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A randomised controlled feasibility trial comparing clinical and cost effectiveness of cognitive behavioural therapy (CBT) and selective serotonin reuptake inhibitors (SSRI) and their combination in the management of obsessive compulsive disorder.

Submission date
08/08/2014

Recruitment status
No longer recruiting

Registration date
08/08/2014

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Obsessive Compulsive Disorder (OCD) is a common and highly disabling psychiatric illness. People with OCD often suffer a lot of stress and anxiety because of their condition which affects their quality of life. We are carrying out a study of 60 patients looking at three different treatments for OCD. We are looking at how people with OCD are referred for treatment, how many complete treatment and the differences between the outcomes of the treatments. Our goal is to see whether it is possible to run such a study so that we can then run a much larger study which will tell us which treatment is best to help people with OCD.

Who can participate?
Patients with OCD, aged 18-65.

What does the study involve?
Patients who agree to enter the study are given one of three treatments: either an approved medication called sertraline, a talking therapy (cognitive behavioural therapy with exposure response prevention [CBT with ERP]), or both the medication and the talking therapy together. Patients cannot choose which treatment they receive as it is randomly decided by a computer program. The treatment lasts for up to one year. Patients who are given sertraline are asked to take the medication once a day for up to 52 weeks. They see a psychiatrist at 2, 4, 8, 16, 24, 32 and 52 weeks after starting the treatment. Patients who have the talking therapy see a psychologist for a total of 16 hours over 8 weeks and for 4 follow-up sessions over the rest of the 52 weeks. The psychologist tries to teach them different ways of thinking to help them overcome the anxiety and fears that they feel. All patients are assessed and asked to complete some questionnaires about how they are feeling after 2, 4, 8, 16, 24, 32 and 52 weeks of

treatment. Patients receiving both the medication and talking therapy see both the psychiatrist and the psychologist for their treatment in the same way patients on the medication or talking therapy do.

What are the possible benefits and risks of participating?
Patients who take part in the study have a chance to receive either treatment with medication called sertraline or psychological therapy with a specialised therapist or treatment with a combination of both, which may help to treat their OCD. They will also have extra assessments by a psychiatrist or a psychologist or both for up to one year. The information we get from this study will help to set up a larger study which should give information to improve the treatment of OCD. Patients will be asked about how they are feeling when they complete the questionnaires and this may be a bit upsetting for them. However, patients do not have to complete any questions they do not want to. The talking therapy, CBT with ERP, tries to get patients to confront the problem they have and also to stop carrying out their obsessions. This may cause distress and anxiety but has been shown to be very effective in treating OCD.

Where is the study run from?
1. Hertfordshire Partnership University NHS Foundation Trust
2. Southwest London and St Georges Mental Health NHS Trust
3. Southern Health NHS Foundation Trust

When is the study starting and how long is it expected to run for?
July 2014 to July 2017.

Who is funding the study?
NIHR Research for Patient Benefit (RfPB) (UK).

Who is the main contact?
Ms Solange Wyatt
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17026

Study information

Scientific Title
A randomised controlled feasibility trial comparing clinical and cost effectiveness of cognitive behavioural therapy (CBT) and selective serotonin reuptake inhibitors (SSRI) and their combination in the management of obsessive compulsive disorder.

Acronym
OTO

Study objectives
Obsessive Compulsive Disorder (OCD) is a major mental illness, ranked as a leading cause of disability and a health-research priority. OCD seriously affects quality of life. Most patients develop secondary disorders, such as depression and anxiety.

Current treatment guidelines for OCD recommend either psychological (cognitive-behavioural) therapy (CBT) or medication first-line and only severe cases are treated with a combination of the two. While it is assumed that the combination of CBT and medication would be more effective than either given alone, the evidence to support this is weak.

The National Institute for Health and Clinical Excellence (NICE CG31; www.NICE.org.uk) recommends the best methods to manage and treat diseases. Their guidance on OCD proposes that a large clinical trial is needed to investigate whether the combination of CBT and medication is more effective than either CBT alone or medication alone.

Large randomised controlled trials are the best method for investigating the effectiveness of different therapies. However, given the large numbers of people and the resources involved, they are costly, time-consuming and require careful planning. As the existing evidence is unclear and we are unable to determine from it to what
extent each of these treatments is likely to be successful, it is recommended that a small version of the trial ('feasibility study') is conducted in advance of the substantive trial. This allows the research-team to calculate more precisely the required number of patients and identify any operational problems early on, so they can be addressed in advance of the full trial.

