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Efficacy of Cognitive Behaviour Therapy versus Anxiety Management for Body Dysmorphic Disorder: A Randomised Controlled Trial

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Key Words

Body dysmorphic disorder · Cognitive behaviour therapy · Anxiety management · Randomised controlled trial

Abstract

Background: The evidence base for the efficacy of cognitive behaviour therapy (CBT) for treating body dysmorphic disorder (BDD) is weak. **Aims:** To determine whether CBT is more effective than anxiety management (AM) in an outpatient setting. **Method:** This was a single-blind stratified parallel-group randomised 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 Scale (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 a DSM-IV diagnosis of BDD, including those with 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 [$\beta = -7.19$; SE (β) = 2.61; $p < 0.01$; 95% CI = -12.31 to -2.07 ; $d = 0.99$] as well as the secondary outcome measures of the BABS, AAI and BIQLI. 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 AM over 12 weeks.

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Introduction

Body dysmorphic disorder (BDD) is characterised by a preoccupation with perceived defects or flaws in physical appearance that are either not noticeable or appear only slight to others. In addition, the preoccupation must be significantly distressing or cause impairment in social, occupational or other important areas of functioning. The DSM-5 has added a further criterion to the diagnosis of BDD, which is that, 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 recognised, 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

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

rate of psychiatric hospitalisations, suicidal ideation and completed suicides [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 undergo dermatological and cosmetic surgery [9–11].

Regarding 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 the outcome. Phillips [14] also showed that adding an antipsychotic, pimozide, to an SSRI was no more effective than adding a placebo in those who had not responded to an SSRI alone. Antipsychotics are therefore not recommended in the NICE (National Institute for Health and Clinical Excellence) 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 their discontinuation [17]. However, the data on relapse rates with discontinuation of SSRIs are very minimal, based on just one chart review study.

There have been three small pilot RCTs of cognitive behaviour therapy (CBT) for adults with BDD that have demonstrated a greater efficacy of CBT compared with a waitlist [18–20]. However, the participants in the study by Rosen et al. [19] were not that representative as the sample contained only women, several of whom 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 three RCTs determined whether CBT was effective for delusional BDD or comorbid depression. Also, none of these studies contained a comparison treatment to control for attention and non-specific therapeutic factors.

Since these pilot trials, the knowledge of the phenomenology of BDD has increased, and we have further developed a cognitive behavioural model to guide treatment [21, 22]. The aim of this trial was therefore to determine whether our CBT that is specific for BDD is more effective than a credible non-specific alternative (anxiety management, AM) over 12 weeks in treating BDD with or without delusion in adults aged 18 years and over. 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 performed 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 on obsessions without prominent compulsions [27].

Objectives

In the current trial, 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 and (b) whether the gains in CBT and AM were maintained at the 1-month follow-up.

Subjects and Method

Design

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

Participants

Inclusion Criteria

The eligibility criteria for participants were as follows:

- (1) Have a diagnosis of BDD according to the DSM-IV diagnostic criterion [1] as their main problem; the 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]; if 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 if the diagnosis referred to delusional beliefs about being ugly or defective (the DSM-IV allows double coding of both BDD and delusional BDD, which does not occur in the 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 years 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 randomisation 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 or 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 were primarily related to weight and/or shape or fulfilled the 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, or
- (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 provides 'secondary care' service, where patients are also under the care of their own local community mental health team). It is also part of a nationally funded highly specialised service for severe treatment-refractory OCD and BDD (which is a 'tertiary care' service).

Interventions

Two interventions were to be evaluated.

Cognitive Behaviour Therapy

In our trial, this focussed form of psychotherapy consisted of 12 weeks of individual sessions of 1 h 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 rescripting followed for past aversive memories that were associated with the onset (e.g. 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 the preoccupation and distress in the long term. The behaviours were aimed at either (1) threat detection and monitoring (e.g. cognitive processes such as self-focussed attention or behaviours such as mirror checking) or (2) preventing feared consequences by avoidance (e.g. comparing or camouflaging a perceived defect) or (3) attempts to undo the appearance concerns (e.g. seeking to undergo 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 were done in vivo within and between sessions for homework. Self-monitoring and habit reversal was used for any skin picking.

