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Cognitive control training for depression

Submission date	Recruitment status	[ ] Prospectively registered
11/09/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/09/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/10/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression is a mental health condition where a person feels constantly very sad and low in mood for two weeks or more. It affects people in different ways. Sufferers can feel hopeless, anxious and lose interest in doing things they used to enjoy. It can also lead to problems with sleeping, feeling constantly tired, a loss of appetite and a low sex drive. In the most extreme cases, it can result in a person harming themselves or attempting to take their own life (suicide). The study aims to compare two treatment methods for depression, cognitive control training and behavioural activation

Who can participate?
Patients aged 18 – 50 with major depressive disorder

What does the study involve?
Participants are randomly allocated into Cognitive Control Training (CCT) or the active control group (Behavioral Activation). They are assessed with questionnaires a before and after the 18-session intervention (twice weekly).

What are the possible benefits and risks of participating?
Possible benefits of participating in this study include improvement in their condition and relief from symptoms. Improvement in cognitive and mood symptoms is likely. The intervention will target mood regulation and long-term sustainable strategies to deal with depression. The study doctor/researcher will be monitoring participants' condition more closely than usual. The findings of this study will be helpful in developing new strategies for patients with depression. There are no costs to participants and they will not be paid for their participation. The tests, examination and treatment will be free of cost. There are no risks involved in the treatment, but since the treatment requires participants to not change the dose of medication a month before and 3 months after the intervention there could be worsening of symptoms, in such a case they will be independently assessed by a psychiatrist and will be removed from the study.

Where is the study run from?
1. NIMHANS OPD
2. NIMHANS Centre for Well Being (NCWB)

When is the study starting and how long is it expected to run for?
October 2017 to October 2019

Who is funding the study?
National Institute of Mental Health and Neuroscience (India)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Cognitive control training for depression: a randomised controlled trial

Acronym
CCT-D

Study objectives

Hypothesis 1: There will be no difference in measures of depression, anxiety, emotion regulation, metacognition, neuro-cognitions and quality of life, before and after cognitive control training
Hypothesis 2: There will be no difference in measures of depression, anxiety, emotion regulation, metacognition, neuro-cognitions and quality of life, between patients who recieve cognitive control training and behavioural activation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/07/2016, NIMHANS (Human) Ethics Committee (National Institute for Mental Health and Neuroscience (NIMHANS), Hosur Road, Hombegowda Nagar, Bangalore, India; +91 (0) 8026995000; ms@nimhans.ac.in), ref: NIMH/DO/ETHICS SUB-COMMITTEE29thMEETING/2016

Study design
Randomised controlled trial with single-blind pre-post and follow up design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
Allocation to groups was done with a computer-generated random number table.

Arm 1 (Intervention) Cognitive Control Training:
18 sessions (twp per week) training executive control processes - working memory, response inhibition and mental flexibility keeping an affective framework to suit patients with depression and decrease rumination and improve metacognition.

Arm 2 (Control) Behavioural Activation:
18 sessions (two per week) behaviour activation adapted from Jacobson (2001) and suggestions by Veale et al (2007).

Post-intervention CGI (Clinical Global Index) was done by an expert blind rater.

Intervention Type
Behavioural

Primary outcome(s)
Depression measured using Beck's Depression Inventory (BDI) at baseline and 9 weeks

Key secondary outcome(s))
1. Illness severity measured using the Clinical Global Index (CGI) at baseline and 9 weeks
2. Neuro-cognitive measures at baseline and 9 weeks:

2.1. Spatial Span
2.2. Digit Span (WMS III)

Completion date
15/10/2019

Eligibility

Key inclusion criteria
1. Major Depressive Disorder (as primary diagnosis)
2. Score of 17 or above on Beck's Depression Inventory (BDI)
3. Age range of 18-50 years
4. Comprehension of written and spoken English/Hindi
5. Right handedness
6. Normal or corrected vision or hearing
7. Stable on medication dosage for one month

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. History suggestive of neurological, neurosurgical conditions and /or history of head injury And /or mental retardation on clinical assessment
2. Diagnosis of schizophrenia, Bipolar Affective Disorder, Severe Depression with psychotic symptoms, Delusional disorder, current psychoactive substance abuse and/or dependence (except nicotine)
3. Any structured psychological intervention in the past 6 months
4. Any neurocognitive intervention and/or neuropsychological assessments
5. Have received ECT (in last 6 months)

Date of first enrolment
01/10/2017

Date of final enrolment
10/09/2019

Locations

Countries of recruitment
United Kingdom

India

Study participating centre
National Institute of Mental Health and Neuroscience (NIMHANS)
Hosur Road
Hombegowda Nagar
Bangalore
Karnataka
India
560029

Study participating centre
National Institute of Mental Health and Neurosciences Centre for Well-Being
9th Main Road
Stage, BTM Layout 1
Bengaluru
Karnataka
United Kingdom
560076

Sponsor information

Organisation
National Institute for Mental Health and Neuroscience (NIMHANS)

ROR
https://ror.org/0405n5e57

Funder(s)

Funder type
Government

Funder Name
National Institute of Mental Health and Neuroscience

Results and Publications

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