Efficacy of Cognitive Behaviour Therapy -v- Anxiety Management for Body Dysmorphic Disorder: a randomised controlled trial

Running head: CBT v Anxiety Management for BDD: a RCT

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Abstract

Background: The evidence base for the effectiveness of cognitive behaviour therapy (CBT) for treating Body Dysmorphic Disorder (BDD) is weak. Aims: To determine if CBT is more effective than anxiety management (AM) in an out-patient setting. Method: A single blind, stratified parallel-group randomized controlled trial. The primary endpoint was at 12 weeks, and the Yale Brown Obsessive Compulsive Scale for BDD (BDD-YBOCS) was the primary outcome measure. Secondary measures for BDD included the Brown Assessment of Beliefs (BABS), the Appearance Anxiety Inventory (AAI) and the Body Image Quality of Life Inventory (BIQLI). The outcome measures were collected at baseline and week 12. The CBT group, unlike the AM group, had 4 further weekly sessions that were analysed for their added value. Both groups then completed measures at their 1-month follow-up. Forty-six participants, with DSM-IV diagnosis of BDD including those with a delusional BDD were randomly allocated to either CBT or AM. Results: At 12 weeks, CBT was found to be significantly superior to AM on the BDD-YBOCS (β = -7.19, *S.E.* (β) = 2.61, $p < .01$, *C.I.* = -12.31, -2.07, d 0.99) as well as the secondary outcome measures of the BABS, AAI and BIQL. Further benefits occurred by Week 16 within the CBT group. There were no differences in outcome for those with delusional BDD or depression. Conclusions: CBT is an effective intervention for people with BDD even with delusional beliefs or depression and is more effective than anxiety management over 12 weeks.

Keywords Body Dysmorphic Disorder, Cognitive Behaviour Therapy, Anxiety Management, randomised controlled trial

Declarations of Interest: None

Introduction

Body Dysmorphic Disorder (BDD) is characterised by a preoccupation with a perceived defect(s) or flaw(s) in physical appearance that is either not noticeable or appears only slight to others. In addition, the preoccupation must be significantly distressing or cause impairment in social, occupational or other important areas of functioning. DSM5 has adder a further criterion to the diagnosis of BDD that is at some time point during the course of the disorder, the individual has performed repetitive behaviours (e.g. mirror checking) or mental acts (e.g. comparing) [1, 2]. BDD is more common than previously recognized with a prevalence of about 2% in the general population [3, 4]. It is a chronic disorder, which persists for many years if left untreated [5]. There is a high rate of psychiatric hospitalisation, suicidal ideation and completed suicide [6, 7]. It is poorly identified in psychiatric populations where, patients often do not reveal their problem, because of shame and stigma, or present with symptoms of depression, social anxiety or obsessive-compulsive disorder (OCD) when their main problem is BDD [5, 8]. In addition, many resources are wasted on those who attend dermatological and cosmetic surgery settings [9-11].

For pharmacotherapy of BDD, there are three randomised controlled trials (RCT) [12-14]. Phillips et al. [12] found that a selective serotonergic reuptake inhibitor (SSRI), fluoxetine was more effective than a placebo, and that delusional BDD made no difference to outcome. Phillips [14] also showed that adding an anti-psychotic, pimozide, to a SSRI was no more effective than adding a placebo in those who had not responded to a SSRI alone. Anti-psychotics are not therefore recommended in the NICE guidelines for the treatment of BDD [15, 16]. SSRIs are recommended for moderate to severe BDD with the proviso that, a high rate of relapse

is likely to occur on discontinuation of the SSRI [17]. However data on relapse rates with discontinuation of SRIs are very minimal, based on just one chart-review study.

There has been three small pilot RCTs of Cognitive Behaviour Therapy (CBT) in adults with BDD that have demonstrated greater effectiveness of CBT compared to a wait-list [18-20]. However, the participants in Rosen et al's [19] study were not that representative as the sample contained only women, several of whom who had disordered eating, and they were less impaired than those seen in psychiatric settings. Furthermore, the therapy was delivered in a group format. None of the previous RCTs determined whether the CBT was effective for delusional BDD or comorbid depression. Lastly none of the studies contained a comparison treatment to control for attention and non-specific therapeutic factors. Since these pilot trials, knowledge of phenomenology of BDD has increased and we have further developed a cognitive behavioural model to guide treatment [21, 22]. The aim of this research was therefore to determine if our CBT that is specific for BDD is more effective than a credible non-specific alternative (anxiety management) over 12 weeks for treating BDD with or without delusional BDD in adults aged 18 and over. Anxiety Management (AM) (based on applied relaxation) was chosen to control for therapist attention and alliance as well as homework. AM is not however a "placebo" – it is an active treatment that is effective for generalised anxiety disorder [23]. It has fared less well in previous studies against CBT for OCD [24] or health anxiety . However AM did as well as CBT in OCD with Asperger's Syndrome [25], and in multiple somatoform symptoms [26] and in the long term in one study for obsessions without prominent compulsions [27].

Objectives

In the current study we tested the hypotheses that CBT would be superior to AM in reducing symptoms of BDD at a primary outcome point of 12 weeks. In addition, an improved outcome within the CBT group after an extra 4 sessions of therapy was tested. Further secondary aims of this study were to explore (a) whether CBT was as effective in those with delusional BDD and depression, (b) whether the gains in CBT and AM were maintained at 1-month follow-up.

Method

Design

This was a single-blind stratified (by presence of delusional BDD and severity of depression), parallel-group randomised controlled trial conducted in the UK. The allocation ratio used was 1:1. There were no changes to the trial design after commencement.

Participants

Inclusion Criteria

The eligibility criteria for participants were as follows:

(1) Have a diagnosis of BDD according to DSM-IV diagnostic criterion [1] as their main problem. DSM-IV was used as this was operational at the time the study began. BDD was defined as their main problem if it was their reason for referral to treatment, their symptoms were not explained better by any other mental disorder, and their clinical outcome measures were indicative of BDD being their most severe mental concern. A trained clinician made the diagnosis on the Structured Clinical Interview for DSM-IV Axis I Disorders [28]. When there was comorbidity, there had to be agreement between the clinician and the patient that their appearance was their main concern. Participants with an additional diagnosis of delusional BDD were included when the diagnosis referred to delusional beliefs about being ugly or defective.

(DSM-IV allows double coding of both BDD and delusional BDD, which does not occur in DSM-5). Other types of somatic delusions and non-appearance related delusions were excluded.

(2) Have a total of 24 or more on the Yale Brown Obsessive Compulsive Scale modified for BDD (BDD-YBOCS) [29]. This was the equivalent of scoring at least 2 ("moderate") on all 12 items.

(3) Be aged 18 or above.

(4) Be willing to travel to the treatment centre for weekly sessions.

(5) Either not be on psychotropic medication or, if taking medication, be on a dose that had been kept stable for at least 12 weeks prior to randomization with no plans to increase the dose during the course of the study. This was subsequently monitored during the study.

Exclusion criteria

Participants were excluded if they:

(1) Had a current or lifetime diagnosis of schizophrenia, schizoaffective or bipolar affective disorder.

(2) Had severe self-neglect or suicidal intent that required hospitalisation.

(3) Had a current diagnosis of alcohol/substance dependence, anorexia nervosa or borderline personality disorder that required treatment first.

