Randomised controlled trial of parent-enhanced CBT compared with individual CBT for Obsessive Compulsive Disorder in young people

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Abstract

Objective: Obsessive Compulsive Disorder (OCD) in young people can be effectively treated with Cognitive Behaviour Therapy (CBT). Practice guidelines in the UK recommend that CBT should be delivered with parental or family involvement; however there is no evidence from randomised trials that this enhances effectiveness. The aim of this trial was to assess if CBT with high parental involvement was more effective than CBT with low parental involvement (individual CBT) in reducing symptoms of OCD. **Method**: Fifty young people aged 12 to 17 years with OCD were randomly allocated to individual CBT or parentalenhanced CBT. In parent enhanced CBT parents attended all treatment sessions; in individual CBT, parents only attended sessions 1, 7 and the final session. Participants received up to 14 sessions of CBT. Data were analysed using intent to treat (ITT) and per-protocol methods. The primary outcome was CY-BOCS score at end of treatment. **Results:** Both forms of CBT significantly reduced symptoms of OCD and anxiety. Change in OCD symptoms was maintained at 6 months. Per-protocol analysis suggested that parent enhanced CBT may be associated with significantly larger reductions in anxiety symptoms. **Conclusions**: High and low parental involvement in CBT for OCD in young people were both effective and there was no evidence that one method of delivery was superior on the primary outcome measure. However this study was small. Future trials should be adequately powered and examine interactions with the age of the young person and co-morbid anxiety disorders.

Parent-enhanced CBT compared with individual CBT for Obsessive Compulsive Disorder in young people

Approximately 1 to 3% of young people meet diagnostic criteria for Obsessive Compulsive Disorder (OCD), and many have co-morbid anxiety disorders (Langley, Lewin, Bergman, Lee & Piancentini, 2010), impaired functioning (Piacentini, Bergman, Keller, & McCracken, 2003), and suffer embarrassment and stigma (Torres et al., 2007). If untreated OCD tends to have a chronic course with periods of remission (Steward, et al., 2004). North American and UK guidelines for the treatment of OCD in young people recommend CBT as the first line treatment (American Academy of Child and Adolescent Psychiatry, 2012; National Institute for Health and Clinical Excellence (NICE), 2005). NICE (2005) recommend that parents are involved in CBT for OCD. There is some evidence that involving parents in CBT for OCD may be helpful (e.g. Freeman et al., 2008; Knox, Albano, & Barlow, 1996; Piacentini et al., 2011) but there are no randomised controlled trials comparing CBT with and without parental involvement. A recent meta-analysis of psychological treatment for anxious children and young people, including OCD, concluded that parental involvement in treatment did not improve effectiveness (Reynolds et al., (2012).

Two specific reasons are typically given for extensively involving parents in CBT for OCD in children and young people.

1. Family accommodation to OCD, i.e. providing reassurance, helping the child carry out their compulsions, organising family events and activities around OCD, is common and is associated with family distress and OCD severity (Renshaw, Steketee, & Chambless, 2005; Storch et al., 2007).
2. .A core component of CBT for OCD involves exposure to feared stimuli, e.g. contamination, combined with the inhibition of the child's compulsions (e.g. washing). Exposure is anxiety provoking and parents can support their child with exposure practice, and help maintain treatment gains beyond the end of therapy.

There are also potential disadvantages to involving parents in CBT sessions. OCD is associated with unwanted, intrusive and unpleasant thoughts and images with sexual, religious and aggressive content (Geller et al., 2001; Macebo et al.,2008). These intrusive images can be highly distressing, may signify 'deviance', and are often associated with embarrassment and shame. CBT can be used to normalise these intrusive images and to help the young person reappraise their thoughts and emotions. However, disclosing 'taboo' images is challenging and the presence of a parent in therapy may be inhibiting.

In addition, some young people may need to develop age appropriate autonomy from their parents, or may be unwilling to involve their parents in therapy. Similarly, some parents are unable or unwilling to support their child in CBT because of other child care responsibilities, employment demands, or because of their own mental health problems. Thus, the involvement of parents in CBT for their child may not be feasible or even desirable (Renshaw, et al., 2005). The primary aim of this trial was to compare the effectiveness of high and low levels of parent involvement in CBT for OCD in young people.

