BMJ Open

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Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-005923
Article Type:	Research
Date Submitted by the Author:	16-Jun-2014
Complete List of Authors:	Enander, Jesper; Karolinska Institutet, Department of Clinical Neuroscience Ivanov, Volen; Karolinska Institutet, Department of Clinical Neuroscience Andersson, Erik; Karolinska Institutet, Department of Clinical Neuroscience Mataix-Cols, David; Karolinska Institutet, Department of Clinical Neuroscience Ljótsson, Brjánn; Karolinska Institutet, Department of Clinical Neuroscience Rück, Christian; Karolinska Institutet, Department of Clinical Neuroscience
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Public health
Keywords:	MENTAL HEALTH, Clinical trials < THERAPEUTICS, Anxiety disorders < PSYCHIATRY, PSYCHIATRY

Title

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

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Running title

Internet-based CBT for BDD: A feasibility study

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Keywords

Body dysmorphic disorder, BDD, CBT, Internet, treatment

ABSTRACT

Objectives: Cognitive behavioral therapy (CBT) is an effective treatment for body dysmorphic disorder (BDD). However, most sufferers do not have access to this treatment. One way to increase access to CBT is to administer the treatment remotely via the Internet. This study piloted a novel therapist-supported, Internet-based CBT program for BDD (BDD-NET).

Design: Uncontrolled clinical trial.

Participants: Patients (*N*=23) were recruited through self-referral and assessed face-to-face at a clinic specializing in obsessive-compulsive and related disorders. Suitable patients were offered secure access to BDD-NET.

Intervention: BDD-NET is a 12-week treatment program based on current psychological models of BDD that includes psycho-education, functional analysis, cognitive restructuring, exposure and response prevention, and relapse prevention modules. A dedicated therapist provides active guidance and feedback throughout the entire process.

Main outcome measure: The clinician-administered Yale-Brown Obsessive Compulsive Scale for BDD (BDD-YBOCS). Symptom severity was assessed pre-treatment, post-treatment and at the 3-month follow-up.

Results: BDD-NET was deemed highly acceptable by patients and led to significant improvements on the BDD-YBOCS (p = < .001) with a large within-group effect size (Cohen's d = 2.01, 95% CI 1.05-2.97). At post-treatment, 82% of the patients were classed as responders (defined as ≥30% improvement on the BBD-YBOCS). These gains were maintained at the 3-month follow-up. Secondary outcome measures of depression, global functioning and quality of life also showed significant improvements with moderate to large effect sizes. On average, therapists spent 10 minutes per patient per week providing support.

Conclusion: The results suggest that BDD-NET has the potential to greatly improve access to CBT, at least for low-risk individuals with moderately severe BDD symptoms and reasonably good insight. A randomized controlled trial of BDD-NET is warranted. Clinicaltrials.gov registration ID: NCT01850433.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is the first to explore the feasibility and acceptability of a novel therapist-guided Internet-based (ICBT) program designed to dramatically increase access to CBT for patients with BDD.

- BDD-NET may be particularly useful in the context of stepped-care for BDD, where low-risk patients with reasonably good insight are offered ICBT and non-responders or more complex and risky patients are offered more intensive, clinic based CBT alone or in combination with medication.

- This was an uncontrolled trial. This limits the possibilities to make causal inferences as to what caused the observed changes.

- There is also bias in this study as participants were self-referred.

- Despite the limitations of this uncontrolled trial, the results suggest that BDD-NET has the potential to reduce symptoms and increase access to CBT for patients with BDD who are motivated to receive treatment.

INTRODUCTION

Body dysmorphic disorder (BDD) is characterized by a preoccupation with perceived defects in physical appearance that are accompanied, at some point during the occurrence of the disorder, by repetitive behaviors or mental acts, such as excessive mirror checking, in response to the appearance concerns. These concerns cause clinically significant distress or functional impairment and are not better explained by an eating disorder.[1] BDD is common, debilitating, associated with relatively high rates of psychiatric hospitalization and suicidality, and with a chronic and unremitting course if left untreated.[2-8] People suffering from BDD often seek non-psychiatric care due to perceived appearance flaws, such as dermatological treatment or plastic surgery.[9] However, these treatments rarely work, and can even results in the deterioration of the BDD symptoms.[9 10]

One treatment modality that has shown promise for BDD is cognitive behavioral therapy (CBT).[11 12] To our knowledge, only four randomized controlled trials (RCT) have been published to date. In the mid-90s, Rosen et al.[13] investigated the effect of group CBT, and Veale et al.[14] conducted a study of individual CBT for BDD with response rates of 81.5% and 78%, respectively. Recently, Wilhelm et al.[15] developed and published a multimodal treatment manual specifically designed for BDD that has been tested in one open trial and one wait-list controlled trial with large within-group effect sizes and response rates around 80-81%.[16 17] In the only RCT to employ a an active comparison group, Veale et al.[18] recently reported superiority of CBT compared to anxiety management, a credible psychological intervention primarily consisting of progressive muscle relaxation and breathing techniques, and a 52% response rate for CBT after 16 therapy sessions.

Despite the growing support for CBT and readily available treatment manuals,[15 19] numerous barriers to treatment exist. One of the biggest challenges of CBT is the restricted access, partly due to a lack of trained therapists, but also due to the direct and indirect costs associated with treatment.[20-22] In two online surveys, only 10 to 17% of people with body dysmorphic concerns reported that they had received an empirically supported psychotherapy (i.e. CBT), with a majority reporting that a major contributing factor for not seeking help was shame associated with talking openly about one's appearance concerns.[21 23] Furthermore, treatment barriers such as a lack of a specialised health care provider close by and logistic problems such as having to take

time of work in order to attend therapy were also reported.[21 23] Therefore, alternative ways of improving access to CBT are sorely needed.

One way to increase access to CBT is to administer the treatment using the Internet.[24 25] In the last decade, there has been a rapid development of Internet-based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are two main forms of ICBT: open access programs without any therapist guidance, and programs with therapist support that try to closely mimic the process of face-to-face CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of modules accompanied by homework assignments, reflecting the content of a traditional face-to-face therapy session. During the entire treatment, an identified therapist provides guidance and gives feedback through a built-in e-mail system. Thus, the therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in traditional CBT, the only difference being the way care is delivered. There is evidence that ICBT that incorporates therapist support may result in better treatment effects when compared to ICBT provided without such guidance.[30-32] Furthermore, in a recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there was no significant difference between the two treatment modalities, suggesting non-inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia, ICBT has already been implemented as part of their regular health care systems.[34-36]

With the primary aim to increase access to evidence based treatment for BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT program based on existing manuals,[15 19] and tested its feasibility and efficacy in an uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to patients, lead to a reduction of BDD and other psychiatric symptoms, and require minimal therapist input.

METHOD

Participants

The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD. Participant demographics and clinical characteristics are presented in Table 1.

Information about the study was posted on the official web page of the clinic (www.internetpsykiatri.se), and flyers were distributed to mental health professionals. The study was also mentioned in a national newspaper that ran a three-part article series about BDD. A total of 66 individuals were considered for eligibility (see Figure 1). To be eligible for the study participants had to be at least 18 years of age, outpatients, and diagnosed with primary DSM-5 BDD. Exclusion criteria were psychotropic medication changes within two months prior to enrolment, completed CBT for BDD within the last 12 months, a score on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BDD-YBOCS) of ≤ 16, current substance dependence, lifetime bipolar disorder or psychosis, acute suicidal ideation, a personality disorder that could jeopardize treatment participation, or concurrent psychological treatment. Participants who were taking psychotropic medication, and had been on a stable dose for at least 2 months prior to enrolment were asked to not change their medication during the study period. The regional ethical review board in Stockholm, Sweden approved the study ID: 2013/117-31/2. Clinicaltrials.gov registration ID: NCT01850433.

<INSERT FIGURE 1 ABOUT HERE>
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Procedure

In the first stage of the recruitment process, potential participants were instructed to complete an online screening consisting of Montgomery-Åsberg Depression Rating Scale, Self-report (MADRS-S),[37] Alcohol Use Disorders Identification Test (AUDIT),[38] Drug User Disorders Identification Test (DUDIT),[39] Dysmorphic Concerns Questionnaire (DCQ),[40] and Body Dysmorphic Disorder Dimensional Scale (BDD-D).[41] All participants who completed the screening were contacted by telephone and assessed for BDD. Twenty-six individuals were invited to the clinic for an in-person assessment by either a psychiatrist or a licensed psychologist. The Mini-International Neuropsychiatric Interview (M.I.N.I.)[42] was used to determine the presence of any DSM-IV-TR Axis-I disorders. A more in depth interview with the BDD Diagnostic Module was conducted to establish the diagnosis of DSM-5 BDD.[43] The questions used in this semi-structured interview were orignially designed for DSM-IV-

TR critera and are similar to those used in the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I).[44] A question about the presence of repetitive behaviors was added to reflect the DSM-5 critera for BDD and the new DSM-5 insight specifiers were also used to determine degree of insight regarding body dysmorphic beliefs (i.e., good or fair insight, poor insight and absent insight/delusional beliefs). The assessors had several years of experience administering structured interviews, such as the BDD-YBOCS, and had undergone extensive training in using the M.I.N.I.

Measures

Participants were assessed with both clinician and self-report measures at pre-treatment, post-treatment and at the three-month follow-up. In addition, the BDD-D and MADRS-S were administered weekly to monitor progress and suicide risk. The primary outcome of interest was BDD symptom severity as measured with the BDD-YBOCS. The self-report measures were administered online, a method which has previously been shown to be as reliable and valid as pen-and-paper administration.[45-47]

Clinician-rated instruments

Yale-Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS)

The BDD-YBOCS[48] can be considered the gold standard for assessing symptom severity and impairment associated with BDD. It is a clinician administered semi-structured interview consisting of 12 items; each rated on a scale from 0-4, which measures symptom severity during the last seven days, in the form of intrusive thoughts (5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe symptoms. BDD-YBOCS has shown high test-retest reliability (r = .88) and internal consistency (α = .80).[48] An empirically defined cut-off point of a 30 % reduction on the BDD-YBOCS was used to determine responder status at post-treatment.[49] To investigate specific effects on insight, the item of the BDD-YBOCS relating to insight was also reported separately.

Clinical Global Impression (CGI)

The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal)

to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was determined to indicate responder status in this study. CGI has shown good reliability and validity for a range of psychiatric disorders.[51 52]

Global Assessment of Functioning (GAF)

The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from 0 to 100 and is used to assess social, occupational, and psychological functioning, with a higher score indicating better health. Overall reliability of the GAF are good, but questions regarding its validity have been raised, see Aas 2010 for a review.[54]

Self-administered measures

Body Dysmorphic Dimensional Scale (BDD-D)

The BDD-D[41] is a self report measure of symptom severity developed alongside the DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and repetitive behaviors, distress, control over symptoms, avoidance, and interference; each rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20. High internal consistency has been reported (α = .80), though further validation work is warranted.[41]

Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)

The MADRS-S[37] is the self-report version of the Montgomery-Åsberg Depression Rating Scale (MADRS)[55], and measures severity of depression. The scale consists of 9 items, each measuring a different symptom (mood, feelings of unease, sleep, appetite, ability to concentrate, initiative, emotional involvement, pessimism, and suicidal ideation) on a seven-point scale with a total score ranging from 0 to 54. Good to excellent test-retest reliability have been reported (r = .80 - .94)[37], as well as a high correlation (r = .87) between the MADRS-S and the Beck Depression Inventory in a comparative study.[56]

Skin Picking Scale-Revised (SPS-R)

As skin picking is common among persons diagnosed with BDD we used the SPS-R[57] to assess skin picking severity and impairment. The SPS-R is a self-report measure that

consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g., extreme). Good internal consistency (α = .83) as well as discriminant and convergent validity have been reported.[57]

Body Image Quality of Life Inventory (BIQLI)

The BIQLI[58] is a self-report measure that consists of 19 items with a 7-point scale ranging from -3 (very negative effect) to +3 (very positive effect) that assesses the impact of body image on various aspects of life (e.g., sexuality, emotional wellbeing, and relations). The total score ranges from -57 to +57. A positive score indicates that one's body image has a positive impact on quality of life, and vice versa. High test-retest (r = .79) and internal consistency (α = .94-95) have been reported.[58 59]

Safety procedures and adverse events

As mentioned earlier, participants with active suicidal ideation were not included in the trial. However, suicidal ideation is common among patients diagnosed with BDD and the following precautions were taken in order to detect patients that could deteriorate during treatment. All participants underwent a structured clinical interview assessing suicidal ideation before starting treatment. Throughout the entire treatment, MADRS-S was administered weekly and participants who, at any time throughout the treatment period, scored > 4 on item 9, which measures suicidal ideation, were immediately contacted by their therapist. If the patient were in need of additional care, an appointment was made with either a senior psychiatrist at the clinic, or at an emergency psychiatric unit.

Adverse events (AE) were recorded mid-treatment and at post-treatment in accordance with guidelines presented by Rozental et al.[60]. AE were defined as negative events that could have occurred due to treatment participation (e.g., deterioration of target symptoms, worse sleep, and general negative well-being such as stress). Participants were asked if they had experienced any AE that they associated with the intervention (yes/no). If yes, the participants were asked to describe the event in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no impact) to 3 (severely negative impact) at the time that the AE had occurred (retrospective self-reports), and if the AE still had a negative impact on well-being at present. A licensed psychologist reviewed the AE reported.

Treatment

The BDD-NET program was delivered via a tailored online platform, using a dedicated server with encrypted traffic and a strong authentication login function in order to guarantee participant confidentiality. The 12-week long treatment was based on a CBT model for BDD, emphasizing the role of avoidance and safety behaviors as maintaining factors of BDD.[15] A central part of the treatment was a self-help text of 104 pages divided into 8 modules (with modules 1–4 containing the core treatment components). The self-help text underwent several revisions, and was reviewed by licensed psychologists with previous experience of either ICBT or obsessive-compulsive and related disorders. Each module was devoted to a special theme and included information and homework assignments that needed to be completed in order to move on to the next module (e.g., filling out online worksheets, doing cognitive restructuring, or conducting in vivo exposure and response prevention; ERP). See Table 2 for a summary of the treatment modules and the number of participants completing each module. The participant had contact with an identified therapist throughout the whole treatment using a built-in e-mail system on the BDD-NET webpage. Participants had unlimited access to the therapist and could use the e-mail system at any time. The role of the therapist was mainly to guide and coach the participant through the treatment, provide feedback on homework assignments, answer questions from the participants, and consecutively grant access to the next treatment module. The therapist also acted proactively by sending e-mails to participants asking them to report on treatment progress. The participants were notified by an automated text-message (SMS) when they had a new e-mail in the treatment platform. All homework assignments and questions from the participants were reviewed and answered within 36 hours, except on weekends. Participants were randomised using random.org to one of two therapists, both licensed psychologists, with previous experience of treating obsessive-compulsive and related disorders. The duration of therapist contact was automatically recorded by the ICBT platform.