(4) Had body image concerns that primarily related to weight and/or shape or fulfilled criteria for "Eating Disorder Not Otherwise Specified".

(5) Were currently receiving any other form of psychotherapy.

(6) Had received CBT for BDD in the past 6 months, which was judged by the clinician as competently delivered.

(7) Did not have sufficient command of English to participate in the therapy and complete rating scales.

The recruitment took place between April 2009 and March 2012 at a single centre, which was an outpatient clinic at the Centre for Anxiety Disorders and Trauma at the Maudsley Hospital, London. The centre is part of an Improving Access to Psychological Therapies (IAPT) or "primary care" service. It also takes national referrals (or "secondary care" service where patients are also under the care of their own local community mental health team). It is also part of a national funded Highly Specialised service for severe treatment refractory OCD and BDD (which is a "tertiary care" service).

Interventions

The two interventions to be evaluated were:

(1) Cognitive behaviour therapy (CBT). This is a focussed form of psychotherapy that consisted of 12 weeks of individual sessions of 1 hour at weekly intervals. It followed a treatment manual [30]. The first stage consisted of engagement in a developmental understanding of the problem and setting up an alternative view of the problem to be tested in therapy. Imagery re-scripting followed for past aversive memories that were associated with the onset (for example bullying) [31]. A formulation further identified factors that were maintaining the person's preoccupation and distress relating to perceived ugliness. These included understanding the unintended consequences of their safety-seeking behaviours that maintain preoccupation and distress in the long term. The behaviours were aimed at either: (i) threat detection and monitoring (for example, cognitive processes such as self-focussed attention or behaviours such as mirror checking) or (ii) preventing feared consequences by avoidance (for example, comparing or camouflaging a perceived

defect) or (iii) attempts to undo the appearance concerns (for example, seeking a cosmetic procedure). The therapist aimed to help individuals to identify their beliefs about processes such as ruminating or mirror gazing [32]; to conduct behavioural experiments that tested out their expectations or an alternative understanding of the problem; and to gradually drop the safety seeking behaviours and test out their fears in situations or activities that are avoided. These are done in vivo within and between sessions for homework. It does not focus on evaluations such as being ugly. Self-monitoring and habit reversal was used for any skin-picking.

(2) Anxiety Management. The treatment followed a standard protocol [33] . It was provided once a week for 12 weeks, with each session lasting one hour. AM was planned to have a similar therapeutic alliance, support, and homework to the CBT group. The rationale provided was that when triggered, the person would experience threat and negative thoughts about their appearance. This in turn would lead to physical symptoms of anxiety and magnify the perceived threat. The treatment consisted of (1) practising progressive muscle relaxation and breathing daily; and (2) identifying triggers and physical symptoms associated with appearance-related anxiety, and utilising brief muscle relaxation and breathing techniques in trigger situations.

The aim was to reduce baseline anxiety, anxiety in trigger situations or when they became anxious about their appearance. AM was not given for 16 weeks, in contrast to CBT, as the researchers did not consider it feasible to continue treatment for such a length of time.

After AM, there was a wait-list for 4 weeks when participants were able to cross-over into CBT, if they still fulfilled criteria for BDD. At the very beginning of treatment, both groups were told that after the end of their treatment they would be

offered another type of treatment, to balance the obligation to provide care. Twelve weeks of hourly sessions were implemented for both treatments, as it was considered unethical to deny participants receiving Anxiety Management, the more established treatment of CBT, for a period longer than 12 weeks. Twelve weeks was considered the maximum time limit for gains from AM and sufficient to determine whether CBT was superior to AM. The primary endpoint was therefore taken at 12 weeks. Further research is required to determine the optimum length of CBT for BDD that may be considered longer than 12 weeks. For both CBT and AM there was no direct targeting of other symptoms such as depression or other comorbidity.

Evaluation of therapy

Participants completed the Credibility and Expectancy Questionnaire at baseline [34]. The questionnaire measures the credibility and treatment expectancy of the treatment assigned. Each sub-scale has a range of 3 to 27. A higher score indicates higher credibility or expectation for improvement.

Three therapists with at least 5 years of experience and either a Doctorate in Clinical Psychology or accreditation by the British Association for Behavioural and Cognitive Psychotherapies delivered the interventions. All three therapists were crossed to deliver both treatments. This was determined by clinician expertise and availability. They were trained and supervised weekly in the delivery of the treatments. Therapy sessions were audio-recorded (when consented to in writing) and a random sample of 1 in 10 audiotapes was rated blind by three accredited CBT therapists using an adherence rating scale developed for the study in order to measure treatment fidelity and quality. Elements of therapy, such as “use of behavioural experiments” (CBT), “teaching breathing techniques” (AM), and other non-specific components of both treatments such as “agenda setting” were rated as to whether they

were included in treatment sessions. Scores for included components of therapy were summed to give a total. In addition, therapist directiveness was rated on a 5-point Likert scale ranging from 0 (very non-directive) to 4 (very directive), and therapeutic relationship was rated on a 4-point Likert scale from 0 (poor) to 3 (very good). Independent t-tests were conducted on therapy components, therapist directiveness and therapeutic relationship mean scores.

Outcomes

Information was collected on age, sex, ethnicity, marital status, occupation, and comorbid diagnoses using the Structured Clinical Interview for DSM-IV Axis I Disorders. For all participants taking a SSRI, a fluoxetine equivalent dose was calculated (for example fluoxetine 20mg was equivalent to citalopram 20mg or sertraline 50mg).

All outcome measures apart from the Credibility Expectancy Questionnaire (CEQ) were repeated at baseline, and week 12 (primary end-point) in both groups. The CBT group also completed measures at 16 weeks, after receiving 4 extra treatment sessions. Measures were repeated at 1-month follow-up in both groups. The CEQ was administered once at pre-treatment.

The primary outcome measure was the Yale Brown Obsessive Compulsive Scale modified for BDD (BDD-YBOCS) [29]. This is a clinician rated scale administered by a trained blind assessor. The range is 0-48. Cronbach's alpha for the scale is .80. Response to treatment is defined as 30% or greater decrease in the total BDD-YBOCS, which best corresponded to "much improved" on the Clinical Global Impression (CGI) scale. In the original validation study, this cut off score produced 1 false negative (96% sensitivity), that is 1 who was rated as much or very much

improved on the CGI was not classified as a responder on the BDD-YBOCS using the 30% threshold [29].

The following were secondary outcome measures:

(1) Brown Assessment of Beliefs Scale (BABS) [35]

The BABS is a 7-item clinician scale rated by a blind assessor to measure the strength of conviction in a belief (e.g. “I am as ugly as the Elephant man”). Each item is rated from 0 (non-delusional belief, or least pathological) to 4 (delusional belief, or most pathological) and total scores range from 0-24. Higher scores represent increasing delusionality of beliefs. Respondents are classified as having delusional BDD beliefs if the total score is 18 or more, and if they score 4 on the first item indicating they are completely convinced that their belief is accurate.

(2) Montgomery Asberg Depression Rating Scale (MADRS) [36]

The MADRS is a 10-item clinician scale rated by a blind assessor to measure symptoms of depression. Each item is rated on a 7-point Likert scale from 0 indicating normal or no difficulties, to 6 and the range is 0 to 60. Higher scores reflect greater symptomatology. A MADRS total score ≥ 25 is regarded as moderate and > 31 as severe symptom [37].

The following self-report measures were administered weekly:

(1) Appearance Anxiety Inventory (AAI) [38]

The AAI is a 10-item self-report questionnaire for measuring frequency of avoidance behaviour and threat-monitoring (e.g. checking; self-focussed attention) that are characteristic of a response to a distorted body image. Each item is scored from 0 (“not at all”) to 4 (“all the time”), and the range of total scores is from 0 to 40 with higher scores reflecting greater frequency of the responses. The AAI has a Cronbach’s alpha of .86.

2) PHQ-9 Depression Severity [39]

The Patient Health Questionnaire (PHQ) is a 9-item self-report measure of depression. Each item is scored from 0 ("not at all") to 3 ("nearly every day"), and the summed total score ranges from 0 to 27 with higher scores reflecting greater symptomatology of depression. Cronbach's alpha for the scale is .89.

3) Generalized Anxiety Disorder (GAD-7)[40]

The GAD-7 is a 7-item self-report measure for symptoms of generalized anxiety. Each item is scored from 0 to 3 and a summed total score ranges from 0 to 21, with higher scores reflecting greater symptomatology. Cronbach's alpha for the measure is .92.

4) Body Image Quality of Life Inventory (BIQLI) [41, 42].

The BIQLI is a 19-item self-report scale that measures the impact of body image concerns on a broad range of life domains (e.g. sense of self, social functioning, sexuality, emotional well-being, exercise, grooming). The BIQLI is scored as an average numeric score of all the items from -3 ("very negative effect") to + 3 ("very positive effect"). Cronbach's alpha of the scale is .95.

Sample size

A sample size of 20 per group was calculated to give 90% power and a two-sided 5% significance for detecting a beneficial difference of 8 and standard deviation of 7 on the BDD-YBOCS between CBT and anxiety management. These assumptions were made based on a previous RCT of CBT in BDD [18] and approximates to a reduction of 30% on the BDD-YBOCS and clinically significant improvement in BDD symptoms [29]. There was an anticipated 10% drop-out giving a planned sample size of 22 per group or 44 in total. There were no planned interim analyses or stopping rules.

Randomization

Sequence generation

Randomization was conducted via the UKCRC-registered King's Clinical Trials Unit using a web-based system. Randomization was at the level of the individual participant, by the method of minimization stratified by (1) the presence or absence of delusional beliefs on the BABS and (2) either high score (25 or above on the MADRS) or a low score (below 25) [37]. The first 4 patients were randomized using simple randomization to create an initial level of imbalance. The minimization algorithm contained a 20% random component for subsequent patients, to maintain pre-randomization allocation concealment. Patients were told they were being randomized to two different types of psychological therapy and if they wished could switch to the alternative therapy after 12 weeks.

Allocation concealment mechanism

The allocation sequence was concealed from the research assessor. An email confirming the treatment allocation was sent directly to the therapist.

Implementation

The research assessor enrolled participants in the trial and gained written informed consent for their participation in the trial as well as treatment.

Blinding

The research assessor administering the observer rated scales was blinded to group assignment at baseline and 12 weeks. She had no access to clinician notes, which were kept in a different office and was not involved in supervision or discussion of treatment. While the blind assessor was located in the same building as the therapists, they worked on separate floors. As all therapists were crossed, should

the assessor have been at risk of seeing a patient entering a therapist's office, blinding would not have been broken.

Statistical methods

All data were entered into Statistical Package for the Social Sciences (SPSS), version 21 for Windows. The analysis of effectiveness was based on "intention to treat", utilising data from those participants who provided baseline and follow-up data, regardless of whether they completed treatment. To reduce missing data from partially filled in questionnaires, the average score was computed for questionnaires where only one item was missing. In order to correct for multiple missing item data for questionnaires with two or more missing items, and in some cases entire missing measures, multiple imputation was used. Group, baseline BDD-YBOCS, MADRS, BABS and AAI scores were entered into the model as predictors of missing data and 30 imputations were run. In order to assess baseline equivalence of the groups, proportions of categorical variables at baseline (for example demographics) were compared between groups using Fisher's exact tests. Values of continuous measures at baseline were compared using the Mann-Whitney *U*-test. Primary and secondary effectiveness analysis for both groups was based at 12 weeks. Results are summarised by mean differences and corresponding 95% confidence intervals. All measures were two-tailed.

Linear mixed models were conducted to determine the predictive value of treatment group, and or time on outcome variable scores. These measures had a significance of 5% (two-sided). Repeated-measures t-tests were then used to determine where significant differences occurred. Where more than one t-test has been conducted on each variable, a Bonferroni correction was used to decrease the risk of type I error. For the CBT group, repeated-measures t-tests had a significance

level of 1.66%, and the AM group had a repeated-measures t-test significance level of 2.5%

A logistic regression analysis was used on binary outcomes as either “much improved” (≥ 30% change on BDD-YBOCS) or not recovered. A 30% or more decrease in BDD-YBOCS score was considered “much improved” on the basis that it is significantly correlated with response of BDD symptoms measured using the Clinical Global Impressions scale (CGI) [29, 43]. We conducted a stepwise multiple regression analysis to determine whether delusional beliefs on the BABS or severely depressed mood on the MADRS (> 31) predict response.

Ethics

The study had ethical approval from the Institute of Psychiatry and South London and Maudsley NHS Trust Ethics Committee. (NHS REC ref no: 09/H0907/9). Neither the original study design, nor the original treatment length was changed during the study.

Results

Figure 1 is a CONSORT trial flowchart of the numbers assessed, allocated to each group, receiving intended treatment, completing the study protocol and being analysed for the primary outcome.

----------FIGURE 1 ABOUT HERE ----------

The recruitment took place between April 2009 and March 2012. Follow-ups took place between December 2009 and September 2012. Participants attended therapy sessions once a week. The trial ended when all participants had completed follow-up.

Treatments were acceptable to both groups with no significant difference in the number of drop-outs between the groups (Chi square with Yates correction 0.33, *p*

= .56). Table 1 provides baseline demographic and clinical characteristics for all participants and for each group. As a group they would be regarded as in the moderate to severe range of BDD. Over half were diagnosed as having a delusional BDD, nearly two-thirds having had a trial of at least one SSRI in the past and one third having had at least one cosmetic procedure in the past. A slightly lower range of general comorbidity is demonstrated in this sample in comparison to previous surveys (see Table 1).

----------TABLE 1 ABOUT HERE ----------

The CBT group had 21 participants and the AM group had 25. There were no significant differences between the two groups in the demographics and other baseline variables. Of note is that both groups rated the credibility of the treatment as equally low and had a poor expectancy of change. Eighty-three percent desired at least one cosmetic or dermatological procedure. Nearly half the participants were stabilised on a selective serotonin reuptake inhibitor (SSRI) (either fluoxetine, citalopram, or sertraline). There was no significant difference between treatment groups in the frequency of participants taking an SSRI or the dose prescribed. Apart from the SSRIs, one participant in the CBT group was taking zopiclone 3.75mg at night, one participant in the AM group was taking a Selective Noradrenergic and Serotonergic reuptake inhibitor (SNRI) (venlafaxine) 150mg daily, one was taking St John's Wort 900mg daily and one was taking quetiapine 50mg daily. There were no changes in medication type or dosage prescription throughout the duration of the study.

