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# A comparison to two types of group behaviour therapy for obsessive compulsive disorder: A pilot randomised controlled trial of behaviour therapy and mindfulness-based behaviour therapy for OCD

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 30/01/2014 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/01/2014 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 11/01/2019 | Mental and Behavioural Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
15996

# Study information

### Scientific Title
A comparison to two types of group behaviour therapy for obsessive compulsive disorder: A pilot randomised controlled trial of behaviour therapy and mindfulness-based behaviour therapy for OCD

### Acronym
Mindfulness-based behaviour therapy for OCD: a pilot RCT

### Study objectives
Obsessive compulsive disorder (OCD) affects up to one million adults in the UK (NICE, 2005). People diagnosed with OCD experience unwanted obsessive thoughts and engage in compulsive behaviours. Exposure and response prevention (ERP) is a behaviour therapy and it is the psychological therapy with the strongest evidence for effectiveness. However, only 60% of people benefit from ERP. Many people do not find ERP acceptable, with about 25% of people starting ERP dropping out.

Mindfulness-based interventions (MBIs) teach people to notice unpleasant thoughts and feelings without reacting unhelpfully. Although effective for depression, psychosis and a range of anxiety disorders, there is very little research on the effectiveness of MBIs for OCD, although the research that is published shows promise.

We conducted a focus group with six people diagnosed with OCD and who had experience of ERP and MBI. We had intended to compare MBI to ERP, however participants advised us to combine ERP with MBI. They suggested that effectiveness might be based by combining the two together. We have followed their advice in this study.

We intend to compare standard ERP group behaviour therapy (BT) to mindfulness-based ERP group behaviour therapy (MBBT) to see if mindfulness practice improves ERP outcomes and reduces drop-out. Before we can answer this question in a fully-sized trial we first need to conduct a pilot study. This pilot study is a small version of the fully-sized trial. It will tell us: (a) the approximate difference in outcome between BT and MBBT, (b) how easily we can recruit to the study, and (c) how many people drop out. This information will allow us to know how many participants we need for the full trial, how long recruitment will take and how to reduce drop-out rates. Once we have this information we will apply for funding for the full trial.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
13/LO/1768

### Study design
Randomised; Interventional; Design type: Treatment

### Primary study design

Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Personality disorder; Disease: Personality disorders

## Interventions
Behaviour Therapy: A 10 session exposure and response prevention for OCD group intervention (maximum 10 participants per group). Each session will run for two hours.
Mindfulness Behaviour Therapy: A 10 session mindfulness-enhanced exposure and response prevention for OCD group intervention (maximum 10 participants per group). Each session will run for two hours. Mindfulness practice and discussion will be added to the standard ERP protocol.
Follow Up Length: 6 month(s); Study Entry : Registration only

## Intervention Type
Behavioural

## Primary outcome measure
Yale-Brown Obsessive Compulsive Scale - Second Edition (Y-BOCS-II; Goodman et al, 2006).; Timepoint(s): Baseline, post-therapy (10 weeks post-baseline) and 6-months post-therapy

## Secondary outcome measures
1. Beck Depression Inventory - second edition (BDI-II; Beck et al, 1996)
2. Change Interview (Elliott et al, 2001).; Timepoint(s): Post-therapy only
3. Five-Facet Mindfulness Questionnaire - Short Form (FFMQ-SF; Bohlmeijer et al, 2011)
4. Mini Neuropsychiatric Interview 6.0.0; Timepoint(s): Baseline, post-intervention and six months post-therapy
5. Obsessional Beliefs Questionnaire - Revised - OBQ-44; Timepoint(s): Baseline, post-therapy and six months post-therapy
6. Short Warwick-Edinburgh Mental Well-Being Scale (2007); Timepoint(s): Baseline, post-therapy and 6-months post-therapy
7. Therapy attrition; Timepoint(s): Percentage of participants who complete their intervention will be recorded as a primary outcome

## Overall study start date
01/02/2014

### Completion date
31/12/2014

# Eligibility

### Key inclusion criteria
1. Meet diagnostic criteria for OCD (MINI 6.0.0 interview)
2. Have been stable on psychiatric medication for at least three months prior to the consent meeting, or not taking psychiatric medication for at least three months prior to the consent meeting
3. Have no plans for changes to psychiatric medication during the course of the study
4. Have not received psychological therapy in the past three months or to have any plans for psychological therapy during the course of the study
5. Be aged over 18 years of age

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

### Key exclusion criteria
Exclusion criteria will be that participants will not have an identified organic cause for their OCD symptoms or a diagnosed learning disability. This will be ascertained through the care team. People will be excluded if they meet diagnostic criteria, based on the MINI interview, for; post-traumatic stress disorder, anorexia nervosa, an autistic spectrum disorder or a psychotic disorder.

To reflect the reality of mental health services and the co-morbidity of OCD with other anxiety disorders and with depressive disorders (NICE, 2005), co-morbidity with these conditions will not be an exclusion criterion. The exception to this is that people meeting diagnostic criteria for PTSD will be excluded given some concerns in the MBI literature about the offering MBIs to this population. People presenting with hoarding only compulsions will be excluded from the study, given the recent move to classify hoarding as a distinct condition from OCD (Pertusa et al, 2008).

### Date of first enrolment
01/02/2014

### Date of final enrolment
31/12/2014

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Surrey**
Guildford
United Kingdom
GU2 7XH

## Sponsor information

### Organisation
Sussex Partnership NHS Foundation Trust (UK)

### Sponsor details
Sussex Education Centre
Nevill View Hospital
Hove
England
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BN3 7HZ

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/05fmrjg27

## Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research: Research for Patient Benefit (RfPB)

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 16/04/2015 | | Yes | No |
| Results article | results | 01/06/2018 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |