**Full Title:**

Low-Intensity CBT Interventions for Obsessive Compulsive Disorder Compared to Waiting List for Therapist-Led CBT: 3-Arm Randomised Controlled Trial of Clinical Effectiveness

**Short Title:**

Low Intensity CBT Interventions for Obsessive Compulsive Disorder

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Abstract

#### Background

Obsessive-compulsive disorder (OCD) is prevalent and without adequate treatment usually follows a chronic course. ‘High intensity’ cognitive-behaviour therapy (CBT) from a specialist therapist is current ‘best practice’. However, access is difficult because of limited numbers of therapists, and because of the disabling effects of OCD symptoms.

There is a potential role for ‘low intensity’ interventions as part of a stepped care model. Low intensity interventions (written or web-based materials with limited therapist support) can be provided remotely, which has the potential to increase access. However, current evidence concerning low intensity interventions is insufficient. We aimed to determine the clinical effectiveness of two forms of low-intensity CBT prior to high-intensity CBT, in adults meeting DSM-IV criteria for OCD.

*Methods and findings*

This study was approved by the National Research Ethics Service Committee North West – Lancaster (reference number 11/NW/0276). All participants provided informed consent to take part in the trial.

We conducted a three-arm, multicentre randomised controlled trial in primary and secondary care UK mental health services. All patients were on a waiting list for therapist-led CBT (treatment as usual). 473 eligible patients were recruited and randomised. Patients had a median age of 33 years, 60% were female. The majority were experiencing severe OCD.

Patients received one of two low-intensity interventions – *computerised CBT* (cCBT – web-based CBT materials and limited telephone support) through ‘OCFighter’ or *guided self-help* (written CBT materials with limited telephone or face-to-face support).

Primary comparisons concerned OCD symptoms, measured using the Yale Brown Obsessive Compulsive Scale – Observer Rated (YBOCS-OR) at 3, 6 and 12 months. Secondary outcomes included health-related quality of life, depression, anxiety and functioning.

At 3 months, guided self-help demonstrated modest benefits over waiting list in reducing OCD symptoms (adjusted mean difference = -1∙91, 95% CI -3∙27 to -0∙55). These effects did not reach a pre-specified level of ‘clinically significant benefit’. cCBT did not demonstrate significant benefit (adjusted mean difference -0∙71, 95% CI -2∙12 to 0∙70). At 12 months, neither guided self-help nor cCBT led to differences in OCD symptoms.

Early access to ‘low intensity’ interventions led to significant reductions in uptake of high intensity CBT over 12 months; 86% of the patients allocated to waiting list for high intensity CBT started treatment by the end of the trial, compared to 62% in supported cCBT and 57% in guided self-help. These reductions did not compromise longer-term patient outcomes. Data suggested small differences in satisfaction at 3-months, with patients most satisfied with guided self-help and least satisfied with supported cCBT. A significant issue in the interpretation of the results concerns the level of access to high intensity CBT before the primary outcome assessment.

*Conclusions*

To our knowledge, we have demonstrated that providing low-intensity interventions does not lead to clinically significant benefits, but may reduce uptake of therapist-led CBT.

*Trial registration*

Current Controlled Trials ISRCTN 73535163

**Author Summary**

*Background*

* Obsessive-compulsive disorder (OCD) is a common disorder. It makes people anxious, unhappy, interferes with everyday activities and rarely improves without treatment.
* UK National Institute of Health and Care Excellence (NICE) guidelines make recommendations for the management of OCD using a stepped care approach. Cognitive behavioural therapy (CBT), including exposure and response prevention (ERP), is the recommended psychological treatment.
* The role of low intensity interventions such as computerised cognitive behaviour therapy (cCBT) or guided self-help for OCD is unclear and current evidence cannot provide accurate estimates of clinical and cost-effectiveness.

*Why Was This Study Done?*

* Many people suffer from Obsessive-compulsive disorder (OCD) and if they do not get treatment, it can be a long-term problem
* Although CBT with a therapist is effective, many people struggle to get access because of limited numbers of therapists
* Low intensity versions of CBT (written or web-based materials with limited therapist support) may increase access to care, but evidence of their effectiveness is limited

*What Did the Researchers Do and Find?*

* We tested two low intensity versions of CBT in a trial (guided self-help and supported cCBT), testing their impact on patients with OCD when provided prior to CBT with a therapist
* Neither low intensity version of CBT led to clinically significant benefits in patient outcomes
* Access to ‘low intensity’ interventions led to significant reductions in uptake of CBT with a therapist over 12 months
* More patients were satisfied with guided self-help and least satisfied with supported cCBT

*What Do These Findings Mean?*

* Providing low-intensity interventions does not lead to clinically significant benefits, but may reduce uptake of therapist-led CBT
* These findings from a large pragmatic trial showing no clinical benefit from low-intensity treatments are in contrast to other studies published recently

**Introduction**

Obsessive compulsive disorder (OCD) has an estimated lifetime prevalence of 2–3% and is rated among the top 10 causes of disability worldwide, with an estimated $8∙4 billion attributable to OCD in the US[1]. Providing accessible and effective care for OCD is a priority worldwide.

However, there is evidence that people with OCD struggle to access treatment, with consistent reports of a marked delay between OCD onset and management. One study found a 10 year gap between onset and seeking help and 17 years between onset and receiving effective help [2].

In OCD, both medication and psychological therapy are effective, with the ‘gold standard’ psychological therapy intervention being therapist-led CBT [3], one hour weekly sessions delivered predominantly face-to-face over 12-16 weeks. However, it is relatively costly and the limited availability of specialist therapists means that access can be poor, with long waiting times. Additionally, OCD is characterised by intrusive, unwanted, recurrent and distressing thoughts, images or impulses (i.e. obsessions) and repetitive actions or rituals (compulsions). These obsessions and compulsions can make it more difficult for patients to engage with treatment, due to fears of contamination or causing harm to others.

Conventional ways of delivering psychological therapy are being challenged. Health systems under financial pressure need to manage demand more effectively through new methods of delivery [4], and innovation is needed to meet the needs of diverse patient populations with complex needs. Research has shown how conventional therapist-led CBT can be delivered effectively in low-intensity forms including *guided self-help* (written CBT materials with limited telephone or face to face support) or *computerised CBT* (cCBT – web based CBT materials and limited telephone support). Both forms are potentially cheaper and more accessible than conventional therapist-led CBT and demonstrate evidence of effectiveness in a range of disorders [5,6]. Low-intensity CBT interventions for OCD, may provide more rapid relief of symptoms, reduce the need for more expensive therapist-led CBT, and encourage more efficient use of health care resources when delivered as part of a stepped care system [7].

At the time this study was commissioned, the evidence base for low-intensity interventions in OCD was far from definitive. Much of the evidence for guided self-help was based on small open or uncontrolled studies [8,9],or comparisons of non-guided with guided self-help [10].A systematic review of cCBT for OCD found only 4 studies [11]. cCBT reduced rituals and obsessions and improved functioning, and was more effective than attention control [12], but not as effective as therapist-led CBT. Clearly, the potential benefits of both guided self-help and cCBT need to be demonstrated in large-scale trials.

We conducted a randomised trial for patients with OCD, allocating patients to either (a) guided self-help prior to therapist-led CBT (b) cCBT prior to therapist-led CBT or (c) waiting list for therapist-led CBT only. We aimed to provide a definitive answer to the following questions:

1. Does access to guided self-help or cCBT provide more rapid improvement in OCD symptoms at 3 months compared to waiting list for therapist-led CBT?
2. Does access to guided self-help or cCBT improve patient satisfaction at 3 months compared to waiting list for therapist-led CBT?
3. Does access to guided self-help or cCBT prior to therapist-led CBT provide longer term improvement in OCD symptoms at 12 months compared to therapist-led CBT alone?
4. Does access to guided self-help or cCBT reduce uptake of therapist-led CBT over 12 months?

**Methods**

This study was approved by the National Research Ethics Service Committee North West – Lancaster (reference number 11/NW/0276). All participants provided informed consent to take part in the trial.

*Study design and participants*

We conducted a pragmatic trial, delivered in routine service settings, to provide a balance between internal and external validity, and maximise relevance to clinical guidelines [13,14]. The study protocol has been published [15]. The study is reported as per CONSORT guidelines and call out the CONSORT checklist (S2 text).

Potential participants were most frequently identified by administrative and clinical staff in primary and secondary care screening waiting lists, although self-referral was used at one site to increase recruitment (via adverts in newspapers, community facilities, and social media). Potential participants were provided with an information pack. Those who provided consent to contact took part in a telephone eligibility screen to determine they were over 18 years old, not currently receiving a psychological therapy for OCD or experiencing severe and distressing psychotic symptoms. Participants passing the initial screen were offered a face-to-face eligibility appointment.

We included patients (1) aged 18+, (2) able to read English, (3) currently waiting for access to therapist-led CBT (4) meeting DSM-IV criteria for OCD (assessed using the Mini-International Neuropsychiatric Interview [16]), and (5) scoring 16+ Yale Brown Obsessive Compulsive Checklist self-report (Y-BOCS-SR [17]).

We excluded patients (1) experiencing active suicidal or psychotic thoughts, (2) meeting DSM IValcohol or substance dependence criteria, (3) receiving psychological treatment for OCD or (4) with language difficulties which would preclude participation.

*Randomisation and masking*

Patients were randomised (ratio 1:1:1) via a secure web system independently administered by a trials unit to ensure concealment of allocation. Allocation was minimised on OCD severity, OCD duration, antidepressant use and depression severity. It was not possible to mask participants or clinical staff to treatment allocation. Research staff undertaking assessments were masked to allocation: un-masking was reported in 30%, 22% and 26% of the 3, 6 and 12 month interviews respectively. Where this occurred, subsequent assessments were done by another researcher to limit bias.

*Procedures*

cCBT *w*as delivered using OCFighter ([www.ccbt.co.uk](http://www.ccbt.co.uk)), a commercial OCD program. OCFighter involves 9 steps (focussed on exposure and response prevention) to help people with OCD carry out treatment and monitor progress. Participants received a secure login and were advised to use cCBT at least 6 times over 12 weeks. Participants received six 10-minute telephone calls, for risk assessment, progress review and problem-solving.

Guided self-help was delivered using the book ‘Overcoming OCD: a workbook’ [18], focussed on exposure and response prevention. Participants received weekly guidance, with an initial session (60 minutes face-to-face or by telephone dependent on patient preference) followed by 10 30-minute sessions over 12 weeks. The support involved an explanation of the workbook; help devising goals, risk assessment, support for conducting CBT homework, progress review and problem-solving.

Support for both cCBT and guided self-help was provided by *psychological well-being practitioners*. These are graduates with no prior clinical qualifications who receive 12 months training, and who are responsible for delivering guided self-help CBT and general education for anxiety and depression in England. Most have limited OCD-specific training. They were trained in both interventions over three days by the research team (with additional support from the company supplying cCBT). All staff received telephone supervision every fortnight from the research team or from experienced therapists within routine services. In total, 93 psychological well-being practitioners managed patients in the trial (range 1-18 patients), with 46 practitioners allocated patients in both interventions. Psychological well-practiitoner characteristics are reported in S1 Appendix Table A.

Psychological well-being practitionersrecorded dates, length and mode of contact for all sessions, and were asked to record sessions to examine fidelity. We also received automated recordings of cCBT use. Fidelity was evaluated by an independent rater blind to outcome. We defined tasks to be carried out in both interventions, which were coded from recordings as ‘implicit’, ‘explicit’ or ‘absent’ and an overall rating generated using a 5 point scale (‘unacceptable’ to ‘excellent’).

The comparator was waiting list for therapist-led CBT. As the trial was a pragmatic design within routine services, we were unable to mandate a waiting period for therapist-led CBT. We expected that most patients would start therapist-led CBT 3-6 months following allocation, after receiving their low-intensity interventions (where allocated). Therapist-led CBT was typically 8-20 face-to-face, 45-60 minute weekly sessions.

In this pragmatic trial, we placed no restrictions on treatment after randomisation. Before seeing a therapist, patients on waiting lists sometimes received interventions other than our low-intensity interventions, including education, medication or non-specific interventions (such as ‘stress management’). All additional care outside the trial protocol was recorded as part of the economic evaluation.

*Clinical outcomes*

We conducted follow-up assessments at 3 months (primary outcome timepoint), 6 and 12 months following randomisation. The primary outcome measure, Yale Brown Obsessive Compulsive Scale Observer-Rated (Y-BOCS-OR) [17], was collected face-to-face at baseline. At follow-up time points where face-to-face collection was not possible following a highly structured standardised operating procedure, telephone or postal assessment using the Y-BOCS-SR was attempted.

The Y-BOCS-OR is an interview administered structured assessment that provides an indication of OCD symptom severity. It consists of two comprehensive symptom checklists, exploring current and past obsession and compulsion symptoms (over the past week and past symptoms) and a 10-item severity scale exploring current obsessive and compulsive symptoms. Impairment over five clinical domains is identified - time consumed, functional impairment, psychological distress, efforts to resist, and perceived sense of control on a five-point Likert scale from 0 (none) to 4 (extreme). Scores from the 10 items are summed to identify level of severity (0–7 sub-clinical, 8–15 mild, 16–23 moderate, 24–31 severe and 32–40 extreme).

Secondary outcomes were collected at baseline, 3, 6 and 12-month follow-up. Outcomes included the Yale-Brown Obsessive Compulsive Scale Self-Rated (Y-BOCS-SR), a self-report version of the Y-BOCS-OR scale. Where it was not possible to complete the Y-BOCS-OR, the Y-BOCS-SR was used as a proxy.

Other secondary outcomes (all self-report) included the Self-reported health-related quality of life (SF-36) [19] for health-related quality of life; Clinical Outcomes in Routine Evaluation (CORE-OM) [20] for distress; Patient Health Questionnaire (PHQ-9) [21] for depression; Generalised Anxiety Disorder (GAD-7) [22] for generalised anxiety disorder; Work and Social Adjustment Scale (WSAS) [23] for functional impairment; IAPT Employment Status Questions (A13-A14) [24] for employment rates and receipt of statutory sick pay; and the Client Satisfacion Questionnaire (CSQ8-UK) [25] for satisfaction. Co-morbidities (Clinical Interview Schedule-Revised; CIS-R) [26] and demographics were collected at baseline only.

*Statistical analysis*

With 3 pair-wise comparisons, alpha was set at 1·67%. We assumed a standard deviation for the primary outcome of 7·3, correlation between baseline and follow up of 0·43 [27] and therapist intra-cluster correlation (ICC) between therapists (0·06), and within therapist (0·015). Assuming 85% retention, 432 patients were required. Trial monitoring suggested a lower follow-up rate and so the sample size was increased to 473 to retain power. In total, 366 patients at follow-up provided power greater than 80% to detect a clinically significant difference of 3 Y-BOCS points for each comparison.

Preliminary modelling determined methods for handling missing data (full details provided in the statistical analysis plan [https://dx.doi.org/10.6084/m9.figshare.3503885](https://outlook.manchester.ac.uk/owa/redir.aspx?SURL=l2GEWSA8GDs-6VXRNFMrmdOmukKYSY82akQjcjqFJKh74-vIzbfTCGgAdAB0AHAAcwA6AC8ALwBkAHgALgBkAG8AaQAuAG8AcgBnAC8AMQAwAC4ANgAwADgANAAvAG0AOQAuAGYAaQBnAHMAaABhAHIAZQAuADMANQAwADMAOAA4ADUA&URL=https%3a%2f%2fdx.doi.org%2f10.6084%2fm9.figshare.3503885)). There was no deviation from the pre-specified plan, all analyses were conducted and those not present in this manuscript are reported in the HTA report [28]. Missing baseline covariates were imputed by single imputation [29]using other covariates. Analyses of the primary outcome were based on a linear mixed model with random effects for psychological well-being practitioners. As practitioners were crossed with treatment, correlated random effects were included for each treatment enabling estimation of the ICC for cCBT and guided self-help. We included the following covariates: OCD duration and severity; anxiety, depression, antidepressant use; and gender. Binary outcomes (e.g. uptake of therapist-led CBT) used logistic regression to estimate adjusted odds ratios (ORs), with the same baseline covariates. Analysis used intention-to-treat subject to the availability of data. Distributional assumptions of the models were checked. All outcomes included in the OCTET protocol are detailed.

*Patient involvement*

Patients and members of the public were involved throughout the trial, including the design, management, and conduct of the trial. From the outset the chief executive of a national user-led organisation (Anxiety UK) was involved as a co-applicant and collaborator. Members of an OCD self-help group assisted with the development of the guided self-help manual and adaptations to one of the trial outcome measures. A service user with OCD was a member of the trial steering committee while another conducted some of the patient acceptability interviews. The findings have been disseminated to trial participants and results presented at a national user conference.

**Results**

*Recruitment, retention, and baseline characteristics*

We opened recruitment in 15 clinical sites in England between February 2011 and May 2014, with last follow up in May 2015. There were two post-randomisation exclusions: one aged under 18 and one at suicide risk. In total 473 eligible patients were randomised (see Fig 1). Baseline sociodemographic characteristics are presented in Table 1 with baseline clinical data presented in Table 2. Data were indicative of severe OCD, mild to moderate depression and moderate anxiety. Just over half reported previous professional help with OCD, and around half were using antidepressants. More than half reported OCD for more than 10 years. There were no substantial differences at baseline.

**Fig 1: CONSORT flow chart illustrating recruitment**

**Table 1: Baseline sociodemographic variables**

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristic** | **cCBT n=157** | **Guided self-help n=158** | **Waiting List****n=158** |
|  |  |  |  |
| Age (years): median (range) | 32∙0 (18-77) | 32∙8 (18-72) | 33∙3 (19- 66) |
|  | freq. (%) | freq. (%) | freq. (%) |
|  |  |  |  |
| Sex |  |  |  |
| Male: n (%) | 66 (42∙0%) | 57 (36∙1%) | 65 (41∙1%) |
| Female: n (%) | 91 (58∙0%) | 101 (63∙9%) | 93 (58∙9%) |
|  |  |  |  |
| Ethnicity |  |  |  |
| White: n (%) | 145 (92∙4%) | 154 (97∙5%) | 149 (94∙3%) |
| Non - white: n (%) | 12 (7∙6%) | 4 (2∙5%) | 8 (5∙1%) |
| Missing: n (%) | 0 (0%) | 0 (0%) | 1 (0∙6%) |
|  |  |  |  |
| Marital Status |  |  |  |
| Married/living with partner: n (%) | 84 (53∙5%) | 81 (51∙3%) | 85 (53∙8%) |
| Other: n (%) | 70 (44∙6%) | 75 (47∙4%) | 73 (46∙2%) |
| Missing: n (%) | 3 (1∙9%) | 2 (1∙3%) | 0 (0%) |
|  |  |  |  |
| Employment status\* |  |  |  |
| Employed: n (%) | 86 (54∙4%) | 95 (60∙1%) | 97 (61∙4%) |
| Unemployed and seeking work: n (%) | 10 (6∙3%) | 14 (8∙9%) | 9 (5∙7%) |
| Student: n (%) | 17 (10∙8%) | 19 (12∙0%) | 17 (10∙8) |
| Long term sick/disabled receiving income support or incapacity benefit: n (%) | 22 (14∙0%) | 23 (14∙6%) | 15 (9∙5%) |
| Homemaker – not actively seeking work: n (%) | 15 (9∙6%) | 9 (5∙7%) | 11 (7∙0%) |
| Not receiving benefits and not actively seeking work: n (%) | 1 (0∙6%) | 0 (0%) | 1 (0∙6%) |
| Unpaid voluntary work and not actively seeking work: n (%) | 1 (0∙6%) | 1 (0∙6%) | 0 (0%) |
| Retired: n (%) | 6 (3∙8%) | 5 (3∙2%) | 6 (3∙8%) |
| Missing: n (%) | 2 (1∙3%) | 1 (0∙6%) | 5 (3∙2%) |
|  |  |  |  |
| Receiving statutory sick pay |  |  |  |
| Yes: n (%) | 8 (5∙1%) | 8 (5∙1%) | 11 (7∙0%) |
| No: n (%) | 144 (91∙7%) | 146 (92∙4%) | 138 (87∙3%) |
| Missing: n (%) | 5 (3∙2%) | 4 (2∙5%) | 9 (5∙7%) |
|  |  |  |  |
| Accessed previous OCD help |  |  |  |
| Yes: n (%) | 76 (48∙4%) | 86 (54∙4%) | 72 (45∙6%) |
| No: n (%) | 80 (51∙0%) | 71 (44∙9%) | 85 (53∙8%) |
| Missing: n (%) | 1 (0∙6%) | 1 (0∙7%) | 1 (0∙6%) |
|  |  |  |  |
| Education |  |  |  |
| Below degree level: n (%) | 107 (68∙2%) | 110 (69∙6%) | 112 (70∙9%) |
| Degree level or higher: n (%) | 45 (28∙6%) | 43 (27∙2%) | 40 (25∙3%) |
| Missing: n(%) | 5 (3∙2%) | 5 (3∙2%) | 6 (3∙8%) |

\* N and % for all groups do not sum (i.e. to sample size or 100%). This is as a result of some participants indicating more than one employment status.

**Table 2:** **Baseline clinical characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristic** | **cCBT** **n=157** | **Guided self-help n=158** | **Waiting List****n=158** |
|  | freq. (%) | freq. (%) | freq. (%) |
| Current antidepressant medication | 82 (52∙2%) | 81 (51∙3%) | 80 (50∙6%) |
| OCD Chronicity |  |  |  |
| 0-5 years | 53 (33∙8%) | 52 (32∙9%) | 51 (32∙3%) |
| 6-9 years | 18 (11∙5%) | 18 (11∙4%) | 19 (12∙0%) |
| ≥ 10 years | 86 (54∙8%) | 88 (55∙7%) | 88 (55∙7%) |
| Co-morbidity (primary diagnosis)  |  |  |  |
| Mixed anxiety and depressive disorder  | 23 (14∙6%) | 23 (14∙6%) | 15 (9∙5%)  |
| Mild depressive disorder  | 18 (11∙5%) | 18 (11∙4%) | 20 (12∙7%) |
| Moderate depressive disorder  | 28 (17∙8%) | 24 (15∙2%) | 26 (16∙5%) |
| Severe depressive disorder  | 7 (4∙5%) | 13 (8∙2%)  | 12 (7∙6%) |
| Generalised anxiety disorder  | 18 (11∙5%) | 27 (17∙1%) | 18 (11∙4%) |
| Specific phobia  | 10 (6∙4%) | 6 (3∙8%) | 6 (3∙8%) |
| Social phobia  | 2 (1∙3%) | 1 (1%) | 0 (0%) |
| Agoraphobia  | 0 (0%) | 2 (0∙6%) | 3 (1∙9%) |
| Panic disorder  | 2 (1∙3%) | 0 (0%) | 5 (3∙2%) |
|  | mean (s.d) n | Mean (s.d) n | Mean (s.d.)n |
| Y-BOCS-ORa | 25∙03 (5∙45) 157 | 25∙01 (5∙02) 158 | 25∙34 (5∙44) 158 |
| Median | 25 | 25 | 25 |
| Min; Max | 13; 38 | 14; 39 | 13; 38 |
| Missing | 0 | 0 | 0 |
|  |  |  |  |
| Y-BOCS-SR |  |  |  |
| Mean (S.D.) | 24∙34 (5∙1) | 24∙18 (4∙82) | 24∙20 (4∙99) |
| Median | 24 | 24 | 24 |
| Min; Max | 16;36 | 16;40 | 16;38 |
|  |  |  |  |
| PHQ9 |  |  |  |
| Mean (S.D.) | 11∙90 (6∙27) 155 | 11∙40 (6∙56)154 | 11∙93 (6∙29) 154 |
| Median | 12 | 11∙5 | 12 |
| Min; Max | 0; 27 | 0; 26 | 0; 26 |
|  |  |  |  |
| GAD-7 |  |  |  |
| Mean (S.D.) | 12∙90 (5∙33) | 12∙72 (5∙56) | 12∙52 (5∙52) |
| Median | 13 | 14 | 13 |
| Min; Max | 2; 21 | 1; 21 | 0; 21 |
| Missing | 2 | 4 | 4 |
|  |  |  |  |
| CORE-OM |  |  |  |
| Mean (S.D.) | 15∙95 (6∙27) | 15∙23 (6∙67) | 15∙79 (6∙63) |
| Median | 16 | 16 | 16 |
| Min; Max | 5; 35 | 1; 34 | 1; 33 |
| Missing | 3 | 3 | 5 |
|  |  |  |  |
| SF36 - PCS |  |  |  |
| Mean (S.D.) | 54∙39 (11∙29) | 54∙18 (9∙57) | 54∙09 (10∙56) |
| Median | 57∙36 | 56∙01 | 57∙14 |
| Min; Max | 18∙04; 71∙89 | 17∙59; 70∙35 | 22∙21; 72∙23 |
| Missing | 3 | 3 | 5 |
|  |  |  |  |
| SF36 - MCS |  |  |  |
| Mean (S.D.) | 32∙89 (9∙87) | 33∙86 (11∙05) | 33∙23 (11∙71) |
| Median | 32∙66 | 34∙33 | 33∙17 |
| Min; Max | 11∙88; 59∙52 | 7∙30; 58∙55 | 10∙64; 65∙08 |
| Missing | 3 | 3 | 5 |
|  |  |  |  |
| WSAS |  |  |  |
| Mean (S.D.) | 14∙78 (9∙85) | 15∙05 (10∙54) | 14∙74 (9∙66) |
| Median | 13 | 14 | 13 |
| Min; Max | 2; 21 | 1; 21 | 0; 21 |
| Missing | 2 | 4 | 4 |

a incorporating YBOC-SR if YBOC-OR missing or incomplete. Patients were included in the trial with a Y-BOCS-SR of 16+, so all patients had a Y-BOCS-SR of 16+ at baseline, but some had a Y-BOCS-OR of less than 16.

*Treatment fidelity and adherence*

Patient flow is shown in Figs 1 and 2. Retention rates were 81% at 3-months, 75% at 6-months, and 71% at 12-months, and were broadly similar across arms (Fig 1). Contrary to expectation, approximately 29% of patients started to access therapist-led CBT prior to the 3 month assessment (Fig 2). More detailed data on CBT uptake and predictors of uptake are detailed separately (S1 Appendix Tables B and C).

**Fig 2: Flow chart illustrating stepped care**

Fifty-nine per cent had at least one session with a psychological well-being practitioner in cCBT. The mean number of sessions was 2·3 (S.D. 2·5) and average length was 13.4 minutes (93% by telephone). Of the 9 cCBT steps, the mean number completed was 3·7 (S.D. 3·2). Sixty-six per cent had at least 1 session with a psychological well-being practitioner in guided self-help. The mean number of sessions was 4·1 (S.D. 4·3) over 57 minutes for session 1 and 31 minutes for sessions 2-11 (48% face-to-face, 26% telephone, 22% both, 4% missing). Rates of recording for fidelity assessment were low (26% guided self-help, 17% cCBT). Of sessions recorded in cCBT, 11 (65%) were rated 'good' and 6 (35%) as 'excellent'. Of sessions in guided self-help, 9 (21%) were rated 'satisfactory', 24 (56%) rated ‘good’ and 10 (23%) 'excellent'.

Table 3 gives the summary statistics for the primary (Y-BOCS-OR) and selected secondary outcomes (Y-BOCS-SR, CSQ-8 & EQ-5D). Complete outcomes are reported separately (S1 Appendix Table D).

**Table 3 Outcome measure summary statistics and intervention effects at 3, 6 and 12 months**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Supported cCBT** | **Guided self-help** | **Waiting List** | **Supported cCBT - Waiting List**  | **Guided self-help –Waiting List**  | **Supported cCBT- guided self-help**  |
|  | Mean | S.D. | n | Mean | S.D.  | n | Mean |  S.D. | n | Adj∙ Mean Diff+ | 95% | C.I.  | p | Adj∙ Mean Diff+ | 95% | C.I.  | p | Adj∙Mean Diff+ | 95% | C.I.  | p |
| Y-BOCS-OR |  |  |   |  |  |   |  |  |   |  |  |  |  |  |  |  |  |  |  |  |  |
| Baseline | 25∙03 | 5∙45 | 157 | 25∙01 | 5∙02 | 158 | 25∙34 | 5∙44 | 158 |  |  |  |   |  |  |  |   |  |  |  |   |
| 3 Mon. | 21∙16 | 6∙89 | 121 | 20∙19 | 6∙83 | 130 | 22∙18 | 6∙54 | 132 | -0∙71 | (-2∙12 | 0∙70) | 0∙325 | -1∙91 | (-3∙27 | -0∙55) | 0∙006\* | 1∙20 | (-0∙22, | 2∙61) | 0∙097 |
| 6 Mon. | 18∙96 | 7∙26 | 112 | 18∙70 | 7∙70 | 122 | 20∙29 | 7∙27 | 122 | -1∙13 | (-2∙84 | 0∙58) | 0∙195 | -1∙32 | (-3∙00 | 0∙35) | 0∙121 | 0∙19 | (-1∙51 | 1∙90) | 0∙824 |
| 12 Mon. | 16∙14 | 8∙69 | 105 | 15∙19 | 8∙35 | 113 | 17∙93 | 8∙07 | 114 | -1∙37 | (-3∙59 | 0∙84) | 0∙224 | -2∙37 | (-4∙37 | -0∙38) | 0∙020 | 1∙00 | (-1∙19 | 3∙19) | 0∙371 |
| Y-BOCS-SR |  |  |   |  |  |   |  |  |   |  |  |  |   |  |  |  |   |  |  |  |   |
| Baseline | 24∙34 | 5∙10 | 157 | 24∙18 | 4∙82 | 158 | 24∙20 | 4∙99 | 158 |  |  |  |   |  |  |  |   |  |  |  |   |
| 3 Mon. | 20∙46 | 7∙06 | 119 | 19∙80 | 6∙90 | 128 | 20∙88 | 6∙48 | 127 | -0∙43 | (-1∙79 | 0∙93) | 0∙531 | -1∙31 | (-2∙65 | 0∙04) | 0∙056 | 0∙87 | (-0∙49 | 2∙23) | 0∙209 |
| 6 Mon. | 18∙60 | 7∙47 | 110 | 18∙29 | 7∙78 | 119 | 19∙34 | 7∙24 | 118 | -0∙87 | (-2∙52 | 0∙78) | 0∙300 | -1∙17 | (-2∙87 | 0∙53) | 0∙178 | 0∙30 | (-1∙42 | 2∙02) | 0∙735 |
| 12 Mon. | 15∙61 | 8∙70 | 101 | 15∙72 | 8∙11 | 109 | 17∙38 | 8∙24 | 107 | -1∙45 | (-3∙67 | 0∙76) | 0∙198 | -1∙52 | (-3∙54 | 0∙49) | 0∙137 | 0∙07 | (-2∙01 | 2∙16) | 0∙946 |
| CSQ-8 |  |  |   |  |  |   |  |  |   |   |  |  |   |   |  |  |   |   |   |   |   |
| 3 Mon. | 22∙41 | 5∙91 | 92 | 24∙37 | 5∙49 | 101 | 22∙75 | 6∙06 | 83 | -0∙31 | (-2∙07 | 1∙45) | 0∙732 | 1∙69 | (-0∙04 | 3∙42) | 0∙055 | -2∙00 | (-3∙63 | -0∙37) | 0∙016\* |
| 6 Mon. | 23∙75 | 5∙78 | 81 | 24∙26 | 6∙29 | 82 | 24∙64 | 5∙80 | 77 | -0∙87 | (-2∙77 | 1∙03) | 0∙371 | -0∙31 | (-2∙23 | 1∙61) | 0∙751 | -0∙56 | (-2∙44 | 1∙32) | 0∙561 |
| EQ-5D |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Baseline | 0∙67 | 0∙29 | 155 | 0∙68 | 0∙26 | 155 | 0∙68 | 0∙26 | 154 |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 Mon. | 0∙69 | 0∙31 | 104 | 0∙73 | 0∙24 | 117 | 0∙67 | 0∙28 | 124 | 0∙03 | (-0∙02 | 0∙09) | 0∙246 | 0∙05 | (0∙00 | 0∙10) | 0∙042 | -0∙01 | (-0∙07 | 0∙04) | 0∙491 |
| 6 Mon. | 0∙71 | 0∙29 | 94 | 0∙72 | 0∙25 | 105 | 0∙71 | 0∙25 | 106 | 0∙00 | (-0∙06 | 0∙06) | 0∙961 | 0∙00 | (-0∙05 | 0∙07) | 0∙815 | -0∙00 | (-0∙07 | 0∙06) | 0∙864 |
| 12 Mon. | 0∙79 | 0∙27 | 84 | 0∙73 | 0∙26 | 100 | 0∙70 | 0∙31 | 99 | 0∙07 | (0∙00 | 0∙15) | 0∙041 | 0∙03 | (-0∙04 | 0∙09) | 0∙449 | 0∙05 | (-0∙02 | 0∙12) | 0∙179 |

+ Mean difference adjusted for *YBOCS-OR, PHQ-9, GAD-7,anti-depressant use, Gender, OCD duration ( 0-5, 6-9, ≥10 years)*

\* Significance level is set at 1∙67% to adjust for 3 pair-wise comparisons

*Does access to guided self-help or cCBT provide more rapid improvement in OCD symptoms at 3 months compared to waiting list for therapist-led CBT?*

There was no significant benefit of access to cCBT (adjusted mean difference -0·71, 95% CI -2·12 to 0∙70 p=0∙325). There was statistically significant benefit of guided self-help (adjusted mean difference -1·91, 95% CI -3·27 to -0·55, p=0·006), although the effect was less than the pre-specified ‘clinically important difference’ of 3 points.

Analyses of secondary outcomes (S1 Appendix Tables E, F and G) showed only one significant difference, an effect of cCBT on anxiety (adjusted mean difference -1·50, 95% CI -2·67 to -0·33, p=0·012).

*Does access to guided self-help or cCBT improve patient satisfaction at 3 months compared to waiting list for therapist-led CBT?*

Satisfaction data is shown in Table 3. There were no differences in patient satisfaction among patients receiving cCBT compared to those allocated to waiting list (adjusted mean difference -0·31, 95% CI -2·07 to 1∙45, p=0∙732). Patients receiving guided self-help tended to be more satisfied than those allocated to waiting list for therapist-led CBT (adjusted mean difference 1·69, 95% CI -0·04 to 3·42, p=0·055), although the estimate did not reach significance according to the corrected significance level. Patients receiving cCBT were less satisfied than those receiving guided self-help (adjusted mean difference -2·00, 95% CI -3·63 to -0·37, p=0·016).

*Does access to guided self-help or cCBT prior to therapist-led CBT provide longer term improvement in OCD symptoms at 12 months compared to therapist-led CBT alone?*

There was no significant long term benefit from access to either guided self-help or cCBT (cCBT adjusted mean difference -1·37, 95% CI -3·59 to 0·84, p=0·224; guided self-help adjusted mean difference -2·37, 95% CI -4·37 to -0·38, p=0·02 - Table 2).

As a post-hoc analysis, we tested whether low-intensity interventions were formally non-inferior to waiting list for therapist-led CBT at 12 months. A 98·33% confidence interval corresponds to 1·67% significance level that we have used for hypothesis testing. For the comparison of cCBT against waiting list the 98·33% confidence interval is -4·07 to 1·33 and for guided self-help against waiting list it is -4·81 to 0·06. Given that the upper limits are substantially smaller than the pre-specified criterion for a clinically important difference (3 points), we conclude that both interventions are non-inferior to waiting list at 12 months.

*Does access to guided self-help or cCBT reduce uptake of therapist-led CBT over 12 months?*

Therapist-led CBT uptake is shown in Fig 2. Both interventions were associated with significantly lower uptake of therapist-led CBT at 12 months (cCBT adjusted OR 0·34, 95% CI 0·15 to 0·79 p=0·011; guided self-help adjusted OR 0·27, 95% CI 0·12 to 0·60 p=0·001) (Table 4).

