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Modular Cognitive-Behavioral Therapy for Body Dysmorphic Disorder: A Randomized Controlled Trial

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Abstract

There are few effective treatments for body dysmorphic disorder (BDD) and a pressing need to develop such treatments. We examined the feasibility, acceptability, and efficacy of a manualized modular cognitive-behavioral therapy for BDD (CBT-BDD). CBT-BDD utilizes core elements relevant to all BDD patients (e.g., exposure, response prevention, perceptual retraining) and optional modules to address specific symptoms (e.g., surgery seeking). Thirty-six adults with BDD were randomized to 22 sessions of immediate individual CBT-BDD over 24 weeks ($n = 17$) or to a 12-week waitlist ($n = 19$). The Yale-Brown Obsessive-Compulsive Scale Modified for BDD (BDD-YBOCS), Brown Assessment of Beliefs Scale, and Beck Depression Inventory-II were completed pre-treatment, monthly, post-treatment, and at 3- and 6-month follow-up. The Sheehan Disability Scale and Client Satisfaction Inventory (CSI) were also administered. Response to treatment was defined as 30% reduction in BDD-YBOCS total from baseline. By week 12, 50% of participants receiving immediate CBT-BDD achieved response versus 12% of waitlisted participants ($p = 0.026$). By post-treatment, 81% of all participants (immediate CBT-BDD plus waitlisted patients subsequently treated with CBT-BDD) met responder criteria. While no significant group differences in BDD symptom reduction emerged by week 12, by post-

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“Disclosure Statement” (Past 3 years)

Drs. Wilhelm, Phillips and Steketee report receiving royalties from Guilford Press for a treatment manual on body dysmorphic disorder (BDD). In addition, we have the following disclosures, which are not directly relevant for this project. Drs. Wilhelm, Phillips, and Steketee receive royalties from Oxford University Press. Drs. Wilhelm and Steketee receive royalties from New Harbinger Publications. Drs. Wilhelm and Phillips receive support in the form of free medication and matching placebo from Forest Laboratories for a clinical trial funded by the National Institutes of Health. Dr. Phillips has received royalties from Merck Manual and the Free Press/Zachary Shuster Harnsworth (potential future royalties). Dr. Phillips also discloses travel/expense reimbursement from academic, federal, professional, and consumer advocacy organizations. Drs. Wilhelm, Phillips, Didie, Buhlmann, Greenberg, Fama, and Steketee have received speaking honoraria from various academic institutions.

treatment CBT-BDD resulted in significant decreases in BDD-YBOCS total over time ($d = 2.1$, $p < 0.0001$), with gains maintained during follow-up. Depression, insight, and disability also significantly improved. Patient satisfaction was high, with a mean CSI score of 87.3% (SD = 12.8%) at post-treatment. CBT-BDD appears to be a feasible, acceptable, and efficacious treatment that warrants more rigorous investigation.

Keywords

Body dysmorphic disorder; BDD; cognitive-behavioral therapy; body image; treatment

Body dysmorphic disorder (BDD) is a common and severe disorder characterized by distressing or impairing preoccupation with nonexistent or slight defects in physical appearance (American Psychiatric Association [DSM-IV-TR], 2000). BDD affects an estimated 1.7 to 2.4% of the population (Buhlmann et al., 2010; Koran, Abujaoude, Large, & Serpe, 2008; Rief, Buhlmann, Wilhelm, Borkenhagen, & Brähler, 2006). The disorder typically begins during early adolescence (Phillips & Diaz, 1997; Phillips, Didie, et al., 2006) and in observational studies is associated with a chronic, unremitting course (Phillips, Menard, et al., 2013). Intrusive appearance-related thoughts occupy an average of 3 to 8 hours per day (Phillips, Gunderson, Mallya, McElroy, & Carter, 1998). Individuals with BDD usually display poor or absent insight, with more than one-third of patients describing delusional beliefs about being disfigured (Eisen, Phillips, Coles, & Rasmussen, 2004; Phillips, 2004; Phillips, McElroy, Keck, Pope, & Hudson, 1994). Two-thirds have ideas/delusions of reference, believing others take special notice of the “defect” (e.g., mock it; Phillips, 2004; Phillips, McElroy, et al., 1994). Sufferers engage in time-consuming ritualistic behaviors aimed at checking, hiding, or improving perceived flaws, such as surgery seeking, self-injurious skin picking, or excessive grooming (Phillips, Gunderson, et al., 1998). BDD often causes marked social, academic, and occupational impairment. Individuals with BDD may drop out of school or work, or have difficulty developing or maintaining meaningful relationships due to appearance concerns (Phillips & Diaz, 1997). BDD is associated with high lifetime rates of psychiatric hospitalization, being housebound, and suicidality (Phillips et al., 2005; Phillips & Menard, 2006).

Despite the prevalence and morbidity associated with BDD, treatment research on BDD is scarce. Case reports, case series, and two studies using waitlist control groups provided initial, preliminary support for the effectiveness of CBT specifically developed for BDD (see Ipser, Sander, & Stein, 2009; Wilhelm, Phillips, Fama, Greenberg, & Steketee, 2011; Williams, Hadjistavropoulos, & Sharpe, 2006, for review). These preliminary studies were promising; however, conclusions about the generalizability and replicability of their results are limited by the small number of studies, small sample sizes, and restrictive inclusion criteria (see Wilhelm et al., 2011, for review). Moreover, most prior studies of CBT did not report on medication use during treatment. This is a major limitation, given that certain medications have been shown to be efficacious for BDD (e.g., Phillips & Hollander, 2008). Furthermore, only one study was based on a treatment manual (unpublished), which focused on weight/shape concerns (which are not among the most common areas of concern in BDD). Treatment manuals allow for standardized dissemination of a new treatment. Thus,

the lack of a widely applicable and tested CBT manual for BDD has been a major limitation for the field.

