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Feasibility of transcranial magnetic stimulation over multiple brain areas compared to a single brain area for obsessive-compulsive disorder in adults

Submission date
12/08/2026

Recruitment status
Recruiting

Registration date
12/08/2026

Overall study status
Ongoing

Last Edited
14/08/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obsessive-compulsive disorder (OCD) is a condition in which individuals experience intrusive thoughts or urges that are highly distressing and often feel very real. To relieve this distress, they often feel compelled to perform certain behaviours or rituals, despite recognising that the relief is only temporary or limited. This can be exhausting, make daily life very difficult and, when severe, become debilitating. Standard treatments, including medication and psychotherapy, help many individuals improve. However, some people do not experience sufficient improvement despite receiving adequate treatment. For these individuals, new treatment options are needed. Transcranial magnetic stimulation (TMS) is a newer treatment that uses magnetic pulses to stimulate specific areas of the brain. Research indicates that TMS may help individuals with OCD, particularly those whose symptoms have not improved with standard treatments. However, it remains unclear which stimulation strategy, including the choice of brain area targeted, is most effective.

Who can participate?
Individuals may be eligible to participate if they are aged 18 to 65 years, live in Lebanon, have moderate-to-severe OCD that has not improved adequately despite at least one adequate medication treatment, and are currently taking stable medication. During screening, the research team conducts a comprehensive assessment to determine eligibility. Individuals cannot participate if they have certain medical or psychiatric conditions, metallic or electronic implants in the body, or if they are pregnant.

What does the study involve?
Eligible participants are randomly assigned to one of two treatment groups. Both groups receive TMS five days per week (Monday to Friday) for six weeks. Each treatment day consists of three sub-sessions, each lasting approximately 80 seconds, with around 30 minutes between sub-sessions. Participants should expect to spend approximately 2.5 hours at the study centre on each treatment day.

One group receives stimulation to a different brain area during each of the three daily sub-sessions, with each area stimulated on both sides of the brain. The other group receives stimulation to the same brain area on the right side during all three daily sub-sessions. Both groups receive the same total number of stimulation pulses each day.
During each TMS sub-session, participants experience tapping sensations on the scalp and hear clicking sounds produced by the machine. Ear protection is provided to improve comfort.
Participants undergo regular assessments of OCD symptoms, mood, other symptoms and any side effects before treatment begins, every two weeks during the six-week treatment period and every three weeks during the subsequent 12-week follow-up period. These assessments allow the research team to monitor progress. Completion of the treatment schedule and assessments is important for evaluating the feasibility of the study procedures and for improving understanding of both treatment approaches.

What are the possible benefits and risks of participating?
Some individuals who receive TMS experience improvements in their OCD symptoms, including fewer intrusive thoughts, a reduced urge to perform rituals and an improved quality of life. Although improvement is possible, the research team cannot guarantee that the treatment will benefit every participant.
The most common side effects are temporary headache and mild scalp or neck discomfort, which usually resolve quickly. Some participants may also feel tired after treatment. The research team asks about side effects at every visit and adjusts care if necessary. Participants are closely monitored throughout the study.

Where is the study run from?
The study takes place within the Department of Psychiatry and Clinical Psychology at Saint George University Medical Center in Achrafieh, Beirut, Lebanon.

When is the study starting and how long is it expected to run for?
The study is scheduled to begin enrolling participants in August 2026, with recruitment expected to continue until February 2027. Once enrolled, participants receive six weeks of treatment followed by 12 weeks of follow-up visits.

Who is funding the study?
The study is funded by the research team and has no commercial involvement.