<INSERT TABLE 2 ABOUT HERE>

Statistical analysis

The primary analyses were done according to intention-to-treat (ITT) including the full sample of 23 participants. Missing data at post-treatment and follow-up assessment were deemed to be missing at random (using logistic regression models, as well as inspecting correlations between indicator variables of missingness and other variables from the dataset that might predict missingness) and imputed using multiple imputation by chained equations.[61] All estimates with standard errors were pooled from five imputations using "Rubin's rules"[62] and the small sample correction for pooled degrees of freedom.[63] Paired *t*-tests were performed to assess if changes from pretreatment to post-treatment and pretreatment to follow-up were statistically significant. Paired *t*-tests comparing post-treatment to follow-up were also performed to test for maintenance of the therapeutic gains. Within-group effect sizes were calculated by dividing the difference between pre-treatment and post-treatment scores by the within-group pooled standard deviation.[64] Fisher's exact test was used to examine weather there was an association between the occurrence of an AE and treatment responder status and independent *t*-tests were used to examine specific therapist effects. All data were analyzed with Stata statistical software, version 13.1[65] and the threshold for statistical significance set at the standard 5%.

RESULTS

Attrition

The participant flow throughout the trial is shown in Figure 1. One participant terminated treatment during the first week due to reported personal problems and did not complete any of the modules and was therefore regarded as a dropout, but was kept in the primary analysis according to the ITT principles. The post-treatment and 3-month follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants, respectively. Self-rated questionnaires administered online were completed by 20 (87 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-up.

Primary and secondary outcomes

Means, standard deviations, and within- group effect sizes, including confidence intervals, for all assessment points with missing values replaced by multiple imputation

are reported in Table 3. Paired t-tests showed significant changes on all measures from pre- to post-treatment (t(df = 13.72 – 20.15) = 3.10 – 7.54, all p-values < .01), and from pretreatment to follow-up (t(df = 10.96 – 19.24) = 3.13 – 8.66, all p-values < .01). On the main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size was d = 2.01, and the pre-treatment to follow-up effect size indicated sustained effects (d = 2.04).

At posttreatment, 82% of completers were responders (≥ 30 % decrease on the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).

The significant pre- to post-treatment improvement on the BDD-YBOCS insight item was in the large range (t(18.44) = 4.30, p = < .001, d = 1.07). Weekly scores and follow-up data on the self-reported BDD-D are presented in Figure 2.

<<INSERT FIGURE 2 ABOUT HERE>>

The distribution of CGI-I scores for completers at posttreatment and follow-up, respectively, was as follows: very much improved, 41 % and 52 %; much improved, 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At posttreatment and follow-up, 64 % and 71 % were responders (very much or much improved), respectively.

On the other outcome measures, the within-group effect sizes from pretreatment to posttreatment and pretreatment to follow-up were in the moderate to large range (d = .55 – 1.82).

<INSERT TABLE 3 ABOUT HERE>

Adverse events

In total, 11 (48%) participants reported that they had experienced AE during the course of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g., nightmares, depressive symptoms and worse sleep), followed by a deterioration of symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus on appearance), and general negative well-being (29%, e.g., stress). The AE reported occurred mostly during the first part of the treatment, and most participants rated the

negative impact of the AE as moderate (*Median* = 2, *M* = 1.8, *SD* = 1.1) when they occurred, and as no longer having a negative impact at posttreatment (*Median* = 0, *M* = .7, *SD* = 1.6) with the exception of one participant who reported that the treatment had led to an increase in appearance concerns and more frequent intrusive thoughts compared to baseline, and was classified as a non-responder at post-treatment. The occurrence of AE during treatment was unrelated to responder status at post-treatment, with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-responders (Fisher's exact test = 0.59).

During treatment, one participant became increasingly depressed and was referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after which treatment continued.

Treatment activity and acceptability

The mean number of messages that the participants sent to and received from their therapist was 22.6 (*SD* = 12.2, range 0–47), and 30.2 (*SD* = 11.3, range 3–51), respectively, and the therapists spent a weekly mean of 10.3 minutes (*SD* = 6.7, range 1.8–35.2), per participant. No significant differences were noted in time spent providing support ($t(21) = 1.19$, $p = .25$), or in treatment effects between the two therapists ($t(21) = -.60$, $p = .56$).

In total, 19 (83%) participants completed the core components of the treatment programme (modules 1–4), and six participants completed all eight of the modules (26 %). The mean number of completed modules was 5.5 (*SD* = 2.35, range 0–8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the treatment, for example doing exercises in vivo and reading material online.

At posttreatment, 6 (30%) of participants reported that they were very pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was somewhat displeased with the treatment provided. One participant did not answer the satisfaction question.

All participants on psychotropic medication had kept their dose stable during treatment, and none had received any other type of psychological intervention. In total, 5 (22%) participants reported that they had received additional care at the 3-month follow-up. Of the participants receiving additional care, four were non-

responders according to the CGI-I at post-treatment, and all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT, respectively, two participants had been prescribed an SRI (of which one was prescribed for an indication other than BDD), and one participant had increased the dose of current SRI.

DISCUSSION

This study explored the feasibility and acceptability of a novel therapist-guided ICBT program designed to dramatically increase access to CBT for patients with BDD. In general the participants felt that BDD-NET was highly acceptable. A significant improvement was seen on the main outcome measure (clinician-rated BDD-YBOCS), with a large effect size, and 82% of the participants classed as responders at post-treatment. These treatment effects were maintained at the three-month follow-up. Clinician-rated insight also improved from pre- to post-treatment. Secondary outcome measures of depression, skin picking, global functioning and body image-related quality of life showed significant improvements from pre- to post-treatment, and from pre-treatment to follow-up, with moderate to large effect sizes.

In general, the results are in line with other trials investigating the effects of individual CBT for BDD delivered in specialized clinic settings.[16-18] However, direct comparisons with previous trials should be made with caution, because ours was a self-referred and moderately ill patient group with relatively good insight. Some research has shown that the source of patient referral may have a bearing on the types of patients seen and the degree of clinical improvement with computerized or internet-based therapies, with patients referred by mental health professionals having more comorbidity, being less motivated for treatment and achieving more modest outcomes, compared to self-referrals or referrals from general practitioners.[66]

A comparison of the demographic and clinical characteristics of our sample with those of two recently published RCTs appears in Table 4. Despite having moderate to severe BDD symptoms, our predominantly female, self-referred sample might have been particularly motivated to engage in psychological treatment, compared to the average BDD patient seen in specialist settings. The proportion of patients with absent or delusional insight also appears to be lower in this sample compared to the

proportions seen in specialist clinic samples. Furthermore, though the rates of comorbid disorders were similar, on average, our participants endorsed mild depressive symptoms, compared to the moderate to severe depressive symptoms reported in the trials published by Wilhelm et al.[17] and Veale et al.[18].

ICBT should not be seen as a substitute for traditional face-to-face treatment but, rather, a clinician extender that may substantially increase access to evidence based treatment for a large proportion of sufferers who are not currently receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input will be required for complex patients who have poor insight and high suicide risk. In this regard, BDD-NET may be particularly useful in the context of stepped-care for BDD, where low-risk patients with reasonably good insight are offered ICBT and non-responders or more complex and risky patients are offered more intensive, clinic based CBT alone or in combination with medication.

<<INSERT TABLE 4 ABOUT HERE>>

Participants in this trial made marked improvements despite no face-to-face contact, beyond the baseline, post-treatment and follow-up assessments. Although the treatment is Internet-based, the mechanisms of change may be the same as in traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still instructed to expose him or herself to feared stimuli in vivo without using maladaptive coping strategies. Each participant had the same identified therapist throughout the entire treatment, and although therapist contact was only around 10 minutes per participant and week, the therapist sent a mean number of 30.2 messages per participant, which averages out to 2-3 contacts per week. Messages sent from the therapist were usually short, with prompts to the participant to engage in ERP and report the outcome, allowing for adjustment of exposure strategies when needed. Thus, the therapist was proactive and had shorter, but more frequent contact with participants compared to traditional CBT, where sessions usually are held once a week. Despite minimal therapist contact, participants often report the feeling of a therapist presence; the therapists' frequent encouragement to engage in daily ERP may be a critical component of the intervention.[32]

In total, 48% of the participants experienced an adverse event during treatment. However, the adverse events were mostly mild, and non-enduring, and a vast majority of participants were very pleased or pleased with the treatment provided. Most (83%) of the participants completed all of the core treatment components and engaged in ERP, suggesting that the treatment was engaging and highly acceptable. The treatment completion rate is in line with previous ICBT studies of various disorders, suggesting that ICBT is as acceptable for patients with BDD as it is for other patient groups (e.g., OCD, SAD, and MDD).[26 27]

Stigma, shame and logistic barriers can be a hindrance for persons with BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is online; this could reduce initial shame and stigma associated with openly talking about one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the clinic while receiving CBT and has the potential to minimize logistic barriers and increase access to evidence-based care in rural areas or where trained therapists are not available. Furthermore, one therapist can have more patients in treatment at the same time compared to face-to-face therapy, while spending less time per patient as the routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT format has the potential to lower the severity threshold for people with BDD to seek and receive adequate treatment. Expert clinicians can dedicate more time and resources to complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is protocol based and delivered as a series of modules online. This greatly reduces the risk of therapist drift,[67] and ensures that all patients receive exactly the same treatment. The control over content delivered also opens up for dismantling studies, as modules can easily be added or taken out to test the specific effect of a treatment component, as shown by Ljótsson et al.[68] where the specific effect of systematic exposure on Irritable Bowel Syndrome symptoms was tested.

This study has several limitations that need to be considered when interpreting the results. First and foremost, this was an uncontrolled trial. This limits the possibilities to make causal inferences as to what caused the observed changes. The improvements observed over the course of treatment could have been due to the mere passage of time. However, when considering the chronicity of BDD,[8 69] we regard it as unlikely that the treatment effects in this trial could be entirely explained by spontaneous remission. Furthermore, the improvements observed could also be due to

unspecific factors, such as caregiver attention. However, the maintenance of improvement from post-treatment to follow-up indicates that treatment gains were temporally stable, and the majority of participants did not receive any further treatment. Both therapists in the study had previous experience of treating BDD, and although the essential components of the treatment are delivered as online modules, there could be a specific therapist factor as the therapists answered questions and gave treatment guidance through the integrated e-mail system. It is unknown if the same outcomes would be obtained with less experienced therapists.

Despite the limitations of this uncontrolled trial, the results suggest that BDD-NET has the potential to reduce symptoms and increase access to CBT for a large majority of moderately ill patients with BDD who are motivated to receive treatment. A randomized controlled trial of BDD-NET is warranted.

ACKNOWLEDGEMENTS

We would like to thank Monica Hellberg, Sofia Eriksson, Vania Panes Lundmark and Kayoko Isomura for their invaluable help.

CONTRIBUTORSHIP STATEMENT

JE was the project manager and participated in designing the study, analyzing data, providing treatment, and drafting the manuscript and the treatment manual. VI participated in designing the study, providing treatment and drafting the manuscript and the treatment manual. EA participated in designing the study and drafting the manuscript and the treatment manual. DMC participated in drafting the manuscript and designing the study. BL participated in designing the study, analyzing data and drafting the manuscript and the treatment manual. CR participated in designing the study and drafting the treatment manual and the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

None

DATA SHARING STATEMENT

Data available on request from the authors.

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Table 1. Patient demographics and clinical characteristics (*N* = 23)

Variable	Mean/*n*	SD/%
Age in years (Mean, *SD*)	30.3	(6.3)
Female (*n*, %)	16	(70%)
Employment status (*n*, %)		
Employed	14	(61%)
Unemployed	4	(17%)
Student	5	(22%)
Married (*n*, %)	7	(30%)
Education (*n*, %)		
High school	16	(70%)
University college	7	(30%)
Previous psychological treatment (*n*, %)	12	(52%)
Previous use of psychotropic medication (*n*, %)	11	(48%)
Current use of psychotropic medication (*n*, %)	7	(30%)
Years with BDD symptoms (Mean, *SD*)	15.3	(8.1)
Current comorbidity (*n*, %)		
Major depressive disorder	10	(43%)
Panic disorder	1	(4%)
Social anxiety disorder	5	(22%)
Obsessive-compulsive disorder	2	(9%)
Bulimia nervosa	2	(9%)
Generalized anxiety disorder	1	(4%)

Table 2. Description of consecutive treatment modules and the number of participants completing each module

Module	Contents	No. of participants[a]
1.	Psychoeducation: Introduction the treatment and information about BDD such as prevalence, known etiology, and common symptoms. Different fictional patient characters are introduced and used as examples to help clarify the treatment components throughout the treatment. Participants begin to register BDD-related behaviors and thoughts in an online diary.	22 (96%)
2.	A cognitive-behavior conceptualization: Explanation of how self-defeating thoughts and BDD related avoidance and safety behaviors maintain appearance concerns and fears. Participants learn how to conduct a functional analysis of how their own BDD symptoms are maintained.	21 (91%)
3.	Cognitive restructuring: A more in-depth rationale for how self-defeating thoughts and maladaptive thinking maintains BDD symptoms. Participants evaluate negative thoughts and engage in cognitive restructuring using online worksheets.	21 (91%)
4.	Exposure and response prevention (ERP): Explanation of exposure and different strategies for conducting response prevention is presented. Participants set treatment goals and conduct their first in vivo ERP exercise. ERP continues during the remainder of treatment, and participants continuously assess outcome of ERP using an online worksheet.	19 (83%)
5.	More on ERP: Different aspects of ERP are highlighted and a more in-depth explanation is given on how to work with ERP over time.	14 (61%)
6.	Values-based behavior change: Participants identify values-based long-term goals within the domains of relationships, career, and leisure activities. An accepting stance towards negative thoughts and experiences is proposed as an alternative to attempts to control these experiences, while at the same time engaging in meaningful values-based activities.	13 (57%)
7.	Difficulties during treatment: Commonly encountered difficulties during treatment such as loss of motivation and problems integrating exercises into daily schedule are presented and discussed, as well as common obstacles associated with ERP and how to overcome them.	10 (44%)
8.	Relapse prevention: How to handle relapses into avoidance behaviors and repetitive behavior. The participants also summarize the main lessons learned, what has been gained through the treatment and their future plans.	6 (27%)

Note. [a] Defined as doing the homework associated with each module.

Table 3. Primary and secondary outcome measures

							Within-group effect size *d*								
	Pre-treatment		Post-treatment		3-month follow-up[a]		Pre to post[a]			Pre to follow-up[a]			Post to follow-up[a]		
Measure	M	SD	M	SD	M	SD	*d*	CI-	CI+	*d*	CI-	CI+	*d*	CI-	CI+
BDD-YBOCS	30.78	6.24	15.70	8.48	13.85	9.57	**2.01**	1.05	2.97	**2.04**	1.18	2.91	**0.20**	-0.14	0.54
BDD-YBOCS i	2.17	0.89	1.42	0.83	1.22	0.91	**0.88**	0.34	1.42	**1.07**	0.39	1.74	**0.23**	-0.24	0.70
BDD-D	13.09	3	7.67	4.03	6.38	4.19	**1.51**	0.62	2.41	**1.82**	0.96	2.68	**0.31**	0.01	0.61
MADRS-S	17.91	8.22	10.23	7.52	11.74	10.17	**0.97**	0.47	1.48	**0.65**	0.18	1.11	**-0.15**	-0.42	0.11
SPS-R	8.83	7.31	4.91	6.78	4.53	6.31	**0.55**	0.15	0.96	**0.63**	0.18	1.07	**0.06**	-0.14	0.25
BIQLI[b]	-27.26	13.38	-10.83	17.36	-11.11	19.66	**1.05**	0.35	1.75	**0.96**	0.17	1.75	**-0.02**	-0.32	0.29
GAF	49.87	7.23	61.75	8.85	63.21	9.05	**1.47**	0.69	2.25	**1.62**	0.90	2.33	**0.16**	-0.09	0.42

Note. BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD. BDD-YBOCS i, Yale-Brown Obsessive Compulsive Scale Modified for BDD insight item. BDD-D, Body Dysmorphic Disorder Dimensional Scale. MADRS-S, Montgomery-Åsberg Depression Rating Scale, self-report. SPS-R, Skin Picking Scale Revised. BIQLI, Body Image Quality of Life Inventory. GAF, Global Assessment of Functioning Scale. Effect sizes are reported with 95% confidence intervals.