The main features of preoccupation in the whole group, in order of prevalence were; skin (*n* = 8, 17.4%), face in general (*n* = 7, 15.2%), nose (*n* = 7, 15.2%), legs (*n* = 3, 6.5%) body hair (*n* = 3, 6.5%), and all other concerns (n = 18, 39.2%).

Blind ratings of session recordings for the CBT group indicated that there was a mean of 15.3 (*SD* = 4.7) components of CBT per session and zero components of AM per session t (46) = 15.75, $p < .001$. For the AM group there was a mean of 15.60 (*SD* = 6.60) components of AM per session and mean of 0.21 (*SD* = 0.50) components of CBT per session t (46) = 11.57, $p < .001$. There were therefore no violations of CBT being used in AM and vice versa. In terms of blind ratings of the therapeutic relationship, CBT (*Mean* = 2.42, *SD* = 0.83) did not differ to AM (*Mean* = 2.17, *SD* = 0.64) t (46) = 1.17, $p = .25$. Equally, for therapist directiveness, CBT (*Mean* = 2.25, *SD* = 0.68) did not differ to AM (*Mean* = 2.38, *SD* = 0.97) t (46) = -.51, $p = .61$.

Table 2 shows the linear change in dependent variable scores from baseline to week 12 and interaction between group and time for all outcome measures.

----------TABLE 2 ABOUT HERE ----------

There was a significant group by time interaction for the primary outcome (BDD-YBOCS) and other body image measures (BABS, AAI, and BIQLI scores) at week 12. There was no group by time interaction for depression (MADRS or PHQ-9) or general anxiety (GAD-7). A main effect of time predicted BDD-YBOCS and AAI scores across both time points. Treatment group predicted BIQLI scores. Table 3 provides mean, standard deviation and effect size, for each group, across measurement points, and the Cohen's *d* effect size between CBT and AM for all outcome measures. Large effect sizes of 1 between CBT and AM at 12 weeks were found for BDD-YBOCS and AAI scores.

----------TABLE 3 ABOUT HERE ----------

For within-group analysis of CBT there was a significant decrease across all the measures (including depression and general anxiety) at week 12. For the AM

group there was a significant decrease only for the BDD-YBOCS and AAI at week 12.

The number of responders (defined as a decrease of 30% or more on the BDD-YBOCS) at 12 weeks was 10/21 (48%) in the CBT group and 3/25 (12%) in the AM group χ^2 (1) = 6.20 p = .013. For the CBT group, after 16 sessions, 11/21 (52%) were responders, McNemar's Test n = 21, Exact p = .25. At one-month follow-up for the CBT group, all 11 responders (100%) had maintained their 30% BDD-YBOCS score decrease (McNemar's Test n = 21, Exact p = 1.00). At 1 month follow-up for the AM group all 3 responders (100%) had also maintained recovery, McNemar's Test n = 25, Exact p = 1.00. CBT was also superior to AM in gradually reducing the cognitive processes and behaviours that are thought to maintain BDD on the AAI (see Figure 2, supplementary material).

Pre-specified subgroups of those with comorbid depression or delusional BDD at baseline were compared over time. Table 4 (in supplementary material) shows the linear change in blind assessor scores from baseline to week 12 for the subgroups (depressed vs non-depressed and delusional BDD vs non-delusional BDD) within both treatment groups.

The interaction between time and comorbidity at baseline was not significant across both treatment groups for the BDD-YBOCS. This indicates that the treatment was just as effective over time for both subgroups. Delusional BDD significantly predicted BDD-YBOCS scores in the CBT group. Table 5 (in supplementary material) shows outcomes with estimated effect sizes for subgroup comparisons at baseline and week 12 and baseline to week 16 for CBT. Both Table 4 and Table 5, display findings with decreased power due to their representation of a smaller subgroup.

Those who with delusional BDD at baseline in the CBT group had significantly higher baseline scores on the BDD-YBOCS than those who did not have delusional BDD. This difference was no longer significant by the end of treatment, indicating that CBT was associated with a large decrease in BDD-YBOCS scores for participants with delusional BDD.

Finally, there was no difference between the groups in terms of treating severe depression. Five out of 9 (56%) participants in the CBT group who were severely depressed at baseline, and 4/11 (36%) who were severely depressed at baseline from the AM group had recovered from depression at week 12, (χ^2 (1)= 1,73. p =.19). Those 5 from the CBT group, remained recovered at week 16 after their final treatment session McNemar's Test n = 21, Exact p = 1.00. At one month follow-up conducted for the CBT group, 5 participants remained recovered, indicating that the effect of treatment on depression was maintained, McNemar's Test n = 9, Exact p = 1.00. Equally, for the AM group, 4 participants indicated recovery from severe depression that at one month follow-up, McNemar's Test n = 21, Exact p = .1.00

Multiple regression analysis was conducted to find predictors of BDD-YBOCS outcomes. Duration of BDD, depression, and strengths of beliefs (on the BABS) at baseline were not significant predictors of BDD-YBOCS outcomes. There were no harms or unintended effects to participants in either group.

Discussion

This is the first study to examine the efficacy of CBT as compared to another credible psychological treatment for BDD. The study demonstrated that CBT that is targeted at BDD is more effective than AM after 12 weeks when evaluated using specific measures for BDD for the group by time interaction. AM also had a significant effect on reducing BDD-YBOCS, AAI and depression over time at week

12 but CBT had a larger effect size than AM that was significant across all the measures. CBT was just as effective in those with delusional BDD or in those who were significantly depressed. Therefore CBT should not be regarded as only suitable for those with good insight or who are not depressed. Overall, the results of the current study support previous studies [18-20] regarding the effectiveness of CBT for BDD, but also advances the field, as the current study included an active psychological treatment (AM) that was compared against CBT, while previous studies only used wait-list control and have not examined effectiveness in comorbid delusional BDD or depression.

It may be a concern that the AM group did not show within-group improvements in GAD-7 scores, whereas the CBT group did. However AM was not targeting generalised anxiety and worry symptoms, it was specifically aimed at anxiety related to appearance, to be applied for use in situations when patients felt particularly anxious about their appearance.

The strengths of the study are that the groups were matched prior to randomization and the comparator controlled for the passage of time and therapist attention. The treatments were rated as equally credible, the therapists were rated as having an equally good therapeutic alliance and both groups had homework tasks for practice. The cohort in the current study was more severe (in terms of severity on the BDD-YBOCS, the proportion who had had a previous treatment with a SSRI and the proportion who desired a cosmetic procedure) than those recruited for previous RCTs in CBT v a wait-list [18-20]. Current comorbidity was however slightly low for this population compared to other studies.

There are two previous RCTs of CBT v a wait-list that used the BDD-YBOCS as the main outcome measure. The within-group effect size in this study at 16 weeks

was 1.67, which is similar to that of Veale et al.[18] (1.57) and Rabiei et al.,[20] (1.49). The frequency of responders in the CBT group on the BDD-YBOCS (52%) is similar to the trial of fluoxetine -v- a placebo in BDD [12]. The fluoxetine trial however had a lower within-group effect size on the BDD-YBOCS of 1.36. Open label case series of SSRIs have however found response rates of between 63-73% [44]. However one should be cautious about comparing effect sizes in previous RCTs of BDD as the numbers in all the trials are small and participants may have been less severe in some of the studies compared to this trial. However the findings strengthen the UK NICE guidelines on BDD in recommending CBT for BDD including those with a delusional BDD or depression [15, 45].