Who is the main contact?
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Study information

Scientific Title
A head-to-head, rater-blinded feasibility randomized controlled trial of sequential bilateral multi-target continuous theta-burst stimulation of the orbitofrontal cortex, dorsomedial prefrontal cortex/anterior cingulate cortex, and supplementary motor area compared with right dorsolateral prefrontal cortex continuous theta-burst stimulation in adults with obsessive-compulsive disorder

Acronym
TRIO-OCD

Study objectives
1. To assess the feasibility, tolerability, adherence, and safety of sequential bilateral multi-target continuous theta-burst stimulation (cTBS) of the orbitofrontal cortex, dorsomedial prefrontal cortex/anterior cingulate cortex, and supplementary motor area compared with right dorsolateral prefrontal cortex cTBS alone in adults with moderate-to-severe obsessive-compulsive disorder who have not achieved an adequate response to at least one standardized medication treatment. cTBS will be administered as an add-on to stable ongoing psychiatric medication, with or without psychotherapy
2. To explore changes in obsessive-compulsive disorder symptom severity and other clinical measures within and between treatment arms at regular intervals: baseline, during treatment,

and post-treatment, with follow-up assessments through 12 weeks post-intervention
3. To generate effect size estimates informing the design of a future adequately powered randomized controlled trial

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2026, Institutional Review Board (IRB-SGUB) / Research Ethics Committee (REC-SGUHMC) (Youssef Sursock Street, Rmeil, Beirut, -, Lebanon; +961 1 577 055; irb@sgub.edu.lb), ref: IRB-REC/O/059-26/4126

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Obsessive-compulsive disorder in adults who did not respond to at least one standard medication regimen

Interventions
Eligible participants will be randomly assigned after consent and baseline assessment to one of two active treatment groups using permuted block randomization with variable block sizes, stratified by baseline obsessive-compulsive disorder (OCD) severity (Yale-Brown Obsessive-Compulsive Scale score 16-23 versus 24 or above). The randomization sequence will be generated by a statistician not involved in participant recruitment, and allocation will remain concealed to the clinician operating TMS and patient until immediately before treatment begins. To minimize assessment bias, all clinical outcome assessments will be conducted by an independent rater blinded to treatment allocation throughout the study. Participants will be instructed not to disclose their treatment allocation at each assessment.

Both groups will receive continuous theta-burst stimulation (cTBS) for 6 weeks, with 5 treatment days per week (Monday to Friday), for a total of 30 treatment days. Each treatment day will consist of three sub-sessions separated by approximately 30 minutes. Brain sites will be located using scalp-based anatomical landmarks. Stimulation intensity will be set at 80% of each

participant's resting motor threshold (RMT), assessed by observation of contralateral leg or toe twitches. Treatment will be delivered as an add-on to stable ongoing psychiatric medication, with or without psychotherapy.

Safety screening will be conducted at each visit throughout the treatment and follow-up phases.

Arm A (Experimental): Participants will receive sequential bilateral (right-then-left) multi-target cTBS across three brain regions. Sub-session 1 will target the orbitofrontal cortex (OFC), sub-session 2 will target the dorsomedial prefrontal cortex/anterior cingulate cortex (DMPFC/ACC), and sub-session 3 will target the supplementary motor area (SMA). Each brain region will receive 600 pulses per hemisphere, delivered sequentially over 40 seconds per hemisphere (80 seconds total per brain region), totaling 1,200 pulses per sub-session. Overall, participants will receive 3,600 pulses per treatment day and 108,000 pulses over the 6-week intervention period.

Arm B (Active Control): Participants will receive unilateral cTBS targeting the right dorsolateral prefrontal cortex (DLPFC) during each of the three daily sub-sessions. Each sub-session will deliver 1,200 pulses over 80 seconds, totaling 3,600 pulses per treatment day and 108,000 pulses over the 6-week intervention period.

Clinical assessments will be conducted at baseline, Weeks 2 and 4 during treatment, and Week 6 post-intervention. After the 6-week intervention, assessments will continue every 3 weeks for 12 weeks, all performed by the independent blinded rater. TMS operators and participants cannot be blinded because treatment procedures are distinguishable.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Transcranial Magnetic Stimulation (TMS) / continuous Theta Burst Stimulation (cTBS)

Primary outcome(s)
1. Feasibility - recruitment measured using participants randomized per month (target: ≥1 per month) at throughout the recruitment period

2. Feasibility - treatment adherence measured using proportion of randomized participants completing at least 24 of 30 treatment days (target: ≥80% of participants) at weeks 1 to 6

3. Feasibility - study retention measured using randomized participants completing the Week 18 assessment (target: ≥75% of participants) at week 18