[a] Pooled estimates based on multiple imputation.

[b] Higher scores indicate better health. Sign of effect sizes changed for clarity.

Table 4. Baseline characteristics of patients in the current study, compared to two recent RCTs of CBT for BDD

Variable	BDD-NET	Veale et al. 2014	Wilhelm et al. 2013[a]
Age in years	30.3 (6.3)	Median = 30	33.2 (11.4)
Female	70%	57%	53%
Employed	61%	46%	65%
Referral	Self-referred	Primary or secondary care	Self-referred
BDD-YBOCS	30.78 (6.24)	35.48 (6.61)[a]	32.5 (3.2)
Delusional BDD	9%	54%	n/a
BABS	n/a	18.24 (4.68)[a]	14.1 (3.9)
MADRS	17.91 (8.22)	28.57 (10.69)[a]	n/a
BDI	n/a	n/a	22.4 (14)
Current comorbidity			
MDD	43%	44%	47%
SAD	22%	11%	24%
OCD	9%	4%	6%
Current use of medications	30%	46%	71%

Note. Values denote means ± SD unless otherwise specified.
BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD; BABS, Brown Assessment of Beliefs Scale; MADRS, Montgomery-Åsberg Depression Rating Scale; BDI, Beck Depression Inventory.
[a] Participant characteristics of those randomised to CBT.

FIGURE LEGEND
Figure 1: Participant flow through the study
Figure 2: Weekly scores on the self-administered Body Dysmorphic Disorder Dimensional Scale, BDD-D (including 95% confidence intervals)

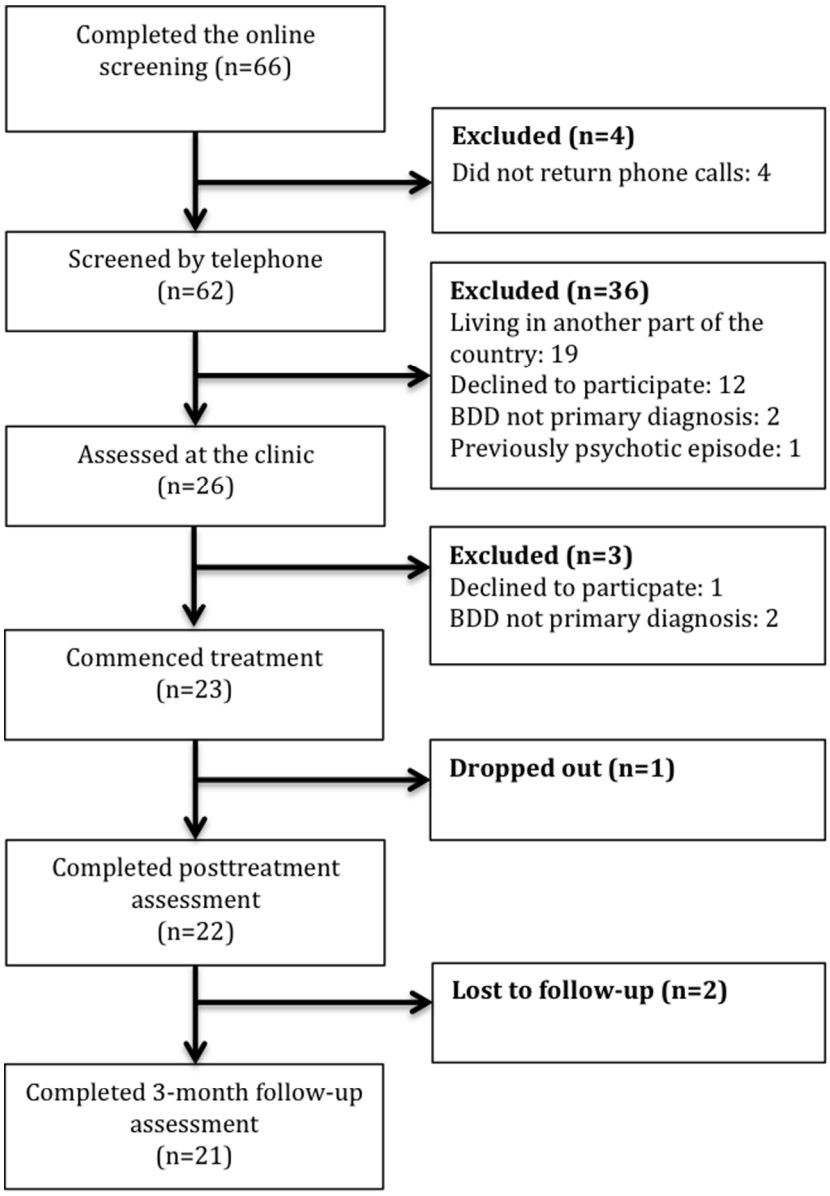
AUTHOR'S CONTRIBUTIONS
JE was the project manager and participated in designing the study, analyzing data, providing treatment, and drafting the manuscript and the treatment manual. VI participated in designing the study, providing treatment and drafting the manuscript and the treatment manual. EA participated in designing the study and drafting the manuscript and the treatment manual. DMC participated in drafting the manuscript and designing the study. BL participated in designing the study, analyzing data and drafting the manuscript and the treatment manual. CR participated in designing the study and drafting the treatment manual and the manuscript. All authors read and approved the final manuscript.

FUNDING

Financial support was provided through the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet. The Swedish Research Council and the Swedish Society of Medicine (Söderströmska Königska sjukhemmet) provided funding for this study.

COMPETING INTERESTS

None declared.



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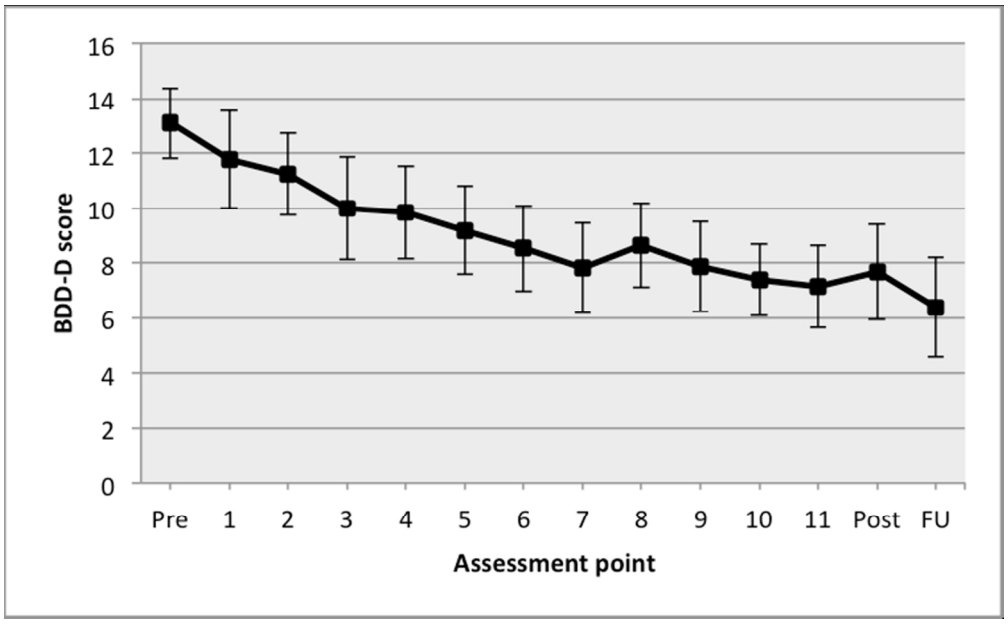

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BMJ Open

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-005923.R1
Article Type:	Research
Date Submitted by the Author:	29-Jul-2014
Complete List of Authors:	Enander, Jesper; Karolinska Institutet, Department of Clinical Neuroscience Ivanov, Volen; Karolinska Institutet, Department of Clinical Neuroscience Andersson, Erik; Karolinska Institutet, Department of Clinical Neuroscience Mataix-Cols, David; Karolinska Institutet, Department of Clinical Neuroscience Ljótsson, Brjánn; Karolinska Institutet, Department of Clinical Neuroscience Rück, Christian; Karolinska Institutet, Department of Clinical Neuroscience
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Public health
Keywords:	MENTAL HEALTH, Clinical trials < THERAPEUTICS, Anxiety disorders < PSYCHIATRY, PSYCHIATRY

Title

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

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Running title

Internet-based CBT for BDD: A feasibility study

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Keywords

Body dysmorphic disorder, BDD, CBT, Internet, treatment

ABSTRACT

Objectives: Cognitive behavioral therapy (CBT) is an effective treatment for body dysmorphic disorder (BDD). However, most sufferers do not have access to this treatment. One way to increase access to CBT is to administer the treatment remotely via the Internet. This study piloted a novel therapist-supported, Internet-based CBT program for BDD (BDD-NET).

Design: Uncontrolled clinical trial.

Participants: Patients (*N*=23) were recruited through self-referral and assessed face-to-face at a clinic specializing in obsessive-compulsive and related disorders. Suitable patients were offered secure access to BDD-NET.

Intervention: BDD-NET is a 12-week treatment program based on current psychological models of BDD that includes psycho-education, functional analysis, cognitive restructuring, exposure and response prevention, and relapse prevention modules. A dedicated therapist provides active guidance and feedback throughout the entire process.

Main outcome measure: The clinician-administered Yale-Brown Obsessive Compulsive Scale for BDD (BDD-YBOCS). Symptom severity was assessed pre-treatment, post-treatment and at the 3-month follow-up.

Results: BDD-NET was deemed highly acceptable by patients and led to significant improvements on the BDD-YBOCS (p = < .001) with a large within-group effect size (Cohen's d = 2.01, 95% CI 1.05-2.97). At post-treatment, 82% of the patients were classed as responders (defined as ≥30% improvement on the BBD-YBOCS). These gains were maintained at the 3-month follow-up. Secondary outcome measures of depression, global functioning and quality of life also showed significant improvements with moderate to large effect sizes. On average, therapists spent 10 minutes per patient per week providing support.

Conclusion: The results suggest that BDD-NET has the potential to greatly improve access to CBT, at least for low-risk individuals with moderately severe BDD symptoms and reasonably good insight. A randomized controlled trial of BDD-NET is warranted.

Clinicaltrials.gov registration ID: NCT01850433.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is the first to explore the feasibility and acceptability of a novel therapist-guided Internet-based (ICBT) program designed to dramatically increase access to CBT for patients with BDD.
- BDD-NET may be particularly useful in the context of stepped-care for BDD, where low-risk patients with reasonably good insight are offered ICBT and non-responders or more complex and risky patients are offered more intensive, clinic based CBT alone or in combination with medication.
- This was an uncontrolled trial. This limits the possibilities to make causal inferences as to what caused the observed changes.
- There is also bias in this study as participants were self-referred.
- Despite the limitations of this uncontrolled trial, the results suggest that BDD-NET has the potential to reduce symptoms and increase access to CBT for patients with BDD who are motivated to receive treatment.

INTRODUCTION

Body dysmorphic disorder (BDD) is characterized by a preoccupation with perceived defects in physical appearance that are accompanied, at some point during the occurrence of the disorder, by repetitive behaviors or mental acts, such as excessive mirror checking, in response to the appearance concerns. These concerns cause clinically significant distress or functional impairment and are not better explained by an eating disorder.[1] BDD is common, debilitating, associated with relatively high rates of psychiatric hospitalization and suicidality, and with a chronic and unremitting course if left untreated.[2-8] People suffering from BDD often seek non-psychiatric care due to perceived appearance flaws, such as dermatological treatment or plastic surgery.[9] However, these treatments rarely work, and can even results in the deterioration of the BDD symptoms.[9 10]

One treatment modality that has shown promise for BDD is cognitive behavioral therapy (CBT).[11 12] To our knowledge, only four randomized controlled trials (RCT) have been published to date. In the mid-90s, Rosen et al.[13] investigated the effect of group CBT, and Veale et al.[14] conducted a study of individual CBT for BDD with response rates of 81.5% and 78%, respectively. Recently, Wilhelm et al.[15] developed and published a multimodal treatment manual specifically designed for BDD that has been tested in one open trial and one wait-list controlled trial with large within-group effect sizes and response rates around 80-81%.[16 17] In the only RCT to employ a an active comparison group, Veale et al.[18] recently reported superiority of CBT compared to anxiety management, a credible psychological intervention primarily consisting of progressive muscle relaxation and breathing techniques, and a 52% response rate for CBT after 16 therapy sessions.

Despite the growing support for CBT and readily available treatment manuals,[15 19] numerous barriers to treatment exist. One of the biggest challenges of CBT is the restricted access, partly due to a lack of trained therapists, but also due to the direct and indirect costs associated with treatment.[20-22] In two online surveys, only 10 to 17% of people with body dysmorphic concerns reported that they had received an empirically supported psychotherapy (i.e. CBT), with a majority reporting that a major contributing factor for not seeking help was shame associated with talking openly about one's appearance concerns.[21 23] Furthermore, treatment barriers such as a lack of a specialised health care provider close by and logistic problems such as having to take

time of work in order to attend therapy were also reported.[21 23] Therefore, alternative ways of improving access to CBT are sorely needed.

One way to increase access to CBT is to administer the treatment using the Internet.[24 25] In the last decade, there has been a rapid development of Internet-based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are two main forms of ICBT: open access programs without any therapist guidance, and programs with therapist support that try to closely mimic the process of face-to-face CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of modules accompanied by homework assignments, reflecting the content of a traditional face-to-face therapy session. During the entire treatment, an identified therapist provides guidance and gives feedback through a built-in e-mail system. Thus, the therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in traditional CBT, the only difference being the way care is delivered. There is evidence that ICBT that incorporates therapist support may result in better treatment effects when compared to ICBT provided without such guidance.[30-32] Furthermore, in a recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there was no significant difference between the two treatment modalities, suggesting non-inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia, ICBT has already been implemented as part of their regular health care systems.[34-36]

With the primary aim to increase access to evidence based treatment for BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT program based on existing manuals,[15 19] and tested its feasibility and efficacy in an uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to patients, lead to a reduction of BDD and other psychiatric symptoms, and require minimal therapist input.

METHOD

Participants

The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD. Participant demographics and clinical characteristics are presented in Table 1.

Information about the study was posted on the official web page of the clinic (www.internetpsykiatri.se), and flyers were distributed to mental health professionals. The study was also mentioned in a national newspaper that ran a three-part article series about BDD. A total of 66 individuals were considered for eligibility (see Figure 1). To be eligible for the study participants had to be at least 18 years of age, outpatients, and diagnosed with primary DSM-5 BDD. Exclusion criteria were psychotropic medication changes within two months prior to enrolment, completed CBT for BDD within the last 12 months, a score on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BDD-YBOCS) of ≤ 16, current substance dependence, lifetime bipolar disorder or psychosis, acute suicidal ideation, a personality disorder that could jeopardize treatment participation, or concurrent psychological treatment. Participants who were taking psychotropic medication, and had been on a stable dose for at least 2 months prior to enrolment were asked to not change their medication during the study period. The regional ethical review board in Stockholm, Sweden approved the study ID: 2013/117-31/2. Clinicaltrials.gov registration ID: NCT01850433.