Anxiety Management

The treatment followed a standard protocol [33]. It was provided once a week for 12 weeks, with each session lasting 1 h. AM was planned to entail a therapeutic alliance, support and homework similar to the CBT group. The rationale provided was that when triggered, the person would experience a 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, (2) identifying triggers and physical symptoms associated with appearance-related anxiety and (3) utilising brief muscle relaxation and breathing techniques in trigger situations.

The aim was to reduce baseline anxiety as well as anxiety in trigger situations or regarding 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 waitlist for 4 weeks, when participants were able to cross over into CBT if they still fulfilled the 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 weekly 1-hour sessions were implemented for both treatments as it was considered unethical to deny participants receiving AM the more established treatment of CBT for a period longer than 12 weeks. Twelve weeks were considered the maximum time limit for gains from AM and sufficient to determine whether CBT was superior to AM. The primary endpoint was therefore set at 12 weeks. Further research is required to determine the optimum length of CBT for BDD that may be considered beyond 12 weeks. For both CBT and AM there was no direct targeting of other symptoms such as depression or other comorbidity.

Evaluation of Therapy

The participants completed the Credibility/Expectancy Questionnaire (CEQ) at baseline [34]. The questionnaire measures the credibility and treatment expectancy of the treatment assigned. Each subscale has a range of 3–27. 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. The therapy sessions were audio recorded (if 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 the treatment sessions. Scores for included components of therapy were summed to give a total. In addition, therapist di-

rectiveness 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 mean scores for therapy components, therapist directiveness and therapeutic relationship.

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 an SSRI, an equivalent dose of fluoxetine was calculated (e.g. fluoxetine 20 mg was equivalent to citalopram 20 mg or sertraline 50 mg).

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

The primary outcome measure was the BDD-YBOCS [29]. This is a clinician-rated scale administered by a trained blinded assessor. The range is 0–48. Cronbach's α for the scale is 0.80. Response to treatment is defined as a 30% or greater decrease in the total BDD-YBOCS score, which best corresponded to 'much improved' on the Clinical Global Impression (CGI) scale. In the original validation study, this cutoff score produced 1 false negative (96% sensitivity), that is, 1 participant 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 blinded 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 the total scores range from 0 to 24; higher scores represent an increasing delusionality of beliefs; respondents are classified as having delusional BDD beliefs if their 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-Åsberg Depression Rating Scale (MADRS) [36] – the MADRS is a 10-item clinician scale rated by a blinded 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 0–60; higher scores reflect a greater symptomatology; a MADRS total score of ≥ 25 is regarded as moderate, and of > 31 as severe [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 the 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 the total scores is 0–40, with higher scores reflecting a greater frequency of the responses; the AAI has a Cronbach's α of 0.86
 - (2) Patient Health Questionnaire (PHQ)-9 Depression Severity [39] – the 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 a greater symptomatology of depression; Cronbach's α for the scale is 0.89

- (3) Generalised Anxiety Disorder (GAD)-7 [40] – the GAD-7 is a 7-item self-report measure for symptoms of generalised anxiety; each item is scored from 0 to 3, and the summed total score ranges from 0 to 21, with higher scores reflecting a greater symptomatology; Cronbach's α for the measure is 0.92
- (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 and grooming); the BIQLI is scored as the average numeric score of all the items from -3 ('very negative effect') to $+3$ ('very positive effect'); Cronbach's α for the scale is 0.95

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 a standard deviation of 7 on the BDD-YBOCS between CBT and AM. These assumptions were made based on a previous RCT of CBT in BDD [18] and approximate to a reduction of 30% on the BDD-YBOCS and clinically significant improvement in BDD symptoms [29]. There was an anticipated 10% dropout rate, giving a planned sample size of 22 per group or 44 in total. There were no planned interim analyses or stopping rules.

