ISRCTN18339113 https://doi.org/10.1186/ISRCTN18339113

Comparing two psychological treatments for the management of primarily obsessional OCD

Submission date
18/09/2019

Recruitment status
No longer recruiting

Registration date
24/10/2019

Overall study status
Completed

Last Edited
08/11/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Obsessive-compulsive disorder (OCD) is where a person has certain thoughts repeatedly or feels that they have to perform certain actions repeatedly. Primarily obsessional OCD involves mostly obsessive thoughts rather than actions. Cognitive Behavioral Therapy (CBT) is a talking therapy that aims to challenge and change unhelpful thoughts and behaviors. CBT is the primary psychological treatment available for primarily obsessional OCD; however, patients often refuse or drop out from the treatment due to anxiety. Also CBT is not effective in many patients with primarily obsessional OCD, because there are few repetitive behaviors that can be targeted. Therefore, there is a need to test other available psychological treatments for these people. Mindfulness Integrated Cognitive Therapy (MICT) is a new type of CBT that includes the development of mindfulness skills. Mindfulness is an approach that encourages people to experience their emotions in the present without judgement. The benefits and positive impacts of MICT have already proven in different mental skills. MICT has shown some benefits in the treatment of various mental illnesses. This study aims to compare MICT and CBT in the treatment of primarily obsessional OCD.

Who can participate?
Adults aged 18-55 years with primarily obsessional OCD

What does the study involve?
The participants will be randomly allocated to receive CBT or MICT. Both grooups will receive 10-14 90-minute sessions of therapy over 6-8 weeks. They may be expected to do 'homework'.

What are the possible benefits and risks of participating?
There is no risk associated with participation. The benefit of participating in the study is that the patients are treated with evidence-based psychological treatments shown to be effective for the treatment of OCD free of charge.

Where is the study run from?
National Institute of Mental Health and Neurosciences (India)

When is the study starting and how long is it expected to run for?
July 2016 to November 2019

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
n/a

Study information

Scientific Title
Efficacy of Mindfulness Integrated Cognitive Therapy (MICT) in comparison with cognitive behavioral therapy (CBT) in patients with Predominantly Obsessions (MICT-PO): A randomized controlled trial

Acronym

MICT-PO

Study objectives
1. There will be no difference between MICT and CBT group with regard to reduction of symptom severity
2. There will be no difference between baseline, post-intervention and 3-months follow-up outcome measures in both MICT and CBT group separately

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2017, National Institute of Mental Health and Neuro Sciences (NIMHANS) Institutional Ethics Committee (Post Box 2900, Hosur Rd, Bengaluru, 560 209, Karnataka, India; +91 80 26995004; chatur@nimhans.ac.in), ref: NO.NIMH/DO/IEC(BEH. SC. DIV)/2016

Study design
Prospective interventional single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files.

Health condition(s) or problem(s) studied
Obsessive Compulsive Disorder (OCD) - Predominantly Obsessive type

Interventions
70 patients with a diagnosis of predominantly obsessional OCD were recruited from inpatient or outpatient departments of NIMHANS. They were randomly allocated into two groups – Mindfulness Integrated Cognitive Therapy (MICT) (n = 35) or Cognitive Behavior therapy (CBT) group (n = 35), based on a computer-generated random table. Seventy chits were prepared and the respective group's name was written in each chit. For each patient, the respective number chit was opened by the therapist after recruitment and baseline assessments were completed.

A two-group randomized controlled design with baseline, post-therapy and 3-month follow-up assessment was adopted. A sample size of n = 70 (35 in MICT and 35 in CBT group) was considered adequate to attain a two tailed significance of ≤ 0.05 with 80% power to detect about 30% difference in response rate based on Yale–Brown Obsessive Compulsive Scale (Y-BOCS) change between the groups.

After the recruitment, informed consent forms were obtained from each patient. Then detailed intake and baseline assessments were administered. The blind rater administered Y-BOCS and Clinical Global Impression (CGI) scale which were primary outcome measures. Thereafter, patients were randomly assigned to either MICT (n =35) or CBT group (n = 35). Patients were delivered 10 to 14 sessions of respective therapies (either MICT or CBT) following structured modules, which were spread over 6 to 8 weeks, and the duration of each session was 90 min.

MICT modules:
- Session 1 – Psychoeducation
• Assessing patient's knowledge about OCD and appraisal of intrusive thoughts
• Discussion on nature of obsessions, when an intrusive thoughts become clinically significant, using unhelpful strategies and their counterproductive result, significance given to intrusions etc.
• Psychoeducating from mindfulness perspectives using metaphors, analogies (normalizing the intrusive thoughts using analogy of cold, reducing significance using analogy of unwanted guest, example of beggar is used to show how to ignore unwanted intrusive thoughts etc)
• Discussion on developing bodily awareness and the concept of informal awareness (mindfulness) on daily functioning
- Sessions 2 and 3 – Concept of mindfulness and the ways one stays trapped in the OCD cycle
• Discussion on pre-metacognitive attitudes (evaluation, judgement etc) that maintain or overactivate obsessive compulsive phenomena and helping the patient to identify where and how he is trapped using model.
• Discussion on concepts of mindfulness – present moment awareness, passive observation, nonjudgmental acceptance, experiential avoidance and psychological contact.
• Practicing formal mindfulness meditation.
• Informal mindfulness practice
- Session 4 – Cognitive distortion
• Discussion on cognitive distortions and educating how to recognize when they occur
• Formal and informal mindfulness
- Session 5 – Deeper understanding of mindfulness
• Using four point strategies to deal with obsession
• Discussion on deeper concepts of mindfulness and how they are related with OCD phenomena with examples and analogies
• Formal and informal mindfulness
- Session 6 – Learning different ways to respond to obsessions
• Educating the patient about positive side of tolerating mild to moderate anxiety and encouraging not performing any neutralizing behavior, rather observing the thoughts and anxiety as passing mental events.
• Preparing for psychological contacting exercise
• Formal and informal mindfulness
- Session 7 – Retraining attention
• Discussion on focus and background in regard to attention
• Educating the patient how to keep unnecessary thoughts in the background and focus on present activity using analogies
• Attentional skill task to improve sustaining and switching attention
• Psychological contacting exercise
• Formal and informal mindfulness practice
- Session 8 – Validating own present experience
• Educating the patient to experience their own present moment real experience and not to rely on experiences due to obsessions, with examples
• Psychological contacting exercise
• Formal and informal mindfulness