<INSERT FIGURE 1 ABOUT HERE>
<INSERT TABLE 1 ABOUT HERE>

Procedure

In the first stage of the recruitment process, potential participants were instructed to complete an online screening consisting of Montgomery-Åsberg Depression Rating Scale, Self-report (MADRS-S),[37] Alcohol Use Disorders Identification Test (AUDIT),[38] Drug User Disorders Identification Test (DUDIT),[39] Dysmorphic Concerns Questionnaire (DCQ),[40] and Body Dysmorphic Disorder Dimensional Scale (BDD-D).[41] All participants who completed the screening were contacted by telephone and assessed for BDD. Twenty-six individuals were invited to the clinic for an in-person assessment by either a psychiatrist or a licensed psychologist. The Mini-International Neuropsychiatric Interview (M.I.N.I.)[42] was used to determine the presence of any DSM-IV-TR Axis-I disorders. A more in depth interview with the BDD Diagnostic Module was conducted to establish the diagnosis of DSM-5 BDD.[43] The questions used in this semi-structured interview were orignially designed for DSM-IV-

TR critera and are similar to those used in the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I).[44] A question about the presence of repetitive behaviors was added to reflect the DSM-5 critera for BDD and the new DSM-5 insight specifiers were also used to determine degree of insight regarding body dysmorphic beliefs (i.e., good or fair insight, poor insight and absent insight/delusional beliefs). The assessors had several years of experience administering structured interviews, such as the BDD-YBOCS, and had undergone extensive training in using the M.I.N.I.

Measures

Participants were assessed with both clinician and self-report measures at pre-treatment, post-treatment and at the three-month follow-up. In addition, the BDD-D and MADRS-S were administered weekly to monitor progress and suicide risk. The primary outcome of interest was BDD symptom severity as measured with the BDD-YBOCS. The self-report measures were administered online, a method which has previously been shown to be as reliable and valid as pen-and-paper administration.[45-47]

Clinician-rated instruments

Yale-Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS)

The BDD-YBOCS[48] can be considered the gold standard for assessing symptom severity and impairment associated with BDD. It is a clinician administered semi-structured interview consisting of 12 items; each rated on a scale from 0-4, which measures symptom severity during the last seven days, in the form of intrusive thoughts (5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe symptoms. BDD-YBOCS has shown high test-retest reliability (r = .88) and internal consistency (α = .80).[48] An empirically defined cut-off point of a 30 % reduction on the BDD-YBOCS was used to determine responder status at post-treatment.[49] To investigate specific effects on insight, the item of the BDD-YBOCS relating to insight was also reported separately.

Clinical Global Impression (CGI)

The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal)

to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was determined to indicate responder status in this study. CGI has shown good reliability and validity for a range of psychiatric disorders.[51 52]

Global Assessment of Functioning (GAF)

The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from 0 to 100 and is used to assess social, occupational, and psychological functioning, with a higher score indicating better health. Overall reliability of the GAF are good, but questions regarding its validity have been raised, see Aas 2010 for a review.[54]

Self-administered measures

Body Dysmorphic Dimensional Scale (BDD-D)

The BDD-D[41] is a self report measure of symptom severity developed alongside the DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and repetitive behaviors, distress, control over symptoms, avoidance, and interference; each rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20. High internal consistency has been reported (α = .80), though further validation work is warranted.[41]

Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)

The MADRS-S[37] is the self-report version of the Montgomery-Åsberg Depression Rating Scale (MADRS)[55], and measures severity of depression. The scale consists of 9 items, each measuring a different symptom (mood, feelings of unease, sleep, appetite, ability to concentrate, initiative, emotional involvement, pessimism, and suicidal ideation) on a seven-point scale with a total score ranging from 0 to 54. Good to excellent test-retest reliability have been reported (r = .80 - .94)[37], as well as a high correlation (r = .87) between the MADRS-S and the Beck Depression Inventory in a comparative study.[56]

Skin Picking Scale-Revised (SPS-R)

As skin picking is common among persons diagnosed with BDD we used the SPS-R[57] to assess skin picking severity and impairment. The SPS-R is a self-report measure that

consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g., extreme). Good internal consistency (α = .83) as well as discriminant and convergent validity have been reported.[57]

Body Image Quality of Life Inventory (BIQLI)

The BIQLI[58] is a self-report measure that consists of 19 items with a 7-point scale ranging from -3 (very negative effect) to +3 (very positive effect) that assesses the impact of body image on various aspects of life (e.g., sexuality, emotional wellbeing, and relations). The total score ranges from -57 to +57. A positive score indicates that one's body image has a positive impact on quality of life, and vice versa. High test-retest (r = .79) and internal consistency (α = .94-95) have been reported.[58 59]

Safety procedures and adverse events

As mentioned earlier, participants with active suicidal ideation were not included in the trial. However, suicidal ideation is common among patients diagnosed with BDD and the following precautions were taken in order to detect patients that could deteriorate during treatment. All participants underwent a structured clinical interview assessing suicidal ideation before starting treatment. Throughout the entire treatment, MADRS-S was administered weekly and participants who, at any time throughout the treatment period, scored > 4 on item 9, which measures suicidal ideation, were immediately contacted by their therapist. If the patient were in need of additional care, an appointment was made with either a senior psychiatrist at the clinic, or at an emergency psychiatric unit.

Adverse events (AE) were recorded mid-treatment and at post-treatment in accordance with guidelines presented by Rozental et al.[60]. AE were defined as negative events that could have occurred due to treatment participation (e.g., deterioration of target symptoms, worse sleep, and general negative well-being such as stress). Participants were asked if they had experienced any AE that they associated with the intervention (yes/no). If yes, the participants were asked to describe the event in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no impact) to 3 (severely negative impact) at the time that the AE had occurred (retrospective self-reports), and if the AE still had a negative impact on well-being at present. A licensed psychologist reviewed the AE reported.

Treatment

The BDD-NET program was delivered via a tailored online platform, using a dedicated server with encrypted traffic and a strong authentication login function in order to guarantee participant confidentiality. The 12-week long treatment was based on a CBT model for BDD, emphasizing the role of avoidance and safety behaviors as maintaining factors of BDD.[15] A central part of the treatment was a self-help text of 104 pages divided into 8 modules (with modules 1–4 containing the core treatment components). The self-help text underwent several revisions, and was reviewed by licensed psychologists with previous experience of either ICBT or obsessive-compulsive and related disorders. Each module was devoted to a special theme and included information and homework assignments that needed to be completed in order to move on to the next module (e.g., filling out online worksheets, doing cognitive restructuring, or conducting in vivo exposure and response prevention; ERP). See Table 2 for a summary of the treatment modules and the number of participants completing each module. The participant had contact with an identified therapist throughout the whole treatment using a built-in e-mail system on the BDD-NET webpage. Participants had unlimited access to the therapist and could use the e-mail system at any time. The role of the therapist was mainly to guide and coach the participant through the treatment, provide feedback on homework assignments, answer questions from the participants, and consecutively grant access to the next treatment module. The therapist also acted proactively by sending e-mails to participants asking them to report on treatment progress. The participants were notified by an automated text-message (SMS) when they had a new e-mail in the treatment platform. All homework assignments and questions from the participants were reviewed and answered within 36 hours, except on weekends. Participants were randomised using random.org to one of two therapists, both licensed psychologists, with previous experience of treating obsessive-compulsive and related disorders. The duration of therapist contact was automatically recorded by the ICBT platform.

<INSERT TABLE 2 ABOUT HERE>

Statistical analysis

The primary analyses were done according to intention-to-treat (ITT) including the full sample of 23 participants. Missing data at post-treatment and follow-up assessment were deemed to be missing at random (using logistic regression models, as well as inspecting correlations between indicator variables of missingness and other variables from the dataset that might predict missingness) and imputed using multiple imputation by chained equations.[61] All estimates with standard errors were pooled from five imputations using "Rubin's rules"[62] and the small sample correction for pooled degrees of freedom.[63] Paired *t*-tests were performed to assess if changes from pretreatment to post-treatment and pretreatment to follow-up were statistically significant. Paired *t*-tests comparing post-treatment to follow-up were also performed to test for maintenance of the therapeutic gains. Within-group effect sizes were calculated by dividing the difference between pre-treatment and post-treatment scores by the within-group pooled standard deviation.[64] Fisher's exact test was used to examine weather there was an association between the occurrence of an AE and treatment responder status and independent *t*-tests were used to examine specific therapist effects. All data were analyzed with Stata statistical software, version 13.1[65] and the threshold for statistical significance set at the standard 5%.

RESULTS

Attrition

The participant flow throughout the trial is shown in Figure 1. One participant terminated treatment during the first week due to reported personal problems and did not complete any of the modules and was therefore regarded as a dropout, but was kept in the primary analysis according to the ITT principles. The post-treatment and 3-month follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants, respectively. Self-rated questionnaires administered online were completed by 20 (87 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-up.

Primary and secondary outcomes

Means, standard deviations, and within- group effect sizes, including confidence intervals, for all assessment points with missing values replaced by multiple imputation

are reported in Table 3. Paired t-tests showed significant changes on all measures from pre- to post-treatment (t(df = 13.72 – 20.15) = 3.10 – 7.54, all p-values < .01), and from pretreatment to follow-up (t(df = 10.96 – 19.24) = 3.13 – 8.66, all p-values < .01). On the main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size was d = 2.01, and the pre-treatment to follow-up effect size indicated sustained effects (d = 2.04).

At posttreatment, 82% of completers were responders (≥ 30 % decrease on the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).

The significant pre- to post-treatment improvement on the BDD-YBOCS insight item was in the large range (t(18.44) = 4.30, p = < .001, d = 1.07). Weekly scores and follow-up data on the self-reported BDD-D are presented in Figure 2.

<<INSERT FIGURE 2 ABOUT HERE>>

The distribution of CGI-I scores for completers at posttreatment and follow-up, respectively, was as follows: very much improved, 41 % and 52 %; much improved, 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At posttreatment and follow-up, 64 % and 71 % were responders (very much or much improved), respectively.

On the other outcome measures, the within-group effect sizes from pretreatment to posttreatment and pretreatment to follow-up were in the moderate to large range (d = .55 – 1.82).

<INSERT TABLE 3 ABOUT HERE>

Adverse events

In total, 11 (48%) participants reported that they had experienced AE during the course of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g., nightmares, depressive symptoms and worse sleep), followed by a deterioration of symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus on appearance), and general negative well-being (29%, e.g., stress). The AE reported occurred mostly during the first part of the treatment, and most participants rated the

negative impact of the AE as moderate (*Median* = 2, *M* = 1.8, *SD* = 1.1) when they occurred, and as no longer having a negative impact at posttreatment (*Median* = 0, *M* = .7, *SD* = 1.6) with the exception of one participant who reported that the treatment had led to an increase in appearance concerns and more frequent intrusive thoughts compared to baseline, and was classified as a non-responder at post-treatment. The occurrence of AE during treatment was unrelated to responder status at post-treatment, with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-responders (Fisher's exact test = 0.59).

During treatment, one participant became increasingly depressed and was referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after which treatment continued.

Treatment activity and acceptability

The mean number of messages that the participants sent to and received from their therapist was 22.6 (*SD* = 12.2, range 0–47), and 30.2 (*SD* = 11.3, range 3–51), respectively, and the therapists spent a weekly mean of 10.3 minutes (*SD* = 6.7, range 1.8–35.2), per participant. No significant differences were noted in time spent providing support ($t(21) = 1.19$, $p = .25$), or in treatment effects between the two therapists ($t(21) = -.60$, $p = .56$).

In total, 19 (83%) participants completed the core components of the treatment programme (modules 1–4), and six participants completed all eight of the modules (26 %). The mean number of completed modules was 5.5 (*SD* = 2.35, range 0–8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the treatment, for example doing exercises in vivo and reading material online.

At posttreatment, 6 (30%) of participants reported that they were very pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was somewhat displeased with the treatment provided. One participant did not answer the satisfaction question.

All participants on psychotropic medication had kept their dose stable during treatment, and none had received any other type of psychological intervention. In total, 5 (22%) participants reported that they had received additional care at the 3-month follow-up. Of the participants receiving additional care, four were non-

responders according to the CGI-I at post-treatment, and all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT, respectively, two participants had been prescribed an SRI (of which one was prescribed for an indication other than BDD), and one participant had increased the dose of current SRI.

DISCUSSION

This study explored the feasibility and acceptability of a novel therapist-guided ICBT program designed to dramatically increase access to CBT for patients with BDD. In general the participants felt that BDD-NET was highly acceptable. A significant improvement was seen on the main outcome measure (clinician-rated BDD-YBOCS), with a large effect size, and 82% of the participants classed as responders at post-treatment. These treatment effects were maintained at the three-month follow-up. Clinician-rated insight also improved from pre- to post-treatment. Secondary outcome measures of depression, skin picking, global functioning and body image-related quality of life showed significant improvements from pre- to post-treatment, and from pre-treatment to follow-up, with moderate to large effect sizes.

In general, the results are in line with other trials investigating the effects of individual CBT for BDD delivered in specialized clinic settings.[16-18] However, direct comparisons with previous trials should be made with caution, because ours was a self-referred and moderately ill patient group with relatively good insight. Some research has shown that the source of patient referral may have a bearing on the types of patients seen and the degree of clinical improvement with computerized or internet-based therapies, with patients referred by mental health professionals having more comorbidity, being less motivated for treatment and achieving more modest outcomes, compared to self-referrals or referrals from general practitioners.[66]

A comparison of the demographic and clinical characteristics of our sample with those of two recently published RCTs appears in Table 4. Despite having moderate to severe BDD symptoms, our predominantly female, self-referred sample might have been particularly motivated to engage in psychological treatment, compared to the average BDD patient seen in specialist settings. The proportion of patients with absent or delusional insight also appears to be lower in this sample compared to the

proportions seen in specialist clinic samples. Furthermore, though the rates of comorbid disorders were similar, on average, our participants endorsed mild depressive symptoms, compared to the moderate to severe depressive symptoms reported in the trials published by Wilhelm et al.[17] and Veale et al.[18].

ICBT should not be seen as a substitute for traditional face-to-face treatment but, rather, a clinician extender that may substantially increase access to evidence based treatment for a large proportion of sufferers who are not currently receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input will be required for complex patients who have poor insight and high suicide risk. In this regard, BDD-NET may be particularly useful in the context of stepped-care for BDD, where low-risk patients with reasonably good insight are offered ICBT and non-responders or more complex and risky patients are offered more intensive, clinic based CBT alone or in combination with medication.