Method

Design

Fifty young people were randomised to 'individual CBT' and 'parent-enhanced CBT' Inclusion criteria were aged 12 to 17 years, met DSM-IV criteria for Obsessive Compulsive Disorder, and if on medication, stable for 6 weeks. Exclusion criteria were a diagnosis of psychosis or bipolar disorder, pervasive developmental disorder, IQ below 70, not living with parent or adult carer, Randomisation was concealed and minimised by site (Norfolk or Suffolk) and participant age (14 years and below, 15 years and over). Assessments were at baseline, the end of treatment, and 6 months after the end of treatment by blinded researchers.

Measures

To establish OCD diagnosis young people and their primary carer were interviewed separately using the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV C/P) (ADIS-P and ADIS-C; Silverman & Albano, 1996). Assessment was conducted by psychology graduate research assistants, trained in diagnostic interviewing. Diagnosis was confirmed following consultation with a clinical psychologist. OCD symptom severity was assessed by interview with the Children's Yale-Brown Obsessive Compulsion Scale (CYBOCS; Scahill et al., 1997). The secondary outcomes, depression and anxiety were assessed by self-report on the Short Mood and Feelings Questionnaire (SMFQ; Angold, Costello, & Messer, 1995) and the Beck Anxiety Inventory – Youth (BAI-Y; Beck, Beck, Jolly, & Steer, 2005).

Cognitive behaviour therapy

CBT was manualized and based on Derisley, Heyman, Robinson & Turner (2008). Participants were offered 14 sessions, typically once a week. An individual formulation was developed around a simple maintenance cycle –'the OCD trap'. Exposure and response prevention were presented as behavioural experiments. Cognitive work focused on OCD related cognitions e.g. inflated responsibility, magical thinking and perfectionism (Libby, Reynolds, Derisley, & Clark, 2004). Session 1 was for psycho-education, session 7 to review progress and plan future sessions, and session 14 (the final session) to review progress and plan for the future without therapy. Adherence was assessed on a random sample of 15% of sessions using the Cognitive Therapy Rating Scale-Revised (CTS-R; James, Blackburn, & Reichelt, 2001).

In parent-enhanced CBT one or both parents attended all sessions and the formulation explicitly included parent/family factors including accommodation. Parents were fully involved in treatment; they helped develop the formulation and treatment plan, helped their

child complete diaries and develop an OCD hierarchy, supported the child in behavioural experiments, and rewarded their child's progress. In individual CBT one or both parents attended session 1 (psycho-education), session 7 and session 14 (or the final scheduled session if fewer than 14 sessions were offered). They did not attend other sessions.

Therapists

CBT was delivered in routine NHS services by six clinicians (four clinical psychologists and two cognitive behaviour therapists). Clinicians were trained in accredited centres and routinely used CBT in their clinical practice and were experienced in working with children and adolescents. CBT supervision was provided routinely within the service. In addition, clinicians had trial-specific training with the treatment manual and monthly peer supervision.

Procedure

NHS ethical and research governance approval were obtained. Eligible participants who consented were randomised at the Norwich Medical School Clinical Trial Unit (CTU). Randomisation information was passed directly to the therapist. Recruitment of participants into the trial, randomisation and retention in the research assessments are detailed in the CONSORT diagram (Figure 1).

Figure 1 about here

Data analysis strategy

The primary outcome was CYBOCS score at the end of treatment. Sample size was adequate to detect a large treatment effect size (i.e. d = 0.8) which was considered to reflect clinical significance and is equivalent to a mean difference of 4 points on the CYBOCS. We compared individual CBT and parent enhanced CBT on CYBOCS score using repeated measures ANOVA with 3 levels of time (baseline, end of treatment and 6 month follow up). Secondary outcomes, i.e. depression and anxiety at end of treatment and at 6 month follow

up were examined using ANCOVA with baseline CYBOCS as covariate. Where appropriate, we made use of bootstrapping, sampling 5000 times with replacement (Chernick, 2008). Parameters were estimated and bias corrected and accelerated (BCa) 95% confidence intervals (CI) were reported. Data were analysed using SPSS 21.0.0.

We used an 'Intent to treat' (ITT) analysis; all randomised participants were included in the analysis. Missing data were imputed using the last observation carried forward (LOCF) procedure. We also examined per-protocol between-group differences with participants who engaged in CBT i.e. who completed 14 sessions or ended treatment by mutual agreement with their therapist and who completed research assessments.

Results

Demographic and clinical characteristics of the young person and their primary carer are shown in Table 1. There was no significant difference in young peoples' age, t (48) = .09, p =.93, BCa 95% CI =-.88 to .83, or gender, χ^2 = .00, p = 1.00, between treatment arms. All participants were of white British or European ethnicity, reflecting the local demographics. Young people had multiple anxiety disorders (mean = 2.7 diagnoses). All primary carers were female.

