

Cognitive control training for depression

Submission date 11/09/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/09/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/10/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?
Meenakshi Banerjee
meenakshi.banerjee@gmail.com

Contact information

Type(s)
Public

Contact name
Ms Meenakshi Banerjee

ORCID ID
<http://orcid.org/0000-0001-9883-9004>

Contact details
225 Cauvery Hostel
NIMHANS
Hosur Road
Bangalore
India
560029
+91 (0)8197292827
meenakshi.banerjee@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

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

Acronym

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 receive 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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Major depressive disorder

Interventions

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

Arm 1 (Intervention) Cognitive Control Training:

18 sessions (two 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 measure

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

Secondary outcome measures

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)

Overall study start date

01/10/2017

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

60

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**

India

United Kingdom

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)

Sponsor details

Hosur Road
Hombegowda Nagar
Bangalore
India
560029
+91 (0)8026995000
ms@nimhans.ac.in

Sponsor type

Government

Website

<http://www.nimhans.ac.in>

ROR

<https://ror.org/0405n5e57>

Funder(s)**Funder type**

Government

Funder Name

National Institute of Mental Health and Neuroscience

Results and Publications**Publication and dissemination plan**

Publication 1: Letter to author/correspondence regarding usefulness of affective material for Cognitive Control Training for Depression
Publication 2: Literature review of CCT in Depression
Publication 3: Methodology
Publication 4: Final paper with results of the trial

Intention to publish date

30/12/2019

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