To this end, Wilhelm and colleagues recently developed a manual for a modular individual CBT for BDD (CBT-BDD; Wilhelm, Phillips, & Steketee, 2013). CBT-BDD is informed by cognitive-behavioral models of the development and maintenance of BDD (e.g., Veale, 2004; Wilhelm, Buhlmann, Hayward, Greenberg, & Dimaite, 2010; Wilhelm & Neziroglu, 2002; Wilhelm et al., 2011), including recent studies suggesting that BDD patients focus on details at the expense of reduced processing of global features (e.g., Deckersbach et al., 2000; Feusner, Townsend, Bystritsky, & Bookheimer, 2007). CBT-BDD utilizes standard core elements relevant to all BDD patients, plus optional modules used as needed. Core treatment elements include psychoeducation, cognitive interventions (e.g., to address maladaptive beliefs related to BDD, the importance of appearance or self-worth), exposure to avoided situations and prevention of rituals, and mindfulness and perceptual retraining (e.g., to reduce selective attention to details such as appearance flaws). Optional treatment modules are provided to flexibly tailor treatment to address symptoms that affect some but not all patients (e.g., skin picking, surgery seeking). For all patients, treatment ends with relapse prevention strategies and booster sessions focused on helping patients maintain their gains.

Wilhelm et al. (2011) piloted their CBT-BDD manual ($n = 12$) using expert therapists (S.W., K.P., G.S.) to test treatment procedures, determine treatment duration, and revise the manual based on actual application. The use of broader inclusion criteria than most prior CBT studies increased the sample's representativeness. The 2011 Wilhelm et al. study included individuals with suicidal thinking, delusional BDD beliefs, and males as well as females. In intent-to-treat (ITT) analyses, BDD symptoms and depressive symptoms improved significantly at post-treatment. Seventy-five percent of the ITT sample were treatment responders (i.e., had at least a 30% reduction in BDD-symptom severity over the course of treatment), as were 80% of the completer sample. Treatment gains were maintained at the six-month follow-up assessment. While these preliminary results were encouraging, they must be interpreted with caution, as there was no comparison condition to control for other factors potentially related to improvement, such as the passage of time. Further, because only expert therapists treated patients in this initial trial, it was unclear whether CBT-BDD could be successfully administered by less experienced clinicians.

In the current study, we evaluated the efficacy of CBT-BDD in a randomized trial with a waitlist control, a reasonable comparison group to test a newly manualized treatment. Although this design does not provide definitive evidence for efficacy, it allows determination of whether active treatment is superior to gains that would be observed simply due to the passage of time or other confounding variables (e.g., history, maturation, testing). We hypothesized that CBT-BDD would be more efficacious for BDD than the waitlist condition. Given earlier findings suggesting maintenance of gains from CBT for BDD following treatment (e.g., McKay, 1999; McKay, Todaro, Neziroglu, Campisi, Moritz, & Yaryura-Tobias, 1997; Rosen, Reiter, & Orosan, 1995; Wilhelm et al., 2011), we also hypothesized that treatment gains would be durable (i.e., maintained at 3- and 6- month follow-up assessments). Because BDD is associated with substantial impairment and

morbidity, we also investigated whether participants who received immediate CBT-BDD relative to those in the waitlist condition would experience improved functioning. Specifically, we hypothesized that participants who received immediate CBT-BDD would (1) more often achieve treatment responder status (defined as 30% decrease in BDD symptom severity) than participants in the waitlist group after 12 weeks of treatment, (2) show greater improvement in BDD symptom severity and associated features (including BDD-related insight, depression, and disability) than participants in the waitlist group after 12 weeks of treatment, (3) show significant improvement in BDD symptom severity, depression, and disability between baseline and post-treatment (24 weeks), and (4) sustain improvement in BDD symptom severity at follow-up (6 months post-treatment). We also examined treatment feasibility and acceptability, and whether CBT-BDD could be delivered successfully by non-expert therapists.

Method

Participants

Participants consisted of 36 adults (61% female) age 18 or older with primary DSM-IV BDD (based on symptom severity). Potential participants were screened initially by phone for BDD and were invited for an in-person assessment if they met eligibility criteria. Participants were recruited with flyers and brochures posted in the community and mailed to clinicians (e.g., mental health professionals, dermatologists, plastic surgeons) in the surrounding areas from August 2005 to December 2008. Recruitment materials included questions such as: “Are you worried about your appearance?” Participants were enrolled in the study if they had BDD symptoms for at least 6 months that were at least moderate in severity as reflected by a minimum score of 24 on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BDD-YBOCS; Phillips et al., 1997). Exclusion criteria included active and clinically significant suicidality as determined by a clinician and/or score on the suicide item (#9) of the Beck Depression Inventory (Beck, Steer, & Brown, 1996) > 1), a psychotic disorder (excluding delusional BDD), bipolar disorder, borderline personality disorder, substance abuse or dependence within the past three months, cognitive impairment that could interfere with one’s ability to participate fully in CBT (e.g., estimated IQ <80 on the Wechsler Abbreviated Scale of Intelligence [WASI, Wechsler, 1999]), self-reported dementia or brain damage, body image/weight concerns accounted for primarily by an eating disorder, concurrent psychotherapy, or a history of at least 10 sessions of CBT for BDD that resembled treatment provided in this study. We included participants taking psychotropic medication if they reported a stable dose for at least two months prior to the initial evaluation and agreed to not change their medication during the study.

Procedures and Allocation Strategy

A total of 44 individuals (24 from Massachusetts General Hospital and 20 from Butler Hospital) signed consent forms and were enrolled in the study. Prior to randomization, eight participants were excluded: seven were ineligible (two had unstable doses of medication, two had symptoms that were too mild, one was already in psychotherapy, one had a

substance use disorder, and one did not have BDD as the primary diagnosis), and one participant declined to participate in treatment.

