Clinical effectiveness, cost-effectiveness and acceptability of low-intensity interventions in the management of obsessive–compulsive disorder: the Obsessive–Compulsive Treatment Efficacy randomised controlled Trial (OCTET)

Karina Lovell,[1]* Peter Bower,[2] Judith Gellatly,[1] Sarah Byford,[3] Penny Bee,[1] Dean McMillan,[4] Catherine Arundel,[5] Simon Gilbody,[4] Lina Gega,[6] Gillian Hardy,[7] Shirley Reynolds,[8] Michael Barkham,[7] Patricia Mottram,[9] Nicola Lidbetter,[10] Rebecca Pedley,[1] Jo Molle,[11] Emily Peckham,[5] Jasmin Knopp-Hoffer,[2] Owen Price,[1] Janice Connell,[12] Margaret Heslin,[3] Christopher Foley,[13] Faye Plummer[5] and Christopher Roberts[13]

[1]Division of Nursing, Midwifery and Social Work, University of Manchester, Manchester, UK
[2]Centre for Primary Care, University of Manchester, Manchester, UK
[3]King's Health Economics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[4]Hull York Medical School and Department of Health Sciences, University of York, York, UK
[5]Department of Health Sciences, University of York, York, UK
[6]Social Work and Communities, Northumbria University, Newcastle, UK
[7]Department of Psychology, University of Sheffield, Sheffield, UK
[8]School of Psychology, University of Reading, Reading, UK
[9]Cheshire & Wirral Partnership, NHS Foundation Trust, Wallasey, UK
[10]Anxiety UK, Manchester, UK
[11]Norwich Medical School, University of East Anglia, Norwich, UK
[12]School of Health and Related Research, University of Sheffield, Sheffield, UK
[13]Centre for Biostatistics in the Institute of Population Health, University of Manchester, Manchester, UK

*Corresponding author karina.lovell@manchester.ac.uk

Declared competing interests of authors: Karina Lovell, Sarah Byford and Shirley Reynolds report grants from the National Institute for Health Research during the conduct of the study. Michael Barkham reports that he was the lead investigator in the development of the Clinical Outcomes in Routine Evaluation – Outcome Measure, which is used in the trial. Simon Gilbody reports previous membership of the Health Technology Assessment Clinical Trials Board.

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

Published June 2017
DOI: 10.3310/hta21370

Scientific summary

Low-intensity interventions in the management of OCD

Health Technology Assessment 2017; Vol. 21: No. 37
DOI: 10.3310/hta21370

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Obsessive–compulsive disorder (OCD) is characterised by intrusive, unwanted, recurrent and distressing thoughts, images or impulses (i.e. obsessions) and repetitive actions or rituals (compulsions), which serve to reduce the distress and anxiety evoked by the obsessions. OCD has an estimated lifetime prevalence of 2–3%. In the absence of adequate treatment, OCD will usually follow a chronic course and is associated with reduced quality of life and a substantial impairment of role.

The UK National Institute for Health and Care Excellence (NICE) guidelines make recommendations for the management of OCD using a stepped-care approach. Steps 3–6 recommend treatment options for people with OCD that range from low-intensity, guided self-help to more intensive psychological and pharmacological interventions. Cognitive–behavioural therapy (CBT), including exposure and response prevention, is the recommended psychological treatment.

Although high-intensity CBT is 'current best practice' according to NICE OCD clinical guidelines, access to such CBT can still involve significant delays. The requirement to visit a therapist for treatments is also poorly suited to the needs of some patients (e.g. patients who are housebound or in rural locations, patients with caring responsibilities or patients whose OCD makes it difficult for them to be with people).

There is clearly a potential role for low-intensity interventions as part of a stepped-care model. However, current evidence concerning low-intensity interventions, such as computerised cognitive–behavioural therapy (cCBT) or guided self-help, cannot provide accurate estimates of clinical effectiveness and cost-effectiveness. No studies have compared different low-intensity interventions, nor do we know the numbers of people who will not improve with low-intensity interventions and will require high-intensity CBT.