<<INSERT TABLE 4 ABOUT HERE>>

Participants in this trial made marked improvements despite no face-to-face contact, beyond the baseline, post-treatment and follow-up assessments. Although the treatment is Internet-based, the mechanisms of change may be the same as in traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still instructed to expose him or herself to feared stimuli in vivo without using maladaptive coping strategies. Each participant had the same identified therapist throughout the entire treatment, and although therapist contact was only around 10 minutes per participant and week, the therapist sent a mean number of 30.2 messages per participant, which averages out to 2-3 contacts per week. Messages sent from the therapist were usually short, with prompts to the participant to engage in ERP and report the outcome, allowing for adjustment of exposure strategies when needed. Thus, the therapist was proactive and had shorter, but more frequent contact with participants compared to traditional CBT, where sessions usually are held once a week. Despite minimal therapist contact, participants often report the feeling of a therapist presence; the therapists' frequent encouragement to engage in daily ERP may be a critical component of the intervention.[32]

In total, 48% of the participants experienced an adverse event during treatment. However, the adverse events were mostly mild, and non-enduring, and a vast majority of participants were very pleased or pleased with the treatment provided. Most (83%) of the participants completed all of the core treatment components and engaged in ERP, suggesting that the treatment was engaging and highly acceptable. The treatment completion rate is in line with previous ICBT studies of various disorders, suggesting that ICBT is as acceptable for patients with BDD as it is for other patient groups (e.g., OCD, SAD, and MDD).[26 27]

Stigma, shame and logistic barriers can be a hindrance for persons with BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is online; this could reduce initial shame and stigma associated with openly talking about one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the clinic while receiving CBT and has the potential to minimize logistic barriers and increase access to evidence-based care in rural areas or where trained therapists are not available. Furthermore, one therapist can have more patients in treatment at the same time compared to face-to-face therapy, while spending less time per patient as the routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT format has the potential to lower the severity threshold for people with BDD to seek and receive adequate treatment. Expert clinicians can dedicate more time and resources to complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is protocol based and delivered as a series of modules online. This greatly reduces the risk of therapist drift,[67] and ensures that all patients receive exactly the same treatment. The control over content delivered also opens up for dismantling studies, as modules can easily be added or taken out to test the specific effect of a treatment component, as shown by Ljótsson et al.[68] where the specific effect of systematic exposure on Irritable Bowel Syndrome symptoms was tested.

This study has several limitations that need to be considered when interpreting the results. First and foremost, this was an uncontrolled trial. This limits the possibilities to make causal inferences as to what caused the observed changes. The improvements observed over the course of treatment could have been due to the mere passage of time. However, when considering the chronicity of BDD,[8 69] we regard it as unlikely that the treatment effects in this trial could be entirely explained by spontaneous remission. Furthermore, the improvements observed could also be due to

unspecific factors, such as caregiver attention. However, the maintenance of improvement from post-treatment to follow-up indicates that treatment gains were temporally stable, and the majority of participants did not receive any further treatment. Both therapists in the study had previous experience of treating BDD, and although the essential components of the treatment are delivered as online modules, there could be a specific therapist factor as the therapists answered questions and gave treatment guidance through the integrated e-mail system. It is unknown if the same outcomes would be obtained with less experienced therapists.

Despite the limitations of this uncontrolled trial, the results suggest that BDD-NET has the potential to reduce symptoms and increase access to CBT for a large majority of moderately ill patients with BDD who are motivated to receive treatment. A randomized controlled trial of BDD-NET is warranted.

ACKNOWLEDGEMENTS

We would like to thank Monica Hellberg, Sofia Eriksson, Vania Panes Lundmark and Kayoko Isomura for their invaluable help.

AUTHOR'S CONTRIBUTIONS

JE was the project manager and participated in designing the study, analyzing data, providing treatment, and drafting the manuscript and the treatment manual. VI participated in designing the study, providing treatment and drafting the manuscript and the treatment manual. EA participated in designing the study and drafting the manuscript and the treatment manual. DMC participated in drafting the manuscript and designing the study. BL participated in designing the study, analyzing data and drafting the manuscript and the treatment manual. CR participated in designing the study and drafting the treatment manual and the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

None declared.

FUNDING

Financial support was provided through the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet. The Swedish Research Council and the Swedish Society of Medicine (Söderströmska Königska sjukhemmet) provided funding for this study.

DATA SHARING

No additional data available.

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Table 1. Patient demographics and clinical characteristics (*N* = 23)

Variable	Mean/*n*	SD/%
Age in years (Mean, *SD*)	30.3	(6.3)
Female (*n*, %)	16	(70%)
Employment status (*n*, %)		
Employed	14	(61%)
Unemployed	4	(17%)
Student	5	(22%)
Married (*n*, %)	7	(30%)
Education (*n*, %)		
High school	16	(70%)
University college	7	(30%)
Previous psychological treatment (*n*, %)	12	(52%)
Previous use of psychotropic medication (*n*, %)	11	(48%)
Current use of psychotropic medication (*n*, %)	7	(30%)
Years with BDD symptoms (Mean, *SD*)	15.3	(8.1)
Current comorbidity (*n*, %)		
Major depressive disorder	10	(43%)
Panic disorder	1	(4%)
Social anxiety disorder	5	(22%)
Obsessive-compulsive disorder	2	(9%)
Bulimia nervosa	2	(9%)
Generalized anxiety disorder	1	(4%)

Table 2. Description of consecutive treatment modules and the number of participants completing each module

Module	Contents	No. of participants[a]
1.	Psychoeducation: Introduction the treatment and information about BDD such as prevalence, known etiology, and common symptoms. Different fictional patient characters are introduced and used as examples to help clarify the treatment components throughout the treatment. Participants begin to register BDD-related behaviors and thoughts in an online diary.	22 (96%)
2.	A cognitive-behavior conceptualization: Explanation of how self-defeating thoughts and BDD related avoidance and safety behaviors maintain appearance concerns and fears. Participants learn how to conduct a functional analysis of how their own BDD symptoms are maintained.	21 (91%)
3.	Cognitive restructuring: A more in-depth rationale for how self-defeating thoughts and maladaptive thinking maintains BDD symptoms. Participants evaluate negative thoughts and engage in cognitive restructuring using online worksheets.	21 (91%)
4.	Exposure and response prevention (ERP): Explanation of exposure and different strategies for conducting response prevention is presented. Participants set treatment goals and conduct their first in vivo ERP exercise. ERP continues during the remainder of treatment, and participants continuously assess outcome of ERP using an online worksheet.	19 (83%)
5.	More on ERP: Different aspects of ERP are highlighted and a more in-depth explanation is given on how to work with ERP over time.	14 (61%)
6.	Values-based behavior change: Participants identify values-based long-term goals within the domains of relationships, career, and leisure activities. An accepting stance towards negative thoughts and experiences is proposed as an alternative to attempts to control these experiences, while at the same time engaging in meaningful values-based activities.	13 (57%)
7.	Difficulties during treatment: Commonly encountered difficulties during treatment such as loss of motivation and problems integrating exercises into daily schedule are presented and discussed, as well as common obstacles associated with ERP and how to overcome them.	10 (44%)
8.	Relapse prevention: How to handle relapses into avoidance behaviors and repetitive behavior. The participants also summarize the main lessons learned, what has been gained through the treatment and their future plans.	6 (27%)

Note. [a] Defined as doing the homework associated with each module.

Table 3. Primary and secondary outcome measures

							Within-group effect size *d*								
	Pre-treatment		Post-treatment		3-month follow-up[a]		Pre to post[a]			Pre to follow-up[a]			Post to follow-up[a]		
Measure	M	SD	M	SD	M	SD	*d*	CI-	CI+	*d*	CI-	CI+	*d*	CI-	CI+
BDD-YBOCS	30.78	6.24	15.70	8.48	13.85	9.57	**2.01**	1.05	2.97	**2.04**	1.18	2.91	**0.20**	-0.14	0.54
BDD-YBOCS i	2.17	0.89	1.42	0.83	1.22	0.91	**0.88**	0.34	1.42	**1.07**	0.39	1.74	**0.23**	-0.24	0.70
BDD-D	13.09	3	7.67	4.03	6.38	4.19	**1.51**	0.62	2.41	**1.82**	0.96	2.68	**0.31**	0.01	0.61
MADRS-S	17.91	8.22	10.23	7.52	11.74	10.17	**0.97**	0.47	1.48	**0.65**	0.18	1.11	**-0.15**	-0.42	0.11
SPS-R	8.83	7.31	4.91	6.78	4.53	6.31	**0.55**	0.15	0.96	**0.63**	0.18	1.07	**0.06**	-0.14	0.25
BIQLI[b]	-27.26	13.38	-10.83	17.36	-11.11	19.66	**1.05**	0.35	1.75	**0.96**	0.17	1.75	**-0.02**	-0.32	0.29
GAF	49.87	7.23	61.75	8.85	63.21	9.05	**1.47**	0.69	2.25	**1.62**	0.90	2.33	**0.16**	-0.09	0.42

Note. BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD. BDD-YBOCS i, Yale-Brown Obsessive Compulsive Scale Modified for BDD insight item. BDD-D, Body Dysmorphic Disorder Dimensional Scale. MADRS-S, Montgomery-Åsberg Depression Rating Scale, self-report. SPS-R, Skin Picking Scale Revised. BIQLI, Body Image Quality of Life Inventory. GAF, Global Assessment of Functioning Scale. Effect sizes are reported with 95% confidence intervals.

[a] Pooled estimates based on multiple imputation.

[b] Higher scores indicate better health. Sign of effect sizes changed for clarity.

Table 4. Baseline characteristics of patients in the current study, compared to two recent RCTs of CBT for BDD

Variable	BDD-NET	Veale et al. 2014	Wilhelm et al. 2013[a]
Age in years	30.3 (6.3)	Median = 30	33.2 (11.4)
Female	70%	57%	53%
Employed	61%	46%	65%
Referral	Self-referred	Primary or secondary care	Self-referred
BDD-YBOCS	30.78 (6.24)	35.48 (6.61)[a]	32.5 (3.2)
Delusional BDD	9%	54%	n/a
BABS	n/a	18.24 (4.68)[a]	14.1 (3.9)
MADRS	17.91 (8.22)	28.57 (10.69)[a]	n/a
BDI	n/a	n/a	22.4 (14)
Current comorbidity			
MDD	43%	44%	47%
SAD	22%	11%	24%
OCD	9%	4%	6%
Current use of medications	30%	46%	71%

Note. Values denote means ± SD unless otherwise specified.
BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD; BABS, Brown Assessment of Beliefs Scale; MADRS, Montgomery-Åsberg Depression Rating Scale; BDI, Beck Depression Inventory.
[a] Participant characteristics of those randomised to CBT.

FIGURE LEGEND
Figure 1: Participant flow through the study
Figure 2: Weekly scores on the self-administered Body Dysmorphic Disorder Dim

Title

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

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Running title

Internet-based CBT for BDD: A feasibility study

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Keywords

BDD, OCD, CBT, Internet, treatment

ABSTRACT

Objectives: Cognitive behavioral therapy (CBT) is an effective treatment for body dysmorphic disorder (BDD). However, most sufferers do not have access to this treatment. One way to increase access to CBT is to administer the treatment remotely via the Internet. This study piloted a novel therapist-supported, Internet-based CBT program for BDD (BDD-NET).

Design: Uncontrolled clinical trial.

Participants: Patients (*N*=23) were recruited through self-referral and assessed face-to-face at a clinic specializing in obsessive-compulsive and related disorders. Suitable patients were offered secure access to BDD-NET.

Intervention: BDD-NET is a 12-week treatment program based on current psychological models of BDD that includes psycho-education, functional analysis, cognitive restructuring, exposure and response prevention, and relapse prevention modules. A dedicated therapist provides active guidance and feedback throughout the entire process.

Main outcome measure: The clinician-administered Yale-Brown Obsessive Compulsive Scale for BDD (BDD-YBOCS). Symptom severity was assessed pre-treatment, post-treatment and at the 3-month follow-up.

Results: BDD-NET was deemed highly acceptable by patients and led to significant improvements on the BDD-YBOCS (p = < .001) with a large within-group effect size (Cohen's d = 2.01, 95% CI 1.05-2.97). At post-treatment, 82% of the patients were classified as responders (defined as ≥30% improvement on the BDD-YBOCS). These gains were maintained at the 3-month follow-up. Secondary outcome measures of depression, global functioning and quality of life also showed significant improvements with moderate to large effect sizes. On average, therapists spent 10 minutes per patient per week providing support.

Conclusion: The results suggest that BDD-NET has the potential to greatly increase access to CBT, at least for low-risk individuals with moderately severe BDD symptoms and reasonably good insight. A randomized controlled trial of BDD-NET is warranted. Clinicaltrials.gov registration ID: NCT01850433.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is the first to explore the feasibility and acceptability of a novel therapist-guided Internet-based (ICBT) program designed to dramatically increase access to CBT for patients with BDD.
- The uncontrolled nature of the study limits the possibility to make causal inferences as to what caused the observed changes.
- All participants were self-referred and hence particularly motivated for treatment.

INTRODUCTION

Body dysmorphic disorder (BDD) is characterized by an intense preoccupation with perceived defects in physical appearance that is accompanied, at some point during the occurrence of the disorder, by repetitive behaviors or mental acts, such as excessive mirror checking, in response to the appearance concerns. These concerns cause clinically significant distress or functional impairment and are not better explained by an eating disorder.[1] BDD is common, debilitating, associated with relatively high rates of psychiatric hospitalization and suicidality, and has a chronic and unremitting course if left untreated.[2-8] People suffering from BDD often seek non-psychiatric care due to perceived appearance flaws, such as dermatological treatment or plastic surgery.[9] However, these treatments rarely work, and can even result in the deterioration of the BDD symptoms.[9 10]

One treatment modality that has shown promise for BDD is cognitive behavioral therapy (CBT).[11 12] To our knowledge, only four randomized controlled trials (RCT) have been published to date. In the mid-90s, Rosen et al.[13] investigated the effect of group CBT, and Veale et al.[14] conducted a study of individual CBT for BDD with response rates of 81.5% and 78%, respectively. Recently, Wilhelm et al.[15] developed and published a multimodal treatment manual specifically designed for BDD that has been tested in one open trial and one wait-list controlled trial with large within-group effect sizes and response rates around 80-81%.[16 17] In the only RCT to employ a an active comparison group, Veale et al.[18] recently reported superiority of CBT compared to anxiety management, a credible psychological intervention primarily consisting of progressive muscle relaxation and breathing techniques, and a 52% response rate for CBT after 16 therapy sessions.

Despite the growing support for CBT and readily available treatment manuals,[15 19] numerous barriers to treatment exist. One of the biggest challenges of CBT is the restricted access, partly due to a lack of trained therapists, but also due to the direct and indirect costs associated with treatment.[20-22] In two online surveys, only 10 to 17% of people with body dysmorphic concerns reported that they had received an empirically supported psychotherapy (i.e. CBT), with a majority reporting that a major contributing factor for not seeking help was shame associated with talking openly about one's appearance concerns.[21 23] Furthermore, treatment barriers such as a lack of a specialised health care provider close by and logistic problems such as having to take

time off work in order to attend therapy were also reported.[21 23] Therefore, alternative ways of improving access to CBT are sorely needed.

One way to increase access to CBT is to administer the treatment using the Internet.[24 25] In the last decade, there has been a rapid development of Internet-based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are two main forms of ICBT: open access programs without any therapist guidance, and programs with therapist support that try to closely mimic the process of face-to-face CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of modules accompanied by homework assignments, reflecting the content of a traditional face-to-face therapy session. During the entire treatment, an identified therapist provides guidance and gives feedback through a built-in e-mail system. Thus, the therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in traditional CBT, the only difference being the way care is delivered. There is evidence that ICBT that incorporates therapist support may result in better treatment effects when compared to ICBT provided without such guidance.[30-32] Furthermore, in a recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there was no significant difference between the two treatment modalities, suggesting non-inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia, ICBT has already been implemented as part of their regular health care systems.[34-36]

With the primary aim to increase access to evidence based treatment for BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT program based on existing manuals,[15 19] and tested its feasibility and efficacy in an uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to patients, lead to a reduction of BDD and other psychiatric symptoms, and require minimal therapist input.

