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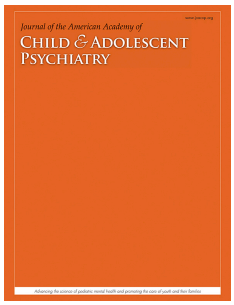

A Pilot Randomized Controlled Trial of Cognitive-Behavioral Therapy for Adolescents With Body Dysmorphic Disorder

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A Pilot Randomized Controlled Trial of Cognitive-Behavioral Therapy for Adolescents With Body Dysmorphic Disorder

Running title: CBT for Adolescents With BDD

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ABSTRACT

Objective: Body dysmorphic disorder (BDD) typically starts in adolescence, but evidence-based treatments are yet to be developed and formally evaluated in this age group. We designed an age-appropriate cognitive-behavioral therapy (CBT) protocol for adolescents with BDD and evaluated its acceptability and efficacy in a pilot randomized controlled trial.

Method: Thirty adolescents aged 12-18 (mean=16.0,SD=1.7) with a primary diagnosis of BDD and their families were randomly assigned to 14 sessions of CBT delivered over four months or a control condition of equivalent duration, consisting of written psycho-education materials and weekly telephone monitoring. Blind evaluators assessed participants at baseline, mid-treatment, post-treatment, and at two-month follow-up. The primary outcome measure was the Yale-Brown Obsessive-Compulsive Scale Modified for BDD, adolescent version (mean baseline score=37.13,SD=4.98; range=24–43).

Results: The CBT group showed a significantly greater improvement than the control group, both at post-treatment (time×group interaction coefficient [95%CI]=-11.26 [-17.22 to -5.31]; p=0.000) and at two-month follow-up (time×group interaction coefficient [95%CI]=-9.62 [-15.74 to -3.51]; p=0.002). Six (40%) participants in the CBT group and one (6.7%) in the control condition were classified as responders at both time points (χ^2=4.658,p=.031). Improvements were also seen on secondary measures, including insight, depression, and quality of life at post-treatment. Both patients and their families deemed the treatment as highly acceptable.

Conclusion: Developmentally tailored CBT is a promising intervention for young people with BDD, though there is significant room for improvement. Further clinical trials incorporating lessons learned in this pilot and comparing CBT and pharmacological therapies, as well as their combination, are warranted.

Clinical trial registration information—A Pilot Randomized Controlled Trial of Cognitive-Behaviour Therapy for Children and Adolescents With Body Dysmorphic Disorder; http://www.isrctn.com/ISRCTN67699666; ISRCTN67699666.

Key Words: Body dysmorphic disorder; children; adolescents; cognitive-behavioral therapy; randomized controlled trial.

INTRODUCTION

Body dysmorphic disorder (BDD) is a potentially severe psychiatric disorder characterized by excessive preoccupation with perceived defects or flaws in physical appearance that are not observable or appear only slight to others. This preoccupation leads to significant distress and impairment, time-consuming repetitive behaviors (e.g., grooming rituals, mirror checking, reassurance seeking), and marked avoidance (e.g., of social situations).[1] The disorder has an estimated prevalence of approximately 2% in community samples of adults[2-4] and is associated with high levels of occupational and social disability, including absenteeism, unemployment, marital dysfunction, and reduced quality of life.[5-7]

BDD has received little empirical attention in adolescents, which is surprising given that an adolescent onset is reported in 70% of cases, with a mean age of onset around 16 years.[8] In young people, BDD results in major functional impairment, including social withdrawal, reduced academic performance, and dropping out of school.[9] Furthermore, the disorder is linked with strikingly high suicidality rates in adolescents, with a reported 21-44% of patients attempting suicide.[9-11] Unfortunately, the disorder often goes undetected in young people, as the symptoms of BDD may be mistakenly interpreted as normal developmental concerns (i.e., most teenagers worry about their appearance to some extent).

There is growing evidence that cognitive-behavioral therapy (CBT) may be efficacious for adults with BDD.[12-17] By contrast, the treatment literature for BDD in adolescents is very sparse; the only published evidence comes from single case studies[18-20] and a small case series of six adolescents.[21] The findings of these studies suggest that CBT is probably a feasible treatment option for adolescents with the disorder. Despite the lack of solid evidence, in the UK, clinical guidelines recommend CBT as a first-line treatment for children and adolescents with BDD.[22] There is an urgent need to develop, evaluate, and disseminate age-appropriate treatment protocols for young people with BDD.

In this study, we aimed to a) develop an age-appropriate CBT protocol for young people with BDD, involving their parents or carers when appropriate, and b) evaluate its acceptability and efficacy in a pilot randomized controlled trial (RCT). We predicted that the intervention would lead to a significantly greater reduction in BDD symptoms, compared to a control condition consisting of written psycho-education materials and weekly telephone monitoring, and that the therapeutic gains would be maintained two months after treatment. We also predicted that the intervention would be deemed acceptable and result in high levels of satisfaction in both the young people and their parents/carers.

METHOD

Design and participants

The study was a single blind RCT with two groups conducted at a single specialist center in England, United Kingdom, between February 2012 and August 2014. Patients were randomly allocated (1:1 ratio) to either 14 sessions of CBT delivered over a 4-month period or a control condition of equivalent duration consisting of written psycho-education materials and weekly telephone monitoring (henceforth "control"). Participants randomised to the control condition were offered CBT after a 2-month follow-up. There were no changes to the trial design after its commencement or any protocol violations.

Participants recruited to the trial were those referred to the National and Specialist OCD [obsessive-compulsive disorder], BDD, and Related Disorders Clinic for Young People at the Maudsley Hospital. In addition to the usual referral channels, the trial was widely advertised across child and adolescent mental health services (CAMHS) using a range of methods, including specifically designed leaflets/posters, talks, and distributing brief screening questionnaires within community CAMHS. Additionally, advertisements were placed in social media sites, relevant charities' websites, and magazines for young people. A website was also created to advertise the study. Individuals showing interest in the treatment trial were requested to see their local CAMHS or general practitioner to seek a formal referral to the clinic.

Eligibility criteria for participants were as follows: a) age ranging from 12-18 years; b) a DSM-IV diagnosis of BDD; c) stable psychotropic medication for 12 weeks prior to randomization (if relevant); d) no plans to commence or increase the dose of psychotropic medication (if relevant); e) willingness to receive psychological treatment; f) willingness/ability to travel to the clinic for CBT; and g) a score of 24 or higher on the Yale-Brown Obsessive-Compulsive Scale Modified for BDD – Adolescent version (BDD-YBOCS-A).[23]

Exclusion criteria were: a) current or past diagnosis of schizophrenia or bipolar affective disorder, current alcohol or substance dependence, severe disabling neurological disorder, global intellectual disability, autism spectrum disorder, or an emerging borderline personality disorder requiring treatment in its own right; b) suicidal intent that requires hospitalization; c) English too poor to engage in treatment; and d) characteristics interfering with completion of treatment (e.g., selective mutism).