**Table 4:** **Logistic regression model for CBT uptake at 6 & 12 months**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Comparison** | **Adj. Odds** **Ratio** | **95%****(lower,** | **CI∙****upper)** | **p-value** |
| **6-months** |  |  |  |  |  |
| Group | cCBT vs WL | 0∙42 | (0∙24, | 0∙73) | 0∙002\* |
|  | GSH vs WL | 0∙48 | (0∙22, | 1∙03) | 0∙06 |
|  | cCBT vs GSH | 0∙87 | (0∙42, | 1∙84) | 0∙718 |
|  |  |  |  |  |  |
| Baseline outcome measures | Y-BOCS-OR | 1∙02 | (0∙97, | 1∙06) | 0∙514 |
| GAD-7 | 0∙99 | (0∙94, | 1∙04) | 0∙591 |
|  | PHQ-9 | 1∙02 | (0∙98, | 1∙07) | 0∙271 |
|  |  |  |  |  |  |
| Anti-depressant medication | Yes | 0∙71 | (0∙46, | 1∙09) | 0∙117 |
|  |  |  |  |  |  |
| Duration of OCD | 6 - 9 years | 1∙26 | (0∙60, | 2∙64) | 0∙552 |
|  | 10 or more years | 0∙89 | (0∙55, | 1∙42) | 0∙619 |
|  |  |  |  |  |  |
| Gender | Male | 1∙12 | (0∙73, | 1∙73) | 0∙606 |
|  |  |  |  |  |  |
| Exp(Constant) |  | 2∙14 | (0∙67, | 6∙82) | 0∙201 |
| **12-months** |  |  |  |  |  |
|  |  |  |  |  |  |
| Group | cCBT vs WL | 0∙34 | (0∙15, | 0∙79) | 0∙011\* |
|  | GSH vs WL | 0∙27 | (0∙12, | 0∙60) | 0∙001\* |
|  | cCBT vs GSH | 1∙27 | (0∙53, | 3∙00) | 0∙59 |
|  |  |  |  |  |  |
| Baseline outcome measures | Y-BOCS-OR | 1∙03 | (0∙97, | 1∙08) | 0∙36 |
| GAD-7 | 1∙03 | (0∙97, | 1∙08) | 0∙341 |
|  | PHQ-9 | 0∙99 | (0∙94, | 1∙04) | 0∙73 |
|  |  |  |  |  |  |
| Anti-depressant medication | Yes | 1∙02 |  (0∙63, | 1∙67) | 0∙933 |
|  |  |  |  |  |  |
| Duration of OCD | 6 - 9 years | 2∙66 | (1∙03, | 6∙89) | 0∙043 |
|  | 10 or more years | 0∙99 | (0∙59, | 1∙67) | 0∙968 |
|  |  |  |  |  |  |
| Gender | Male | 1∙25 | (0∙76, | 2∙03) | 0∙395 |
|  |  |  |  |  |  |
| Exp(Constant) |  | 2∙86 | (0∙76, | 10∙81) | 0∙121 |

\* Note, the Bonferroni corrected significance level is 1∙67%, for 3 pair-wise comparisons

\*\* Note, results are taken from a logistic regression model and any `effect’ should be interpreted as an odds ratio

Post-hoc, we compared intervention use and 12 month OCD outcomes among guided self-help and cCBT patients who did and did not access therapist-led CBT (S1 Appendix Table H). Although lacking randomisation, the data do not suggest that those who accessed only guided self-help or cCBT demonstrated markedly worse outcomes than those who accessed both a low-intensity intervention and therapist-led CBT (S1 Appendix Table I).

**Discussion**

*Principal outcomes*

We assessed the role of two low-intensity interventions (guided self-help and cCBT) in OCD. Prior to access to therapist-led CBT, guided self-help demonstrated statistically significant benefits over waiting list, but the difference did not meet the pre-specified criterion for clinical significance. cCBT did not demonstrate significant benefit at 3 or 12 month follow-up. Access to low-intensity interventions does not provide more rapid symptom relief.

Over 12 months, access to low-intensity interventions prior to therapist-led CBT did not significantly augment the effects of therapist-led CBT on OCD symptoms in the longer term. Rapid access to low-intensity interventions did lead to significant reductions in uptake of therapist-led CBT, which did not compromise patient outcomes at 12 months.

*Strengths and limitations*

To our knowledge, we conducted the largest trial of psychological therapy for OCD worldwide. We achieved acceptable levels of retention. Where patients were not able to provide the primary clinical outcome using the observer-reported version, we used self-report as a proxy. These different measures show high associations [30,31], with some evidence of lower scores in the self-reported version, but proxy measures were only used in 8%  and 11% of cases at 3 and 12 months, with minimal differences in rates of use between arms. In this pragmatic trial, recruitment was over multiple sites and involved a large number of psychological well-being practitioners. This enhances external validity, as delivery was not restricted to a small number of specialised sites or highly selected professionals. However, many psychological well-being practitioners only saw a few patients, which restricted the opportunity to practice their skills. Uptake of the interventions was reasonable (65% guided self-help and 59% cCBT). Collecting detailed data on fidelity proved difficult, but analysis of the data provided some evidence that delivery of guided self-help and cCBT was in line with protocols.

Several issues are worth noting in this pragmatic design. First, we did not mandate a defined waiting time for therapist-led CBT, although the expectation was 3-6 months. In practice, around 40% of patients allocated to waiting list for therapist-led CBT started to receive *some* contact with their therapist before 3 months, compared with just over 20% in the guided self-help and cCBTgroups. This would reduce differences in outcomes between guided self-help, cCBT and the waiting list comparator at 3 months, leading to conservative estimates of effect. Still, this data refers to patients receiving *any* contact with therapist-led CBT, which in most cases would involve an initial session or two, rather than a full ‘dose’ of treatment. Nevertheless, relatively quick access to CBT in the waiting list arm would have reduced short-term benefit associated with the low-intensity interventions. The effects of low-intensity interventions may have been more pronounced at 3 months if CBT was less accessible than in the current trial. The longer-term analyses are less affected, as all patients were expected to receive both a low-intensity intervention (where allocated) and therapist-led CBT over 12 months.

We have shown that uptake of therapist-led CBT was lower in the groups allocated to low-intensity treatment. This could reflect positive outcomes from some aspects of the low-intensity interventions, although our analysis showed that this was largely restricted to patient satisfaction rather than clinical benefits. Even in the absence of significant clinical benefits, providing low intensity treatments may give patients a sense of support and progress. When combined with natural improvement in symptoms over time (as found in all groups), this may mean that patients do not feel a need for further intensive support or no longer wish to engage with services. However, the numbers of patients attending therapist-led CBT increased in all groups over time. It is possible that, had our follow-up been longer than 12 months, eventual uptake of therapist-led CBT across all groups would be the same.

