided transcranial magnetic stimulation in depression

Submission date	Recruitment status
01/10/2018	No longer recruiting
Registration date	**Overall study status**
02/10/2018	Completed
Last Edited	**Condition category**
28/07/2025	Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The study is testing the effectiveness of a new approach to treat treatment-resistant depression using pulses of magnetic stimulation applied to the forehead or scalp. Treatment-resistant depression (TRD) is depression that has not improved with at least two previous antidepressant treatments delivered at a minimum clinically effective dose and duration. The treatment that is being tested is called Transcranial Magnetic Stimulation (TMS) and has been recommended for use in the NHS in the UK by the National Institute for Care Excellence (NICE) as a treatment for TRD. There are uncertainties about how to achieve the best results from this procedure, in terms of where it needs to be targeted on the forehead or scalp and the pattern of the magnetic pulses. Recent developments in magnetic resonance brain imaging means that a part of the brain can be located in each person where three different brain systems involved in producing depression symptoms meet. Targeting the magnetic pulses at this site, which varies slightly in its position in each person, can be assessed to see if proportion of people 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 participate?
Patients aged over 18 with moderate to severe treatment-resistant depression

What does the study involve?
The study lasts for 60 months and participant involvement ends after 48 months. Patients are assessed for eligibility and asked to attend an appointment. If still eligible they undergo an MRI brain scan and are randomly allocated to one of two treatment groups, either repetitive TMS (rTMS) standard treatment or the new treatment connectivity guided intermittent theta-burst stimulation (cgiTBS). Patients are asked to attend 20 treatment sessions over 4-6 weeks. They are followed up over 26 weeks at 8, 16 and 26 weeks with another MRI scan at 16 weeks.

What are the possible benefits and risks of participating?
Current evidence suggests that 1 in 20 people who receive TMS will experience a side 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 side effects happen, participants will be advised how to manage these problems. A small proportion

(estimated as 1 in 1000) may experience a seizure upon receiving TMS. If participants have a seizure they will be medically reviewed before any further treatment is offered. The researchers cannot promise the study will help participants, but the information from this study may help to determine the most favourable method for administering TMS for the treatment of treatment-resistant depression in the future.

Where is the study run from?
1. Queens Medical Centre (UK)
2. St Nicholas' Hospital (UK)
3. St Pancras Hospital (UK)
4. Pennine Care NHS Trust (UK)
5. Berrywood Hospital (UK, no longer open to recruitment).

When is the study starting and how long is it expected to run for?
February 2018 to January 2023

Who is funding the study?
National Institute for Health Research (NIHR) EME Program (UK)

Who is the main contact?
Mr Luke Ingram
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Contact information

Type(s)
Scientific

Contact name
Mr Luke Ingram

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Additional identifiers

EudraCT/CTIS number

IRAS number
245025

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 39297, IRAS 245025

Study information

Scientific Title
Randomised double-blind controlled trial of connectivity guided theta burst transcranial magnetic stimulation versus repetitive transcranial magnetic stimulation for treatment resistant moderate to severe depression evaluation of efficacy, cost effectiveness and mechanism of action

Acronym
BRIGhTMIND Version 1.0

Study objectives
Added study hypotheses as of 13/10/2021:
Primary clinical objective
The primary hypothesis is that cgiTBS is more efficacious at 16 weeks than standard rTMS in patients with TRD as assessed by the proportion of patients who show a response (50% reduction in depression symptoms from baseline on the 17-item
Hamilton Depression Rating Scale [HDRS-17]).

Secondary clinical objectives
1. To explore secondary efficacy outcomes of the mean change in HDRS-17 scores between the two treatment arms and the proportion of patients meeting criteria for remission (HDRS-17 score ≤7) at 16 weeks.
2. To explore secondary clinical outcomes of importance to patients and clinicians namely cognition, anxiety, social function and quality of life.
3. To examine the cost-effectiveness of cgiTBS versus rTMS in a UK NHS population.
4. To examine the patient acceptability and patient experience of cgiTBS and rTMS.