Interventions

CBT: Existing adult CBT protocols/treatment manuals for BDD[24, 25] were adapted to ensure developmentally appropriate content for young people with BDD. These adaptations were guided by the existing pediatric OCD[26] and BDD[20] literature, as well as by our own previous experience treating

these patients.[21] For example, language was simplified, and age-appropriate worksheets and handouts were produced. In all cases, effort was made to include parents in psycho-education sessions at the start of treatment in order to ensure a shared understanding of BDD and learn how to best support the child in treatment. The extent to which parents/carers were included in subsequent sessions was decided in collaboration with the young person and guided by the individual case formulation, specifically considering the following factors: a) the level of parental involvement in BDD-related rituals**,** reassurance, and/or avoidance; b) the extent to which additional parental beliefs and/or behaviors were a barrier in treatment (e.g., high levels of parental criticism); and c) the extent to which parental involvement might inhibit disclosure or discussion of relevant experiences (e.g., shaming and humiliating experience within the family or within an intimate relationship).

The 14-session treatment protocol consisted of three main phases. Sessions 1-2 (90 minutes each) focused on psycho-education about: a) normal appearance worries versus BDD in order to explain why the diagnosis was made, in a way that would facilitate engagement with a psychological model; b) body image versus physical appearance in order to demonstrate the role that perception might play in BDD; c) recognizing anxiety and its reduction over time in order to provide a rationale for exposure and response prevention (ERP); d) developing an individualized cognitive behavioral formulation to offer an alternative perspective on current difficulties; and d) goal setting and constructing an ERP hierarchy. Sessions 3-12 (60 minutes each) focused primarily on ERP as guided by the hierarchy. ERP tasks were conducted in sessions with therapist assistance (e.g., going to a café or a swimming pool while dropping safety behaviors) as well as being set as homework tasks. Other optional modules (primarily mirror retraining and attention training)[24, 25] were included as needed, determined by the individual formulation, in order to promote engagement with ERP (details in Supplement 1, available online). Sessions 13 and 14 (60 minutes each) included relapse prevention strategies and developing a plan for maintaining and building on treatment gains.

The treating therapists were clinical psychologists who were highly experienced in the delivery of CBT and with particular expertise in treating OCD and related disorders in children and adolescents. Additionally, the therapists received ongoing monthly supervision during the trial from two senior therapists with particular expertise in CBT for adults with BDD (M.A. and D.V.) and weekly supervision from more experienced peer therapists.

Control group: Participants randomized to the control condition were given written materials containing age-appropriate information about BDD, anxiety, and the link between thoughts, emotions, and behaviors (for details, see Supplement 1, available online). Importantly, these materials did not contain information regarding the treatment of BDD. Patients were able to email or phone the clinic with any questions they may have about the materials and for general support. Additionally, a research assistant phoned each patient once a week to monitor mood and suicidal ideation/intent or other risks. During each call, the Patient Health Questionnaire (PHQ),[27, 28] which contains a question about suicide intent, was completed. All participants assigned to the control condition were offered CBT after the end of the two-month follow-up.

Assessment and outcomes

All patients and their families attended an initial assessment of approximately three hours with a multidisciplinary specialist team. Assessment included a mental state examination and an interview with the young person to obtain a detailed account of their BDD symptoms, and an interview with parents/carers to obtain a full developmental history and an independent account of current difficulties. In addition, patients completed a number of standardized symptom measures. Demographic information (i.e., age, gender, ethnicity) was also collected.

Diagnosis of BDD was made according to DSM-IV criteria using the BDD section of the Structured Clinical Interview for DSM-IV (SCID-I).[29] Comorbid psychiatric diagnoses were established using the child version of the Anxiety Disorders Interview Schedule (ADIS-IV-C).[30]

All measures were administered at each of the time-points (baseline, post-treatment, and two-month follow-up). Additionally, the BDD-YBOCS-A[23] and the Anxiety Appearance Inventory (AAI)[31] were also administered at mid-treatment (session 7).

The primary outcome measure was the BDD-YBOCS-A, a widely used 12-item semi-structured clinician-administered interview that rates the severity of BDD symptoms during the past week (score range 0-48). Treatment response was defined as at least 30% reduction in symptoms on the BDD-YBOCS-A.[32]

Secondary outcome measures comprised self-reported measures, including the AAI,[31] the Brown Assessment of Beliefs Scale (BABS),[33, 34] the Cosmetic Procedures Screening Questionnaire (COPS),[35] the Body Image Quality of Life Inventory (BIQLI),[36, 37] and the Beck Depression Inventory for Youth (BDI-Y),[38] as well as clinician-administered measures, including the Children's Global Assessment Scale (CGAS)[39] and the Clinical Global Impression–Severity (CGI-S) and –Improvement (CGI-I) Scales.[40]

Additionally, a treatment satisfaction questionnaire was developed to assess participant and parent/carer satisfaction with the intervention; this was administered at post-treatment to the CBT group only.

Power calculation

Based on data from two previous adult waitlist-controlled trials,[12, 13] calculations showed that, in order to detect a large effect size (i.e., $d \geq 0.8$) on the primary outcome measure at two-sided 5% alpha and 90% power, 11 participants would be required in each group. To allow for potential dropouts (up to 20% expected), cell sizes were set at 15 participants in each arm.

Randomization and concealment

Prior to the inclusion of patients, a randomization sequence was computer-generated using permuted block randomization (blocks of 4 patients, 1:1 ratio), chosen to avoid imbalanced group sizes.[41]

Patients received their randomization number consecutively, based on the order of their inclusion in the trial. Sealed envelopes with information on treatment allocation were stored in a secure locker in case of emergency un-blinding. The allocation sequence was concealed from the research assessors. The therapist was directly informed of the treatment allocation by the trial coordinator. Blinding was only broken after the last patient had completed the two-month follow-up appointment.

Implementation

The research assessor enrolled suitable participants in the trial and gained written informed consent from them (if they were 16 years of age or older) and their parents/carers for their participation in the study. Informed assent was gained from participants younger than 16 years of age after a detailed description of the study had been given. Participants were either randomized to receive 14 weekly sessions of BDD-specific CBT over four months, followed by a two-month follow-up, or to a control condition of equivalent duration (i.e., four months followed by another 2 months of follow-up).

Blinding

Trained independent assessors who were blind to condition completed all clinician-administered measures at all time-points. Treating therapists and participants/parents were instructed not to discuss the arm that they had been allocated to with the blinded assessors, and reminder cards were placed in the interview rooms. Where blindness was inadvertently broken (four patients at mid-treatment, three at post-treatment, and one at two-month follow-up), assessors were immediately changed.

Treatment Integrity

A random sample of n=49 (25%) audio-recorded therapy sessions were checked for integrity, using an adherence-to-protocol rating form developed for this study. The rate of adherence to the treatment manual was 86.7%, which is considered a high rate of treatment fidelity.[42]

Statistical analyses

Across mid-treatment, post-treatment, and follow-up, there were four missing data points on the BDD-YBOCS-A and a similar number of missing data points on the secondary outcome measures. Logistic regression analyses indicated that data were missing at random. Intent-to-treat (ITT) mixed-effects regression analyses for repeated measures with maximum likelihood estimation (MLE) of parameters were implemented in Stata. Mixed-effects models use all available data, can properly account for correlation between repeated measurements on the same participant, have greater flexibility to model time effects, and can handle missing data.[43] For each outcome measure, the model included fixed effects of time (baseline, mid-treatment [only available for the BDD-YBOCS-A and the AAI], post-treatment, and two-month follow-up), study group (CBT *vs* control), and the interaction time×group. Participant effects were added as a random intercept factor to account for the variances between participants and within participants. Additionally, within- and between-group effect sizes for change across time points were calculated with Cohen's *d*.[44] Alpha (two-tailed) was set at $p<0.05$ for all analyses.

Ethics and trial monitoring

The study protocol was approved by the National Research Ethics Service Committee South East Coast – Kent (REC reference 11/LO/1605). External quality management of the study was provided by a steering committee including the project management team, carer and user representatives, expert advisors, and trial therapists.

RESULTS

Participant characteristics

Recruitment of participants took place between February 2012 and March 2014. Table 1 shows the demographic and clinical characteristics of the sample, which was predominantly female and Caucasian. One fifth were on medication at the time of the assessment and approximately 35% had had previous medication and CBT. Half were completely convinced that their perceived defect was real (delusional insight) and nearly half expressed desire to have a cosmetic procedure at baseline.

Approximately 43% had current or a history of self-harm, and 17% a history of suicide attempts. More than half of the sample was either inconsistently or not attending school due to their BDD. Nearly 70% had at least one comorbid psychiatric diagnosis; the most frequent comorbidities were mood disorders (major depressive disorder or dysthymia; n=10, 33.3%), social phobia (n=10, 33.3%), specific phobias (n=8, 26.7%), and generalized anxiety disorder (n=4, 13.3%). More details can be found in Table S1 (available online).

- Insert Table 1 about here –

Participants reported the following main feature(s) of concern: nose (n=7; 23.3%), hair (n=6; 20%), skin (n=4; 13.3%), face in general (n=3; 10.0%), jaw line (n=2; 6.7%), body hair (n=2; 6.7%), breasts (n=2; 6.7%), stomach (n=3; 10.0%), and other (including spots, mole, bags under the eyes, teeth, ears, body shape, thighs, hips, weight, feet, and genitalia; n=11; 36.7%).

Primary outcome

The participants' flow during the trial is depicted in Figure 1. All patients in the CBT group completed treatment and provided data. In the control group, one participant dropped out immediately after randomization, and another was lost to follow-up.

- Insert Figure 1 about here -

Table 2 shows the estimated means and standard errors (SE) from the mixed-effects model for each group and time-point. Raw means and SDs per group across measurement points for the BDD-YBOCS-A appear in Table S2, available online. In the linear mixed-effects regression model, the time×group interaction was not significant at mid-treatment (coefficient [95%CI]=-4.19 [-10.15 to 1.76]; p=.167) but, as expected, it was significant both at post-treatment (coefficient [95%CI]=-11.26 [-17.22 to -5.31]; p=0.000) and at two-month follow-up (coefficient [95%CI]=-9.62 [-15.74 to -3.51]; p=0.002), favoring the CBT group. Post-hoc between-group contrasts showed significantly lower BDD-YBOCS-A scores in the CBT group at post-treatment (estimated mean difference between CBT and control groups at post-treatment=-10.20 [95%CI=-16.02 to -4.38], SE=2.97; p=0.001). These

gains were maintained at the two-month follow-up (estimated mean difference=-8.56 [95%CI=-14.54 to -2.58], SE=3.05; p=0.005).

- Insert Table 2 and Figure 2 about here –

Using one definition of treatment response (≥ 30% reduction in the BDD-YBOCS),[32] 6 (40%) participants in the CBT group and one (6.7%) participant in the control condition were classified as responders at both post-treatment and follow-up (χ^2=4.658, p=.031).

Between-groups effect sizes (for completers) were 1.13 (95%CI=0.31 to 1.96) at post-treatment and 0.85 (95%CI=0.02 to 1.69) at follow-up (**Table S2, available online**). Within-group effect sizes at post-treatment were 1.47 (0.46 to 2.47) and 0.32 (-0.29 to 0.94) for the CBT and control groups, respectively. Similarly, at two-month follow-up, within-group effect sizes were 1.38 (0.34 to 2.41) and 0.35 (-0.45 to 1.14), respectively (**Table S2, available online**).

Secondary outcomes

Table 2 shows the estimated means, standard error, and results of the mixed-effects model for all the secondary outcomes. Raw means and SD per group across measurement points for these variables are shown in **Table S2** (available online). Overall, results from the mixed-effects models in the secondary measures were consistent with the magnitude of the between- and within-group effect sizes both at post-treatment and at two-month follow-up (see **Table S2, available online**).

The time×group interactions were significant for all the self-reported measures (all p's≤0.007) at post-treatment, favoring the CBT condition; this trend was maintained at two-month follow-up, although some of the interaction effects failed to reach statistical significance (see **Table 2**).

Eight (53%) CBT-treated patients were classed as improved or much improved on the clinician-rated CGI-I, compared to 0 in the control condition at post-treatment (see **Figure S1**, available online).

Treatment satisfaction and acceptability

Thirteen parents and 12 young people from the group receiving CBT provided data on treatment satisfaction and acceptability. Eleven (91.7%) adolescents reported high levels of satisfaction with the treatment received, stating that they were very happy or happy with their treatment. Similarly, a majority of parents/carers (76.9%) judged the treatment to be very convenient or convenient. Eleven (91.7%) patients and 11 (91.7%) parents reported that CBT had taught them (or their children) many or some useful techniques to cope with BDD. Finally, 11 (91.7%) patients and 11 (84.6%) parents stated that the treatment had helped them (or their children) to greatly improve or somewhat improve the child's BDD problems.

Protocol deviations

The protocol stipulated duration of 14 CBT sessions over four months, but eight out of the 15 patients in the CBT group required more time to complete treatment (mean and median=18 weeks; range=13–28).

Three participants obtained or changed treatment off-protocol during their involvement in the trial. One participant (control group) discontinued medication (fluoxetine 10mg) without medical consultation approximately one month after being randomized. One patient (CBT group) started decreasing medication (fluoxetine 20mg) until discontinuation after the end of the CBT sessions and before they had reached the two-month follow-up. A third patient (CBT group) commenced fluoxetine (up to 40mg) during the active treatment phase (between sessions 1 and 7) and started additional psychological treatment in an inpatient psychiatric unit at post-treatment due to the persistence of severe BDD concerns and a suicide attempt (participant's BDD-YBOCS-A score at baseline=41; score at post-treatment=46).