METHOD

Participants

The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD. Participant demographics and clinical characteristics are presented in Table 1. The most

common body areas of concern reported by at least 50% of the participants at baseline included: face (i.e., shape or size) 18 (78%), skin 14 (61%), part of the face (e.g., nose, ears, eyes) 14 (61%), hair 13 (57%), and weight 12 (52%).

Information about the study was posted on the official web page of the clinic (www.internetpsykiatri.se), and flyers were distributed to mental health professionals. The study was also mentioned in a national newspaper that ran a three-part article series about BDD. A total of 66 individuals were considered for eligibility (see Figure 1). To be eligible for the study participants had to be at least 18 years of age, outpatients, and diagnosed with primary DSM-5 BDD, and currently living in Stockholm or Uppsala county. As this was a pilot study exploring the feasibility of BDD-NET, geographic proximity was required to facilitate in person assessments, and the opportunity to intervene in case of safety concerns.

Exclusion criteria were psychotropic medication changes within two months prior to enrolment, completed CBT for BDD within the last 12 months, a score on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BDD-YBOCS) of ≤ 16, current substance dependence, lifetime bipolar disorder or psychosis, acute suicidal ideation, a personality disorder that could jeopardize treatment participation (e.g., borderline personality disorder with self-harm), or concurrent psychological treatment. Participants who were taking psychotropic medication, and had been on a stable dose for at least 2 months prior to enrolment were asked to not change their medication during the study period. After a complete description of the study, written informed consent was obtained from all the participants. The regional ethical review board in Stockholm, Sweden approved the study ID: 2013/117-31/2. Clinicaltrials.gov registration ID: NCT01850433.

<INSERT FIGURE 1 ABOUT HERE>

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Procedure

In the first stage of the recruitment process, potential participants were instructed to complete an online screening consisting of Montgomery-Åsberg Depression Rating Scale, Self-report (MADRS-S),[37] Alcohol Use Disorders Identification Test

(AUDIT),[38] Drug User Disorders Identification Test (DUDIT),[39] Dysmorphic Concerns Questionnaire (DCQ),[40] and Body Dysmorphic Disorder Dimensional Scale (BDD-D).[41] All participants who completed the screening were contacted by telephone and assessed for BDD. Twenty-six individuals were invited to the clinic for an in-person assessment by either a psychiatrist or a licensed psychologist. The Mini-International Neuropsychiatric Interview (M.I.N.I.)[42] was used to determine the presence of any DSM-IV-TR Axis-I disorders. A more in depth interview with the BDD Diagnostic Module was conducted to establish the diagnosis of DSM-5 BDD.[43] The questions used in this semi-structured interview were orignially designed for DSM-IV-TR criteria and are similar to those used in the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I).[44] A question about the presence of repetitive behaviors was added to reflect the DSM-5 criteria for BDD and the new DSM-5 insight specifiers was also used to determine degree of insight regarding body dysmorphic beliefs (i.e., good or fair insight, poor insight and absent insight/delusional beliefs). The assessors had several years of experience administering structured interviews, such as the BDD-YBOCS, and had undergone extensive training in using the M.I.N.I. However, inter-rater reliablity of the BDD-YBOCS was not established in this study.

Measures

Participants were assessed with both clinician and self-report measures at pre-treatment, post-treatment and at the three-month follow-up. In addition, the BDD-D and MADRS-S were administered weekly to monitor progress and suicide risk. The primary outcome of interest was BDD symptom severity as measured with the clinician-administered BDD-YBOCS. The self-report measures were administered online, a method which has previously been shown to be as reliable and valid as pen-and-paper administration.[45-47]

Clinician-rated instruments

Yale-Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS)

The BDD-YBOCS[48] can be considered the gold standard for assessing symptom severity and impairment associated with BDD. It is a clinician administered semi-structured interview consisting of 12 items; each rated on a scale from 0-4, which measures symptom severity during the last seven days, in the form of intrusive thoughts

(5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe symptoms. BDD-YBOCS has shown high test-retest reliability (r = .88) and internal consistency (α = .80).[48] An empirically defined cut-off point of a 30 % reduction on the BDD-YBOCS was used to determine responder status at post-treatment.[49] To investigate specific treatment effects on insight, the item of the BDD-YBOCS relating to insight was also reported separately.

Clinical Global Impression (CGI)

The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal) to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was determined to indicate responder status in this study. CGI has shown good reliability and validity for a range of psychiatric disorders.[51 52]

Global Assessment of Functioning (GAF)

The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from 0 to 100 and is used to assess social, occupational, and psychological functioning, with a higher score indicating better health. Overall reliability of the GAF is good, but questions regarding its validity have been raised; see Aas 2010 for a review.[54]

Self-administered measures

Body Dysmorphic Dimensional Scale (BDD-D)

The BDD-D[41] is a self report measure of symptom severity developed alongside the DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and repetitive behaviors, distress, control over symptoms, avoidance, and interference; each rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20. High internal consistency has been reported (α = .80), though further validation work is warranted.[41]

Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)

The MADRS-S[37] is the self-report version of the Montgomery-Åsberg Depression Rating Scale (MADRS)[55], and measures severity of depression. The scale consists of 9 items, each measuring a different symptom (mood, feelings of unease, sleep, appetite, ability to concentrate, initiative, emotional involvement, pessimism, and suicidal ideation) on a seven-point scale with a total score ranging from 0 to 54. Good to excellent test-retest reliability have been reported (r = .80 - .94)[37], as well as a high correlation (r = .87) between the MADRS-S and the Beck Depression Inventory in a comparative study.[56]

Skin Picking Scale-Revised (SPS-R)

As skin picking is common among persons diagnosed with BDD we used the SPS-R[57] to assess skin picking severity and impairment. The SPS-R is a self-report measure that consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g., extreme). Good internal consistency (α = .83) as well as discriminant and convergent validity have been reported.[57]

Body Image Quality of Life Inventory (BIQLI)

The BIQLI[58] is a self-report measure that consists of 19 items with a 7-point scale ranging from -3 (very negative effect) to +3 (very positive effect) that assesses the impact of body image on various aspects of life (e.g., sexuality, emotional wellbeing, and relations). The total score ranges from -57 to +57. A positive score indicates that one's body image has a positive impact on quality of life, and vice versa. High test-retest (r = .79) and internal consistency (α = .94-95) have been reported.[58 59]

Safety procedures and adverse events

As mentioned earlier, participants with active suicidal ideation were not included in the trial. However, suicidal ideation is common among patients diagnosed with BDD and the following precautions were taken in order to detect patients that could deteriorate during treatment. All participants underwent a structured clinical interview assessing suicidal ideation before starting treatment. Throughout the entire treatment, MADRS-S was administered weekly and participants who, at any time throughout the treatment period, scored > 4 on item 9, which measures suicidal ideation, were immediately contacted by their therapist. If the patient were in need of additional care, an

appointment was made with either a senior psychiatrist at the clinic, or at an emergency psychiatric unit.

Adverse events (AE) were recorded mid-treatment and at post-treatment in accordance with guidelines presented by Rozental et al.[60]. AE were defined as negative events that could have occurred due to treatment participation (e.g., deterioration of target symptoms, worse sleep, and general negative well-being such as stress). Participants were asked if they had experienced any AE that they associated with the intervention (yes/no). If yes, the participants were asked to describe the event in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no impact) to 3 (severely negative impact) at the time that the AE had occurred (retrospective self-reports), and if the AE still had a negative impact on well-being at present. A licensed psychologist reviewed the AE reported.

Treatment

The BDD-NET program was delivered via a tailored online platform, using a dedicated server with encrypted traffic and a strong authentication login function in order to guarantee participant confidentiality. The 12-week long treatment was based on a CBT model for BDD, emphasizing the role of avoidance and safety behaviors as maintaining factors of BDD.[15] Most existing treatment protocols for BDD involve a larger number of face-to-face sessions, ranging from 12 to 22.[17 18] However, considering the format of ICBT (where therapists often make several contacts during the week), as well as previous ICBT research in OCD showing that 10 weeks of treatment yields the same results as 15 weeks of treatment, a 12-week long treatment was deemed appropriate.[26 61]

A central part of the treatment was a self-help text of 104 pages divided into 8 modules (with modules 1–4 containing the core treatment components). The self-help text underwent several revisions, and was reviewed by licensed psychologists with previous experience of either ICBT or obsessive-compulsive and related disorders. Each module was devoted to a special theme and included information and homework assignments. The participants were given consecutive access to the next module after correctly answering a quiz about the material that they had read, as well as filling out at least one worksheet corresponding to the homework assignment given in the module. See Table 2 for a summary of the treatment modules and the number of participants

completing each module. The participant had contact with an identified therapist throughout the whole treatment using a built-in e-mail system on the BDD-NET webpage. The two therapists providing the treatment were both licensed psychologists with several years of experience in treating obsessive-compulsive and related disorders. To ensure treatment integrity and adherence to protocol, a licensed psychologist monitored the messages sent by the therapists throughout the entire treatment. Participants had unlimited access to the therapist and could use the e-mail system at any time. The role of the therapist was mainly to guide and coach the participant through the treatment, provide feedback on homework assignments, answer questions from the participants, and consecutively grant access to the next treatment module. The therapist also acted proactively by sending e-mails to participants asking them to report on treatment progress. The participants were notified by an automated text-message (SMS) when they had a new e-mail in the treatment platform. All homework assignments and questions from the participants were reviewed and answered within 36 hours, except on weekends. Participants were randomised using random.org to one of two therapists, both licensed psychologists, with previous experience of treating obsessive-compulsive and related disorders. The duration of therapist contact was automatically recorded by the ICBT platform. None of the participants had face-to-face contact with a therapist.

<INSERT TABLE 2 ABOUT HERE>

Statistical analysis

The primary analyses were done according to intention-to-treat (ITT) including the full sample of 23 participants. Missing data at post-treatment and follow-up assessment were deemed to be missing at random (using logistic regression models, as well as inspecting correlations between indicator variables of missingness and other variables from the dataset that might predict missingness) and imputed using multiple imputation by chained equations.[62] All estimates with standard errors were pooled from five imputations using "Rubin's rules"[63] and the small sample correction for pooled degrees of freedom.[64] Paired *t*-tests were performed to assess if changes from pretreatment to post-treatment and pretreatment to follow-up were statistically significant. Paired *t*-tests comparing post-treatment to follow-up were also performed to test for maintenance of the therapeutic gains. Within-group effect sizes were calculated

by dividing the difference between pre-treatment and post-treatment scores by the within-group pooled standard deviation.[65] Fisher's exact test was used to examine weather there was an association between the occurrence of an AE and treatment responder status and independent *t*-tests were used to examine specific therapist effects. All data were analyzed with Stata statistical software, version 13.1[66] and the threshold for statistical significance set at the standard 5%.

RESULTS

Attrition

The participant flow throughout the trial is shown in Figure 1. One participant terminated treatment during the first week due to reported personal problems and did not complete any of the modules and was therefore regarded as a dropout, but was kept in the primary analysis according to the ITT principles. The post-treatment and 3-month follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants, respectively. Self-rated questionnaires administered online were completed by 20 (87 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-up.

Primary and secondary outcomes

Means, standard deviations, and within- group effect sizes, including confidence intervals, for all assessment points with missing values replaced by multiple imputation are reported in Table 3. Paired t-tests showed significant changes on all measures from pre- to post-treatment (t(df = 13.72 – 20.15) = 3.10 – 7.54, all p-values < .01), and from pretreatment to follow-up (t(df = 10.96 – 19.24) = 3.13 – 8.66, all p-values < .01). On the main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size was d = 2.01, and the pre-treatment to follow-up effect size indicated sustained effects (d = 2.04).

At posttreatment, 82% of completers were responders (≥ 30 % decrease on the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).

The significant pre- to post-treatment improvement on the BDD-YBOCS insight item was in the large range ($t(18.44) = 4.30$, p = < .001, $d = 1.07$). Weekly scores and follow-up data on the self-reported BDD-D are presented in Figure 2.

<<INSERT FIGURE 2 ABOUT HERE>>

The distribution of CGI-I scores for completers at posttreatment and follow-up, respectively, was as follows: very much improved, 41 % and 52 %; much improved, 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At posttreatment and follow-up, 64 % and 71 % were responders (very much or much improved), respectively.

On the other outcome measures, the within-group effect sizes from pretreatment to posttreatment and pretreatment to follow-up were in the moderate to large range (d = .55 – 1.82).

<INSERT TABLE 3 ABOUT HERE>

Adverse events

In total, 11 (48%) participants reported that they had experienced AE during the course of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g., nightmares, depressive symptoms and worse sleep), followed by a deterioration of symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus on appearance), and general negative well-being (29%, e.g., stress). The AE reported occurred mostly during the first part of the treatment, and most participants rated the negative impact of the AE as moderate (*Median* = 2, *M* = 1.8, *SD* = 1.1) when they occurred, and as no longer having a negative impact at posttreatment (*Median* = 0, *M* = .7, *SD* = 1.6) with the exception of one participant who reported that the treatment had led to an increase in appearance concerns and more frequent intrusive thoughts compared to baseline, and was classified as a non-responder at post-treatment. The occurrence of AE during treatment was unrelated to responder status at post-treatment, with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-responders (Fisher's exact test = 0.59).

During treatment, one participant became increasingly depressed and was referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after which treatment continued.

Treatment activity and acceptability

The mean number of messages that the participants sent to and received from their therapist was 22.6 (*SD* = 12.2, range 0–47), and 30.2 (*SD* = 11.3, range 3–51), respectively, and the therapists spent a weekly mean of 10.3 minutes (*SD* = 6.7, range 1.8–35.2), per participant. No significant differences were noted in time spent providing support ($t(21) = 1.19$, $p = .25$, *d* = 0.5 95% CI -0.39-1.39), or in treatment effects between the two therapists ($t(21) = -.60$, $p = .56$, *d* = -0.26 95% CI -1.11-0.60).

In total, 19 (83%) participants completed the core components of the treatment programme (modules 1–4), and six participants completed all eight of the modules (26 %). The mean number of completed modules was 5.5 (*SD* = 2.35, range 0–8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the treatment, for example doing exercises in vivo and reading material online.

At posttreatment, 6 (30%) participants reported that they were very pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was somewhat displeased with the treatment provided. One participant did not answer the satisfaction question.

All participants on psychotropic medication prior to treatment had kept their dose stable during treatment, and none had received any other type of psychological intervention. In total, 5 (22%) participants reported that they had received additional care at the 3-month follow-up. Of the participants receiving additional care, four were non-responders according to the CGI-I at post-treatment, and all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT, respectively, two participants had been prescribed an SRI (of which one was prescribed for an indication other than BDD), and one participant had increased the dose of current SRI.

DISCUSSION

This study explored the feasibility and acceptability of a novel therapist-guided ICBT program designed to increase access to CBT for patients with BDD. In general the participants felt that BDD-NET was highly acceptable. A significant improvement was seen on the main outcome measure (clinician-rated BDD-YBOCS), with a large effect size, and 82% of the participants classed as responders at post-treatment. These treatment effects were maintained at the three-month follow-up. Clinician-rated insight also improved from pre- to post-treatment. Secondary outcome measures of depression, skin picking, global functioning and body image-related quality of life showed significant improvements from pre- to post-treatment, and from pre-treatment to follow-up, with moderate to large effect sizes.