We randomized the remaining 36 participants to one of two conditions: immediate CBT-BDD or 12-week waitlist control. Randomization was performed by an urn randomization program (Stout, Wirtz, Carbonari, & Del Boca, 1994; Wei, 1978. Based on previous research on CBT for BDD (Neziroglu, Stevens, McKay, & Yaryura-Tobias, 2001) and for disorders similar to BDD (e.g., Foa, 1979; Foa, Abramowitz, Franklin, & Kozak, 1999; Keijsers, Hoogduin, & Schaap, 1994) we were concerned that pretreatment delusionality and current depression might be related to improvement in BDD symptom severity. Thus, to control for these variables we stratified our randomization by delusionality and current depression.

Of the 36 participants, 17 (9 females) were randomized to 12 weeks of immediate CBT-BDD, and 19 (13 females) were randomized to 12 weeks of waitlist¹. We limited the duration of the waitlist to 12 weeks as it seemed ethically problematic to ask very ill individuals (including those who were passively suicidal, i.e., had thoughts of killing themselves but had no plans of acting on those thoughts) and were eager to start treatment to wait more than 3 months. After the first 12 weeks of the study, CBT-BDD participants continued on to complete the remainder of the 22-session treatment, whereas waitlist participants were crossed over to 22 sessions of CBT-BDD.

Audiotaped therapy sessions were rated by an independent doctoral-level psychologist for fidelity and quality. Adherence to session structure and session content was rated on a 7-point scale ranging from 1 (*not at all adherent*) to 7 (*completely adherent*). Competence was rated on a 5-point scale ranging from 1 (*not at all competent*) to 5 (*completely competent*). (Adherence and competence forms are available upon request from the authors.) Our protocol also specified procedures for retraining or replacing any therapist who had recurrent difficulties meeting adherence and competence requirements, but we did not encounter these difficulties in the study. Twenty-percent of sessions were randomly selected. Eight therapists treated in this study, all of whom had at least 1 session rated for adherence/competence.

We also randomly selected 15% of audiotaped interviews to review and assess inter-rater reliability between independent evaluators on the main outcome measure (Yale-Brown Obsessive Compulsive Scale Modified for BDD [BDD-YBOCS], see below) and the measure of insight/delusionality (Brown Assessment of Beliefs Scale [BABS], see below). This study had two independent evaluators, and tapes from both interviewers were rated. Inter-rater reliability, calculated via intraclass correlations between independent ratings, for the BDD-YBOCS was .93 ($p < 0.001$) and .90 for the BABS ($p < 0.001$), indicating that ratings were highly reliable. Any concomitant medication use was monitored throughout the project by study clinicians on a monthly basis to ensure that medications and dosages did not change. The study methods were approved by Institutional Review Boards at Massachusetts

¹The target sample size was met, although treatment group allocation was not perfectly balanced by the randomization algorithm.

General Hospital, Boston, MA, and Butler Hospital, Providence, RI. All participants provided written informed consent to participate in the study.

Measures

Interested study candidates who called our programs were first screened by highly trained bachelors level research assistants. Those who appeared eligible on the phone screen were scheduled for an in-person assessment. The screening visit included a diagnostic interview for Axis I and II disorders (SCID-I/P [First, Spitzer, Gibbon, & Williams, 1995]² and SCID-II [First, Gibbon, Spitzer, Williams, & Benjamin, 1997]). A full-scale IQ score was estimated with the WASI Vocabulary and Matrix Reasoning subtests (Wechsler, 1999) to assess cognitive impairment. Those deemed eligible were scheduled for a baseline visit and randomized to immediate CBT-BDD or to waitlist. Follow-up assessments were performed 3- and 6-months after treatment cessation. Participants allocated to waitlist had assessments at baseline and at weeks 4, 8, and 12 before receiving 24 weeks of CBT-BDD. Participants completed self-report questionnaires and participated in semi-structured interviews conducted by a doctoral-level independent evaluator who was blind to treatment condition.

The Yale-Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS; Phillips et al., 1997) is a 12-item semi-structured clinician-administered measure of BDD symptom severity that has demonstrated good internal consistency ($\alpha = .80$), high test-retest reliability ($r = 0.88$), and good convergent validity ($r = 0.55$; Phillips et al., 1997). The scale's maximum score is 48, with higher scores indicating more severe BDD symptoms. The BDD-YBOCS was the primary measure of treatment outcome. We classified responder status using the empirically defined cut-point of a BDD-YBOCS reduction $\geq 30\%$ (Phillips et al., 1997). A missing BDD-YBOCS total score was imputed using the mean imputation method if exactly one question ($< 10\%$) was unanswered (Barzi & Woodward, 2004; Shrive, Stuart, Quan, & Ghali, 2006). The BDD-YBOCS was administered at baseline, monthly during treatment, at week 24 (post-treatment), and at follow-up.

The **Brown Assessment of Beliefs Scale** (BABS; Eisen et al., 1998) is a valid, reliable 7-item interview that dimensionally measures insight regarding inaccurate beliefs (e.g., "I look like a hideous monster"). Scores range from 0-24, with higher scores reflecting poorer insight/greater delusional. The BABS has been shown to have high internal consistency ($\alpha = 0.87$), interrater reliability (ICC = 0.96), and test-retest reliability (range: 0.79 to 0.98, median = 0.95; Eisen et al., 1998). Additionally, the BABS has been shown to have excellent convergent validity with various measures (Eisen et al., 1998). It was administered at baseline, monthly during treatment, at week 24 (post-treatment), and at follow-up.

The **Beck Depression Inventory-II** (BDI-II; Beck, Steer, & Brown, 1996) is a widely used self-report scale examining depressive symptoms during the past two weeks. Specifically, participants endorse their agreement with 21 items reflecting DSM-IV criteria for major depression. The BDI-II has been shown to have excellent internal consistency with psychiatric subjects ($\alpha = 0.92$) and among non-psychiatric controls ($\alpha = 0.93$) and to have

²Trichotillomania was assessed using the Trichotillomania Diagnostic Interview (Rothbaum & Ninan, 1994) given that the SCID does not include a separate section assessing Trichotillomania.

excellent test-retest reliability ($r = 0.93$; Beck et al., 1996). The BDI-II has also been shown to have excellent concurrent validity with various measures (Beck et al., 1996). The BDI-II was administered at baseline, monthly during treatment, at week 24 (post-treatment), and at follow-up.

The **Sheehan Disability Scale** (SDS; Sheehan, 1983) is a 4-item self-report measure of functional impairment/disability. Items 1-3 (disability in work, social life/leisure, and family life/home responsibilities) are scored from 0 (*not at all*) to 10 (*very severe*). Item 4 (overall impairment) ranges from 1 (*no symptoms/normal activities*) to 5 (symptoms radically change or prevent normal work or social life). The SDS has been shown to have good internal consistency ($\alpha = 0.89$) and mental disorder diagnoses are consistently associated with higher SDS scores (Leon et al., 1992). For this study, we summed the first three items to yield a total SDS score. The SDS was administered at baseline, week 12, week 24 (post-treatment), and at follow-up.

The **Client Satisfaction Inventory** (CSI; McMurtry & Hudson, 2000) is a 25-item reliable and valid self-report questionnaire that yields a measure of overall satisfaction with treatment ranging from 0% to 100% satisfied. The CSI has been shown to have excellent internal consistency ($\alpha = 0.93$; McMurtry & Hudson, 2000). The CSI was administered monthly during treatment and at week 24 (post-treatment).

CBT-BDD Intervention

The manualized treatment protocol is described in more detail elsewhere (Wilhelm et al., 2011) and is available fully in Wilhelm et al. (2013). Briefly, subjects received 22 sessions of CBT-BDD that included the following core components: psychoeducation and cognitive-behavioral case formulation of patients' specific symptoms as derived jointly by patient and therapist; *motivational enhancement strategies* to help address ambivalence about initiating or complying with treatment; *cognitive restructuring* targeting unrealistic negative thoughts and beliefs about appearance; exposure/behavioral experiments and ritual prevention to reduce avoidance and safety behaviors/rituals (e.g., camouflaging perceived defects, excessive grooming, mirror checking, or reassurance seeking); mindfulness interventions and perceptual retraining to help patients learn to broaden their perspective and attend to aspects of appearance other than perceived defects. Mindfulness/perceptual retraining helped patients learn to observe and describe their entire body in objective, non-judgmental language (e.g., "My hair is curly" instead of "My hair is a kinky rat's nest") while standing a normal distance (e.g., two to three feet) from the mirror and refraining from safety or ritualistic behaviors while in front of the mirror. In addition, patients practiced shifting their attention away from their perceived flaws to characteristics of others (appearance and non-appearance related) and to the task at hand (e.g., towards a conversation). *Advanced cognitive restructuring* helped patients learn to modify deeply held core beliefs (e.g., "I am unlovable") and included interventions to decrease the importance of appearance and help patients to base their self-esteem on other aspects of themselves (e.g., being a good friend). *Relapse prevention* focused on consolidation of skills and maintenance of gains.

In addition to these core components, which all participants received, the treatment included four optional treatment modules selected for use by therapists if relevant to a participant's

particular symptoms. Therapists chose from the following modules: (1) *compulsive skin picking and hair pulling*, (2) *concerns about muscularity/shape/weight*, (3) *cosmetic treatment*, and (4) *mood management*. Selection of modules was based on: (1) scores on the BDD-Symptom Scale (BDD-SS), a self-report measure that organizes symptoms into conceptually similar clusters that map onto treatment modules (≥ 5 for the relevant subscale); (2) scores on the BDI-II (>20 for the depression module); (3) participant input; and (4) clinician judgment that a module was relevant to that participant's symptoms. If criteria 1, 2, 3, or 4 were met, use of a module was discussed in supervision to ensure similar selection standards across subjects and sites. Usually a therapist would select specialized modules after the patient had been introduced to all core CBT-BDD skills. In sessions when modular interventions were used, they were employed instead of continued work on core treatment components (and therefore the use of modular strategies did not alter the length of therapy).

Treatment was delivered by advanced graduate students and post-doctoral-level psychologists with a basic knowledge of BDD. Therapists received rigorous training in the study protocol and were supervised weekly by Dr. Wilhelm. Individual therapy sessions lasted 60 minutes. Sessions were scheduled once weekly except that the last two sessions (relapse prevention) were spaced two weeks apart. Participants received treatment free of charge and were compensated \$25 for completing follow-up assessments.

Statistical Analyses

A target sample size of 36 participants (18 per group) was determined *a priori* to be sufficient to detect a large effect size ($d \approx 1$), as has been observed in the BDD literature (Veale et al., 1996; Cororve & Gleaves, 2001) for CBT compared to a waitlist control, with 90% power at a two-sided alpha = 0.05. Intent-to-treat (ITT) analyses included all randomized participants, using their last assessment prior to study termination. We also examined factors associated with early termination. For each measure analyzed, we conducted three sets of efficacy analyses: (1) CBT-BDD vs. waitlist by week 12; (2) Efficacy of CBT-BDD (vs. null change) by week 24 in the combined sample; and (3) Maintenance of treatment gains during follow-up.

In the week 12 analyses, we compared change in outcome over the first 12 weeks by randomized treatment group (immediate CBT-BDD vs. waitlist) using random slopes models that included terms for waitlist, week, and the interaction between waitlist and week (the term of interest). Random slopes models have the benefit of including in the analysis all participants who contributed any data, even those who dropped out immediately after baseline. Random effects were included for both slope and intercept. An unstructured covariance was used if possible, and otherwise covariance structures were tested to find the best fit to the observed data. Linearity of each outcome with respect to week was verified through visual inspection of graphs and likelihood ratio tests. For the SDS (which was not administered monthly), Student's t-test was used to compare the change in total score from baseline to week 12 between the treatment groups. Fisher's exact test was used to compare the proportion of responders in each treatment group ($\geq 30\%$ reduction in BDD-YBOCS from baseline to week 12 or last post-baseline assessment).