Adverse events

Two participants –one in each condition– attempted suicide during the trial. The attempts consisted of drug overdoses that required emergency attendance at hospital. Both patients stayed in the trial after the overdoses, though one patient in the CBT group (mentioned in the previous section) deviated from protocol and received additional pharmacological and psychological treatment in an inpatient unit. The participant in the control condition continued to be monitored by their local child and adolescent mental health service (this monitoring was not focused on the BDD symptoms and did not include active treatment for BDD).

DISCUSSION

To our knowledge, this is the first RCT to test the feasibility, acceptability, and efficacy of a developmentally tailored CBT protocol for young people with BDD. Both the patients and their families deemed the intervention highly acceptable and useful. CBT was superior to a control condition of equivalent duration (consisting of psycho-education materials and weekly risk monitoring) on both primary and secondary measures (e.g., insight, depression, general function) and the gains were generally maintained at two-month follow-up. Between-group effect sizes were large (1.13 at post-treatment and 0.85 at follow-up), as were the within-group effect sizes of CBT (1.47 at post-treatment and 1.38 at follow-up).

The results are broadly comparable to those in the adult CBT trials for BDD,[15-17] which reported response rates ranging from 48% to 61% and within-group effect sizes ranging from 0.83 to 1.30 after 12 weeks of treatment. Although these comparisons need to be made cautiously, because recruited samples and treatment protocols differ, our results suggest that CBT can also be developmentally tailored and successfully delivered to young people with the disorder, supporting the UK National Institute for Health and Care Excellence guidelines.[22] Despite this, the results could be described as modest, as only 40% of the treated patients were considered responders according to one prevailing operational definition of treatment response in BDD[32]. Employing another definition, approximately 53% of CBT-treated patients were classed as improved or much improved on the

clinician-rated CGI-I. The mean BDD-YBOCS score at post-treatment and follow-up (around 25 points) corresponds to mild/moderate BDD symptoms, suggesting that there is considerable room for improvement.

It is important to note that ours was a severely ill sample (11 patients [37% of the sample] had BDD-YBOCS scores over 40, and a further 6 patients had scores of 38 or 39, indicating very severe symptoms). Half of the sample was classed as having no insight (delusional) at baseline. A substantial proportion had a history of self-harm and suicidal attempts. Nearly 60% were off school or only attending sporadically due to their BDD symptoms. Nearly half desired cosmetic procedures. Though the study protocol stipulated that the 14 CBT sessions should be delivered in four months, many patients missed sessions or had unproductive sessions, which were used to deal with low mood, family conflict, or risky situations like suicidal ideation or attempts. This resulted in a protocol adherence of around 87%, which is somewhat lower than that reported in the OCD literature.[45] Outside the tight control conditions of a clinical trial, we suspect that many of these patients would have dropped out from treatment. Our experience from this trial suggests that a considerable proportion of youths with BDD may require longer than 14 sessions, delivered weekly but with flexibility in terms of location and time of appointments, in order to achieve symptom relief. In support of this possibility, two recent adult trials[12,14] showed that further improvements occurred when treatment was prolonged beyond the acute phase (12 sessions).

Compared to the adult BDD trials, our trial had a lower proportion of male patients (only 13%). A similar female predominance was observed in previous pediatric BDD studies.[9, 10] It is unclear whether BDD is less prevalent in adolescent boys or simply harder to detect. Further epidemiological research will be required to address this question and possibly identify barriers to seeking help amongst adolescent males. BDD is associated with considerable stigma and reluctance to disclose symptoms[46, 47] and perhaps this is particularly problematic in adolescent boys.

This study had some limitations. First, there were a number of protocol deviations. These included a slightly longer duration and higher variability of the active treatment phase for the CBT group compared to the control group (a median of 18 weeks [range 13-28 weeks] instead of the predicted 17.4 weeks [4 months] needed to complete treatment). Additionally, three participants (two in the CBT group and one in the control group) either discontinued (n=2) or commenced (n=1) medication during the trial. Exclusion of all data points after these medication changes did not alter the results. Second, blindness to condition was inadvertently broken in eight occasions during the duration of the trial. However, assessors were immediately changed when that occurred, thus minimizing the consequences of the un-blinding in posterior assessments. Third, though adequately powered to test the study hypotheses, this pilot study was too small to examine whether comorbidity (e.g., depression), low insight, or other variables are predictive of treatment outcome in youths with BDD. The identification of reliable predictors of outcome will be invaluable to inform future refinements of the protocol and to devise more personalized interventions. Fourth, the study was conducted in the context of a highly specialist clinic and the results may not generalize to other settings or less complex BDD populations. Finally, we used a control condition which included psychoeducation materials and careful monitoring of risk; however, despite weekly phone calls, patients in the control condition did not receive a comparable amount of therapist contact, potentially resulting in an inherent advantage for the CBT group beyond the active elements of the intervention (that is, non-specific effects associated with therapist contact). A larger RCT comparing an optimized version of this treatment with an active control condition, such as anxiety management,[13] is warranted. Similarly, a longer follow-up of these patients is also warranted to establish the durability of the treatment.

To conclude, developmentally tailored CBT is a promising intervention for young people with BDD, though there is substantial room for improvement and further need to compare it with active control conditions. Further clinical trials comparing optimized CBT and pharmacological therapies, as well as their combination, both in young people and adults with BDD, are sorely needed.

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FIGURES

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram. Note: CBT = cognitive-behavioral therapy; ITT = intent-to-treat.

Figure 2. Time×group interaction effects on the primary outcome measure (Yale-Brown Obsessive-Compulsive Scale Modified for BDD–Adolescent version, BDD-YBOCS-A), derived from the mixed-effects regression model. Note: Error bars indicate 95% CI. CBT = cognitive-behavioral therapy; 2m FU = 2-month follow-up.

Table 1. Demographic and Clinical Characteristics of the Sample.

	Combined sample (N=30)		CBT group (n=15)		Control group (n=15)	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age at assessment	16.0	1.7	16.1	1.8	15.8	1.5
Age of BDD onset	12.5	1.9	12.2	2.4	12.8	1.4
	n	**%**	**n**	**%**	**n**	**%**
Gender						
Female	26	86.7	11	73.3	15	100
Male	4	13.3	4	26.7	0	0
Ethnicity						
White	24	80.0	14	93.3	10	66.7
Black	2	6.7	0	0	2	13.3
Mixed	3	10.0	1	6.7	2	13.3
Asian	1	3.3	0	0	1	6.7
Presence of comorbidities (any)[a]						
Yes	20	66.7	11	73.3	9	60.0
No	10	33.3	4	26.7	6	40.0
Medicated at time of assessment						
Yes	6[b]	20.0	3	20.0	3	20.0
No	24	80.0	12	80.0	12	80.0
Previous SSRI						
Yes	11	36.7	7	46.7	4	26.7
No	19	63.3	8	53.3	11	73.3
Previous CBT for BDD						
Yes	11	36.7	7	46.7	4	26.7
No	19	63.3	8	53.3	11	73.3
Delusional BDD at baseline						
Yes	15	51.7	8	57.1	7	46.7
No	14	48.3	6	42.9	8	53.3
Desire for cosmetic procedure at baseline						
Yes	14	46.7	5	33.3	9	53.3
No	16[d]	53.3	10[c]	67.7	6	46.7
History of or current self-harm						
Yes	13	43.3	6	40.0	7	46.7
No	17	56.7	9	60.0	8	53.3
History of suicide attempts						
Yes	5	16.7	4	26.7	1	6.7
No	25	83.3	11	73.3	14	93.3
Attending school at baseline						
Yes	13	43.3	6	40.0	7	46.6
Part-time (due to BDD)[e]	6	20	2	13.3	4	26.7
No (dropped-out due to BDD)	11	36.7	7	46.7	4	26.7