Randomisation

Sequence Generation

Randomisation was conducted via the UKCRC (UK Clinical Research Collaboration)-registered King's Clinical Trials Unit, using a web-based system. Randomisation was at the level of the individual participant, by the method of minimisation stratified by (1) the presence or absence of delusional beliefs on the BABS and (2) either a high (25 or above) or a low score (below 25) on the MADRS [37]. The first 4 patients were randomised using simple randomisation to create an initial level of imbalance. The minimisation algorithm contained a 20% random component for subsequent patients to maintain prerandomisation allocation concealment. The patients were told they were being randomised to two different types of psychological therapy and that if they wished, they 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 the 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 the supervision or discussion of treatments. While the blinded 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 the Statistical Package for the Social Sciences (SPSS) version 21 for Windows. The analysis of efficacy was based on the 'intention to treat', utilising data from those participants who provided baseline and follow-up data regardless of whether they completed the treatment. To reduce the amount of missing data from partially filled-in questionnaires, the average score was computed for questionnaires where only 1 item was missing. In order to correct for multiple missing-item data for questionnaires with 2 or more missing items, and in some cases for entire missing measures, multiple imputation was used. The 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 the baseline equivalence of the groups, proportions of categorical variables at baseline (e.g. demographics) were compared between groups using Fisher's exact tests. Values of continuous measures at baseline were compared using the Mann-Whitney U test. The primary and secondary effectiveness analysis for both groups was based at 12 weeks. The results were summarised by mean differences and corresponding 95% CI. All measures were two-tailed.

Linear mixed models were conducted to determine the predictive value of treatment group and/or time on the 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 1 t test had been conducted on each variable, a Bonferroni correction was used to decrease the risk of type I error. For the CBT group, the 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' ($\geq 30\%$ change on the BDD-YBOCS) or not recovered. A decrease of 30% or more in the BDD-YBOCS score was considered 'much improved' on the basis that it is significantly correlated with the response of BDD symptoms measured using the 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 (score of >31) predicted a response.

Ethics

The study had ethics approval from the Institute of Psychiatry and South London and Maudsley NHS Foundation 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 flowchart of the numbers of participants assessed, allocated to each group, receiving the intended treatment, completing the study protocol and being analysed for the primary outcome.

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

The treatments were acceptable to both groups, with no significant difference in the number of dropouts between the groups (χ^2 test with Yates' correction: 0.33; $p = 0.56$). Table 1 provides the 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 1 SSRI in the past and one third having had at least 1 cosmetic procedure in the past. A slightly lower range of general comorbidity is demonstrated by this sample in comparison with previous surveys (table 1).

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 1 cosmetic or dermatological procedure. Nearly half the participants were stabilised on an SSRI (either fluoxetine or citalopram or sertraline). There was no significant difference between the treatment groups in the frequency of participants taking an SSRI or the dose prescribed. Apart from the SSRIs, 1 participant in the CBT group was taking zopiclone 3.75 mg at night, 1 participant in the AM group was taking a selective noradrenergic and serotonergic reuptake inhibitor (venlafaxine) 150 mg daily, 1 was taking St John's wort 900 mg daily and 1 was taking quetiapine 50 mg 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%).

The blinded 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 0 components of AM per session [$t(46) = 15.75$; $p < 0.001$]. For the AM group there was a mean of 15.60 (SD = 6.60) components of AM per session and a mean of 0.21 (SD = 0.50) components of CBT per session [$t(46) = 11.57$; $p < 0.001$]. There were therefore no violations of the condition that