Table 1 about here

Before treatment, OCD severity was moderate to high. There was no significant between group differences in OCD, t (48) = .31, p =.76, BCa 95% CI =-[-2.48, 3.64], anxiety, t (44) = < 1, p = .63, BC_a 95% CI [-5.07, 8.74], or depression symptoms t (44) = < 1, p = .34, BC_a 95% CI [-4.50, 1.47 (see Table 2). OCD symptoms were significantly correlated with symptoms of anxiety, r = .47, p < .001, BC_a 95% CI [.24, .67], and depression, r = .43, p = .004, BC_a 95% CI [.17, .67]. Participants attended between 0 and 14 sessions of CBT (Individual CBT, mean = 10.7, family enhanced CBT, mean = 9.0; t (48) = 1.33, p = .19, BC_a

95% CI [-.70, 4.08]. Treatment adherence was good and did not differ between arms; mean CTS-R was 51.76 (4.41) for individual CBT and 51.43 (4.79) for family CBT. Three families dropped out of family enhanced CBT and zero families dropped out of individual CBT.

Table 2 about here

Primary Outcomes: OCD Symptoms

For the effect of treatment on OCD symptoms there was a significant main effect of time, $F\ (2, 47) = 67.28$, $p < .001$, $\eta^2 = .58$. Pairwise comparisons showed that OCD symptoms at baseline were significantly different than OCD symptoms at the end of treatment and at follow up and OCD symptoms at the end of treatment and at follow up did not differ. There was no significant main effect of treatment (individual CBT vs. parent enhanced CBT), $F\ (1, 48) = < 1$, $p = .94$, $\eta^2 = 0.00$ and no significant time by treatment interaction, $F\ (1, 48) = < 1$, $p = .94$, $\eta^2 = .001$. Participants in both groups reported significant reductions in OCD symptoms. The within-group effect size from baseline to end of treatment was d = 1.45 in individual CBT and d = 1.27 in parent-enhanced CBT. The within-group effect size from baseline to 6 month follow up was d = 1.53 in individual CBT and d = 1.50 for parent-enhanced CBT.

Storch, Lewin, DeNadai & Murphy, (2010) suggested that treatment response in OCD may be indicated by CYBOCS scores of 14 and below. We classified participants' CYBOCS scores to estimate treatment response. At the end of treatment 46% of participants had CYBOCS scores of 14 or below (48% in family CBT and 44% in individual CBT); at 6 month follow up 58% of participants had CYBOCS scores under 14 (60% in the family arm and 56% in the individual arm). This was not significant; end of treatment; $\chi^2\ (2) = < 1$, $p = .62$, 6 month follow up; $\chi^2\ (2) = < 1$, $p = .50$. There was also no significant difference in

treatment response amongst the participants who engaged in treatment (per protocol analysis) at the end of treatment or at 6 month follow up.

Secondary Outcomes: Symptoms of Depression and Anxiety

Data on anxiety and depression were available from 48 participants for ITT analysis. There were no differences between the groups for anxiety, $F\ (1, 45) = 3.11$, $p = .09$, $\eta^2 = .07$, BC_a 95% CI [-.18, 10.14], or depression, $F\ (1, 45) = 2.12$, $p = .15$, $\eta^2 = .05$, BC_a 95% CI [.57, 4.94], following treatment, or for anxiety, $F\ (1, 45) = 1.84$, $p = .19$, $\eta^2 = .04$, BC_a 95% CI [-1.51, 10.13], or depression at 6-month follow-up, $F\ (1, 45) = .17$, $p = .69$, $\eta^2 = .004$, BC_a 95% CI [-1.98, 3.03].

End of treatment and follow up data were also examined in per-protocol analyses. At the end of treatment 23 participants in individual CBT and 16 in family CBT provided data. Those in the family arm scored significantly lower than those in the individual arm on the measure of anxiety, $F\ (1, 36) = 6.91$, $p = .01$, $\eta^2 = .16$, BC_a 95% CI [2.31, 13.94], and depression, $F\ (1, 36) = 7.07$, $p = .02$, $\eta^2 = .16$, BC_a 95% CI [1.44, 7.21]. At six month follow up, 22 young people in the individual CBT arm and 18 in the family CBT arm provided data. There was no difference between the groups on the measure of anxiety, $F\ (1, 37) = 3.33$, $p = .08$, $\eta^2 = .08$, BC_a 95% CI [.11, 12.28], or depression, $F\ (1, 37) = 2.04$, $p = .16$, $\eta^2 = .05$, BC_a 95% CI [-.53, 3.88].