Original study hypotheses:
Mechanistic objectives:
The specific hypotheses for the mechanistic component of the study are:
1. To determine the differential change at 16 weeks between responders and non-responders to treatment (in either treatment arm) in functional connectivity between affective, default and cognitive control networks. The main hypotheses are that connectivity between insula and DLPFC at baseline will distinguish responders from non-responders, and that DLPFC-DMPFC connectivity decrease will be greater in responders than in non-responders.
2. To discern whether DLPFC-DMPFC FC change at 16 weeks is correlated with change in HDRS-17 score at 16 weeks. The hypothesis is that a greater reduction in DLPFC-DMPFC FC is correlated with a greater reduction in HDRS-17.
3. To assess whether prefrontal GABA change at 16 weeks is correlated with change in HDRS-17 score at 16 weeks. The hypothesis is that TBS-induced GABA changes are correlated with a reduction in HDRS-17.
4. To evaluate neurophysiological defined brain signatures at baseline as predictors of depression response or nonresponse to cgiTBS or rTMS. The exploratory hypothesis is that functional connectivity based biotypes can be optimised using advanced computational analytics to individually predict treatment response in TRD patients.

5. To further study the neural mechanisms underlying therapeutic efficacy we will assess interrelations of changes in complex brain network metrics (including the use of graph analysis) with improvement of clinical symptoms. This is an exploratory aim.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands Leicester Central, 30/08/2018, ref: 18/EM/0232

Study design
Randomized; Interventional; Design type: Treatment, Device, Imaging, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Current interventions as of 13/10/2021:
The study is a multicentre parallel-group, double-blinded randomised controlled trial of the efficacy of Connectivity Guided Intermittent theta-burst stimulation (cgiTBS) versus no connectivity guided standard Repetitive Transcranial Magnetic Stimulation (rTMS); in patients over the age of 18 who have a diagnosis of moderate to severe major depressive disorder and have treatment-resistant depression. The study will look to recruit 266 patients (133 in each treatment group) from 4/5 sites. Initially, recruitment sites were Nottingham, London, Newcastle and Northampton until 1/9/20; after 1/9/20 with restart following a break in recruitment with the COVID-19 pandemic the following sites reopened to recruitment; Nottingham, London, Newcastle and Oldham with a revision to recruitment rates and use of remote methods when possible. Recruitment will be from both primary and secondary care settings by a letter of invitation requesting a reply slip to be returned to the research team and will also recruit from patient self-referrals..

Eligibility screening
Interested patients will receive an eligibility screening telephone call, and if eligible they will be invited to attend a remote baseline assessment.

Baseline assessment
With the restart of the study following the COVID-19 pandemic, baseline assessments can be done either face to face or remotely (digital or telephone).
The baseline assessment, which will take a maximum of 2 hours, will be to obtain consent and answer any questions, then to assess their clinical symptoms by the completion of researcher interviews and self-rated questionnaires which will further establish their eligibility to take part. Further checks on medical history may be required.

Baseline MRI scan
Following this, they will be invited to attend within 14 days, an MRI scan of the brain which will last for no longer than 1 hour.

Randomisation and treatment
Within 14 days of the scan participants will be invited to attend for their first treatment session, at this stage they will be randomly allocated to one of two treatment groups, either Repetitive Transcranial Magnetic Stimulation (rTMS) Standard Treatment or Connectivity Guided Intermittent theta-burst stimulation (cgiTBS) Novel treatment. TMS machines used for the study will involve placing a device on the surface of the forehead or scalp whilst in a seating position. The position of the device will be determined either from the previously obtained brain scan using the standard region for rTMS or the optimal location for cgiTBS. Participants will receive a sequence of several short bursts of stimulation via the device, with routine gaps in between or a period of continuous stimulation for nearly 40 minutes, depending on which random group they are allocated to. Allocation of treatment will not be disclosed to the participant. All participants first treatment session will take up to 2 hours, there will be 20 treatment sessions over a 4-6 weeks period, with each treatment session taking 45- 60 minutes for both groups. Both groups will be asked if they have any side effects arising from the therapy, after every treatment session or a maximum of 72 hours after. In addition, all groups will have access to email and telephone advice from the research team in case of any problems or side effects arising from the treatments.