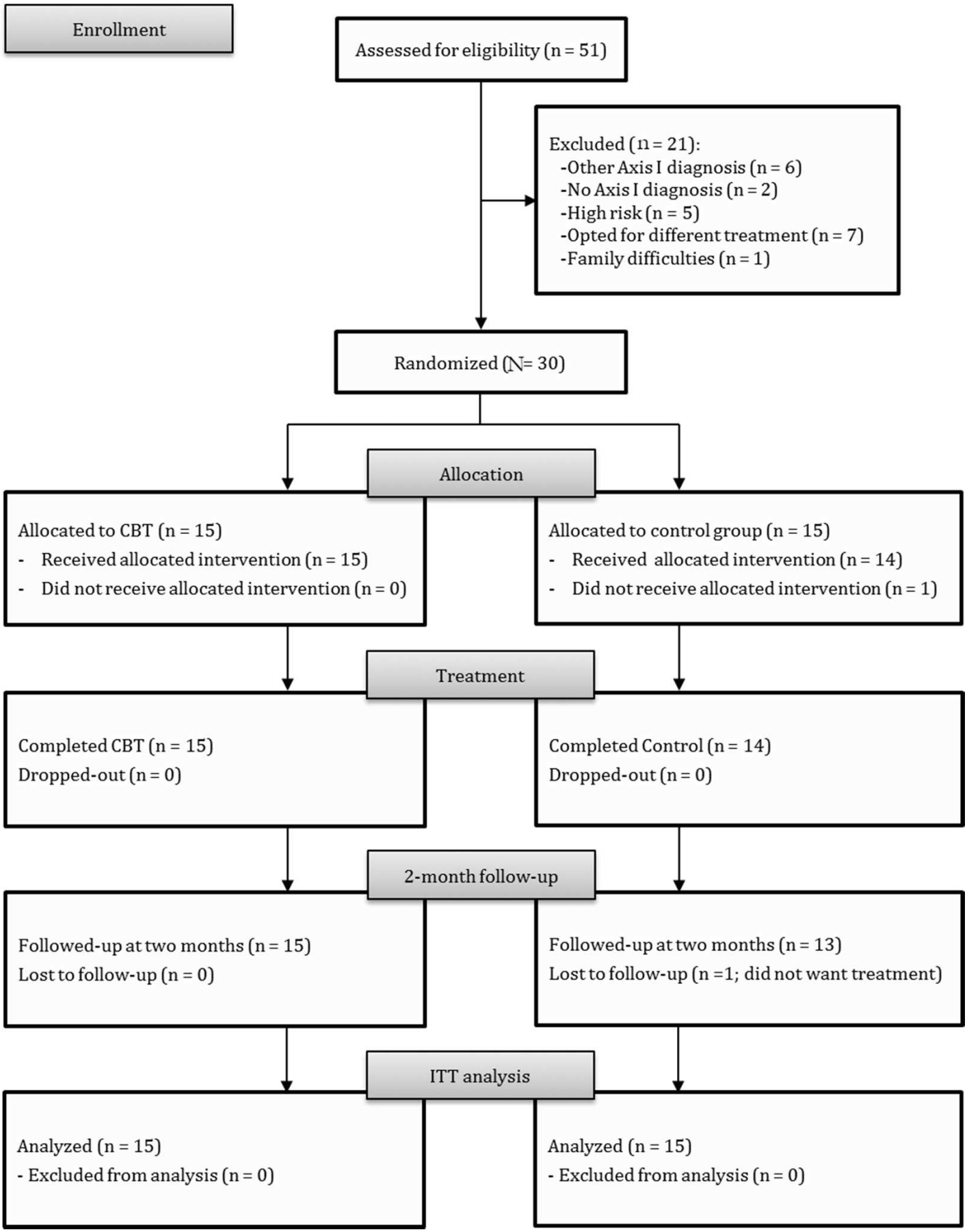
Note: BDD = body dysmorphic disorder; CBT = cognitive-behavioral therapy; SSRI = selective serotonin reuptake inhibitors.

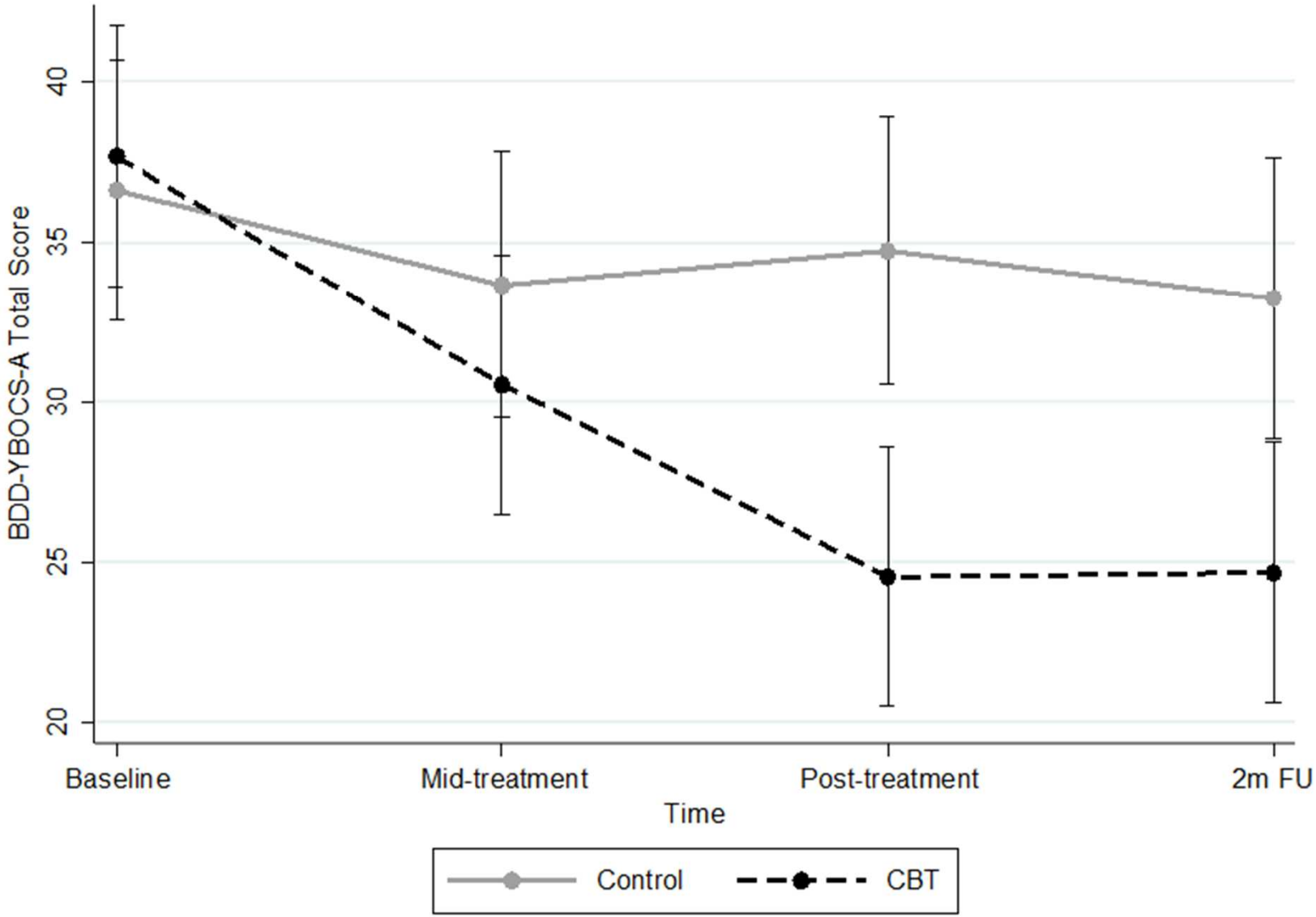
[a] According to the Anxiety Disorders Interview Schedule–child version. [b] Five patients were on SSRIs and one on quetiapine. [c] Patients are classified as having delusional BDD beliefs if their total score in the Brown Assessment of Beliefs Scale (BABS) is 18 or more, and if they score 4 on the first item, indicating they are completely convinced that their belief is accurate. [d] This group includes one young person who did not have further desire for a cosmetic procedure after having had laser surgery for acne. [e] Includes missing days, missing lessons, or being late due to BDD behaviors.