The trial included participants of a representative population of BDD (for example both sexes, varied ages, symptoms of features that are common in BDD and participants with or without medication and who are likely to present in a psychiatric setting). Given the wide variety of demographic characteristics and recruitment from standard routes of referral, it is reasonable to assume that the intervention can potentially generalise to other settings if a therapist can build experience in treating BDD. When considering CBT for BDD, slight caution is required in future meta-analyses as not all forms of CBT for BDD are identical. For example, meta-cognitive therapy [18] evaluated in a recent trial, or CBT for BDD as published by Wilhelm et al., (2013)[46] overlaps with our protocol, but is based on somewhat different conceptualisation and interventions.

We do not have sufficient information on the mechanism of change in either group. The AAI was measured weekly to identify the frequency of the cognitive processes and safety seeking behaviours that are conceptualised to be important in maintaining preoccupation, distress and handicap related to a distorted body image in

BDD. During CBT these processes decreased steadily, and more than they did in AM and were associated with reductions in symptoms of BDD. A much larger study would be required to demonstrate that such processes may mediate change. The optimum length of treatment would appear to be *at least* 16 sessions. The trajectory of the outcome scores beyond 16 weeks suggests that some patients may benefit from more than 20 sessions especially if one includes modules for depression or other comorbidity [47]. Future protocols of CBT might also include loading the frequency of sessions at the beginning of therapy (for example twice weekly for the first 4 weeks). This would be similar to the original cognitive therapy protocol for treating depression [48], the rationale being to maximize engagement and also improve symptoms of depression.

Limitations

The study has a relatively small sample that may over-estimate effect size. Although there were no significant differences for the CEQ and other measures between the groups at baseline, the small sample size may have led to a Type II error. The analysis of the sub-sample for depression and delusional BDD may also be subject to a Type II error. Small sample size may also have led to the difficulty in identifying any predictors of outcome. Trials of clinical effectiveness with larger sample sizes are therefore required. No formal testing of blindness of the rater was conducted and our group could be accused of having an investigator bias towards CBT. However we believed that requesting the research assessor to guess blinding would be biased as it may be influenced by her rating of the outcome. The study is also limited by not reporting reliability data on the directiveness and therapeutic relationship scales, which may have been biased by measurement error. The study may have benefitted from a standard quality of life measure alongside the main

outcomes and reporting on the inter-rater reliability of the adherence ratings. Delivering 12 sessions of therapy may have resulted in less gains being achieved at our primary outcome. A 12 week duration may have been too brief to achieve significant changes BDD and depression. An optimal therapy length may well be between 16 and 24 sessions. However, the aim of this particular study was to demonstrate the specific nature of the CBT in comparison to AM.

The design of the study compared unequal lengths of treatments as the CBT group received 16 weeks of sessions whereas the AM group received only 12. However the outcome measures were only compared between the groups at 12 weeks. Within-group effects were only analysed for CBT from 12 to16 weeks. It would have been beneficial to do the same for AM so that implications of the findings could go beyond 12 weeks for both interventions, however it was deemed unethical to continue AM for longer than 12 weeks (discussed above). Currently we are unable to conclude higher effectiveness of CBT in comparison to AM post 12 weeks of intervention. In addition, follow-up outcomes analysed for both AM and CBT groups were only conducted at 1 month post-treatment. It may have been optimal to consider the maintenance of study outcomes over a longer-term follow-up period. The research was conducted at a single centre with specialist expertise in BDD and further research is required to determine the generalizability of the findings in other settings.

Further research

The study suggests that gains are maintained at 1-month follow-up for the CBT group. Further research is required to compare treatments at the same end-point beyond 12 weeks and to determine long-term follow-up of one year or more, in order to better consider efficacy of treatments. CBT is a complex intervention and there is a need to unbundle specific modules such as imagery rescripting to determine their

effectiveness and contribution to the package. Although about half our participants were already stabilised on a SSRI at enrolment, many were not taking a maximum dose. Future controlled trials are required to determine whether the outcome of CBT is enhanced by augmentation of SSRIs at the maximum tolerated dose. Although it is gratifying that there was a large effect size by 16 weeks and 52% had a significant clinical response, nearly half remain non-responders. It may be that a longer or more intensive CBT or in a residential setting will be more beneficial to some participants. This is not surprising given the chronicity of their problems, previous failure of treatment and the frequent comorbidity. Further research is required to develop CBT for this difficult to treat population. Lastly it would be helpful to determine the cost-effectiveness of CBT, whether CBT can be successful in adolescents, how long it should optimally be delivered for in different groups and whether it can be adapted to different settings especially in dermatology and cosmetic surgery clinics, where a cognitive behaviour therapist could be sited alongside the physician or surgeon.

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Registration

Trial registration: isrctn.org identifier: 96566335. ClinicalTrials.gov identifier: NCT00871143.

Protocol

The protocol is available from the authors.

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References

1. American Psychiatric Association. Diagnostic & Statistical Manual of Mental Disorders 4th edition. Washington DC: American Psychiatric Association; 1994.

2. Phillips KA, Wilhelm S, Koran LM, Didie ER, Fallon BA, Feusner J, Stein DJ. Body dysmorphic disorder: Some key issues for DSM-V. Depress Anxiety 2010;27:573-91.

3. Koran L, Abujaoude E, Large M, Serpe R. The prevalence of body dysmorphic disorder in the United States adult population. CNS Spectrums 2008;13:316-22.

4. Rief W, Buhlmann U, Wilhelm S, Borkenhagen A, Brahler E. The prevalance of body dysmorphic disorder: A population-based survey. Psychol Med 2006;36:877-85.

5. Veale D, Boocock A, Gournay K, Dryden W, Shah F, Willson R, Walburn J. Body dysmorphic disorder. A survey of fifty cases. Brit J Psychiat 1996;169:196-201.

6. Phillips KA, Coles M, Menard W, Yen S, Fay C, Weisberg RB. Suicidal ideation and suicide attempts in body dysmorphic disorder. J Clin Psychiatry 2005;66 717-25.

7. Phillips KA, Menard W, Pagano ME, Fay C, Stout RL. Delusional versus nondelusional body dysmorphic disorder: Clinical features and course of illness. J Psychiat Res 2006;40:95-104.

8. Phillips KA, Nierenberg AA, Brendel G, Fava M. Prevalence and clinical features of body dysmorphic disorder in atypical major depression. J Nerv Ment Dis 1996;184:125-9.

9. Phillips KA, Dufresne RG. Body dysmorphic disorder: A guide for dermatologists and cosmetic surgeons. Am J Clin Dermatol 2000;1:235-43.

10. Sarwer DB, Pertschuk MJ, Wadden TA, Whitaker LA. Psychological investigations in cosmetic surgery: A look back and a look ahead. Plast Reconstr Surg 1998;101:1136-42.