The second set of analyses examined efficacy of 24 weeks of CBT-BDD by comparing the rate of change of each measure with a null change in the combined sample of immediate CBT-BDD and waitlist participants subsequently crossed over to CBT-BDD (for whom assessments made prior to crossing over to CBT-BDD were excluded). These analyses employed random slopes models with a term for week, whose parameter estimate was compared to 0. We also examined whether the effect of CBT-BDD on BDD-YBOCS total score over time differed by original randomized treatment assignment. For the SDS, we used Student's t-test to determine whether the difference between baseline and week 24 (or week 12 if the patient terminated early) differed significantly from a null change. We also calculated the proportion of patients who achieved response (≥ 30% reduction in BDD-YBOCS score from baseline to week 24 or last post-baseline assessment) in the combined sample.

The third set of analyses used Student's t-tests to determine whether the change from week 24 (post-treatment) to follow-up month 6 (or follow-up month 3 if the patient was lost to follow-up) differed significantly from a null change.

We averaged ratings for therapist adherence to CBT-BDD session structure and content and for therapist competence. We also calculated the Client Satisfaction Inventory (CSI) percent of total score at post-treatment.

For comparison with other studies, we calculated effect sizes (Cohen's *d*) for each outcome (Cohen, 1988), based on a t-test with pooled variance. Participants who terminated the study immediately after baseline (for week 12 analyses) or during the waitlist (for week 24 analyses in the combined sample) were included in analyses that employed random effects modeling, but were excluded from analyses employing t-tests to examine change from baseline onwards (e.g., analyses of response and of the SDS).

Per the protocol for this study, significance was based on a two-sided alpha of 0.05 in the primary and secondary analyses of this pilot trial to avoid inflating the type II error rate and to control the type I error rate (Feise, 2002). However, to properly communicate the level of significance of each result, we have reported the precise p-values out to two significant digits (unless <0.0001). All analyses were conducted using SAS v9.3 (SAS Inc, Cary, NC).

Results

Descriptive Characteristics at Study Baseline

Baseline characteristics including demographics, medication use, and comorbidity for the CBT-BDD and waitlist groups are presented in Table 1. Participants reported the following primary appearance concerns: face (*n* = 6), hair (*n* = 6), skin (*n* = 6), stomach (*n* = 6), nose (*n* = 3), body build (*n* = 2), face profile (*n* = 2), cheeks (*n* = 1), chest (*n* = 1), pectoral muscles/torso (*n* = 1), hips (*n* = 1), and weight (*n* = 1). Additional areas of concern reported by at least 50% of participants at baseline included: hair (81%), skin (81%), face being ugly (67%), body build (64%), stomach (61%), weight (56%), nose (53%), and thighs (50%). No significant differences were detected in baseline characteristics between the waitlist and immediate CBT-BDD groups.

Figure 1 shows the flow of participants through the study. Seven (19%) participants (3 immediate CBT-BDD, 4 waitlist) terminated from the study early. In the immediate CBT-BDD group, one dropped because the study became too much of a time commitment after a death in the family, one moved out of the country, and the third was withdrawn because of a medication dosage change. Of the waitlist patients, one was withdrawn due to assessment noncompliance, and one dropped because the patient could not manage the time commitment due to starting a new job. Two waitlist patients dropped after crossing over to CBT-BDD: one prior to starting treatment as she felt that outpatient treatment was insufficient to treat her symptoms, and one because travel to the study site was too burdensome (a one-way trip took about 2-3 hours).

Participants who dropped out or were withdrawn from the study had a higher BDD-YBOCS total score ($p = 0.022$), a higher BDI-II total score ($p = 0.023$), and one or more personality disorders ($p = 0.033$) at baseline, compared with the 29 treatment completers.

Effect of CBT-BDD vs. Waitlist on BDD Symptom Severity

As shown in Figure 2, by week 12, 50% (8 of 16) of participants receiving immediate CBT-BDD were responders, compared to 12% (2 of 17) of waitlisted participants ($p = 0.026$). The average percent decrease in BDD-YBOCS total (calculated using patient's individual scores rather than the data summaries reported in Table 2) was 25% ($SD = 22\%$) for immediate CBT-BDD participants and 15% ($SD = 16\%$) for waitlisted participants. Response rates were identical when restricted to participants who completed all assessments through week 12 ($p = 0.044$). Contrary to our hypothesis, no significant differences in BDD symptom reduction emerged between immediate CBT-BDD and waitlisted participants by week 12. As seen in Table 2, participants receiving immediate CBT-BDD had an average drop of 8.8 points ($SD = 7.2$) in BDD-YBOCS total over the first 12 weeks, whereas participants on the waitlist had an average drop of 5.5 points ($SD = 6.3$). The mean difference of 3.3 points translated to a moderate effect size of $d = 0.6$ among the 33 participants who had at least one post-baseline assessment. Results were similar among the 31 participants who completed all assessments through week 12.

By post-treatment (week 24), 81% (26 of 32) of participants in the combined ITT CBT-BDD sample, and 83% (24 of 29) of treatment completers met the definition for response (Figure 2). The effects of 24 weeks of treatment are also shown in Table 2. Over the course of 24 weeks of CBT-BDD, the average percent decrease in BDD-YBOCS was 53% ($SD = 26\%$) in the combined ITT sample, and 55% ($SD = 25\%$) among treatment completers. BDD-YBOCS scores significantly decreased over 24 weeks ($p < 0.0001$), with an average drop of 16.5 points ($SD = 8.3$ points) over the treatment period. The decrease in BDD-YBOCS translated to a large effect size of $d = 2.1$ (Cohen, 1988) among the 32 participants with at least one assessment after starting CBT-BDD in the combined sample. Mean BDD-YBOCS total scores at baseline reflected moderate to severe BDD symptoms, whereas mean scores at post-treatment reflected subclinical BDD symptoms. The magnitude of decrease in BDD-YBOCS over 24 weeks of CBT-BDD therapy in the combined sample did not significantly vary depending on whether participants received CBT-BDD immediately or after the 12-week waitlist ($p = 0.64$).

Durability of Treatment Gains

Treatment gains were maintained during the six-month follow-up period (Table 2), with a small decrease in BDD-YBOCS total score of 0.6 points observed among the 24 participants with at least one follow-up assessment (Cohen's $d = 0.1$, $p = 0.63$).

Effect of CBT-BDD vs. Waitlist on Depressive Symptoms, Insight, and Disability

We did not detect any significant differences in changes in secondary measures between the immediate CBT-BDD and waitlist group within the first 12 weeks of the study (Table 2); effect sizes ranged from 0.1 – 0.2. However, over 24 weeks of CBT-BDD, participants in the combined sample showed significant improvement with regard to BDD-related insight/delusionality (Cohen's $d = 1.5$, $p < 0.0001$) and disability (Cohen's $d = 0.6$, $p = 0.0028$), as well as borderline significant improvement in depressive symptoms (Cohen's $d = 0.4$, $p = 0.013$). Mean BABS total scores at baseline reflected poor BDD-related insight, whereas mean scores at post-treatment reflected good insight. During six months of follow-up, the magnitude of changes in secondary measures were minimal (less than a one-point difference, on average, as seen in Table 2), and no clinically or statistically significant differences were detected between post-treatment and 6-month follow-up, indicating that participants maintained their treatment gains.

Treatment Feasibility and Acceptability

CBT-BDD proved feasible to deliver by non-expert therapists who received regular supervision. Therapist competence and adherence were good among a random sample of 16 participants whose sessions were rated. The mean therapist competency score was 4.9 out of 5.0 ($SD = 0.049$), the mean adherence to session content score was 6.4 out of 7.0 ($SD = 0.13$), and the mean adherence to session structure score was 6.7 out of 7.0 ($SD = 0.092$). Patient satisfaction was high among 31 of the 32 participants treated with CBT-BDD (1 patient did not complete any self-rated forms at last contact). The mean CSI score was 82.9% out of 100% ($SD = 12.4\%$) at mid-treatment, and 87.3% ($SD = 12.8\%$) at post-treatment. This high satisfaction was reflected in comments such as: "This study has changed my life." "The change in my life has been incredible." "This treatment has helped me in 6 months in ways that years of other therapy have not." No adverse events were reported.

Discussion

In this study, we examined the efficacy of CBT-BDD relative to a waitlist control condition in adults with BDD. Results from this study are consistent with prior research and advance the literature in several ways. The high response rate after 22 sessions of treatment (81-83%) is similar to that reported in our open trial of this new treatment in which 75% of the ITT sample and 80% of treatment completers were responders based on the BDD-YBOCS criterion (Wilhelm et al., 2011). Consistent with earlier CBT studies (McKay, 1999; McKay, et al., 1997; Rosen, Reiter, & Orosan, 1995; Wilhelm et al., 2011), our research showed that post-treatment gains of CBT-BDD were maintained during an extended follow-up period. Participant inclusion/exclusion criteria in this study were broad to enhance the representativeness of the BDD sample (e.g., both men and women, unmedicated and stably

medicated, moderately-severely ill, delusional, and passively suicidal participants). Despite the fact that this sample included participants who were more severely ill at the beginning of treatment relative to previous studies, BDD-YBOCS total scores decreased by an average of 16.5 points over 22 sessions. The reduction in BDD-YBOCS scores was somewhat larger than that previously reported by Veale et al. (1996) for their 12-session individual treatment (11.25). The BDD-YBOCS decrease in the current study was also larger than in Wilhelm et al.'s (1999) 12-week group treatment (9.6). Rosen et al. (1995) did not administer the BDD-YBOCS, but reported an 81.5% response rate in patients randomized to an 8-week CBT group treatment. However, the focus of preoccupation (i.e., shape/weight) and lack of men in Rosen et al.'s sample raise questions about the representativeness of the sample and generalizability of their results to more typical BDD patients.

The lack of significance of the change in BDD-YBOCS total score from baseline to week 12 between the CBT-BDD and waitlist arms appears to be due to a smaller observed effect size ($d = 0.6$) than the study was powered to detect ($d = 1.0$). This finding suggests that 12 weeks of treatment may not be sufficient to treat BDD, which is not surprising, given that patients with BDD are typically very impaired and that BDD-related insight is usually absent or poor (Phillips, 2004). However, it is worth noting that in a post-hoc sensitivity analysis, after excluding three participants (1 randomized to immediate CBT-BDD and 2 to waitlist) with extreme (outlying) values for the percent change in BDD-YBOCS during the first 12 weeks, immediate CBT-BDD fared significantly better than waitlist over the first 12 weeks, and the effect size was as hypothesized (Cohen's $d = 1.1$, $p = 0.011$). Two of the three participants had an increase of 8 points in the BDD-YBOCS (all 34 others had a decrease), and the third participant had a 17-point drop in the BDD-YBOCS, which was by far the largest drop observed. While significance was achieved after excluding only a small number of participants (8% of the analysis population), we conservatively chose to retain these outliers in the main ITT analysis to improve the generalizability of our results. Still, it is important to consider that improvement on the BDD-YBOCS approximately doubled between week 12 and post-treatment, reflecting the potential benefits of three additional months of treatment. Thus, it is likely that we would have found differential effects of CBT-BDD and the waitlist comparison group if the controlled phase of trial had been longer than 12 weeks.

Our findings suggest that CBT specifically developed for BDD also improves BDD-related insight and associated symptoms such as depression and disability. The seven (19%) participants who dropped out or were withdrawn early from the study had a higher BDD-YBOCS total score, a higher BDI-II total score, and were more likely to have a personality disorder than those who completed the study. This difference suggests that data from participants who terminated early may not have been missing at random (MAR), a necessary condition for the random slopes model estimates to be valid. However, the similarity of results in sensitivity analyses that excluded early terminators, and in analyses that controlled for drop-out, suggests that our findings are robust to the assumption of MAR. From a clinical perspective, it appears that those who terminated early were more severely ill. Of the seven patients who dropped out, four terminated prior to beginning CBT (2 at baseline and 2 during/immediately after the waitlist). It might not have been tolerable for those who were suffering to this degree to comply with all of the study procedures (baseline and screening

visits) and a delayed start of treatment. The remaining three drop-outs dropped during CBT-BDD (1 at week 4 and 2 at week 8); we examined whether satisfaction with treatment might have been a factor related to drop out. One participant did not complete the CSI prior to dropping because the measure had not been administered yet, and the CSI scores for the remaining two patients (both collected at week 4) were relatively high (77.3% and 95.3% out of 100% total). Thus, while this study is small and available information is limited, it appears that dissatisfaction with treatment does not appear to be the primary reason for dropout, other reasons mentioned above appear to be more compelling (e.g., moving out of the area). Our predictors of early termination indicate that in future treatment studies special attention may be needed to retain participants with more severe BDD, more severe depression, and those with comorbid personality disorders.

Taken together, we used a manualized modular treatment (Wilhelm et al., 2013) delivered by new therapists, and measured treatment adherence and fidelity. Our results indicate that new therapists can learn how to administer, adhere to, and deliver this treatment competently. The promising results of our two-site design further suggest that CBT-BDD is an exportable treatment. However, although the therapists on our CBT-BDD study were novices, they not only reviewed the treatment manual but also received six hours of didactic training followed by weekly supervised casework with a CBT-BDD expert. This type of training and intensive supervision by experts will be difficult to replicate in community settings. There has only been limited research on the effectiveness of different training strategies on a therapist's ability to effectively implement an empirically supported therapy (e.g., Sholomskas Syracuse-Siewert, Rounsaville, Ball, Nuro, & Carroll, 2005). But it is possible that successful therapist training in CBT-BDD might entail more than simply having therapists read the treatment manual. Thus, future research needs to explore the most beneficial methods CBT dissemination in general, and in particular those for CBT-BDD. The incorporation of CBT-BDD in nationwide training efforts, such as the ones offered by the International Obsessive Compulsive Disorder Foundation for various obsessive-compulsive spectrum disorders, should be examined as well.

One study limitation is the relatively small sample size, which limited statistical power (i.e., inflated type II error) at week 12 in analyses of change on continuous outcome measures. Given that modest treatment gains were observed in the waitlist group (an average decrease of 5.5 points on the BDD-YBOCS) in the first 12 weeks of the study, it is possible that some effects of CBT-BDD were due in part to non-specific elements of treatment (e.g., attention received during assessments, being hopeful about being in treatment/or starting a treatment soon). Thus, some caution is needed when attributing gains to CBT-BDD, and replication in a larger sample is clearly needed. From a design perspective, comparison with a control/waitlist group for the full 24 weeks of treatment would have been preferable, but such a lengthy wait engenders ethical problems for very ill individuals, such as those with BDD. As a next step, a more definitive test of CBT-BDD's efficacy is required, and the full length (24-week) CBT-BDD should be tested against an alternative treatment (such as supportive psychotherapy) to control for nonspecific factors of therapy.

We chose inclusion and exclusion criteria that were broader than those used in most previous studies of CBT for BDD, allowing for inclusion of individuals with delusional

BDD beliefs (absent insight), and of both genders. Individuals with passive suicidal ideation were also included, but for safety reasons, we chose to exclude actively suicidal patients from the study. To address some comorbid features, such as more severe depression, the optional treatment modules that therapists could choose from allowed for some flexibility. However, future large scale studies should test the frequency with which the specific modules are employed. Future research is also needed to develop and test a CBT-BDD module for more highly suicidal patients.

Although BDD typically onsets in adolescence and usually has a chronic unremitting course if untreated (Phillips, Menard, et al., 2013), the adolescent treatment literature is scarce. We excluded young children and adolescents in this early stage of treatment development and testing of this CBT-BDD, but preliminary findings from case reports of CBT for BDD in adolescents are promising (Aldea, Storch, Geffken, & Murphy, 2009; Greenberg et al., 2010; Horowitz, Gorfinkle, Lewis, & Phillips, 2002; Sobanski & Schmidt, 2000). Thus, future research will need to focus on the development and testing of CBT-BDD for adolescents.

For the purposes of the current treatment outcome study we conceptualized BDD symptom severity (BDD-YBOCS), impairment, delusional/insight, and depression as distinct problems. However, it is possible that the relationships among these symptoms are much more complex and that changes in one area precede change in another. Thus, future research should explore relationship of changes in these symptoms.

In addition, future research is needed to explore the role of attention and interpretation biases, as well as maladaptive beliefs, as potential mediators of treatment outcome. CBT-BDD strategies in our manual address these deficits via BDD-specific mindfulness/perceptual retraining techniques and cognitive restructuring. Exploring possible mediators of treatment response in larger samples is expected to advance the understanding of processes that maintain BDD. Moreover, identifying mechanisms of change should lead to the development of more potent and efficient therapy (Kraemer, Wilson, Fairburn, & Agras, 2002).

In summary, CBT-BDD is a comprehensive, flexible treatment that is applicable to a broad range of patients and includes unique strategies to address symptoms (e.g., delusions of reference, perceptual distortions, surgery seeking, and self-injurious skin picking) that distinguish BDD from other disorders. The current study indicates that CBT-BDD is feasible, acceptable, and very promising, and that it warrants more rigorous investigation. Moreover, this new treatment, specifically developed for a complex and often-severe disorder, was successfully learned and delivered by novice therapists. Given that BDD is an understudied and common disorder for which efficacious treatment options are currently very limited, follow-up controlled studies that include larger samples and compare the efficacy of CBT-BDD to alternative treatment conditions are greatly needed.