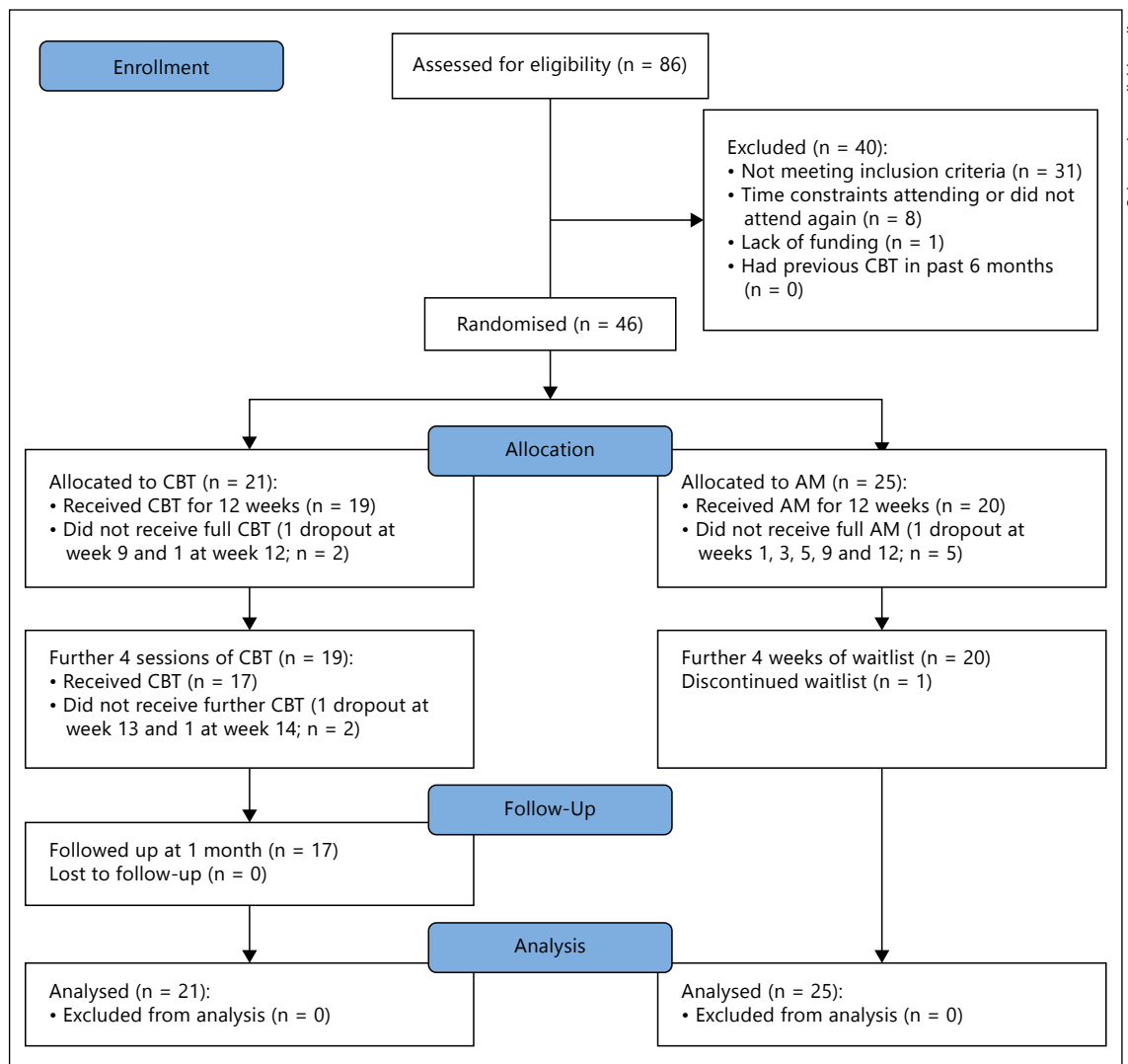


Fig. 1. CONSORT flow diagram of participants.

CBT should not be used in AM and vice versa. In terms of blinded ratings of the therapeutic relationship, CBT (mean = 2.42, SD = 0.83) did not differ to AM [mean = 2.17, SD = 0.64; $t(46) = 1.17$; $p = 0.25$]. Equally, for therapist directiveness, CBT (mean = 2.25, SD = 0.68) did not differ to AM [mean = 2.38, SD = 0.97; $t(46) = -0.51$; $p = 0.61$].

Table 2 shows the linear change in dependent variable scores from baseline to week 12 and the interaction between group and time for all outcome measures. There was a significant group \times time interaction for the primary outcome (BDD-YBOCS score) and other body image measures (BABS, AAI and BIQLI scores) at week 12. There was no group \times time interaction for depression

(MADRS or PHQ-9 score) or general anxiety (GAD-7 score). A main effect of time predicted BDD-YBOCS and AAI scores across both time points. Treatment group predicted BIQLI scores.