Table 2. Model Estimates for Each Treatment Group Across Time-Points and Results of the Group×Time Interaction Effects From the Linear Mixed-Effects Models

Measures	Model estimates								Group × Time interaction effects					
	Baseline		Mid-treatment (session 7)		Post-treatment (session 14)		Two-month follow-up		Mid-treatment (session 7) outcomes		Post-treatment (session 14) outcomes		Two-month follow-up outcomes	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE	Coefficient (95%CI)	p value	Coefficient (95%CI)	p value	Coefficient (95%CI)	p value
BDD-YBOCS-A									-4.19 (-10.15 to 1.76)	0.167	-11.26 (-17.22 to -5.31)	0.000	-9.62 (-15.74 to -3.51)	0.002
CBT	37.67	2.07	30.53	2.07	24.53	2.07	24.67	2.07						
Control	36.60	2.07	33.66	2.13	34.73	2.13	33.22	2.24						
AAI									-5.08 (-13.63 to 3.46)	0.243	-14.75 (-23.28 to -6.23)	0.000	-7.59 (-16.45 to 1.27)	0.093
CBT	39.93	3.02	30.07	3.02	19.39	3.09	21.57	3.17						
Control	42.80	3.02	38.02	3.18	37.01	3.10	32.02	3.26						
BABS									–	–	-5.46 (-9.15 to -1.77)	0.004	-0.94 (-4.59 to 2.71)	0.615
CBT	19.01	1.34	–	–	14.32	1.34	15.87	1.32						
Control	19.33	1.32	–	–	20.10	1.42	17.50	1.42						
COPS									–	–	-15.42 (-26.73 to -4.12)	0.007	-11.57 (-23.21 to 0.72)	0.051
CBT	58.07	3.68	–	–	36.15	3.89	39.72	4.01						
Control	60.87	3.68	–	–	54.37	4.02	54.09	4.15						
BIQLI									–	–	21.54 (6.90 to 36.19)	0.004	5.44 (-9.83 to 20.71)	0.485
CBT	-35.43	4.06	–	–	-11.83	4.21	-21.52	4.74						
Control	-30.39	4.37	–	–	-28.33	4.55	-21.91	4.55						
BDI-Y									–	–	-15.75 (-25.61 to -5.90)	0.002	-5.15 (-15.27 to 4.97)	0.319
CBT	69.07	3.40	–	–	53.78	3.59	60.84	3.59						
Control	66.20	3.40	–	–	66.71	3.49	63.13	3.69						
CGAS									–	–	7.89 (1.40 to 14.38)	0.017	9.75 (3.15 to 16.35)	0.004
CBT	40.20	2.56	–	–	50.47	2.61	51.13	2.56						
Control	41.20	2.56	–	–	43.57	2.62	42.39	2.74						
CGI-S									–	–	-1.40 (-2.17 to -0.64)	0.000	-0.74 (-1.53 to 0.05)	0.066
CBT	5.06	0.28	–	–	3.40	0.27	3.53	0.27						
Control	4.93	0.27	–	–	4.69	0.28	4.14	0.29						

Note: AAI = Appearance Anxiety Inventory; BABS = Brown Assessment of Beliefs Scale; BDD-YBOCS-A = Yale-Brown Obsessive-Compulsive Scale Modified for Body Dysmorphic Disorder–Adolescent version; BDI-Y = Beck Depression Inventory-Youth; BIQLI = Body Image Quality of Life Inventory; CBT = cognitive-behavioral therapy; CGAS = Children's Global Assessment Scale; CGI-S = Clinical Global Impression–Severity; COPS = Cosmetic Procedures Screening Questionnaire.


Enrollment
Assessed for eligibility (n = 51)
Excluded (n = 21):
-Other Axis I diagnosis (n = 6)
-No Axis I diagnosis (n = 2)
-High risk (n = 5)
-Opted for different treatment (n = 7)
-Family difficulties (n = 1)
Randomized (N= 30)
Allocation
Allocated to CBT (n = 15)
- Received allocated intervention (n = 15)
- Did not receive allocated intervention (n = 0)
Allocated to control group (n = 15)
- Received allocated intervention (n = 14)
- Did not receive allocated intervention (n = 1)
Treatment
Completed CBT (n = 15)
Dropped-out (n = 0)
Completed Control (n = 14)
Dropped-out (n = 0)
2-month follow-up
Followed-up at two months (n = 15)
Lost to follow-up (n = 0)
Followed-up at two months (n = 13)
Lost to follow-up (n =1; did not want treatment)
ITT analysis
Analyzed (n = 15)
- Excluded from analysis (n = 0)
Analyzed (n = 15)
- Excluded from analysis (n = 0)


BDD-YBOCS-A Total Score
20
25
30
35
40
Baseline
Mid-treatment
Post-treatment
2m FU
Time
Control
CBT

SUPPLEMENT 1

Cognitive-Behavioral Therapy (CBT) Group: Additional Modules

The following modules were also included in the treatment manual and were used as appropriate depending on the case formulation, although they were not the main focus of treatment: a) mirror retraining; b) attention training; c) imagery rescripting for past aversive experiences (e.g., bullying, teasing); d) relaxation training; e) behavioral activation; f) mindfulness; g) distancing thoughts technique; and g) the "inner bully" technique. The emphasis of the treatment was exposure with response prevention (ERP) tasks. These additional modules were thus not the main focus of treatment, but rather used as appropriate, to either enhance ERP tasks or to enable the young person to fully engage in EPR tasks. This depended on the case formulation; for example, mirror retraining was used if the young person was particularly involved in rituals involving mirrors, and attention training was completed if young people were unable to effectively manipulate their internal focus of attention when doing exposure tasks. Among the group of 15 patients receiving CBT, 66.7% (n=10) completed the mirror retraining module, 53.3% (n=8) completed the attentional training module, 20.0% (n=3) the inner bully module, 6.7% (n=1) the imagery rescripting technique, and another 6.7% (n=1) completed the distancing thoughts module.