Discussion

This study is the first to directly compare low and high parental involvement in CBT for OCD in young people. Treatment effect sizes were large in both treatment groups and there was no significant difference in OCD symptoms at the end of treatment or after 6 months. However, many young people reported significant OCD symptoms after treatment. The trial was small and underpowered: a much larger study might report statistically

significant treatment differences but the between treatment effect size suggests that differences are unlikely to be clinically important. In addition, we did not assess diagnosis at the end of treatment so do not know how many participants were free of OCD or anxiety disorders at the end of treatment.

The study had some strengths: diagnosis of OCD at baseline was confirmed using the gold standard diagnostic interview schedule, randomisation was concealed, assessments were conducted by blinded assessors and the ITT analysis provides a conservative estimate of the treatment effect. CBT treatment was manualized, treatment fidelity was assessed, and well validated instruments were used to assess symptom severity. The external validity of the trial was good, participants were recruited from, and treated in routine NHS services and exclusion criteria were minimal. Thus, this sample of participants is probably characteristic of young people treated for OCD in the UK.

We did not assess diagnosis at the end of treatment so cannot judge how many participants were free of OCD or other anxiety disorders after treatment. Self-report data suggested that for participants who engaged in CBT, high parental involvement led to significantly lower anxiety symptoms than CBT with low parental involvement. If replicated this is of clinical importance because most young people with OCD have multiple co-morbid anxiety disorders. It is possible that when parents were fully involved in CBT that this provided greater opportunity for generalisation of exposure principles and cognitive strategies to other anxiety problems.

This study was not sufficiently large to detect a difference between high and low parental involvement in CBT for OCD in youth. Both types of CBT worked well and effect sizes were comparable to other trials of CBT for OCD. Important factors in clinical decision making include the preferences of the young person and their parents, family accommodation, co-morbidity, and the severity of other anxiety symptoms. Different ways of involving

parents and other family members in CBT for OCD require further attention. This study focused on adolescents, where extensive parental involvement may be less important than for younger children. Most studies have recruited a wide age range of participants and this may obscure important developmental differences which may interact with treatment delivery and outcomes. Future trials are needed to examine possible interactions between the age of the child or young person and parental involvement in treatment, the acceptability of involving parents extensively in CBT for adolescents, as well as the effects of CBT for OCD on other anxiety disorders.

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Figure 1: CONSORT Flow Diagram showing flow of participants through the trial and data available for primary outcome (CY-BOCS)