We are therefore conducting a small-scale trial to investigate whether the design of the study is appropriate. The findings may be used to develop a larger, future study to investigate whether CBT and medication in combination is more effective than either therapy alone in the treatment of adults with OCD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/EE/0431

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

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

Interventions
CBT with ERP, 16hrs over 8 weeks; Sertraline, dose 50-200mg aiming for 200mg; Sertraline + CBT with ERP, Sertraline 50-200mg with CBT with ERP 16 hours over 8 weeks; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Variation in Y-BOCS within and between treatment arms; Timepoint(s): Screening, baseline, weeks 2,4,8,16,24,32 and 52.

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/07/2014

Completion date
07/07/2017

Eligibility

Key inclusion criteria
1. Community based service-users, aged 18-65 years.
2. DSM-IV OCD, determined by a psychiatrist using the MINI for DSM-IV

3. Duration of symptoms >1 year (from medical history)
4. Baseline score >16 on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
49

Key exclusion criteria
1. History of psychotic disorder (schizophrenia, psychotic symptoms, bipolar disorder), Tourette syndrome(tic disorders not amounting to Tourette syndrome will not be exclusionary), organic mental disorder, psychosurgery, personality disorder of borderline or histrionic type.
2. Alcohol/substance-abuse disorders within the past 12 months.
3. Any other DSM-IV Axis I disorder that is considered the primary focus of treatment
4) Severe depression, defined by a Montgomery-Asberg Depression Rating Scale (MADRS) >30 at baseline.
5. Actively planning suicide (scoring >4 on item 10 of MADRS)or judged by the clinician to be at significant risk of self-harm.
6. Attended CBT involving ERP from an accredited (British Association of Behavioural and Cognitive Psychotherapies (BABCP) approved or equivalent) therapist (eg. IAPTs stage 2) in the last 6 months.
7. Failed (inadequate clinical response, equivalent to <25% improvement) >=2 previous adequate (>12weeks) trials of CBT involving ERP from an accredited (BABCP-approved or equivalent) therapist.
8. Failed (inadequate clinical response,equivalent to <25% improvement) >=2 previous adequate (>12weeks) trials of any SSRI or clomipramine taken at optimal doses (if maximum SPC dose, evidence of intolerance of the higher dose is needed) with adequate adherence.
9. Needing regular psychotropic drugs other than study medication during the study (except hypnotics which will be allowed provided the dose has been stable for >12 weeks and remains so throughout the study period).
10. Currently involved in a treatment research study.
11. Acute or unstable physical illness including Hepatitis, HIV/AIDS, Creutzfeldt-Jakob disease
12. Needing regular specified medication known to interact adversely with sertraline.
13. Individual reasons making it difficult to comply with the treatment-programme, including the washout-period.

14. Inadequate understanding of English to participate in treatment or give informed consent.
15. Women of child-bearing age not using reliable contraception.
16. Pregnant or breast-feeding women. Women of child bearing potential will be asked to perform a urine pregnancy test at screening.
17. History of liver disease.
18. Epilepsy.
19. History of cardiovascular disease or blood disorders that increase bleeding tendency. Eg. Platelet disorder.

Date of first enrolment
19/07/2014

Date of final enrolment
17/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
Rosanne House
Welwyn Garden City
United Kingdom
AL8 6JE

Study participating centre
Southwest London and St Georges Mental Health NHS Trust
61 Glenburnie Road
London
United Kingdom
SW17 7DJ

Study participating centre
Southern Health NHS Foundation Trust
Mood Disorders Service
College Keep
4-12 Terminus Terrace
Southampton
United Kingdom
SO14 3DT

Sponsor information

Organisation
Hertfordshire Partnership University NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.hpft.nhs.uk/

ROR
https://ror.org/0128dmh12

Organisation
University of Hertfordshire (UK)

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Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme; Grant Codes: PB-PG-0712-28044

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to publish the protocol in Trials. The results will be submitted for publication in the British Journal of Psychiatry and the British Journal of Clinical Psychology.

Intention to publish date

Individual participant data (IPD) sharing plan
The data will be shared with any applicant(s) who requests the data for a reasonable purpose related to evaluating a valid health-related question for this patient population, or a more widely defined patient population. The applicant(s) are requested to email a request to uhclinicaltrialsupportnetwork@herts.ac.uk outlining the organisation they are representing, the research question, the purpose of the analysis, and what they intend to do with the results of the analysis. The intention is to make the data as widely available as possible, and all requests will be judged on that basis, while taking account of relevant GDPR (or subsequent) regulation. A data-sharing agreement may be required. The data will be provided in tab-delimited format. Full consent has been obtained from participants and all data is anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018	27/08/2020	Yes	No
HRA research summary			28/06/2023	No	No