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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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust (UK)

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

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?
Results article	results	01/06/2018		Yes	No
Protocol article	protocol	16/04/2015		Yes	No
HRA research summary			28/06/2023	No	No