Table 3 provides means, SD and effect sizes 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. In the 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 scores at week 12.

Table 1. Characteristics of participants and by group

	Total (n = 46)	CBT (n = 21)	AM (n = 25)	Statistic
Median age (IQR), years	30.0 (25.0–36.5)	30.0 (24.5–37.5)	29.0 (25.5–37.0)	U = 256, Z = -0.14, p = 0.87
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 = 0.35
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 = 0.62
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 = 0.22
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, n (%)				
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)	
Median duration of problem (IQR), years	11.0 (6.75–16.5)	14.0 (8.0–23.0)	10.0 (6.0–15.5)	U = 206, Z = -1.25, p = 0.21
Current comorbidity, n (%)	28 (60.9)	12 (57.1)	16 (64.0)	Fisher's exact test p = 0.69
Delusional BDD	25 (54.3)	11 (52.4)	14 (56.0)	
Depression	20 (43.5)	9 (42.9)	11 (44.0)	
Social phobia	5 (10.9)	1 (4.8)	4 (16.0)	
OCD	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 = 0.80
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, Z = -1.3, p = 0.22
Median prescribed daily SSRI dosage (IQR), mg	60 (20.0–60.0)	40 (32.5–55.0)	20 (20.0–60.0)	
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 = 0.74
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 = 0.70
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 = 0.07
No	30 (66.7)	17 (81.0)	13 (54.2)	
CEQ (range: 3–27)				
Median credibility score (IQR)	5.7 (3.33–7)	6.0 (3.17–7.67)	5.2 (3.33–6.50)	U = 89.5, Z = -0.7, p = 0.94
Median expectancy score (IQR)	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 = 0.58

Table 2. Linear growth models for change in outcomes over time

Growth parameter		Baseline to week 12 parameter estimates			
		β	SE (β)	p	95% CI
BDD-YBOCS	treatment	4.99	3.24	0.124	-1.36 to 11.34
	time	-4.81	1.84	<0.01	-8.43 to -1.20
	treatment \times time	-7.19	2.61	<0.01	-12.31 to -2.07
MADRS	treatment	1.33	5.02	0.791	-8.51 to 11.16
	time	-4.06	2.15	0.059	-8.28 to 0.155
	treatment \times time	-2.80	3.12	0.370	-8.91 to 3.32
BABS	treatment	3.72	2.76	0.178	-1.69 to 9.14
	time	-1.04	1.42	0.467	-3.83 to 1.76
	treatment \times time	-4.45	2.11	<0.05	-8.58 to -0.315
AAI	treatment	6.98	4.06	0.085	-0.972 to 14.94
	time	-4.41	2.09	<0.05	-8.53 to -0.287
	treatment \times time	-7.87	2.87	<0.01	-13.50 to -2.24
PHQ-9	treatment	3.14	3.64	0.389	-4.00 to 10.28
	time	-0.327	1.75	0.852	-3.77 to 3.11
	treatment \times time	-3.64	2.53	0.149	-8.60 to 1.31
GAD-7	treatment	1.08	3.28	0.742	-5.36 to 7.52
	time	-1.50	1.53	0.330	-4.51 to 1.52
	treatment \times time	-2.83	2.13	0.185	-7.02 to 1.36
BIQLI	treatment	-1.20	0.564	<0.05	-2.31 to -0.098
	time	-0.368	0.240	0.125	-0.838 to 0.103
	treatment \times time	0.908	0.350	<0.01	0.223 to 1.59

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 [$\chi^2(1) = 6.20$; $p = 0.013$]. For the CBT group, after 16 sessions, 11/21 (52%) were responders (McNemar's test: $n = 21$; exact test: $p = 0.25$). At the 1-month follow-up for the CBT group, all 11 responders (100%) had maintained their 30% decrease in BDD-YBOCS score (McNemar's test: $n = 21$; exact test: $p = 1.00$). At the 1-month follow-up for the AM group, all 3 responders (100%) had maintained their recovery as well (McNemar's test: $n = 25$; exact test: $p = 1.00$). CBT was again superior to AM in gradually reducing the cognitive processes and behaviours that are thought to maintain BDD on the AAI (see online suppl. fig. 1; for all online suppl. material, see www.karger.com/doi/10.1159/000360740).