11. Veale D, De Haro L, Lambrou C. Cosmetic rhinoplasty in body dysmorphic disorder. Brit J Plast Surg 2003;56:546-51.

12. Phillips KA, Albertini RS, Rasmussen SA. A randomized placebo-controlled trial of fluoxetine in body dysmorphic disorder. Arch Gen Psychiat 2002;59:381-8.

13. Hollander E, Allen A, Kwon J, Aronowitz B, Schmeidler J, Wong C, Simeon D. Clomipramine vs desipramine crossover trial in body dysmorphic disorder: Selective efficacy of a serotonin reuptake inhibitor in imagined ugliness. Arch Gen Psychiat 1999;56:1033-42.

14. Phillips KA. Placebo-controlled study of pimozide augmentation of fluoxetine in body dysmorphic disorder. Am J Psychiat 2005;162:377-9.

15. National Institute for Health and Clinical Excellence (NICE). Obsessive-compulsive disorder: Core interventions in the treatment of obsessive-compulsive disorder and body dysmorphic disorder and body dysmorphic disorder: NICE clinical guidelines 31; 2005.

16. The National Collaborating Centre for Mental Health (NCCMH). Obsessive compulsive disorder: Core interventions in the treatment of obsessive compulsive disorder and body dysmorphic disorder. Leicester and London: The British Psychological Society and Royal College of Psychiatrists.2006.

17. Jain S, Grant JE, Menard W, Cerasoli S, Phillips KA. A chart-review study of SRI continuation treatment versus discontinuation in body dysmorphic disorder. Abstracts, National Institute of Mental Health NCDEU 44th Annual Meeting; Phoenix, AZ. 2004. p. 231

18. Veale D, Gournay K, Dryden W, Boocock A, Shah F, Willson R, Walburn J. Body dysmorphic disorder: A cognitive behavioural model and pilot randomised controlled trial. Behav Res Ther 1996;34:717-29.

19. Rosen JC, Reiter J, Orosan P. "Cognitive-behavioral body image therapy for body dysmorphic disorder": J Consult Clin Psych 1995;63:263-9.

20. Rabiei M, Mulkens S, Kalantari M, Molavi H, Bahrami F. Metacognitive therapy for body dysmorphic disorder patients in Iran: Acceptability and proof of concept. J Behav Ther Exp Psychiatry 2012;43:724-9.

21. Veale D. Advances in a cognitive behavioural model of body dysmorphic disorder. Body Image 2004;1:113-25.

22. Neziroglu F, Khemlani-Patel S, Veale D. Social learning theory and cognitive behavioral models of body dysmorphic disorder. Body Image 2008;5:28-38.

23. Manzoni GM, Pagnini F, Castelnuovo G, Molinari E. Relaxation training for anxiety: A ten-years systematic review with meta-analysis. BMC Psychiatry 2008;8:41.

24. Lindsay M, Crino R, Andrews G. Controlled trial of exposure and response prevention in obsessive-compulsive disorder. B J Psychiatr 1997;171:138-9.

25. Russell AJ, Jassi A, Fullana MA, Mack H, Johnston K, Heyman I, Murphy DG, Mataix-Cols D. Cognitive behaviour therapy for comorbid obsessive-compulsive disorder in high-functioning autism spectrum disorders: A randomized controlled trial. Depress Anxiety 2013;30:697-708.

26. Schröder A, Heider J, Zaby A, Göllner R. Cognitive behavioral therapy versus progressive muscle relaxation training for multiple somatoform symptoms: Results of a randomized controlled trial. Cog Ther Res 2013;37:296-306.

27. Whittal ML, Woody SR, McLean PD, Rachman S, Robichaud M. Treatment of obsessions: A randomized controlled trial. Behav Res Ther 2010;48:295-303.

28. First M, Gibbon M, Spitzer R. Structured Clinical Interview for DSM-IV Axis I Disorders, Patient Edition (SCID-I/P, Version 2.0) Biometrics Research 1996.

29. Phillips KA, Hollander E, Rasmussen SA, Aronowitz BR, DeCaria C, Goodman WK. A severity rating scale for body dysmorphic disorder: development, reliability, and validity of a modified version of the Yale-Brown Obsessive Compulsive Scale. Psychopharmacol Bull 1997;33:17-22.

30. Veale D, Neziroglu F. Body Dysmorphic Disorder: A treatment manual. Chichester: John Wiley & Sons; 2010.

31. Osman S, Cooper M, Hackmann A, Veale D. Imagery in people with body dysmorphic disorder: A study of its characteristics and links to early beliefs and memories. Memory 2004;12:428-36.

32. Baldock E, Anson M, Veale D. The stopping criteria for mirror-gazing in body dysmorphic disorder. B J Clin Psychol 2012;51:323-44.

33. Andrews G, Crino R, Hunt C, Lampe L, Page A. The treatment of anxiety disorders. Clinician's guide and patient manuals: Cambridge University Press; 1994.

34. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psy 2000;31:73-86.

35. Eisen JL, Phillips KA, Baer L, Beer DA, Atala KD, Rasmussen SA. The Brown Assessment of Beliefs Scale: reliability and validity. Am J Psychiat 1998;155:102-8.

36. Montgomery SA, Asberg M. A new depression rating scale designed to be sensitive to change. B J Psychiatr 1979;134:382-9.

37. Müller MJ, Himmerich h, Kienzle B, Szegedi A. Differentiating moderate and severe depression using the Montgomery–Åsberg depression rating scale (MADRS). J Affect Disorders 2003;77:255-60.

38. Veale D, Eshkevari E, Ellison N, Costa A, Werner T. The Appearance Anxiety Inventory: Validation of a process measure in the treatment of body dysmorphic disorder. Behavioural and Cognitive Psychotherapy 2013;doi: 10.1017/S1352465813000556.

39. Kroenke K, Spitzer RL. The PHQ-9: A new depression diagnostic and severity measure. Psychiat Ann 2002;32:509-15.

40. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. Arch Intern Med 2006;166:1092-7.

41. Cash TF, Fleming EC. The impact of body-image experiences: Development of the Body Image Quality of Life Inventory. Int J Eat Disorder 2002;31:455-60.

42. Hrabosky JI, Cash TF, Veale D, Neziroglu F, Soll EA, Garner DM, Strachan-Kinser M, Bakke B, Clauss LJ, Phillips KA. Multidimensional body image comparisons among patients with eating disorders, body dysmorphic disorder, and clinical controls: A multisite study. Body Image 2009;6:155-63.

43. National Institute of Mental Health. Special feature: rating scales and assessment instruments for use in paediatric psychopaharmacology research. Psychopharmacol Bull 1985, 21: 714-1124.

44. Phillips, K.A, Hollander, E. Treating Body Dysmorphic Disorder with Medication: Evidence, Misconceptions, and a Suggested Approach. Body Image, 2008, 5(1): 13–27.

45. National Collaborating Centre for Mental H. Obsessive compulsive disorder: Core interventions in the treatment of obsessive compulsive disorder and body dysmorphic disorder. London: Gaskell and BPS; 2006.

46. Simpson HB, Maher MJ, Wang Y, Bao Y, Foa EB, Franklin M. Patient adherence predicts outcome from cognitive behavior therapy for obsessive-compulsive disorder. J Consult Clin Psych 2011;79:247-52.