The core question for patients, clinicians and policy-makers is 'what is the role of low-intensity interventions for OCD in relation to usual care (i.e. referral to a waiting list for high-intensity CBT)?'. Implicit in the stepped-care model is the idea that giving patients on the waiting list access to low-intensity interventions prior to high-intensity CBT could potentially augment care by:

- improving patient outcomes either through more rapid improvement in clinical outcomes prior to high-intensity CBT or by augmenting the effect of high-intensity CBT in the longer term
- reducing costs either by reducing the number of patients who need to access high-intensity CBT or by reducing general health-care utilisation in the short and longer term.

Objectives

The Obsessive–Compulsive Treatment Efficacy randomised controlled Trial (OCTET) emerged from a research recommendation in the NICE OCD guidelines that specified the need to evaluate CBT treatment intensity formats among adults with OCD.

In response, the Health Technology Assessment programme commissioned research on low-intensity interventions for OCD, with specific reference to cCBT and guided self-help compared with a waiting list for high-intensity CBT.

Our aims were to determine:

- the clinical effectiveness and cost-effectiveness of two low-intensity CBT interventions (supported cCBT and guided self-help) compared with a waiting list for high-intensity CBT in adults with OCD at 3 months
- the clinical effectiveness and cost-effectiveness of two low-intensity interventions (supported cCBT and guided self-help) plus high-intensity CBT compared with a waiting list plus high-intensity CBT at 12 months
- the acceptability of the two low-intensity CBT interventions among patients and professionals.

Methods

Design

A multicentre, randomised controlled trial with economic and process evaluation. Participants were randomised to supported cCBT or guided self-help prior to high-intensity CBT, compared with a waiting list for high-intensity CBT. The primary outcome was OCD symptoms, as measured by Yale–Brown Obsessive Compulsive Scale – Observer Rated (Y-BOCS-OR) at 3, 6 and 12 months. Researchers collecting outcomes were blind to treatment allocation.

Setting

Improving Access to Psychological Therapies (IAPT), primary or secondary care mental health services in 15 NHS trusts.

Inclusion criteria

- Adults aged ≥ 18 years.
- On a waiting list for high-intensity CBT.
- Met *Diagnostic and Statistical Manual of Mental Disorders*-Fourth Edition (DSM-IV) criteria for OCD, assessed using six OCD questions from the Mini-International Neuropsychiatric Interview.
- Scored ≥ 16 on the Yale–Brown Obsessive Compulsive Scale – Self-Report.
- Reported an ability to read English at an age level of ≥ 11 years.

Exclusion criteria

- Actively suicidal.
- Organic brain disease.
- Current psychosis.
- A diagnosis of alcohol or substance dependence using DSM-IV criteria.
- Currently receiving psychological treatment for OCD.
- Literacy or language difficulties to an extent that would preclude participants from reading written or web-based materials, or conversing with a health professional.

Recruitment/participants

Participants were identified by psychological wellbeing practitioners (PWPs) or via screening waiting lists in IAPT, primary or secondary care mental health services. Eligible patients providing written informed consent were randomised through a central randomisation service provided by York Clinical Trials Unit, minimised by OCD severity, antidepressant medication, duration of OCD (0–5 years; 6–10 years; > 10 years) and depression severity.

Interventions

Participants were randomised to one of three arms:

1. Supported cCBT: OCFighter (www.ccbt.co.uk) is a commercial cCBT program for OCD. OCFighter consists of a nine-step CBT approach (focused on exposure and response prevention) to help people with OCD to design, carry out and monitor their treatment and progress. Participants randomised to OCFighter were given an access ID and password to log in to the system and advised to use the program at least six times over a 12-week period. Participants received six 10-minute brief scheduled telephone calls from a PWP.
2. Guided self-help consisted of a self-help book (focused on exposure and response prevention), *Overcoming OCD: A Workbook*, written by the trial team. Participants received weekly guidance from a PWP for one initial session of 60 minutes (either face to face or by telephone, depending on patient preference) followed by up to 10 30-minute sessions over a 12-week period.
3. The control group was a waiting list for high-intensity CBT.

Main outcome measures

The primary outcome was a measure of OCD symptoms, as measured using the Y-BOCS-OR. Secondary outcomes included quality of life, self-reported OCD symptoms, psychological well-being, depression, anxiety, functioning and satisfaction at 3, 6 and 12 months. Economic measures included health-related quality of life [using the European Quality of Life-5 Dimensions-3 levels to calculate quality-adjusted life-years (QALYs)] and resource use from the health- and social-care perspective and societal perspective (which additionally included productivity losses and out-of-pocket expenses and savings).