Prespecified subgroups of those with comorbid depression or delusional BDD at baseline were compared over time. Online supplementary table 1 shows the linear change in blinded 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 time \times 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. Online supplementary table 2 shows outcomes with estimated effect sizes for subgroup comparisons at baseline and week 12 and baseline to week 16 for CBT. Both online supplementary tables 1 and 2 display findings with decreased power due to their representation of a smaller subgroup.

Those 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.

Table 3. Comparisons of group outcomes

	Within-group										Between-group		
	CBT (n = 21)										CBT vs. AM		
	AM (n = 25)												
	baseline	week 12	week 16	1-m FU	statistics baseline to week 12	statistics baseline to week 16	statistics baseline to 1-m FU	baseline	week 12	1-m FU	statistics baseline to week 12	statistics baseline to 1-m FU	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 < 0.001, d = 1.30	t(20) = 5.70, p < 0.001, d = 1.67	t(20) = 5.35, p < 0.001, d = 1.42	37.68±4.77	32.87±7.45	33.30±8.72	t(24) = 3.19, p < 0.01, d = 0.77	t(24) = 2.32, p < 0.05, 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 < 0.01, d = 0.63	t(20) = 3.75, p < 0.001, d = 0.95	t(20) = 2.53, p < 0.05, d = 0.68	30.04±9.62	25.98±10.80	28.63±13.32	t(24) = 1.87, p > 0.05, d = 0.40	t(24) = 0.55, p > 0.05, 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 < 0.01, d = 0.83	t(20) = 3.87, p < 0.001, d = 1.22	t(20) = 4.58, p < 0.001, d = 1.28	18.96±4.14	17.92±5.42	18.88±4.62	t(24) = 0.86, p > 0.05, d = 0.22	t(24) = 0.97, p > 0.05, 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 < 0.001, d = 1.53	t(20) = 6.06, p < 0.001, d = 1.50	t(20) = 5.13, p < 0.001, d = 1.55	27.78±7.03	23.37±8.29	23.21±8.86	t(24) = 1.99, p < 0.05, d = 0.57	t(24) = 1.95, p > 0.05, d = 0.57	1.00
PHQ-9	13.10±6.50	9.12±7.01	8.88±7.24	9.41±6.67	t(20) = 0.100, p < 0.05, d = 0.59	t(20) = 2.40, p < 0.05, d = 0.61	t(20) = 1.82, p > 0.05, d = -0.56	13.60±5.44	13.28±7.18	15.79±7.05	t(24) = 0.190, p > 0.05, d = 0.05	t(24) = -1.45, p > 0.05, 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 < 0.01, d = 0.70	t(20) = 2.31, p < 0.05, d = 0.65	t(20) = 1.68, p > 0.05, d = 0.43	13.09±5.24	11.59±5.89	13.22±5.45	t(24) = 1.04, p > 0.05, d = 0.27	t(24) = -0.107, p > 0.05, d = -0.02	0.77
BIQLI	-1.97±0.56	-1.43±0.85	-1.30±0.90	-1.29±0.92	t(20) = -0.560, p < 0.05, d = -0.75	t(20) = -2.89, p < 0.01, d = -0.89	t(20) = -2.38, p < 0.05, d = -0.89	-1.68±1.04	-2.04±0.71	-1.95±0.81	t(24) = 1.37, p > 0.05, d = 0.40	t(24) = 0.920, p > 0.05, d = 0.29	0.78

Values denote means ± SD unless specified otherwise. 1-m FU = 1-month follow-up.