- Session 9 – Responding to anxiety in different way
• Discussion on impermanence, detachment, acceptance of anxiety as another emotion
• Psychological contacting exercise
• Formal and informal mindfulness
- Session 10 – Distancing further from thoughts and emotions
• Patient is encouraged to separate the self from the passing mental phenomena like thoughts and feelings as well as bodily sensations. These are temporary while the patient, as a person, remains unchanged regardless of what comes in the conscious mind.
• Psychological contacting exercise
• Practicing mindfulness breathing exercise, formal and informal mindfulness
- Sessions 11 to 14 - Relapse prevention and revision of previous sessions

CBT modules:
- Session 1 – Psychoeducation
• Assessing patient's knowledge about OCD and his appraisal of intrusive thoughts
• Educating the patient from cognitive behavioral perspective
• Discussion on importance given on intrusive thoughts
• Discussion on how neutralizing behaviors (both overt and covert) maintain the illness using CBT model
- Session 2 – Preparing for exposure response prevention (ERP)
• Presenting ERP model to educate that distress or anxiety comes down by itself after some time
• Preparing for ERP
• Initiation of developing hierarchy or appropriate stimulus list for exposure
- Session 3 – Cognitive Distortions
• Discussion on cognitive distortions including fusion thoughts and how to identify and restructure or correct them.
• Thought diary maintained by the patient and monitored by the therapist
- Sessions 4 to 10 – ERP and cognitive restructuring
• Final preparation of list of stimuli for exposure, audio tape recording, developing hierarchy where needed.
• ERP
• Cognitive restructuring
- Sessions 11 to 14 sessions – Relapse prevention and revision of previous sessions

Each session of both MICT and CBT arms starts with discussion about previous homework and sessions and ends with summarization of current session and homework assignments.

Intervention Type
Behavioural

Primary outcome measure
1. Severity, avoidance and insight of obsessive compulsive symptoms assessed using the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) at baseline, post-intervention and 3 months follow-up
2. Severity of overall illness assessed using the Clinical Global Impression Scale (CGI) at baseline, post-intervention and 3 months follow-up

Secondary outcome measures
1. Depression, anxiety and stress assessed using the Depression Anxiety Stress Scale (DASS-21) at baseline, post-intervention and 3 months follow-up
2. Dysfunctional beliefs assessed using the Obsessive Belief Questionnaire (OBQ-21) at baseline,

post-intervention and 3 months follow-up
3. Mindfulness skills assessed using the Five facet Mindfulness Questionnaire (FFMQ) at baseline, post-intervention and 3 months follow-up
4. Experiential avoidance assessed using the Acceptance and Action Questionnaire (AAQ-II) at baseline, post-intervention and 3 months follow-up
5. Overall quality of life assessed using the World Health Organization Quality of Life (WHOQOL-BREF) questionnaire at baseline, post-intervention and 3 months follow-up
6. Social and functional impairment assessed using the Work and Social Adjustment Scale (WSAS) at baseline, post-intervention and 3 months follow-up
7. Degree and quality of homework assessed using the Homework Compliance Scale at post intervention and 3-months follow-up

Overall study start date
10/07/2016

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Patients with a primary diagnosis of OCD - predominantly obsessions as per DSM 5 criteria
2. Few or no overt compulsions
3. Y-BOCS score at baseline 10 or more
4. CGI – severity criteria – moderately ill
5. Aged between 18 and 55 years
6. Minimum education of class X
7. Patients fluent in Bengali, English or Hindi with ability to comprehend English text in assessment tools
8. Patients who are either drug-naïve, drug-free or stabilized on medication for 2 months prior to the entry to the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Motor compulsions which cause significant distress or significantly interferes with daily functioning

2. History of head injury, neurological illness or history suggestive of organicity
3. Primary diagnosis of schizophrenia and any other psychosis, current psychoactive substance dependence except nicotine dependence, or mental retardation
4. Patients who had received any adequate trial of cognitive behavior therapy or any other structured psychotherapy in the previous year

Date of first enrolment
10/06/2017

Date of final enrolment
05/07/2019

Locations

Countries of recruitment
India

Study participating centre
National Institute of Mental Health and Neurosciences (NIMHANS)
Hosur Road
Bangalore
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Sponsor information

Organisation
National Institute of Mental Health and Neurosciences

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Sponsor type
Research organisation

ROR
https://ror.org/0405n5e57

Funder(s)

Funder type
University/education

Funder Name
National Institute of Mental Health and Neurosciences

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available for the purpose of confidentiality. Patients were informed (in the Informed Consent Form) that their data would not be shared under any circumstances.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			08/11/2019	No	Yes