In general, the results are in line with other trials investigating the effects of individual CBT for BDD delivered in specialized clinic settings.[16-18] However, direct comparisons with previous trials should be made with caution, because ours was a self-referred and moderately ill patient group with relatively good insight. Some research has shown that the source of patient referral may have a bearing on the types of patients seen and the degree of clinical improvement with computerized or internet-based therapies, with patients referred by mental health professionals having more comorbidity, being less motivated for treatment and achieving more modest outcomes, compared to self-referrals or referrals from general practitioners.[67]

A comparison of the demographic and clinical characteristics of our sample with those of two recently published RCTs appears in Table 4. A cut-off of 16 on the BDD-YBOCS was used for entry into the study, which would represent minimal symptoms. However, only one participant had a score on the BDD-YBOCS below 22, and the range of baseline BDD-YBOCS scores was 16-42, and the score median was 30. Thus, our sample had moderate to severe symptoms. Despite having moderate to severe BDD symptoms, our predominantly female, self-referred sample might have been particularly motivated to engage in psychological treatment, compared to the average BDD patient seen in specialist settings. The proportion of patients with absent or delusional insight also appears to be lower in this sample compared to the proportions seen in specialist clinic samples. Furthermore, though the rates of comorbid disorders were similar, on average, our participants endorsed mild depressive symptoms, compared to the

moderate to severe depressive symptoms reported in the trials published by Wilhelm et al.[17] and Veale et al.[18].

ICBT should not be seen as a substitute for traditional face-to-face treatment but, rather, a clinician extender that may substantially increase access to evidence based treatment for a large proportion of sufferers who are not currently receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input will be required for complex patients who have poor insight and high suicide risk. In this regard, BDD-NET may be particularly useful in the context of stepped-care for BDD, where low-risk patients with reasonably good insight are offered ICBT and non-responders or more complex and risky patients are offered more intensive, clinic based CBT alone or in combination with medication.

<INSERT TABLE 4 ABOUT HERE>

Participants in this trial made marked improvements despite no face-to-face contact, beyond the baseline, post-treatment and follow-up assessments. Although the treatment is Internet-based, the mechanisms of change may be the same as in traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still instructed to expose him or herself to feared stimuli in vivo without using maladaptive coping strategies. Each participant had the same identified therapist throughout the entire treatment, and although therapist contact was only around 10 minutes per participant and week, the therapist sent a mean number of 30.2 messages per participant, which averages out to 2-3 contacts per week. Messages sent from the therapist were usually short, with prompts to the participant to engage in ERP and report the outcome, allowing for adjustment of exposure strategies when needed. Thus, the therapist was proactive and had shorter, but more frequent contact with participants compared to traditional CBT, where sessions usually are held once a week. Despite minimal therapist contact, participants often report the feeling of a therapist presence; the therapists' frequent encouragement to engage in daily ERP may be a critical component of the intervention.[32]

In total, 48% of the participants experienced an adverse event during treatment. However, the adverse events were mostly mild, and non-enduring, and a vast majority of participants were very pleased or pleased with the treatment provided. Most

(83%) of the participants completed all of the core treatment components and engaged in ERP, suggesting that the treatment was engaging and highly acceptable. The treatment completion rate is in line with previous ICBT studies of various disorders, suggesting that ICBT is as acceptable for patients with BDD as it is for other patient groups (e.g., OCD, SAD, and MDD).[26 27]

Stigma, shame and logistic barriers can be a hindrance for persons with BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is online; this could reduce initial shame and stigma associated with openly talking about one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the clinic while receiving CBT and has the potential to minimize logistic barriers and increase access to evidence-based care in rural areas or where trained therapists are not available. Furthermore, one therapist can have more patients in treatment at the same time compared to face-to-face therapy, while spending less time per patient as the routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT format has the potential to lower the severity threshold for people with BDD to seek and receive adequate treatment. Expert clinicians can dedicate more time and resources to complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is protocol based and delivered as a series of modules online. This greatly reduces the risk of therapist drift,[68] and ensures that all patients receive exactly the same treatment. The control over content delivered also opens up for dismantling studies, as modules can easily be added or taken out to test the specific effect of a treatment component, as shown by Ljótsson et al.[69] where the specific effect of systematic exposure on Irritable Bowel Syndrome symptoms was tested.

This study has several limitations that need to be considered when interpreting the results. First and foremost, this was an uncontrolled trial. This limits the possibilities to make causal inferences as to what caused the observed changes. The improvements observed over the course of treatment could have been due to the mere passage of time. However, when considering the chronicity of BDD,[8 70] we regard it as unlikely that the treatment effects in this trial could be entirely explained by spontaneous remission. Furthermore, the improvements observed could also be due to unspecific factors, such as caregiver attention. However, the maintenance of improvement from post-treatment to follow-up indicates that treatment gains were temporally stable, and the majority of participants did not receive any further treatment.

Due to safety concerns, the presence of severe suicidal ideation and substance dependence, both of which are common comorbidities in BDD, were criteria for exclusion. Thus, it is unknown if BDD-NET would be appropriate for patients with these comorbidities. The insight item on the BDD-YBOCS was used to assess change in insight before and after treatment; other available instruments such as the Brown Assessment of Beliefs Scale (BABS)[71] may have provided a more precise and sensitive measure of overvalued ideation. Both therapists in the study had previous experience of treating BDD, and although the essential components of the treatment are delivered as online modules, there could be a specific therapist factor as the therapists answered questions and gave treatment guidance through the integrated e-mail system. It is unknown if the same outcomes would be obtained with less experienced therapists.

Despite the limitations of this uncontrolled trial, the results suggest that BDD-NET has the potential to reduce symptoms and increase access to CBT for a large majority of moderately ill patients with BDD who are motivated to receive treatment. A randomized controlled trial of BDD-NET is warranted.

ACKNOWLEDGEMENTS

We would like to thank Monica Hellberg, Sofia Eriksson, Vania Panes Lundmark and Kayoko Isomura for their invaluable help.

AUTHOR'S CONTRIBUTIONS

JE was the project manager and participated in designing the study, analyzing data, providing treatment, and drafting the manuscript and the treatment manual. VI participated in designing the study, providing treatment and drafting the manuscript and the treatment manual. EA participated in designing the study and drafting the manuscript and the treatment manual. DMC participated in drafting the manuscript and designing the study. BL participated in designing the study, analyzing data and drafting the manuscript and the treatment manual. CR participated in designing the study and drafting the treatment manual and the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

None declared.

FUNDING

Financial support was provided through the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet. The Swedish Research Council and the Swedish Society of Medicine (Söderströmska Königska sjukhemmet) provided funding for this study.

DATA SHARING

No additional data available.

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Table 1. Socio-demographic and clinical characteristics of the sample (*N* = 23)

Variable	Mean/*n*	SD/%
Age in years (Mean, *SD*)	30.3	(6.3)
Female (*n*, %)	16	(70%)
Employment status (*n*, %)		
Employed	14	(61%)
Unemployed	4	(17%)
Student	5	(22%)
Married (*n*, %)	7	(30%)
Education (*n*, %)		
High school	16	(70%)
University college	7	(30%)
Previous psychological treatment (*n*, %)	12	(52%)
Previous use of psychotropic medication (*n*, %)	11	(48%)
Current use of psychotropic medication (*n*, %)	7	(30%)
Years with BDD symptoms (Mean, *SD*)	15.3	(8.1)
Number of body areas of concern (Mean, *SD*)	6	(3)
BDD-5 insight specifier (*n*, %)		
Good or fair insight	10	43%
Poor insight	11	(48%)
Absent/delusional beliefs	2	(9%)
Current comorbidity (*n*, %)		
Major depressive disorder	10	(43%)
Panic disorder	1	(4%)
Social anxiety disorder	5	(22%)
Obsessive-compulsive disorder	2	(9%)
Bulimia nervosa	2	(9%)
Generalized anxiety disorder	1	(4%)

Table 2. Description of consecutive treatment modules and the number of participants completing each module

Module	Contents	No. of participants[a]
1.	Psychoeducation: Introduction the treatment and information about BDD such as prevalence, known etiology, and common symptoms. Different fictional patient characters are introduced and used as examples to help clarify the treatment components throughout the treatment. Participants begin to register BDD-related behaviors and thoughts in an online diary.	22 (96%)
2.	A cognitive-behavior conceptualization: Explanation of how self-defeating thoughts and BDD related avoidance and safety behaviors maintain appearance concerns and fears. Participants learn how to conduct a functional analysis of how their own BDD symptoms are maintained.	21 (91%)
3.	Cognitive restructuring: A more in-depth rationale for how self-defeating thoughts and maladaptive thinking maintains BDD symptoms. Participants evaluate negative thoughts and engage in cognitive restructuring using online worksheets.	21 (91%)
4.	Exposure and response prevention (ERP): Explanation of exposure and different strategies for conducting response prevention is presented. Participants set treatment goals and conduct their first in vivo ERP exercise. ERP continues during the remainder of treatment, and participants continuously assess outcome of ERP using an online worksheet.	19 (83%)
5.	More on ERP: Different aspects of ERP are highlighted and a more in-depth explanation is given on how to work with ERP over time.	14 (61%)
6.	Values-based behavior change: Participants identify values-based long-term goals within the domains of relationships, career, and leisure activities. An accepting stance towards negative thoughts and experiences is proposed as an alternative to attempts to control these experiences, while at the same time engaging in meaningful values-based activities.	13 (57%)
7.	Difficulties during treatment: Commonly encountered difficulties during treatment such as loss of motivation and problems integrating exercises into daily schedule are presented and discussed, as well as common obstacles associated with ERP and how to overcome them.	10 (44%)
8.	Relapse prevention: How to handle relapses into avoidance behaviors and repetitive behavior. The participants also summarize the main lessons learned, what has been gained through the treatment and their future plans.	6 (27%)

Note. [a] *Defined as doing the homework associated with each module.*

Table 3. Primary and secondary outcome measures

							Within-group effect size *d*								
	Pre-treatment		Post-treatment		3-month follow-up[a]		Pre to post[a]			Pre to follow-up[a]			Post to follow-up[a]		
Measure	M	SD	M	SD	M	SD	*d*	CI-	CI+	*d*	CI-	CI+	*d*	CI-	CI+
BDD-YBOCS	30.78	6.24	15.70	8.48	13.85	9.57	**2.01**	1.05	2.97	**2.04**	1.18	2.91	**0.20**	-0.14	0.54
BDD-YBOCS i	2.17	0.89	1.42	0.83	1.22	0.91	**0.88**	0.34	1.42	**1.07**	0.39	1.74	**0.23**	-0.24	0.70
BDD-D	13.09	3	7.67	4.03	6.38	4.19	**1.51**	0.62	2.41	**1.82**	0.96	2.68	**0.31**	0.01	0.61
MADRS-S	17.91	8.22	10.23	7.52	11.74	10.17	**0.97**	0.47	1.48	**0.65**	0.18	1.11	**-0.15**	-0.42	0.11
SPS-R	8.83	7.31	4.91	6.78	4.53	6.31	**0.55**	0.15	0.96	**0.63**	0.18	1.07	**0.06**	-0.14	0.25
BIQLI[b]	-27.26	13.38	-10.83	17.36	-11.11	19.66	**1.05**	0.35	1.75	**0.96**	0.17	1.75	**-0.02**	-0.32	0.29
GAF	49.87	7.23	61.75	8.85	63.21	9.05	**1.47**	0.69	2.25	**1.62**	0.90	2.33	**0.16**	-0.09	0.42

Note. BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD. BDD-YBOCS i, Yale-Brown Obsessive Compulsive Scale Modified for BDD insight item. BDD-D, Body Dysmorphic Disorder Dimensional Scale. MADRS-S, Montgomery-Åsberg Depression Rating Scale, self-report. SPS-R, Skin Picking Scale Revised. BIQLI, Body Image Quality of Life Inventory. GAF, Global Assessment of Functioning Scale. Effect sizes are reported with 95% confidence intervals.

[a] Pooled estimates based on multiple imputation.

[b] Higher scores indicate better health. Sign of effect sizes changed for clarity.

Table 4. Baseline characteristics of patients in the current study, compared to two recent RCTs of CBT for BDD

Variable	BDD-NET	Veale et al. 2014	Wilhelm et al. 2014[a]
Age in years	30.3 (6.3)	Median = 30	33.2 (11.4)
Female	70%	57%	53%
Employed	61%	46%	65%
Referral	Self-referred	Primary or secondary care	Self-referred
BDD-YBOCS	30.78 (6.24)	35.48 (6.61)[a]	32.5 (3.2)
Delusional BDD	9%	54%	n/a
BABS	n/a	18.24 (4.68)[a]	14.1 (3.9)
MADRS	17.91 (8.22)	28.57 (10.69)[a]	n/a
BDI	n/a	n/a	22.4 (14)
Current comorbidity			
MDD	43%	44%	47%
SAD	22%	11%	24%
OCD	9%	4%	6%
Current use of medications	30%	46%	71%

Note. Values denote means ± SD unless otherwise specified.

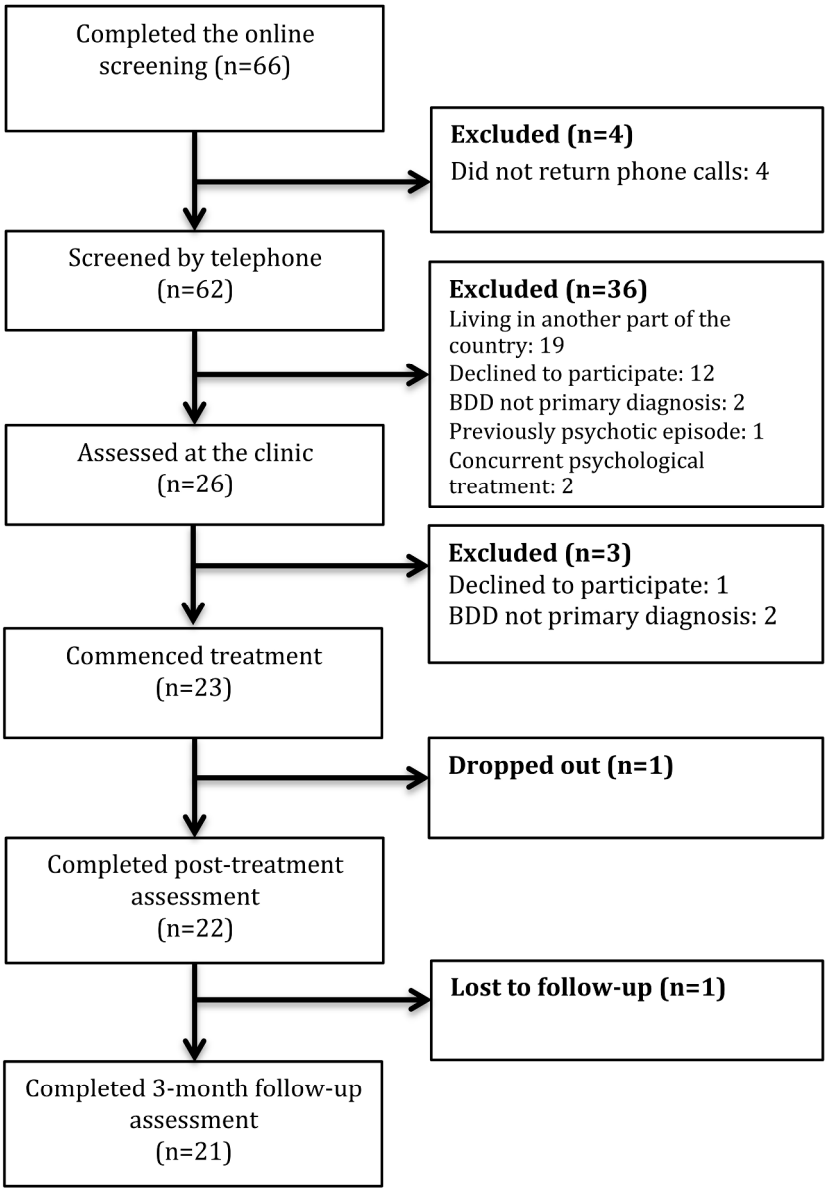
BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD; BABS, Brown Assessment of Beliefs Scale; MADRS, Montgomery-Åsberg Depression Rating Scale; BDI, Beck Depression Inventory.