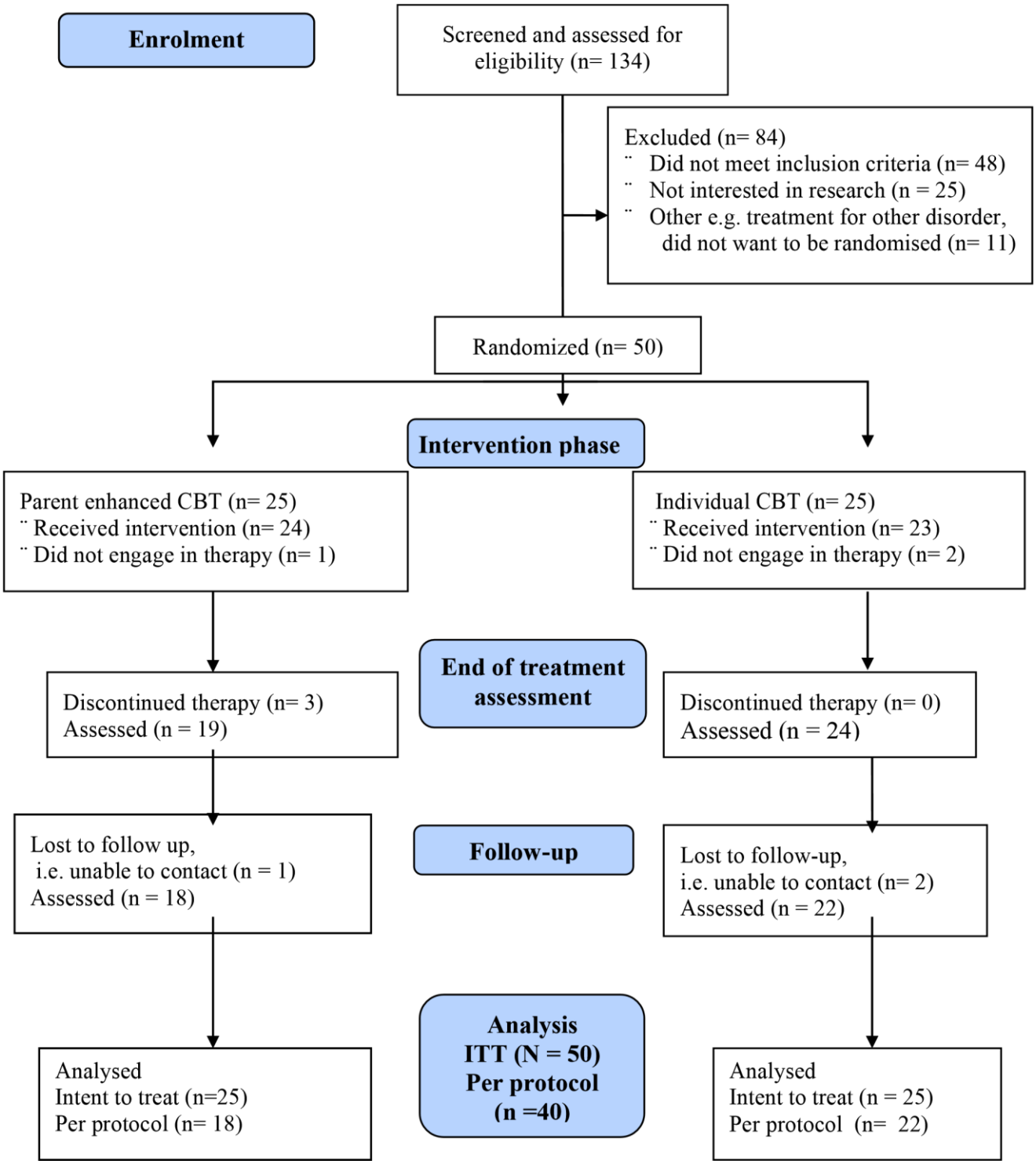

Table 1

Clinical and demographic characteristics of young people and primary carer

	Individual CBT N = 25		Parent enhanced CBT N = 25	
	X	SD	X	SD
Age - young person (in years)	14.4	1.35	14.6	1.61
Age – primary carer	43.9	5.04	46.4	6.92
<u>Co-morbid anxiety diagnoses</u>		%age		%age
Separation anxiety	6	24	7	28
Social phobia	15	60	14	56
Panic	2	8	2	8
Agoraphobia with panic	1	4	1	4
Agoraphobia without panic	1	4	5	20
Generalised anxiety disorder	17	68	16	64
PTSD/Acute stress disorder	1	4	2	8
Medication for mental health difficulties	4	16	5	20
<u>Primary carer education level</u>				
Secondary (to age 18)	16	64	21	84
College / university	9	36	4	16
<u>Primary carer occupational status</u>				
Full time employment	12	48	8	32
Part time employment	11	44	11	44
Not employed	2	8	6	24

Note. CBT= Cognitive Behavioural Therapy; PTSD= Post Traumatic Stress Disorder.

Table 2

Young person primary and secondary outcomes at baseline, end of treatment and follow up – intent to treat data.

Measure	Individual CBT		Parent enhanced CBT	
	X (SD)	95% CI	X (SD)	95% CI
Baseline				
CY-BOCS	24.32 (4.55)	22.44, 26.19	23.84 (6.13)	21.31, 26.37
BAI-Y	19.09 (13.55)	13.08, 25.10	17.29 (11.92)	12.26, 22.33
SMFQ	6.32 (5.45)	3.90, 8.73	7.88 (5.38)	5.61, 10.14
End of treatment				
CY-BOCS	14.32 (8.57)	10.78,17.86	14.08 (8.53)	10.55, 17.60
BAI-Y	16.41 (11.31)	11.71, 21.11	12.25 (10.58)	7.78, 16.72
SMFQ	5.95 (6.07)	3.99, 8.62	4.13 (4.33)	1.97, 6.28
6 month follow up				
CY-BOCS	12.12 (9.27)	8.29,15.95	12.40 (8.79)	8.78, 16.01
BAI-Y	13.82 (12.78)	8.86, 18.77	10.63 (10.25)	5.88, 15.37
SMFQ	3.82 (4.41)	1.90, 5.74	3.71 (4.51)	1.87,5.34

Note. CYBOCS= Children's Yale-Brown Obsessive Compulsive Scale, BAI-Y= Beck Anxiety Inventory Youth, SMFQ= Short Mood and Feelings Questionnaire,

Young person individual CBT n = 25, parent enhanced CBT n = 25

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