Repetitive Transcranial Magnetic Stimulation (rTMS)
Individuals assigned to rTMS will follow the standard US Food and Drug Administration (FDA) approved protocol. A single coil is placed over the left DLPFC. Stimulation is at 120% motor threshold with 75 x 4-second trains of 10Hz interspersed by 26-second intertrain intervals. The site of stimulation will be determined using a neuronavigation device that computes the F3 electrode site for TMS stimulation from just three fiducial points, the nasion, left preauricular and right preauricular sites. The change has been made because the neuronavigation has been made simple to use for nurses, will be more tolerable for patients, and provides a more precise and reproducible site of stimulation over 20 TMS sessions. There is no need for patients to wear a cap or for a mark to be made on the skin; instead, the neuronavigation device shines a green light onto the scalp and guides the nurse to the right site for stimulation.

Connectivity Guided Intermittent Theta Burst Stimulation (cgiTBS)
Individuals assigned to cgiTBS will receive bursts of 3 pulses (80% motor threshold) at 50Hz applied at a frequency of 5 Hz (i.e. every 200 ms). Each 10-second cycle will consist of 10 bursts (consisting of 2 seconds of stimulation and 8 seconds rest) with a total of 20 cycles performed per run over a site determined from the assessment of maximal strength of connectivity between the anterior insula and the left dorsolateral prefrontal cortex (DLPFC) from fMRI and structural MRI using neuronavigation which computes the nearest location for TBS stimulus on the scalp from the same three fiducial points, the nasion, left preauricular and right preauricular sites. The pulses are repeated for a total of 5 runs with 5-minute rest intervals between runs.

Follow up visits 8 and 16 weeks post-randomisation
Follow up Visits will take place at 8, 16 after randomisation, participant's clinical symptoms will be reassessed with repeated completion of researcher interviews and self-rated questionnaires from the baseline assessment. With the restart of the study following the COVID-19 pandemic, assessments are done remotely (digital or telephone). If at 16 weeks there have been no improvements the participants Clinical Care will be reviewed, by a clinical expert in treatment-resistant depression to assess whether further changes to their treatment regime is required

MRI scan - 16 weeks
Within 14 days of the 16 week follow up appointment participants will also have another MRI brain scan, this will help us in estimating the lasting effects of TMS on the brain, so we can assess predictors of treatment response. This appointment will last 60 minutes.

Follow up assessment at 26 weeks
26 weeks post-randomisation a final assessment will be completed and disclosure to the participant of what treatment they have received will be made. With the restart of the study following the COVID-19 pandemic, assessments are done remotely (digital or telephone). All participants will have their clinical care reviewed by a clinical expert in treatment-resistant depression. This will complete the participants' involvement in the study.

Previous interventions:
The study is a multicentre parallel group, double blinded randomised controlled trails of efficacy of Connectivity Guided Intermittent theta-burst stimulation (cgiTBS) versus no connectivity guided standard Repetitive Transcranial Magnetic Stimulation (rTMS); in patients over the age of 18 who have a diagnosis of moderate to severe major depressive disorder and have treatment-resistant depression. The study will look to recruit 368 patients (184 in each treatment group) from 4 sites beginning in Nottingham then Northampton, London and Newcastle. Recruitment will be from both primary and secondary care settings by a letter of invitation requesting a reply slip to be returned to the research team.

Eligibility screening
Interested patients will receive a eligibility screening telephone call, and if eligible they will be invited to attend a baseline assessment.

Baseline assessment
The baseline assessment, which will take a maximum of 2 hours, will be to obtain consent and answer any questions, then to assess their clinical symptoms by the completion of researcher interviews and self-rated questionnaires which will further establish their eligibility to take part. Further checks on medical history may be required.

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standard region for rTMS or optimal location for cgiTBS. Participants will receive a sequence of several short bursts of stimulation via the device, with routine gaps in between or a period of continuous stimulation for nearly 40 minutes, depending on which random group they are allocated to. Allocation of treatment will not be disclosed to the participant. All participants first treatment session will take up to 2 hours,there will be 20 treatment sessions over a 4-6 weeks period, with each treatment session taking 45- 60 minutes for both groups. Both groups will asked if they have any side effects arising from the therapy, after every treatment session or a maximum of 72 hours after. In addition, all groups will have access to email and telephone advice from the research team in case of any problems or side effects arising from the treatments.