Finally, there was no difference between the groups in terms of treating severe depression. Five out of 9 participants (56%) 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 [$\chi^2(1) = 1.73$; $p = 0.19$]. Those 5 from the CBT group remained recovered at week 16 after their final treatment session (McNemar's test: $n = 21$; exact test: $p = 1.00$). At the 1-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 test: $p = 1.00$). Equally, in the AM group, 4 participants indicated a recovery from severe depression at the 1-month follow-up (McNemar's test: $n = 21$; exact test: $p = 1.00$).

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

Discussion

This is the first study to examine the efficacy of CBT as compared with another credible psychological treatment for BDD. The study demonstrated that CBT that is targeted at BDD is more effective than AM after 12 weeks if evaluated using specific measures for BDD for the group \times time interaction. AM also had a significant effect on reducing BDD-YBOCS scores, AAI scores and depression over time at week 12, but CBT had a larger effect size than AM, which 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 they also advance the field, as the current study included an active psychological treatment (AM) that was set against CBT, whereas previous studies only used waitlist controls and did not examine treatment 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 randomisation 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 showed more severe symptoms (in terms of severity on the BDD-YBOCS, the proportion who had had a previous treatment with an SSRI and the proportion who desired a cosmetic procedure) than those recruited for previous RCTs of CBT versus a waitlist [18–20]. The current comorbidity rate was, however, slightly lower in this population than in other studies.

There are two previous RCTs of CBT versus a waitlist 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 in the study by Veale et al. [18] (1.57) and Rabiei et al. [20] (1.49). In the CBT group, the frequency of responders on the BDD-YBOCS (52%) is similar to that in a trial of fluoxetine versus a placebo in BDD [12]. The fluoxetine trial, however, had a lower within-group effect size of 1.36 on the BDD-YBOCS. On the other hand, open-label case series of SSRIs have found response rates of 63–73% [44]. In general, one should be cautious about comparing effect sizes in previous RCTs of BDD as the numbers in all these trials were small and the participants may have shown less severe symptoms in some of the studies than in this trial. Nevertheless, 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 from a representative population with BDD (e.g. 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 via standard routes of referral, it is reasonable to assume that the intervention can potentially be generalised to other settings if a therapist can build up 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] as evaluated in a recent trial or CBT for BDD as reported by Wilhelm et al. [46] overlaps with our protocol but is based on somewhat different conceptualisations and interventions.

We do not have sufficient information on the mechanism of change in either group. The AAI score was measured weekly to identify the frequency of the cognitive processes and safety-seeking behaviours that are conceptualised to be important in maintaining the 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 [46]. Future protocols of CBT might also include loading the frequency of sessions at the beginning of therapy (e.g. twice weekly for the first 4 weeks). This would be similar to the original cognitive therapy protocol for treating depression [47], the rationale being to maximise engagement and also improve symptoms of depression.

Limitations

The study has a relatively small sample that may overestimate the 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 subsample of depression and delusional BDD may also be subject to a type II error. The 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 test 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 interrater reliability of the adherence ratings. Delivering 12 sessions of therapy may have resulted in less gain being achieved at our primary outcome. The 12-week duration may have been too brief to achieve significant changes in 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 CBT in comparison with 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 to 16 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, but it was deemed unethical to continue AM for longer than 12 weeks (discussed above). Currently, we are unable to conclude that there is a higher efficacy of CBT in comparison with AM beyond 12 weeks of intervention. In addition, follow-up outcome analyses for both the AM and CBT groups were only conducted 1 month after treatment. It may have been optimal to consider the maintenance of the 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 generalisability of the findings in other settings.

Further Research

The study suggests that gains are maintained at the 1-month follow-up for the CBT group. Further research is required to compare treatments at the same endpoint beyond 12 weeks and to determine a long-term follow-up of 1 year or more in order to better consider the 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 an 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 an augmentation of SSRI doses to the maximum tolerated dose. Even though it is gratifying that there was a large effect size by 16 weeks and 52% of the participants had a significant clinical response, nearly half remained non-responders. It may be that a longer or more intensive CBT or CBT 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 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 in different groups and whether it can be adapt-

ed to different settings, especially in dermatology and cosmetic surgery clinics, where a cognitive behaviour therapist could be sited alongside a physician or surgeon.

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None.

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