ISRCTN73535163 https://doi.org/10.1186/ISRCTN73535163

Obsessive Compulsive Treatment Efficacy Trial (OCTET)

Submission date	Recruitment status	[X] Prospectively registered
05/04/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Obsessive compulsive disorder (OCD) is a common problem which affects many people and rarely improves without help. Experts recommend that people with OCD receive a 'talking treatment' called cognitive behavioural therapy (CBT). However, waiting lists for this treatment can be very long. Experts also suggest that some patients might benefit from CBT provided as 'self-help' through a book or computer, with assistance from a mental health professional. The aim of this study is to find out whether the new treatments (computerised CBT and guided self-help) work well for people with OCD, and if people like the treatments.

Who can participate?
Adults aged 18 and above with OCD on a waiting list for therapist-led CBT

What does the study involve?
Two different self-help treatments for OCD are tested by comparing them with patients on a waiting list for scheduled individual CBT. People who are happy to take part are asked a series of questions relating to their health. They are then randomly allocated to one of the following three treatments:
1. Computerised CBT using an online computer system called OCFighter, with help from a mental health professional, usually by phone, but can be face-to-face
2. Guided self-help, using a book which helps people use CBT, with help from a mental health professional either face-to-face or by phone
3. Waiting list for scheduled individual CBT (the currently recommended treatment route for OCD)
Both self-help treatments are delivered over a 12-week period. Taking part in the study does not mean that participants cannot have individual CBT later. Participants can stay on the waiting list for CBT whatever happens in the study. Participants are asked a further set of questions to see how they are feeling at 3, 6 and 12 months after the start of the study. The study takes 4 years to complete, but participants are only involved for 12 months. Some participants are asked for permission to conduct a separate interview to discuss how they found their treatment, and whether it has helped them. Only about 1 in 10 participants are asked; participants can take part in the study without agreeing to this interview.

What are the possible benefits and risks of participating?
Computerised CBT and guided self-help are quite new treatments for OCD. At the moment it is not known how well they work. It may be that people do not find these treatments helpful. People can choose to stop using them at any point during the study without having to give a reason why. There are no known side effects of either treatment. Waiting list times for scheduled individual CBT vary from area to area. If the waiting list in a local area is less than 12 weeks people may have to wait slightly longer for their scheduled CBT appointment. People still have the opportunity to receive individual CBT after taking part in the study.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
September 2011 to August 2015

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. Karina Lovell
Karina.Lovell@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Karina Lovell

Contact details
University of Manchester
School of Nursing, Midwifery & Social Work
Room 6.322A
Jean McFarlane Building
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 306 7853
Karina.Lovell@manchester.ac.uk

Additional identifiers

Protocol serial number
HTA 09/81/01

Study information

Scientific Title

Obsessive Compulsive Treatment Efficacy Trial (OCTET)

Acronym
OCTET

Study objectives
1. Identify and confirm estimated recruitment rates for an obsessive compulsive disorder (OCD) treatment trial via an internal pilot phase aimed at evaluating recruitment rates and primary outcome point
2. Proceed seamlessly to a full RCT (if recruitment is successful in the pilot phase) to determine:
2.1. The clinical and cost-effectiveness of two self-managed CBT interventions (cCBT and bibliotherapy) compared to a CBT waiting list in the management of OCD patients in the short term at 3- and 6-month follow-up
2.2. The clinical and cost-effectiveness of self-managed therapies plus conventional CBT compared to waiting list plus conventional CBT at 12-month follow-up
3. Determine patient compliance and patient and health professional acceptability of the two self-managed therapy packages (cCBT & GSH)

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster; 24/05/2011, ref: 11/NW/0276

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive compulsive disorder

Interventions
1. Computer-aided cognitive based therapy (cCBT) package (OC Fighter) over 12 weeks
2. Supported by six, 10-minute brief scheduled telephone calls, face to face or email contact (depending on patient preference) from a mental health professional (total direct clinical input 60 minutes)
3. Bibliotherapy (Guided Self-Help) will consist of a self-help book 'Overcoming OCD: a workbook' written by Karina Lovell
4. Participants will receive weekly guidance from a mental health professional for an initial session of 60 minutes (either face to face or telephone dependent on patient preference)
5. This is followed by up to 10 brief (30 minute) scheduled telephone, email or face to face (dependent on patient preference) sessions over a 12-week period (total direct clinical input: 6 hours).
6. Comparator - patients on a waiting list for CBT

Updated 17/09/2014: Recruitment is now complete.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Yale-Brown Obsessive Compulsive Scale (Y BOCS) checklist

Key secondary outcome(s)
1. Self-reported health-related quality of life (SF-36)
2. Self-reported OCD symptoms (YBOCs self-rated)
3. Generic mental health (CORE-OM)
4. Depression (PHQ9)
5. Anxiety (GAD-7)
6. Functioning (WSA)
7. Health-related quality of life (EQ5D)
8. Employment status (IAPT Employment Status questions A13 A15)
9. Patient satisfaction (CSQ) and acceptability (qualitative interviews)
10. Percentage of patients not improved or partially improved requiring more intensive CBT

Added 17/09/2014:
11. Adult Service Use Schedule (AD-SUS) self complete and interview

Completion date
31/08/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/09/2014:
1. Adults aged 18 and above meeting Diagnostic and Statistical Manual of Mental Disorders (DSM) IV criteria for obsessive compulsive disorder (assessed using six OCD questions from the Mini-International Neuropsychiatric Interview [M.I.N.I.])
2. Scoring 16 or over on the Yale Brown Obsessive Compulsive Checklist (YBOCS)
3. On a waiting list for therapist-led cognitive behavioral therapy (CBT) in either primary or secondary mental health care settings
4. Able to read English at a level of 11 years and above

Previous inclusion criteria:
1. Adults aged 18 and above meeting Diagnostic and Statistical Manual of Mental Disorders (DSM) IV criteria for obsessive compulsive disorder (assessed using the Structured Clinical Interview for DSM-IV [SCID-IV])
2. Scoring 16 or over on the Yale Brown Obsessive Compulsive Checklist (YBOCS)
3. On a waiting list for therapist-led cognitive behavioral therapy (CBT) in either primary or secondary mental health care settings
4. Able to read English at a level of 11 years and above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
475

Key exclusion criteria
Current exclusion criteria as of 17/09/2014:
1. Participants who are actively suicidal
2. Patients with organic brain disease
3. Those who are experiencing psychosis
4. Those who have a diagnosis (DSM IV) criteria of drug or alcohol misuse
5. Patients who are currently receiving a psychological treatment for OCD
6. Those who have literacy or language difficulties to an extent which would preclude them from reading written or web-based materials or conversing with a health professional

Previous exclusion criteria:
1. Participants who are actively suicidal
2. Patients with organic brain disease
3. Those who are experiencing psychosis
4. Those who have a diagnosis (DSM IV) criteria of drug or alcohol misuse
5. Patients who are currently receiving a psychological treatment for OCD
6. Patients who have received CBT for OCD in the last 6 months
7. Those who have literacy or language difficulties to an extent which would preclude them from reading written or web-based materials or conversing with a health professional
8. Patients who have been prescribed or changed to an alternative anti-depressant in the 12 weeks prior to assessment will be excluded. These patients will be offered a further assessment following 12 weeks of stable medication if there are no plans to increase the medication

Date of first enrolment
01/02/2012

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research organisation

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/06/2017		Yes	No
Results article	Clinical effectiveness, cost-effectiveness and acceptability	01/06/2017	24/01/2023	Yes	No
Protocol article	protocol	10/07/2014		Yes	No