Repetitive Transcranial Magnetic Stimulation (rTMS)
Individuals assigned to rTMS will follow the standard US Food and Drug Administration (FDA) approved protocol. A single coil is placed over the left DLPFC. Stimulation is at 120% motor threshold with 75 x 4-second trains of 10Hz interspersed by 26-second intertrain intervals. The site of stimulation will be determined using the Beam F3 method which has been shown to be highly comparable in terms of the site of stimulation to expensive but gold standard MRI neuronavigation methods BeamF3 is an algorithm to provide accurate localization of the F3 electrode site from just three measurements: head circumference, nasion-inion distance, and left tragus-right tragus distance.

Connectivity Guided Intermittent Theta Burst Stimulation (cgiTBS)
Individuals assigned to cgiTBS will receive bursts of 3 pulses (80% motor threshold) at 50Hz applied at a frequency of 5 Hz (i.e. every 200 ms) for 40 seconds duration over a site determined from the assessment of maximal strength of connectivity between the anterior insula and the left dorsolateral prefrontal cortex (DLPFC) from fMRI as described above. The pulses are repeated for a total of 5 runs with 5 minutes rest intervals between runs.

Follow up visits 8 and 16 weeks post randomisation
Follow up Visits will take place at 8, 16 after randomisation, participant's clinical symptoms will be reassessed with repeated completion of researcher interviews and self-rated questionnaires from the baseline assessment. If at 16 weeks there has been no improvements the participants Clinical Care will be reviewed, by a clinical expert in treatment resistant depression to assess whether further changes to their treatment regime is required

MRI scan - 16 weeks
Within 14 days of the 16 week follow up appointment participants will also have another MRI brain scan, this will help us in estimating the lasting effects of TMS on the brain, so we can assess predictors of treatment response. This appointment will last 60 minutes.

Follow up assessment at 26 weeks
26 weeks post randomisation a final assessment will be completed and disclosure to the participant of what treatment they have received will be made. All participants will have their clinical care reviewed by a clinical expert in treatment resistant depression. This will complete the participants involvement in the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Connectivity Guided Intermittent theta-burst stimulation (cgiTBS), Repetitive Transcranial Magnetic Stimulation (rTMS)

Primary outcome measure
Current primary outcome measure as of 13/10/2021:
The efficacy of cgiTBS compared with standard rTMS measured using the Hamilton Depression Rating Scale (HDRS-17) at baseline, 8, 16 and 26 weeks post randomisation date

Previous primary outcome measure:
The efficacy of cgiTBS at 16 weeks (primary clinical outcome, 50% drop in HDRS-17 score from baseline to 16 weeks) and 26 weeks compared with standard rTMS; in people with TRD ;
Timepoint(s): 16 and 26 weeks post randomisation

Secondary outcome measures
Current secondary outcome measures as of 13/10/2021:
1. Depression scored using the Hamilton Depression Rating Scale (HDRS-17) score measured at baseline 8, 16 and 26 weeks post randomisation date
2. Remission rate measured using the Hamilton Depression Rating Scale (HDRS-17) score (defined as a score of 8 or less on the HDRS-17) at 8, 16 and 26 weeks
3. Depression symptoms measured using the Beck Depression Inventory 11 (BDI2), a self-rated measure at baseline, 8, 16 and 26 weeks post randomisation date.
4. Cognitive functioning measured using the THINC Integrated Tool (THINCIT), at baseline, 8, 16 and 26 weeks post randomisation date. Due to the pandemic to reduce face to face contact this is only measured at baseline and 16 weeks post randomisation date
5. Self-rated measure of symptoms of depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 8, 16 and 26 weeks post randomisation date
6. Self-rated measure of anxiety and depression measured using the Generalised Anxiety Disorder Assessment (GAD-7), baseline, 8, 16 and 26 weeks post randomisation date
7. Self-rated measure of impairment in functioning measured using the Work and Social Adjustment Scale (WSAS) at baseline, 8, 16 and 26 weeks post randomisation date
8. Self-rated health utility, quality of life and pain measured using EuroQol-5D-5L, at baseline, 8, 16 and 26 weeks post randomisation date
9. Mood measured using the Quick Inventory of Depressive Symptomology (QIDS-SR16) at baseline, 8 and 16 weeks post randomisation date
10. Patient acceptability and patient experience of overall improvement measured using the Patient Global Impression of Change (1-5 scale very much improved to very much worse) after each treatment session and at 8, 16 and 26 weeks post randomisation date
11. Adverse events measured using a checklist which will be asked after each TMS session
12. Neural mechanism of efficacy in cgiTBS and rTMS measured using FC, eFC, GABA at baseline and 16 weeks post randomisation
13. Mechanisms by which cgiTBS improves mood measured using FC and eFC, at baseline and 16 weeks post randomisation