Secondly, we placed no restrictions on medication use and in line with most psychological therapy trials in OCD, a proportion of patients were taking medication3. Baseline self-reported use of antidepressant treatment is provided in Table 1, showing that about half the patients reported antidepressants with no differences between groups. Data on antidepressant use after allocation showed that, over the 12 month period of the trial, self-reported use of antidepressants decreased (cCBT 26%, GSH 32%, waiting list 27%) [28]. We do not have details of the nature or quality of antidepressant prescription. Although antidepressants are effective in OCD [3,32], it seems unlikely that such small differences between arms would be a major driver of study outcomes.

Thirdly, there was no attempt to match level or type of clinician contact across the two low-intensity interventions: indeed, the study was specifically designed to test the relative value of two different forms of low-intensity intervention. Guided self-help involved both a different delivery format and more clinician contact, so our trial is not a strict comparison of paper and digital interventions. Although increased clinician contact may well enhance acceptability and effectiveness, its additional costs were accounted for in the economic analysis.

Fourth, we did not undertake quality assurance of the therapist-led CBT provided to all patients. As noted above, therapist-led CBT was provided by a range of practitioners in a range of areas, and is likely to be reasonably representative of the treatment provided in the NHS in England, which remains optimal for a pragmatic trial. Formal measurement of quality would have been preferable, but logistically complex.

The trial adopted aspects of a stepped care model, whereby patients are offered a low-intensity intervention first, with a proportion progressing to therapist-led CBT. However, unlike true stepped care, there was no regular assessment of outcome, and access to therapist-led CBT was available to all, rather than as part of a defined ‘stepping’ mechanism following non-response to treatment or deterioration. Therefore our analysis does not assess the benefits of low-intensity treatment in a full stepped care model.

*Interpretation of the results in the context of the wider literature*

At the initiation of this trial the evidence base was very limited [11].Whilethe current trial was being delivered, a number of additional studies were published. One small trial (n=56) used similar interventions to the present study (guided self-help and supported cCBT), and compared their effects in a group of volunteers recruited through a website. Very large effects were found post-treatment [33]. A second trial (n=86) exploring a minimally supported cCBT intervention again found very large effects in a sample recruited online through a research centre [34]. A third trial randomised 34 patients with OCD to a supported internet-based writing therapy, and again found very large effects among a sample recruited via public notices. A long-term follow up [35] of a previous trial [12] showed enduring effects for cCBT and that ‘booster‘ treatments were effective in maintaining gains. Finally, one trial (n=128) explored the effects of unsupported written material about meta-cognitive therapy in patients with OCD from internet groups, self-help organisations and clinical facilities, and found small benefits [36].

The picture from these trials is more positive about the clinical benefits of ‘low intensity’ treatments, especially supported cCBT, with most effect sizes over 0.5 and some exceeding 1.0. This contrasts markedly with the modest clinical impacts observed in the current study. There are a number of reasons that could account for these differences. The interventions do vary, although it is not clear that the variation is large enough to account for the large variation in effects. The current sample of patients have more severe symptoms at baseline (YBOCS scores of 25, compared to 20-21 in the other studies), although again it is not clear that such modest differences would be expected to lead to such profound variation in impact. Our current study is far larger than the other trials, and some report quite large differences at baseline which can occur when small numbers of patients are randomised [33,36]. A potentially important issue is the method of recruitment. The vast majority of the patients in the current study were recruited through routine clinical services, whereas a number of the other trials used recruitment through the internet; this may produce a sample with different clinical features and one which is much more amenable to online cCBT interventions. Similar differences in effects between large pragmatic trials in routine services and smaller trials recruiting through the internet have been recently reported in depression [37].

*Implications for service delivery*

The trial demonstrated that neither form of low-intensity CBT was responsible for clinically significant improvements in OCD symptoms among patients on the waiting list.

In the absence of any significant clinical benefit over waiting list only, readers may have concerns about reductions in the use of therapist-led CBT at 12 months, as this might reflect the substitution, or delay, of an evidence-based treatment. It may be that access to guided self-help or cCBT means that patients are put off from engaging in subsequent therapist-led CBT. We found no evidence that lower uptake of therapist-led CBT was associated with worse outcome over 12 months. Concerns that guided self-help or cCBT inappropriately discourages patients from engaging in subsequent therapist-led CBT are not supported by the wider literature which shows an increased likelihood of help-seeking and greater healthcare use following self-help [38,39]. It is possible that some patients who are offered guided self-help or cCBT improve so that they do not need subsequent therapist-led CBT, or make an informed choice to discontinue therapy sooner rather than later. However, as noted earlier, differences in uptake between arms may have reduced if a longer follow up had been possible.

Our results raise questions about the targeting of low-intensity interventions. Recruiting from waiting lists identified a sample with severe symptoms and a relatively long history of treatment. Although most showed significant improvements over time (around 8-9 points on the YBOCS across groups), the means at 12 months still showed significant symptoms (around 16 points) meaning many would continue to be eligible for the trial. Routine provision of CBT within the NHS in line with clinical guidelines clearly leaves many patients with clinically significant residual symptoms. Low-intensity treatments may be better targeted at a less severely ill group, closer to the onset of their OCD. However, as this patient group is characterised by late presentation to services, the viability of this is unclear.

Neither cCBT nor guided self-help showed clinically significant benefits at 3 months. Further development of more effective low-intensity interventions may be required. Uptake of the interventions was relatively low, although not abnormally so for a pragmatic trial. Both interventions may benefit from enhancements that might improve motivation or adherence, which might translate to greater clinical benefit.

The clinical results alone do not support an important role for low-intensity interventions in the care pathway for OCD. However, full interpretation of the benefits of low-intensity interventions for OCD also demands consideration of cost-effectivness, using comprehensive assessments of costs, as well as appropriate measures of the impact of these interventions on health-related quality of life and associated utility. We report the results of this analysis separately [28].

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**Supporting information file legend**

Fig 1: CONSORT flow chart illustrating recruitment

Fig 2: Flow chart illustrating stepped care

S1 Appendix: Supplementary information file

S1 Text: HTA OCTET study protocol v11 02.07.2015

S2 Text: CONSORT checklist