Results

Improving Access to Psychological Therapies services in 15 NHS trusts were recruited and 204 PWPs trained to deliver the interventions. Patients were recruited from 14 NHS trusts between February 2011 and May 2014. Follow-up data collection was complete by May 2015. A total of 475 patients were randomised, with 158 allocated to guided self-help, 158 to supported cCBT and 159 to the waiting list for high-intensity CBT. Two patients were excluded post randomisation (one supported cCBT and one waiting list for high-intensity CBT); therefore, data were analysed for 473 patients [supported cCBT ($n = 157$), guided self-help ($n = 158$) and waiting list for high-itensity CBT ($n = 158$)]. Retention was 81% at the 3-month follow-up, 75% at the 6-month follow-up and 71% at the 12-month follow-up. Of the 473 patients, 95% were white, 60% were female and the mean age was 33 years. Just over 50% reported previous professional help for OCD, around half were currently using antidepressant medication and 55% had suffered from OCD for $\geq$ 10 years. The mean baseline Y-BOCS-OR score was 25 (indicating severe OCD) and the mean Patient Health Questionnaire-9 score was 12 (indicating moderate depression). Low-intensity intervention uptake was reasonable: 66% accessed guided self-help and 61% supported cCBT, with the mean number of sessions 4.1 (guided self-help) and 2.3 (supported cCBT).

A significantly higher number of patients allocated to the waiting list for high-intensity CBT started CBT prior to the 3-month outcome assessment than those with supported cCBT and guided self-help.

In the short term, prior to accessing high-intensity CBT, guided self-help demonstrated statistically significant benefits over waiting list, but these benefits did not meet the prespecified criterion for clinical significance [adjusted mean difference –1.91, 95% confidence interval (CI) –3.27 to 0.55; $p = 0.006$]. In contrast, supported cCBT did not demonstrate any statistically or clinically significant benefit (adjusted mean difference –0.71, 95% CI –2.12 to 0.70).

Over a 12-month period, access to guided self-help and supported cCBT, prior to high-intensity CBT, did not lead to differences in outcomes compared with access to high-intensity CBT alone. Access to either of the low-intensity interventions does not augment the effect of high-intensity CBT in the longer term.

Early access to either of the low-intensity interventions led to significant reductions in the uptake of high-intensity CBT over the full 12 months of OCTET, with 86% of the patients allocated to a waiting list for high-intensity CBT starting CBT by the end of the trial, compared with 62% in the supported cCBT group and 57% in the guided self-help group. These reductions in high-intensity CBT utilisation do not seem to compromise patient outcomes at 12 months.

In economic analyses, guided self-help was more expensive to deliver than supported cCBT, although both are cheaper than a course of high-intensity CBT. Health- and social-care costs, and broader societal costs, including productivity losses and out-of-pocket expenditure and savings, were not significantly different between the three groups at either 3 or 12 months. Differences in European Quality of Life-5 Dimensions and associated QALY scores were minor in magnitude. There were no significant differences in QALYs.

Taking a decision-making approach, which focuses on which decision has a higher probability of being cost-effective, rather than the statistical significance of the results, there was little evidence that supported cCBT and guided self-help were more cost-effective at the 3-month follow-up than a waiting list. However, by the 12-month follow-up (primary end point), the data suggest that there was a greater probability of guided self-help being cost-effective compared with a waiting list from the health- and social-care perspective (60%) and the societal perspective (80%), and of cCBT being cost-effective compared with a waiting list from both perspectives (70%).

The data suggested some small differences in satisfaction at 3 months, with patients most satisfied with guided self-help and least satisfied with supported cCBT.

Qualitative studies explored the acceptability of both supported cCBT and guided self-help from the perspective of patients, and the feasibility and acceptability of delivering the interventions from the perspective of the PWPs. The results suggested that the provision of low-intensity psychological interventions may confer substantial benefits in terms of increasing the accessibility of psychological treatments for this population. Both guided self-help and supported cCBT increased service flexibility, overcame intervention access barriers and sustained, where desired, a sense of anonymity or privacy in care. Guided self-help attracted stronger support than supported cCBT, mainly because of technical difficulties of cCBT compounded by significance placed on interpersonal contact. PWPs were consistent in acknowledging the advantages of low-intensity interventions at a population level. Both guided self-help and supported cCBT were advocated to overcome long-standing barriers to the delivery of mental health care, improving accessibility via enhanced service flexibility and patient choice.