Previous secondary outcome measures:
1. Depression is measured using Hamilton Depression Rating Scale (HDRS)-17 at baseline (repeated at before treatment is exceeds 4 weeks from baseline), 8, 16 and 26 weeks post randomisation
2. Treatment resistant depression is measured using Massachusetts Generalised Hospital scale at baseline (MGH)
3. Information on socio-demographics, diagnosis measured using Socio Demographics (SCID-11)

at baseline
4. Childhood emotional trauma measured using Childhood Trauma Questionnaire (CTQ) at baseline
5. Characteristic attitudes and symptoms of depression are measured using Beck Depression Inventory (BDI-2) at baseline and 8, 16 and 26 weeks post randomisation
6. Symptoms of depression measured using Patient Health Questionnaire (PHQ-9) at baseline and 8, 16 and 26 weeks post randomisation
7. Health utility and quality of life measured using EuroQol-5D-5L Questionnaire (EQ-5D-5l) at baseline and 8, 16 and 26 weeks post randomisation
8. Anxiety and depression measured using Generalised Anxiety and Depression scale (GAD-7) at baseline and 8, 16 and 26 weeks post randomisation
9. Cognitive functioning in patients with major depression measured using Thinc –Integrated Tool (Thinc-It) at baseline and 8, 16 and 26 weeks post randomisation
10. Impairment in functioning measured using Work and Social Adjustment (WSAS) at baseline and 8, 16 and 26 weeks post randomisation
11. Acceptability of recruitment and barriers assessed using Patient Rating Acceptability after every treatment session and at 8, 16 and 26 weeks post randomisation
12. Health economics measured using specially designed Client Resource Proforma at baseline and 16 and 26 weeks post randomisation
13. Side effects measured using side effect checklist after every treatment session and at 8 weeks post randomisation
14. Mechanisms of therapeutic efficacy using multimodal MRI at baseline and 16 weeks pot randomisation

Overall study start date
01/02/2018

Completion date
31/01/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/10/2021:
1. Adults >18 years
2. Diagnosis of MDD (defined according to DSM-5) that is treatment resistant (defined as scoring 2 or more (42) on the Massachusetts General Hospital Treatment Resistant Depression staging score (51) See appendix on more detailed scoring of treatment resistance
3. HDRS-17 score of 16 or more (moderate to severe depression) (52)
4. Capacity to provide informed consent before any trial-related activities

Previous inclusion criteria:
1. Adults >18 years
2. Diagnosis of MDD (defined according to DSM-5) that is treatment resistant (defined as scoring 2 or more on the Massachusetts General Hospital Treatment Resistant Depression staging score)
3. Capacity to provide informed consent before any trial-related activities