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Highlights

- Examined feasibility, acceptability, and treatment outcome of modular cognitive-behavioral therapy for BDD (CBT-BDD) in 36 BDD patients
- At post-treatment, BDD and related symptoms (e.g., mood) were significantly improved
- Treatment gains were maintained at 6-month follow-up

Figure 1. Consort Chart

Figure 2. Response to CBT (30% Decrease from Baseline in BDD-YBOCS Total Score)

*Excludes participants who terminated the study immediately after baseline (Week 12 CBT-BDD vs. Waitlist) or during the waitlist (Week 24 combined sample) assessments.

Table 1
Baseline Demographic and Clinical Characteristics by Group

Characteristic	CBT-BDD (n=17)	Waitlist (n=19)
Age in years: Mean (SD)	33.2 (11.4)	36.3 (11.8)
Years of education: Mean (SD)	16.3 (3.0)	16.3 (3.0)
Gender		
Female	9 (53%)	13 (68%)
Male	8 (47%)	6 (32%)
Race		
White	15 (88%)	17 (89%)
Black	2 (12%)	1 (5%)
Multi-racial	0 (0%)	1 (5%)
Ethnicity		
Non-Hispanic	14 (82%)	15 (79%)
Unknown	3 (18%)	4 (21%)
Occupation		
Laborer/Homemaker/Clerical	1 (6%)	3 (16%)
Professional	11 (65%)	11 (58%)
Student/Unemployed/Unknown	5 (29%)	5 (26%)
Marital status (N, %)		
Single	10 (59%)	11 (58%)
Married	6 (35%)	6 (32%)
Divorced	1 (6%)	2 (11%)
Current use of medications	12 (71%)	11 (58%)
Current comorbidity		
Major depressive disorder	8 (47%)	8 (42%)
Social phobia	4 (24%)	4 (21%)
Generalized anxiety disorder	2 (12%)	4 (21%)
Specific phobia	0 (0%)	3 (16%)
Dysthymia	1 (6%)	1 (5%)
Obsessive compulsive disorder	1 (6%)	1 (5%)
Pain disorder	1 (6%)	0 (0%)
Trichotillomania	1 (6%)	0 (0%)
Personality disorders		
Obsessive compulsive	4 (24%)	2 (11%)
Avoidant	0 (0%)	3 (16%)
Dependent	1 (6%)	1 (5%)
Paranoid	0 (0%)	1 (5%)

Note. No significant differences between the groups were detected in baseline characteristics.

Table 2
Baseline, Week 12, Week 24, and Follow-up Scores

	CBT-BDD		Waitlist		Combined Sample ^a			
Scale	Mean	(SD)	Mean	(SD)	Mean	(SD)	Effect Size ^b	p-value ^c
BDD-YBOCS Total								
Baseline	32.5	(3.2)	31.9	(4.1)				
Week 12	23.6	(7.1)	26.6	(6.6)				
Week 24 (N=30)					14.9	(8.7)		
Follow-up Month 6 (N=20)					13.2	(8.8)		
Baseline – Week 12 ^d	8.8	(7.2)	5.5	(6.3)			0.6	0.15
Baseline – Week 24 ^d					16.5	(8.3)	2.1	<0.0001 [*]
Week 24 – Follow-up					0.6	(6.2)	0.1	0.63
BABS Total								
Baseline	14.1	(3.9)	15.0	(3.2)				
Week 12	11.6	(4.0)	13.3	(5.2)				
Week 24 (N=30)					7.0	(5.1)		
Follow-up Month 6 (N=20)					5.1	(5.2)		
Baseline – Week 12 ^d	2.5	(3.9)	1.5	(3.4)			0.2	0.43
Baseline – Week 24 ^d					7.7	(5.0)	1.5	<0.0001 [*]
Week 24 – Follow-up					0.9	(3.7)	0.2	0.25
BDI Total								
Baseline	22.4	(14.0)	22.6	(12.0)				
Week 12	19.2	(14.1)	17.4	(13.7)				
Week 24 (N=27)					16.0	(14.9)		
Follow-up Month 6 (N=19)					11.9	(11.6)		
Baseline – Week 12 ^d	2.3	(21.5)	4.0	(18.7)			0.2	0.80
Baseline – Week 24 ^d					7.4	(15.8)	0.4	0.013 [*]
Week 24 – Follow-up					0.9	(7.0)	0.1	0.57
SDS Total								
Baseline	17.5	(7.0)	17.1	(8.5)				
Week 12	15.1	(7.8)	13.9	(8.0)				
Week 24 (N=27)					11.0	(9.3)		
Follow-up Month 6 (N=21)					9.5	(11.0)		
Baseline – Week 12	2.5	(6.0)	1.7	(6.6)			0.1	0.74
Baseline – Week 24					5.5	(8.9)	0.6	0.0028 [*]
Week 24 – Follow-up					0.0	(4.5)	0.0	1.00

Note. BDD-YBOCS = Yale-Brown Obsessive Compulsive Scale Modified for BDD; BABS = Brown Assessment of Beliefs Scale; SDS = Sheehan Disability Scale; CSI = Client Satisfaction Inventory.

^aIncludes all CBT-BDD and Waitlist patients with 1 assessment made after starting CBT-BDD.

^b Cohen's $d = \text{Mean} / \text{Pooled SD}$ (); CBT-BDD vs. Waitlist: = change from baseline to week 12 (completers) or last post-baseline assessment prior to week 12 (early terminators); Combined sample: = change from week 24 to month 6 (completers) or month 3 (lost to follow-up).

^c Based on Student's t -test, unless noted.

^d Based on a random effects model for rate of change over time.

* Significant ($p \leq 0.05$).