47. Wilhelm S, Phillips KA, Steketee G. Cognitive-behavioural therapy for body dysmorphic disorder: A treatment manual: Guildford Press; 2013.

48. Beck AT, Rush AJ, Shaw BF, Emery G. Cognitive therapy of depression. New York: Guilford Press; 1979.

Table 1. Characteristics of participants and by group

	Total	Cognitive Behaviour Therapy	Anxiety Management Training	Statistic
	n = 46	*n* = 21	*n* = 25	
Age in years, Median & Interquartile Range (IQR)	30.0 (25.0-36.5)	30.0 (24.5-37.5)	29.0 (25.5-37.0)	*U* = 256, *Z* = -.14, *p* = .87
Sex, *n* (%)				
Male	19 (41.3)	9 (42.9)	10 (40.0)	Fisher's Exact Test *p* = 1
Female	27 (58.7)	12 (57.1)	15 (60.0)	
Marital Status, *n* (%)				
Single	30 (65.2)	13 (61.9)	17 (68.0)	Fisher's Exact Test *p* = .35
Married	12 (26.1)	8 (38.1)	5 (20.0)	
Separated or Divorced	3 (6.5)	0 (0.0)	3 (12.0)	
Ethnicity, *n* (%)				
White	37 (80.4)	16 (76.2)	21 (84.0)	Fisher's Exact Test *p* = .62
Black	5 (10.9)	2 (9.5)	3 (12.0)	
Mixed black and white	2 (4.3)	2 (9.5)	1 (4.0)	
South Asian	2 (4.3)	1 (4.8)	0 (0.0)	
Employment, *n* (%)				
Unemployed	14 (30.4)	3 (14.3)	11 (44.0)	Fisher's Exact Test *p* = .22
Long-term sick leave	2 (4.3)	1 (4.8)	1 (4.0)	
Employed or self-employed	21 (45.7)	12 (57.1)	9 (36.0)	
Retired	1 (2.2)	0 (0)	1 (4.0)	
Student (full time)	5 (10.9)	3 (14.3)	2 (8.0)	
Homemaker	3 (6.5)	2 (9.5)	1 (4.0)	
Referral				
Local Primary care	37 (80.4)	17 (81.0)	20 (80)	Fisher's Exact Test *p* = 1
Secondary care	9 (19.6)	4 (19.0)	5 (20)	

Duration of problem in years, Median (IQR)	11.0 (6.75-16.5)	14.0 (8.0-23.0)	10.0 (6.0-15.5)	*U* = 206, *Z* = -1.25, *p* = .21
Current Comorbidity, *n* (%)	28 (60.9)	12 (57.1)	16 (64.0)	
Delusional BDD	25 (54.3)	11 (52.4)	14 (56.0)	Fisher's Exact Test *p* =.69
Depression	20 (43.5)	9 (42.9)	11 (44.0)	
Social Phobia	5 (10.9)	1 (4.8)	4 (16.0)	
Obsessive Compulsive Disorder	2 (4.3)	1 (4.8)	1 (4.0)	
MADRS score at baseline, *n* (%)				
Moderate depression >25	12 (26.1)	5 (23.8)	7 (28.0)	Fisher's Exact Test *p* = .80
Severe depression >31	21 (45.7)	9 (42.9)	12 (57.1)	
Current SSRI, *n* (%)	21 (45.7)	12 (57.1)	9 (36.0)	*U* = 36.5,
Median prescribed daily SSRI dosage (mg) (*IQR*)	60 (20.0-60.0)	40 (32.5-55.0)	20 (20.0-60.0)	*Z* = -1.3, *p* = .22
Previous CBT for BDD, *n* (%)				
Yes	17 (37.0)	8 (38.1)	9 (36.0)	Fisher's Exact Test *p* = 1
No	29 (63.0)	13 (61.9)	16 (64.0)	
Previous SSRI, *n* (%)				
Yes	22 (61.1)	11 (64.7)	11 (57.9)	Fisher's Exact Test *p* = .74
No	14 (38.9)	6 (35.3)	8 (42.1)	
Desire at least 1 cosmetic procedure *n* (%)				
Yes	36 (83.7)	17 (81.0)	19 (86.4)	Fisher's Exact Test *p* = .70
No	7 (16.3)	4 (19.0)	3 (13.6)	
At least 1 past cosmetic procedure *n* (%)				
Yes	15 (33.3)	4 (19.0)	11 (45.8)	Fisher's Exact Test *p* = .07
No	30 (66.7)	17 (81.0)	13 (54.2)	
Credibility Expectancy Questionnaire				*U* = 89.5,
Credibility, Median (IQR) (Range 3-27)	5.7 (3.33-7)	6.0 (3.17-7.67)	5.2 (3.33-6.50)	*Z* = -0.7, *p* = .94
Expectancy, Median (IQR) (Range 3-27)	3.2 (2.03-7.12)	6.0 (1.62-7.71)	3.0 (2.26-4.35)	*U* = 79.0, *Z* = -0.6, *p* = .58