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 368; UK Sample Size: 368

Total final enrolment
255

Key exclusion criteria
Current exclusion criteria as of 02/07/2019:
History of bipolar disorder (due to risk of mania) or depression secondary to other mental disorder
2. Neurological conditions e.g. brain neoplasm, cerebrovascular events, epilepsy, neurodegenerative disorders, and prior brain surgery
3. Standard contraindications to MRI i.e. irremovable metal objects in and around body e.g. cardiac pacemaker, implanted medication pump and pregnancy (any doubt resolved by pregnancy test, women of childbearing age taking precautions against pregnancy) This will include other potential complicated factors such as red tattoo's which consist of iron on the head, neck and back and claustrophobia (we offer mock scanner testing and training in some sites)
4. Major unstable medical illness requiring further investigation or treatment.
5. Change in prescribed medication 2 weeks before baseline assessment.
6. Prescription of lamotrigine, gabapentin, pregabalin in the 2 weeks prior to baseline assessment.
7. Daily prescription of benzodiazepine above 5 mg diazepam equivalents, zopiclone above 7.5 mg, zolpidem above 10 mg or zaleplon above 10 mg. These
drugs should not be used intermittently in the 2 weeks before baseline assessment.
8. Current substance abuse or dependence defined by DSM-5 criteria)
9. Prior TMS treatment.
10. At risk of suicidality.
11. Potential complicated factors relating to the TMS treatment i.e. hairstyles which would impair magnetic transmission and piercings. (Participants would only be excluded if they chose to not make the changes required to ensure effective treatment.)
12. Involved with any other clinical trial at the time of consent or 6 months prior.
13. Unable to read or understand English.

Previous exclusion criteria:
1. History of bipolar disorder (due to risk of mania) or depression secondary to other mental disorder
2. Neurological conditions e.g. brain neoplasm, cerebrovascular events, epilepsy, neurodegenerative disorders, and prior brain surgery
3. Standard contradictions to MRI i.e. irremovable metal objects in and around body e.g. cardiac pacemaker, implanted medication pump and pregnancy (any doubt resolved by pregnancy test, women of childbearing age taking precautions against pregnancy). This will include other potential complicated factors such as red tattoos which consist of iron on the head, neck and

back and claustrophobia (we offer mock scanner testing and training in some sites)
4. Major unstable medical illness requiring further investigation or treatment
5. Change in prescribed medication in the 2 weeks preceding the start of TMS trial or prescription of lamotrigine, pregabalin, gabapentin or benzodiazepines that act on brain glutamate or GABA (only occasional use of other hypnotic drugs zopiclone, zolpidem, zoleplon and promethazine will be allowed)
6. Current substance abuse or dependence (defined by DSM-5 criteria)
7. Prior TMS treatment
8. At risk of suicidality
9. Potential complicated factors relating to the TMS treatment i.e hairstyles which would impair magnetic transmission and piercings (participants would only be excluded if they chose to not make the changes required to ensure effective treatment)
10. Involved with any other clinical trial at the time of consent or 6 months prior
11. Unable to read or understand English

Date of first enrolment
15/10/2018

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Bridge Room
ECT clinic
A Floor, South Block
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Berrywood Hospital
Centre for Neuromodulation
Quayside
Duston
Northampton
United Kingdom
NN5 6UD

Study participating centre
St Nicholas' Hospital
Gibside Ward
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
St Pancras Hospital
TMS Clinic
Camley Centre
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-Lyne
United Kingdom
OL6 7SR

Sponsor information

Organisation
Nottinghamshire Healthcare NHS Foundation Trust

Sponsor details
The Resource
Trust HQ
Duncan Macmillan House
Dorchester Road
Nottingham
England
United Kingdom
NG3 6AA
+44 (0)1156961300
RandIenquiries@nottshc.nhs.uk

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/04ehjk122

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/44/22

Results and Publications

Publication and dissemination plan
All participants will be sent a report summary of the results. Publication plans will be approved by the Trial Steering Committee will be written by the TMG during the study with the sponsor and funder approvals. It is envisaged that the results of the study will be published in the relevant peer-reviewed journals. Acknowledgement of any supporting organisations, including funders, and the Nottinghamshire Healthcare NHS Foundation Trust and the LCTU, will be included.

Intention to publish date
14/02/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/07/2020	18/09/2020	Yes	No
Protocol article	Magnetic Resonance Imaging Protocol and SARS-CoV-2-Induced Changes	20/01/2022	21/01/2022	Yes	No
Statistical Analysis Plan		04/10/2022	02/11/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		16/01/2024	22/01/2024	Yes	No

Other publications	Facilitators and barriers to participation	25/07/2025	28/07/2025	Yes	No