4. Feasibility - protocol deliverability measured using number and type of protocol deviations, summarized by treatment arm at weeks 1 to 6

5. Feasibility - treatment tolerability (dose needs) measured using number of treatment days required to reach the target protocol-specified intensity, summarized by treatment arm at weeks 1 to 6

6. Feasibility - adverse events measured using number and proportion of participants experiencing adverse or serious adverse events, summarized by treatment arm at each treatment day during weeks 1 to 6 and weeks 9, 12, 15, and 18

Key secondary outcome(s)
1. Change in obsessive-compulsive symptoms measured using Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) [clinician-rated] at baseline; weeks 2 and 4 (during treatment); week 6 (post-intervention); and weeks 9, 12, 15, and 18 (follow-up)

2. Change in depressive symptoms measured using Montgomery-Asberg Depression Rating Scale (MADRS) [clinician-rated] at baseline; weeks 2 and 4 (during treatment); week 6 (post-intervention); and weeks 9, 12, 15, and 18 (follow-up)

3. Change in anxiety symptoms measured using Hamilton Anxiety Rating Scale (HAM-A) [clinician-rated] at baseline; weeks 2 and 4 (during treatment); week 6 (post-intervention); and weeks 9, 12, 15, and 18 (follow-up)

4. Change in insight into obsessive beliefs measured using Brown Assessment of Beliefs Scale (BABS) [clinician-rated] at baseline; weeks 2 and 4 (during treatment); week 6 (post-intervention); and weeks 9, 12, 15, and 18 (follow-up)

5. Clinical global impression of severity measured using Clinical Global Impression-Severity Scale (CGI-S) [clinician-rated] at baseline; weeks 2 and 4 (during treatment); week 6 (post-intervention); and weeks 9, 12, 15, and 18 (follow-up)

6. Clinical global impression of improvement measured using Clinical Global Impression-Improvement Scale (CGI-I) [clinician-rated] at weeks 2 and 4 (during treatment); week 6 (post-intervention); and weeks 9, 12, 15, and 18 (follow-up). CGI-I is not assessed at baseline because it is relative to previous assessment

7. Change in tic severity measured using Yale Global Tic Severity Scale (YGTSS) total tic score among participants with tics at baseline [clinician-rated] at baseline; weeks 2 and 4 (during treatment); week 6 (end of treatment); and weeks 9, 12, 15, and 18 (follow-up)

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. Age 18 to 65 years
2. Diagnosis of moderate-to-severe obsessive-compulsive disorder according to DSM-5-TR criteria
3. Current Yale-Brown Obsessive Compulsive Scale (Y-BOCS) score of 16 or above (clinician-administered)
4. Lack of sufficient response to standard pharmacological therapy for OCD at an optimal dose and duration
5. Stable medication for at least 4 weeks before baseline assessment, with or without psychotherapy

6. Right-handedness
7. Capacity to understand the study materials and procedures and provide informed consent
8. Ability to attend daily treatment for 6 weeks

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Acute active suicidality
2. Psychotic disorders, bipolar disorder, or autism spectrum disorder
3. Substance use disorder within the past 3 months, except tobacco use
4. Hoarding
5. Use of antiepileptic drugs, unless used as mood stabilizers
6. Use of benzodiazepines at a dose greater than 1 mg lorazepam equivalent per day
7. Prior transcranial magnetic stimulation (TMS) treatment
8. Electroconvulsive therapy (ECT) within the past 12 months or a history of non-response to 8 or more adequate ECT sessions
9. History of deep brain stimulation (DBS)
10. Any life-threatening illness
11. History of epilepsy, brain surgery, or clinically significant brain abnormalities, including malformations or neoplasms
12. Stroke, dementia, or neurodegenerative disorders
13. Intracranial implants or other metallic or ferromagnetic devices contraindicated for transcranial magnetic stimulation
14. Pregnancy (self-reported)

Date of first enrolment
14/08/2026

Date of final enrolment
26/02/2027

Locations

Countries of recruitment

Lebanon

Study participating centre
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Sponsor information

Organisation
Institute for Development, Research, Advocacy and Applied Care

ROR
https://ror.org/04q71jj82

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available