Control group: Written Psycho-Education Materials

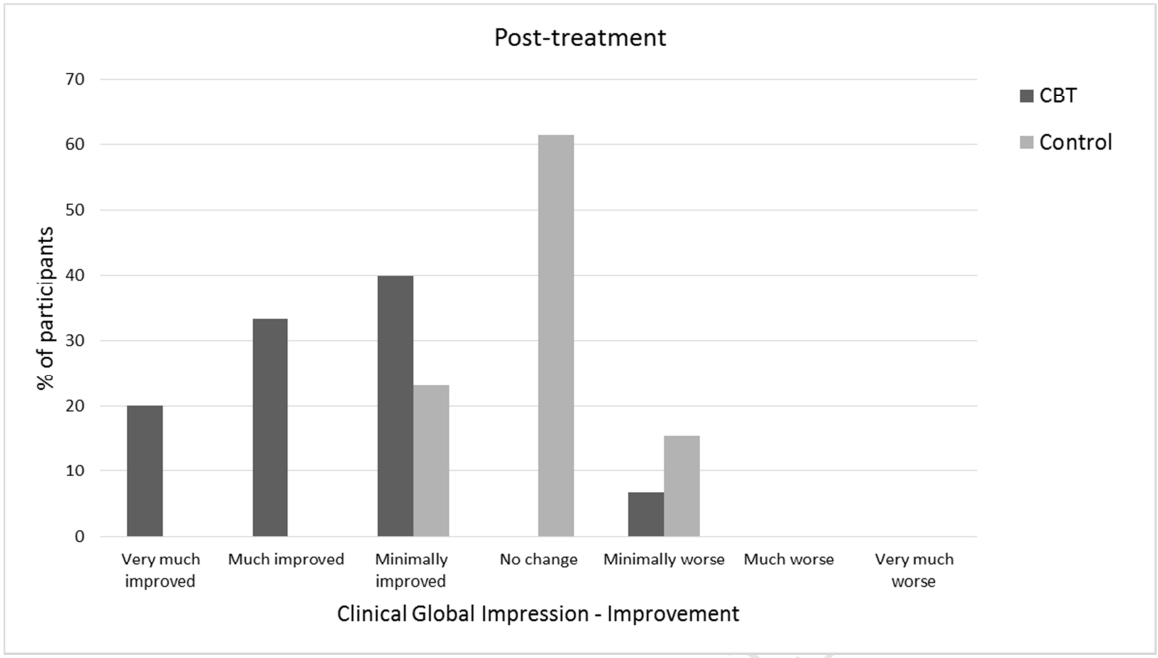
Participants in the control group were given the following reading materials:

- Week 1
  - Claiborn J, Pedrick C. The BDD Workbook: Overcome Body Dysmorphic Disorder and End Body Image Obsessions. Oakland, CA: New Harbinger Publications, Inc; 2002: 17-20.
  - Phillips KA. The Broken Mirror: Understanding and Treating Body Dysmorphic Disorder. New York, NY: Oxford University Press; 2005: 3-24.
- Week 7

- Claiborn J, Pedrick C. The BDD Workbook: Overcome Body Dysmorphic Disorder and End Body Image Obsessions. Oakland, CA: New Harbinger Publications, Inc.; 2002: 26-27, 36-39.

- Week 14
  - Veale D, Willson R, Clarke A. Overcoming Body Image Problems including Body Dysmorphic Disorder: A self-help guide using Cognitive Behavioral Therapy. London, UK: Constable & Robinson Ltd.; 2009: 1-14.

A.



B.

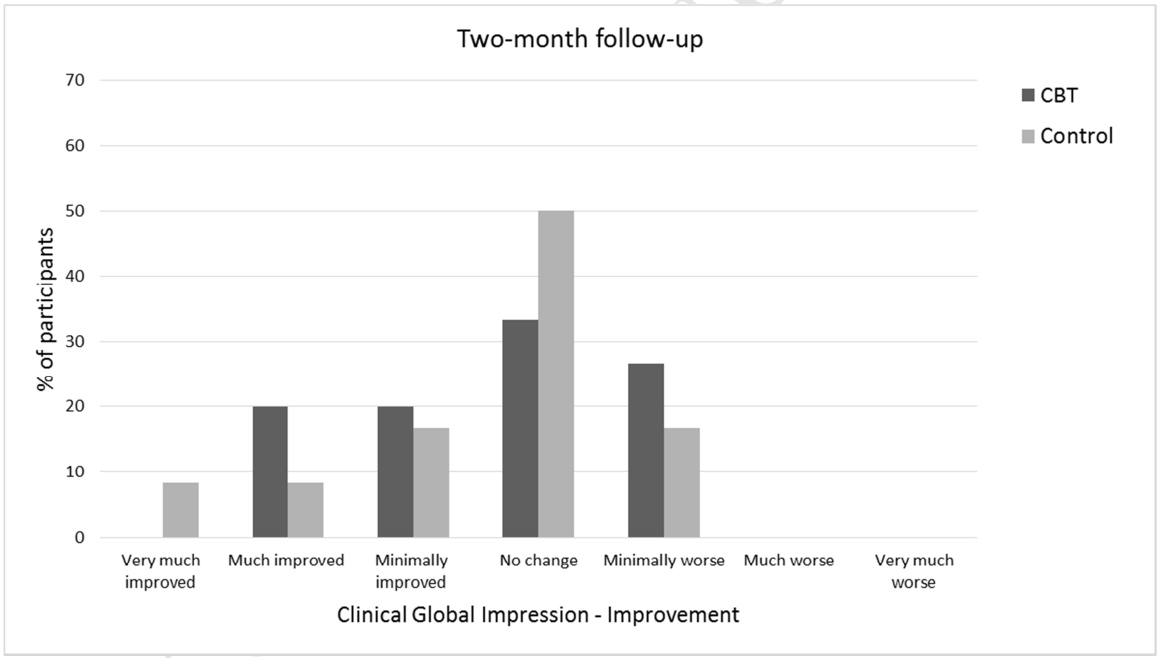


Figure S1. Results of the Clinical Global Impression (CGI) – Improvement in each treatment group at post-treatment (A) and at two-month follow-up (B). Note that at the two-month follow-up clinicians rated improvement relative to post-treatment. CBT = cognitive-behavioral therapy.