No adverse events occurred during the trial that were deemed to be suspected or unexpected serious events.

Conclusions

In designing OCTET, we hypothesised that providing patients on the waiting list access to low-intensity interventions prior to high intensity CBT could have two positive effects:

1. augmenting patient outcomes through either:

    i. more rapid improvement in clinical outcomes prior to high-intensity CBT or
    ii. augmenting the effect of high-intensity CBT in the longer term.

2. increasing efficiency of service delivery, either by reducing the numbers of patients who need to access high-intensity CBT or by reducing general health-care utilisation in the short and longer term, without compromising patient outcomes.

We found no evidence that low-intensity interventions led to clinically significant improvements in OCD symptoms compared with the waiting list, prior to high-intensity CBT.

We did not find evidence that low-intensity interventions augmented the effects of high-intensity CBT over the longer term.

In terms of service efficiency, both low-intensity interventions were also associated with a reduced uptake of high-intensity CBT. The lack of differences in clinical outcomes over 12 months suggests that, on average, provision of low-intensity interventions is potentially efficient and does not lead to poor outcomes.

Taking a decision-making approach, which focuses on which decision has a higher probability of being cost-effective, rather than the statistical significance of the results, economic evidence suggests that the provision of both low-intensity interventions could be cost-effective compared with the waiting list prior to high-intensity CBT at conventional levels of willingness-to-pay for QALYs, with a > 50% chance of being cost-effective compared with the waiting list for high-intensity CBT.

Implications for health care compared with the waiting list for high-intensity cognitive–behavioural therapy

- Despite the lack of clinically significant differences in outcomes, the economic analyses suggest an important role for low-intensity interventions in the care pathway for OCD. Following receipt of either low-intensity intervention, a proportion of patients do not progress to high-intensity CBT. There is no evidence that this leads to poorer outcomes in this group of patients and the overall health- and social-care costs associated with these patients are not different. Both low-intensity interventions appear cost-effective compared with high-intensity CBT.
- Providing low-intensity CBT as part of a care pathway may reduce pressure on high-intensity psychological therapy services, without any obvious disbenefit for patients.
- The two low-intensity interventions differ in the pattern of results. Guided self-help showed statistically significant reductions in OCD symptoms, and patients were more satisfied than those receiving supported cCBT in the short term. However, supported cCBT may be more cost-effective. From a service perspective, focusing on one low-intensity intervention would simplify delivery and the associated training and infrastructure needs. However, the qualitative patient acceptability data do suggest that providing options may be preferable to meet variation in patient preferences for low-intensity interventions.

Recommendations for research

- Given the cost-effectiveness analysis, then, it would be prudent to implement low-intensity interventions at sites where waiting lists are disproportionally high. If services are to implement low-intensity interventions for OCD into routine practice, high-quality health services and delivery research is required to integrate these interventions into the care pathway and to identify those patients likely to derive greater benefit. Qualitative analysis has highlighted individual variability of intervention acceptability and large-scale quantitative analysis of engagement predictors are now required.
- Neither intervention showed clinically significant effects at 3 months within the prespecified margin; however, given the magnitude of effect that was shown with guided self-help, we advocate caution of the wholesale rejection of low-intensity interventions delivered within a stepped-care model, as advocated by NICE. Further development and rigorous evaluation of more effective low-intensity interventions is required, particularly in relation to guided self-help. Our qualitative work demonstrates that those aspects of the interventions might benefit from modifications to enhance uptake.
- If more effective low-intensity interventions can be developed, there would be a case for trials to actively compare low-intensity interventions with high-intensity CBT head to head (rather than the sequential delivery tested within OCTET). This could evaluate whether or not enhanced low-intensity interventions can achieve equivalent (or at least non-inferior) outcomes to high-intensity CBT.

Trial registration

This trial is registered as ISRCTN73535163.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.236

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/81/01. The contractual start date was in September 2011. The draft report began editorial review in October 2015 and was accepted for publication in April 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).