Doelgroep: patiënten met depressie

Timestamp	3/29/2022 11:08:24
Email Address	sara.dewitte@ugent.be
What type of research?	Clinical/translational
Title of the study	Stepped Care intervention for treatment-resistant Depression (aiTBS 2)
Describe your study in two sentences (max. 500 characters)	Stepped care treatment in unipolar depressed patients with non-invasive brain stimulation (TBS), followed by a Cognitive Control Training and antidepressants (SSRI).
Principle investigator (PI) + Instituut	Chris Baeken (University of Ghent)
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Co-investigators + Institutes	Sara De Witte (University of Ghent)
Study period	December 31, 2023
Status of project	Recruitment ongoing
Funding	BOF16/GOA/017
Number of participating centers	1
Link to study website	https://www.gheplab.ugent.be/projects/stepped-care-treatment/
Link to trial registration	https://clinicaltrials.gov/ct2/show/NCT03288675
Research question(s)	STEP 1: Patients will be treated with in total 20 accelerated intermittent Theta Burst Stimulation (aiTBS) sessions. Patients will be randomized to receive either the real aiTBS or sham treatment (first week). However, the sham group will receive active aiTBS treatment with 10 days' time interval. The investigators expect that real aiTBS treatment and not sham will result in a significant and clinical meaningful response. STEP 2: To optimize treatment and reduce relapse following the iTBS treatment, in a stepped care approach, all patients then continue with cognitive control training (CCT) ten days later. This CCT consists of 20 sessions, spread over 4 weeks. During this follow-up treatment, all patients will be prescribed antidepressant medication (SSRI) again. As iTBS treatment effects are known to decline over time, the investigators expect that combining aiTBS with a follow-up CCT therapy will stabilize the clinical effects over time compared to receiving the iTBS treatment alone.
Study population (disorder)	Unipolar depression
Total sample size (as in METC protocol)	68
Neuromodulation modality	rTMS (including TBS)
TMS hardware	MagStim
Coil type	fig-8
Sample size	68 patients and 68 controls

Stimulation target	lDLPFC
Method used for coil placement	fMRI-based neuronavigation
Frequency	iTBS
Inter-train interval	2sec
Train duration	8sec
Number of pulses per session	3000
% of resting motor threshold	110
Other relevant rTMS parameters (e.g. priming)	No
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Adjuvant treatment	Medication, Cognitive control training
Number of sessions	20
Frequency of sessions	20sessions/1month
Primary outcome	Changes in depression severity - clinician-rated
Secondary outcomes	Changes in depression severity - self-report Changes in suicidal thoughts - clinician-rated Changes in anxiety features, rumination, perceived stress, responses to positive affect
Inclusion criteria	- Unipolar major depression (with melancholic features) - Not responding to at least two trials with an antidepressant - Aged between 18-65 years old - Healthy volunteers may be accepted as control subjects
Exclusion criteria	- Depression with bipolar/psychotic features - Dysthymia - Active substance abuse/dependence within a year prior to inclusion - Pregnancy - ECT non-responder

	- Any neurological problem (e.g. epilepsy) - Any implanted electronic/metal device susceptible for magnetic field radiation (e.g. pacemaker) - Known allergic reaction to radio-tracers or associated compounds