Table S1. Detailed Comorbidities at Baseline, According to the Anxiety Disorders Interview Schedule – Child Version

	Combined sample (N=30)		CBT group (n=15)		Control group (n=15)	
	n	**%**	**n**	**%**	**n**	**%**
Separation Anxiety Disorder	0	0	0	0	0	0
Social Phobia	10	33.3	5	33.3	5	33.3
Specific Phobia	8	26.7	4	26.7	4	26.7
Panic Disorder	0	0	0	0	0	0
Agoraphobia With Panic Disorder	0	0	0	0	0	0
Agoraphobia Without Panic Disorder	0	0	0	0	0	0
Generalized Anxiety Disorder	4	13.3	3	20	1	6.7
Obsessive-Compulsive Disorder	1	3.3	0	0	1	6.7
Posttraumatic (or Acute) Stress Disorder	0	0	0	0	0	0
Dysthymia	3	10.0	2	13.3	1	6.7
Major Depressive Disorder	7	23.3	3	20.0	4	26.7
Attention-Deficit/Hyperactivity Disorder	1	3.3	0	0	1	6.7
Substance Abuse	0	0	0	0	0	0
Schizophrenia	0	0	0	0	0	0
Selective Mutism	0	0	0	0	0	0
Eating Disorders	1	3.3	1	6.7	0	0
Somatoform Disorders	0	0	0	0	0	0

Note: CBT = cognitive-behavioral therapy.

Table S2. Raw Means and Standard Deviations by Treatment Group Across Time-Points and Cohen's d Effect Sizes at Each Time-Point

Measures	Baseline			Mid-treatment (session 7)			Post-treatment (session 14)			Two-month follow-up			Cohen's d effect sizes					
													Mid-treatment (session 7)		Post-treatment (session 14)		Two-month follow-up	
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	Within-group (95% CI)	Between-group (95% CI)	Within-group (95% CI)	Between-group (95% CI)	Within-group (95% CI)	Between-group (95% CI)
BDD-YBOCS-A														0.42 (-0.35 to 1.20)		1.13 (0.31 to 1.96)		0.85 (0.02 to 1.69)
CBT	15	37.67	4.53	15	37.67	4.53	15	24.53	11.31	15	24.67	12.32	0.95 (0.24 to 1.67)		1.47 (0.46 to 2.47)		1.38 (0.34 to 2.41)	
Control	15	36.60	5.50	15	36.60	5.50	14	34.79	5.67	12	34.79	8.87	0.51 (-0.06 to 0.96)		0.32 (-0.29 to 0.94)		0.35 (-0.45 to 1.14)	
AAI														0.58 (-0.21 to 1.38)		1.60 (0.71 to 2.50)		0.84 (-0.03 to 1.70)
CBT	15	39.93	14.22	15	30.53	8.81	14	18.57	13.07	13	20.54	14.14	0.67 (-0.01 to 1.35)		1.56 (0.39 to 2.74)		1.37 (0.30 to 2.43)	
Control	15	42.80	7.39	14	33.71	5.77	14	36.86	9.42	12	31.67	12.34	0.64 (0.15 to 1.13)		0.70 (-0.01 to 1.40)		1.07 (0.10 to 2.05)	
BABS														–		1.26 (0.43 to 2.09)		0.26 (-0.54 to 1.06)
CBT	14	19.21	4.74	–	–	–	14	13.60	6.80	15	15.87	6.85	–		0.92 (0.27 to 1.57)		0.55 (-0.08 to 1.19)	
Control	15	19.33	3.73	–	–	–	14	20.43	3.34	12	17.50	5.49	–		-0.31 (-0.88 to 0.27)		0.39 (-0.40 to 1.17)	
COPS				–	–	–								–		1.20 (0.30 to 2.10)		0.97 (0.05 to 1.88)
CBT	15	58.07	15.27	–	–	–	13	35.15	17.56	12	38.92	17.57	–		1.39 (0.21 to 2.58)		1.16 (0.10 to 2.23)	
Control	15	60.87	10.21	–	–	–	12	54.67	14.72	11	54.36	14.03	–		0.46 (-0.10 to 1.02)		0.50 (-0.02 to 1.01)	
BIQLI				–	–	–								–		-0.92 (-1.82 to -0.03)		-0.09 (-1.00 to 0.83)
CBT	14	-35.21	11.12	–	–	–	13	-11.31	23.25	10	-20.30	12.90	–		-1.36 (-2.78 to 0.07)		-1.24 (-2.65 to 0.17)	
Control	12	-31.17	13.29	–	–	–	11	-28.73	11.59	11	-21.73	18.92	–		-0.20 (-0.93 to 0.54)		-0.56 (-1.29 to 0.17)	
BDI-Y				–	–	–								–		0.94 (0.10 to 1.78)		0.24 (-0.59 to 1.07)
CBT	15	69.07	13.27	–	–	–	13	52.23	18.35	13	60.15	14.57	–		1.05 (-0.02 to 2.13)		0.64 (-0.05 to 1.33)	
Control	15	66.20	10.78	–	–	–	14	66.71	12.07	12	63.42	12.03	–		-0.04 (-0.56 to 0.47)		-0.24 (-0.02 to 0.49)	
CGAS				–	–	–								–		-0.53 (-.32 to 0.26)		-0.81 (-1.63 to 0.02)
CBT	15	40.20	7.81	–	–	–	14	49.86	12.56	15	51.13	13.98	–		-0.86 (-1.46 to -0.26)		-0.90 (-1.56 to -0.24)	
Control	15	41.20	7.53	–	–	–	14	43.93	9.65	12	41.75	7.72	–		-0.30 (-0.76 to 0.15)		-0.07 (-0.70 to 0.56)	
CGI-S				–	–	–								–		1.16 (0.34 to 1.99)		1.16 (0.34 to 1.99)
CBT	15	5.07	0.80	–	–	–	15	3.40	1.30	15	3.53	1.55	–		1.51 (0.56 to 2.46)		1.51 (0.56 to 2.46)	
Control	15	4.93	0.80	–	–	–	14	4.64	0.74	12	4.17	0.94	–		0.38 (-0.26 to 1.01)		0.38 (-0.26 to 1.01)	

Note: AAI = Appearance Anxiety Inventory; BABS = Brown Assessment of Beliefs Scale; BDD-YBOCS-A = Yale-Brown Obsessive-Compulsive Scale Modified for Body Dysmorphic Disorder – Adolescent version; BDI-Y = Beck Depression Inventory-Youth; BIQLI = Body Image Quality of Life Inventory; CBT = cognitive-behavioral therapy; CGAS = Children's Global Assessment Scale; CGI-S = Clinical Global Impression – Severity; COPS = Cosmetic Procedures Screening Questionnaire.