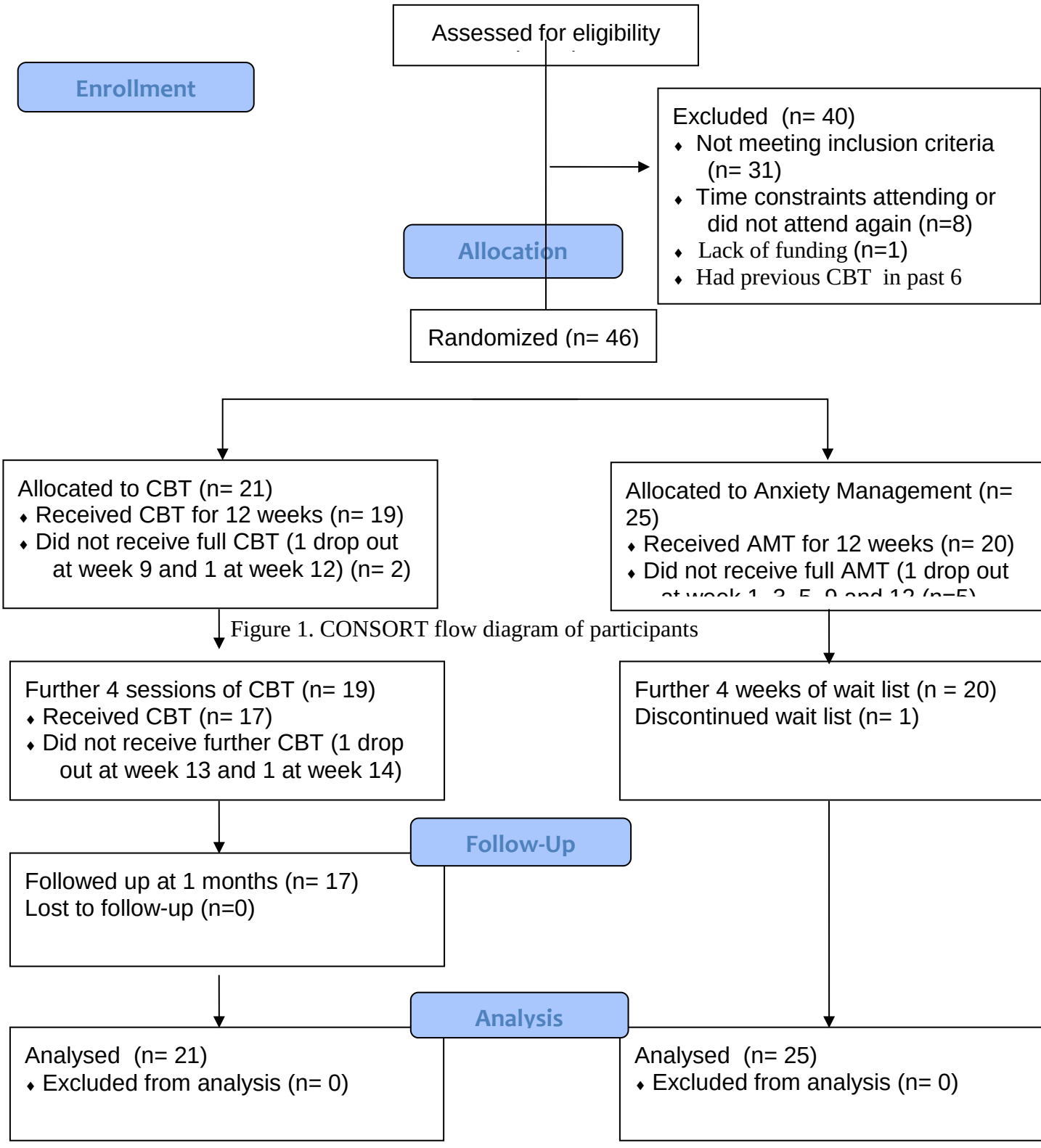

Figure 1. CONSORT flow diagram of participants

Table 2 Linear growth models for change in outcomes over time. (C.I Confidence Interval)

		Baseline – W12			
	Growth Parameter	Parameter Estimates			
		β	Standard Error β	p	C.I.
Dependent Variable					
BDD-YBOCS	Treatment	4.99	3.24	.124	-1.36, 11.34
	Time	-4.81	1.84	< .01	-8.43, -1.20
	Treatment*Time	-7.19	2.61	< .01	-12.31, -2.07
MADRS	Treatment	1.33	5.02	.791	-8.51, 11.16
	Time	-4.06	2.15	.059	-8.28, .155
	Treatment*Time	-2.80	3.12	.370	-8.91, 3.32
BABS	Treatment	3.72	2.76	.178	-1.69, 9.14
	Time	-1.04	1.42	.467	-3.83, 1.76
	Treatment*Time	-4.45	2.11	< .05	-8.58, -.315
AAI	Treatment	6.98	4.06	.085	-.972, 14.94
	Time	-4.41	2.09	< .05	-8.53, -.287
	Treatment*Time	-7.87	2.87	< .01	-13.50, -2.24
PHQ-9	Treatment	3.14	3.64	.389	-4.00, 10.28
	Time	-.327	1.75	.852	-3.77, 3.11
	Treatment*Time	-3.64	2.53	.149	-8.60, 1.31

GAD-7	Treatment	1.08	3.28	.742	-5.36, 7.52
	Time	-1.50	1.53	.330.	-4.51, 1.52
	Treatment*Time	-2.83	2.13	.185	-7.02, 1.36
BIQLI	Treatment	-1.20	.564	< .05	-2.31, -.098
	Time	-.368	.240	.125	-.838, .103
	Treatment*Time	.908	.350	< .01	.223, 1.59

Table 3 Comparisons of group outcomes.

	Within-group												Between-group
	Cognitive Behavioural Therapy n = 21							Anxiety Management Training n = 25					CBT vs AM
Measure	Baseline *M (SD)*	Week 12 *M (SD)*	Week 16 *M (SD)*	1mFU *M (SD)*	Statistics Baseline-W12	Statistics Baseline-W16	Statistics Baseline-1mFU	Baseline *M (SD)*	Week 12 *M (SD)*	1mFU *M (SD)*	Statistics Baseline-W12	Statistics Baseline-1mFU	Week 12 Cohen's *d*
BDD-YBOCS	35.48 (6.61)	23.47 (11.23)	20.87 (10.5)	21.37 (12.42)	t (20) = 5.18 p < .001 d = 1.30	t (20) = 5.70 p < .001 d = 1.67	t (20) = 5.35 p < .001 d = 1.42	37.68 (4.77)	32.87 (7.45)	33.30 (8.72)	t (24) = 3.19 p < .01 d = 0.77	t (24) = 2.32 p < .05 d =0.62	0.99
MADRS	28.57 (10.69)	21.71 (11.20)	17.64 (12.38)	20.40 (13.14)	t (20) = 3.13, p < .01 d = 0.63	t (20) = 3.75, p < .001 d = 0.95	t (20) = 2.53 p < .05 d = 0.68	30.04 (9.62)	25.98 (10.80)	28.63 (13.32)	t (24) = 1.87 p > .05 d = 0.40	t (24) = .55 p > .05 d = 0.12	0.39
BABS	18.24 (4.68)	12.75 (8.11)	10.90 (7.07)	10.28 (7.41)	t (20) = 3.12 p < .01 d = 0.83	t (20) = 3.87 p < .001 d = 1.22	t (20) = 4.58 p <.001 d = 1.28	18.96 (4.14)	17.92 (5.42)	18.88 (4.62)	t (24) = .86 p > .05 d = 0.22	t (24) = .097 p > .05 d = 0.02	0.75
AAI	26.89 (6.62)	14.61 (9.20)	13.70 (10.51)	14.16 (9.53)	t (20) = 6.98 p < .001 d = 1.53	t (20) = 6.06 p < .001 d = 1.50	t (20) = 5.13 p <.001 d = 1.55	27.78 (7.03)	23.37 (8.29)	23.21 (8.86)	t (24) = 1.99 p < .05 d = 0.57	t (24) = 1.95 p > .05 d = 0.57	1.00
PHQ-9	13.1 (6.50)	9.12 (7.01)	8.88 (7.24)	9.41 (6.67)	t (20) = .100 p < .05 d = 0.59	t (20) = 2.40 p < .05 d = 0.61	t (20) = 1.82 p > .05 d = -0.56	13.60 (5.44)	13.28 (7.18)	15.79 (7.05)	t (24) = .190 p > .05 d = 0.05	t (24) = -1.45 p > .05 \d = -0.35	0.59
GAD-7	11.33 (6.32)	7.00 (6.02)	7.23 (6.24)	8.53 (6.60)	t (20) = 2.70 p < .01 d = 0.70	t (20) = 2.31 p < .05 d = 0.65	t (20) = 1.68, p > .05 d = 0.43	13.09 (5.24)	11.59 (5.89)	13.22 (5.45)	t (24) = 1.04 p > .05 d = 0.27	t (24) = -.107 p > .05 d = -0.02	0.77
BIQLI	-1.97 (0.56)	-1.43 (0.85)	-1.30 (0.90)	-1.29 (0.92)	t (20) = -.560 p < .05 d = -0.75	t (20) = -2.89 p < .01 d = -0.89	t (20) = -2.38, p < .05 d = .-0.89	-1.68 (1.04)	-2.04 (0.71)	-1.95 (0.81)	t (24) = 1.37 p > .05 d = 0.40	t (24) = .920 p > .05 d = 0.29	0.78