[a] Participant characteristics of those randomised to CBT.

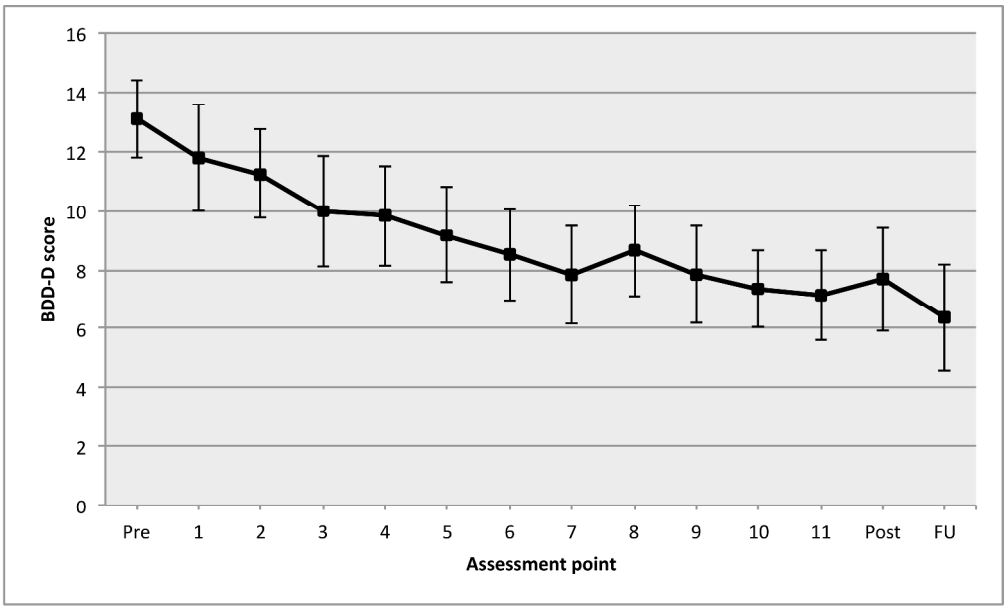
FIGURE LEGEND

Figure 1: Participant flow through the study

Figure 2: Weekly scores on the self-administered Body Dysmorphic Disorder Dimensional Scale, BDD-D (including 95 % confidence intervals)



Participant flow through the study.



Weekly scores on the self-administered Body Dysmorphic Disorder Dimensional Scale, BDD-D (including 95 % confidence intervals)

BMJ Open

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-005923.R2
Article Type:	Research
Date Submitted by the Author:	03-Sep-2014
Complete List of Authors:	Enander, Jesper; Karolinska Institutet, Department of Clinical Neuroscience Ivanov, Volen; Karolinska Institutet, Department of Clinical Neuroscience Andersson, Erik; Karolinska Institutet, Department of Clinical Neuroscience Mataix-Cols, David; Karolinska Institutet, Department of Clinical Neuroscience Ljótsson, Brjánn; Karolinska Institutet, Department of Clinical Neuroscience Rück, Christian; Karolinska Institutet, Department of Clinical Neuroscience
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Public health
Keywords:	MENTAL HEALTH, Clinical trials < THERAPEUTICS, Anxiety disorders < PSYCHIATRY, PSYCHIATRY

Title

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

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Running title

Internet-based CBT for BDD: A feasibility study

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Keywords

BDD, OCD, CBT, Internet, treatment

ABSTRACT

Objectives: Cognitive behavioral therapy (CBT) is an effective treatment for body dysmorphic disorder (BDD). However, most sufferers do not have access to this treatment. One way to increase access to CBT is to administer the treatment remotely via the Internet. This study piloted a novel therapist-supported, Internet-based CBT program for BDD (BDD-NET).

Design: Uncontrolled clinical trial.

Participants: Patients (*N*=23) were recruited through self-referral and assessed face-to-face at a clinic specializing in obsessive-compulsive and related disorders. Suitable patients were offered secure access to BDD-NET.

Intervention: BDD-NET is a 12-week treatment program based on current psychological models of BDD that includes psycho-education, functional analysis, cognitive restructuring, exposure and response prevention, and relapse prevention modules. A dedicated therapist provides active guidance and feedback throughout the entire process.

Main outcome measure: The clinician-administered Yale-Brown Obsessive Compulsive Scale for BDD (BDD-YBOCS). Symptom severity was assessed pre-treatment, post-treatment and at the 3-month follow-up.

Results: BDD-NET was deemed highly acceptable by patients and led to significant improvements on the BDD-YBOCS (p = < .001) with a large within-group effect size (Cohen's d = 2.01, 95% CI 1.05-2.97). At post-treatment, 82% of the patients were classified as responders (defined as ≥30% improvement on the BDD-YBOCS). These gains were maintained at the 3-month follow-up. Secondary outcome measures of depression, global functioning and quality of life also showed significant improvements with moderate to large effect sizes. On average, therapists spent 10 minutes per patient per week providing support.

Conclusion: The results suggest that BDD-NET has the potential to greatly increase access to CBT, at least for low-risk individuals with moderately severe BDD symptoms and reasonably good insight. A randomized controlled trial of BDD-NET is warranted.

Clinicaltrials.gov registration ID: NCT01850433.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is the first to explore the feasibility and acceptability of a novel therapist-guided Internet-based (ICBT) program designed to dramatically increase access to CBT for patients with BDD.
- The uncontrolled nature of the study limits the possibility to make causal inferences as to what caused the observed changes.
- All participants were self-referred and hence particularly motivated for treatment.

INTRODUCTION

Body dysmorphic disorder (BDD) is characterized by an intense preoccupation with perceived defects in physical appearance that is accompanied, at some point during the occurrence of the disorder, by repetitive behaviors or mental acts, such as excessive mirror checking, in response to the appearance concerns. These concerns cause clinically significant distress or functional impairment and are not better explained by an eating disorder.[1] BDD is common, debilitating, associated with relatively high rates of psychiatric hospitalization and suicidality, and has a chronic and unremitting course if left untreated.[2-8] People suffering from BDD often seek non-psychiatric care due to perceived appearance flaws, such as dermatological treatment or plastic surgery.[9] However, these treatments rarely work, and can even result in the deterioration of the BDD symptoms.[9 10]

One treatment modality that has shown promise for BDD is cognitive behavioral therapy (CBT).[11 12] To our knowledge, only four randomized controlled trials (RCT) have been published to date. In the mid-90s, Rosen et al.[13] investigated the effect of group CBT, and Veale et al.[14] conducted a study of individual CBT for BDD with response rates of 81.5% and 78%, respectively. Recently, Wilhelm et al.[15] developed and published a multimodal treatment manual specifically designed for BDD that has been tested in one open trial and one wait-list controlled trial with large within-group effect sizes and response rates around 80-81%.[16 17] In the only RCT to employ a an active comparison group, Veale et al.[18] recently reported superiority of CBT compared to anxiety management, a credible psychological intervention primarily consisting of progressive muscle relaxation and breathing techniques, and a 52% response rate for CBT after 16 therapy sessions.

Despite the growing support for CBT and readily available treatment manuals,[15 19] numerous barriers to treatment exist. One of the biggest challenges of CBT is the restricted access, partly due to a lack of trained therapists, but also due to the direct and indirect costs associated with treatment.[20-22] In two online surveys, only 10 to 17% of people with body dysmorphic concerns reported that they had received an empirically supported psychotherapy (i.e. CBT), with a majority reporting that a major contributing factor for not seeking help was shame associated with talking openly about one's appearance concerns.[21 23] Furthermore, treatment barriers such as a lack of a specialised health care provider close by and logistic problems such as having to take

time off work in order to attend therapy were also reported.[21 23] Therefore, alternative ways of improving access to CBT are sorely needed.

One way to increase access to CBT is to administer the treatment using the Internet.[24 25] In the last decade, there has been a rapid development of Internet-based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are two main forms of ICBT: open access programs without any therapist guidance, and programs with therapist support that try to closely mimic the process of face-to-face CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of modules accompanied by homework assignments, reflecting the content of a traditional face-to-face therapy session. During the entire treatment, an identified therapist provides guidance and gives feedback through a built-in e-mail system. Thus, the therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in traditional CBT, the only difference being the way care is delivered. There is evidence that ICBT that incorporates therapist support may result in better treatment effects when compared to ICBT provided without such guidance.[30-32] Furthermore, in a recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there was no significant difference between the two treatment modalities, suggesting non-inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia, ICBT has already been implemented as part of their regular health care systems.[34-36]

With the primary aim to increase access to evidence based treatment for BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT program based on existing manuals,[15 19] and tested its feasibility and efficacy in an uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to patients, lead to a reduction of BDD and other psychiatric symptoms, and require minimal therapist input.

METHOD

Participants

The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD. Participant demographics and clinical characteristics are presented in Table 1. The most

common body areas of concern reported by at least 50% of the participants at baseline included: face (i.e., shape or size) 18 (78%), skin 14 (61%), part of the face (e.g., nose, ears, eyes) 14 (61%), hair 13 (57%), and weight 12 (52%).

Information about the study was posted on the official web page of the clinic (www.internetpsykiatri.se), and flyers were distributed to mental health professionals. The study was also mentioned in a national newspaper that ran a three-part article series about BDD. A total of 66 individuals were considered for eligibility (see Figure 1). To be eligible for the study participants had to be at least 18 years of age, outpatients, and diagnosed with primary DSM-5 BDD, and currently living in Stockholm or Uppsala county. As this was a pilot study exploring the feasibility of BDD-NET, geographic proximity was required to facilitate in person assessments, and the opportunity to intervene in case of safety concerns.

Exclusion criteria were psychotropic medication changes within two months prior to enrolment, completed CBT for BDD within the last 12 months, a score on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BDD-YBOCS) of ≤ 16, current substance dependence, lifetime bipolar disorder or psychosis, acute suicidal ideation, a personality disorder that could jeopardize treatment participation (e.g., borderline personality disorder with self-harm), or concurrent psychological treatment. Participants who were taking psychotropic medication, and had been on a stable dose for at least 2 months prior to enrolment were asked to not change their medication during the study period. After a complete description of the study, written informed consent was obtained from all the participants. The regional ethical review board in Stockholm, Sweden approved the study ID: 2013/117-31/2. Clinicaltrials.gov registration ID: NCT01850433.

<INSERT FIGURE 1 ABOUT HERE>

<INSERT TABLE 1 ABOUT HERE>

Procedure

In the first stage of the recruitment process, potential participants were instructed to complete an online screening consisting of Montgomery-Åsberg Depression Rating Scale, Self-report (MADRS-S),[37] Alcohol Use Disorders Identification Test

(AUDIT),[38] Drug User Disorders Identification Test (DUDIT),[39] Dysmorphic Concerns Questionnaire (DCQ),[40] and Body Dysmorphic Disorder Dimensional Scale (BDD-D).[41] All participants who completed the screening were contacted by telephone and assessed for BDD. Twenty-six individuals were invited to the clinic for an in-person assessment by either a psychiatrist or a licensed psychologist. The Mini-International Neuropsychiatric Interview (M.I.N.I.)[42] was used to determine the presence of any DSM-IV-TR Axis-I disorders. A more in depth interview with the BDD Diagnostic Module was conducted to establish the diagnosis of DSM-5 BDD.[43] The questions used in this semi-structured interview were orignially designed for DSM-IV-TR criteria and are similar to those used in the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I).[44] A question about the presence of repetitive behaviors was added to reflect the DSM-5 criteria for BDD and the new DSM-5 insight specifiers was also used to determine degree of insight regarding body dysmorphic beliefs (i.e., good or fair insight, poor insight and absent insight/delusional beliefs). The assessors had several years of experience administering structured interviews, such as the BDD-YBOCS, and had undergone extensive training in using the M.I.N.I. However, inter-rater reliablity of the BDD-YBOCS was not established in this study.

Measures

Participants were assessed with both clinician and self-report measures at pre-treatment, post-treatment and at the three-month follow-up. In addition, the BDD-D and MADRS-S were administered weekly to monitor progress and suicide risk.
Questionnaires used in this trial have previously been translated into Swedish and gone through a rigorous back-translation process to check for any inconsistencies.
The primary outcome of interest was BDD symptom severity as measured with the clinician-administered BDD-YBOCS. The self-report measures were administered online, a method which has previously been shown to be as reliable and valid as pen-and-paper administration.[45-47]

Clinician-rated instruments

Yale-Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS)

The BDD-YBOCS[48] can be considered the gold standard for assessing symptom severity and impairment associated with BDD. It is a clinician administered semi-

structured interview consisting of 12 items; each rated on a scale from 0-4, which measures symptom severity during the last seven days, in the form of intrusive thoughts (5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe symptoms. BDD-YBOCS has shown high test-retest reliability (r = .88) and internal consistency (α = .80).[48] An empirically defined cut-off point of a 30 % reduction on the BDD-YBOCS was used to determine responder status at post-treatment.[49] To investigate specific treatment effects on insight, the item of the BDD-YBOCS relating to insight was also reported separately.

Clinical Global Impression (CGI)

The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal) to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was determined to indicate responder status in this study. CGI has shown good reliability and validity for a range of psychiatric disorders.[51 52]

Global Assessment of Functioning (GAF)

The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from 0 to 100 and is used to assess social, occupational, and psychological functioning, with a higher score indicating better health. Overall reliability of the GAF is good, but questions regarding its validity have been raised; see Aas 2010 for a review.[54]

Self-administered measures

Body Dysmorphic Dimensional Scale (BDD-D)

The BDD-D[41] is a self report measure of symptom severity developed alongside the DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and repetitive behaviors, distress, control over symptoms, avoidance, and interference; each rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20. High internal consistency has been reported (α = .80), though further validation work is warranted.[41]

Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)

The MADRS-S[37] is the self-report version of the Montgomery-Åsberg Depression Rating Scale (MADRS)[55], and measures severity of depression. The scale consists of 9 items, each measuring a different symptom (mood, feelings of unease, sleep, appetite, ability to concentrate, initiative, emotional involvement, pessimism, and suicidal ideation) on a seven-point scale with a total score ranging from 0 to 54. Good to excellent test-retest reliability have been reported (r = .80 - .94)[37], as well as a high correlation (r = .87) between the MADRS-S and the Beck Depression Inventory in a comparative study.[56]

Skin Picking Scale-Revised (SPS-R)

As skin picking is common among persons diagnosed with BDD we used the SPS-R[57] to assess skin picking severity and impairment. The SPS-R is a self-report measure that consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g., extreme). Good internal consistency (α = .83) as well as discriminant and convergent validity have been reported.[57]

Body Image Quality of Life Inventory (BIQLI)

The BIQLI[58] is a self-report measure that consists of 19 items with a 7-point scale ranging from -3 (very negative effect) to +3 (very positive effect) that assesses the impact of body image on various aspects of life (e.g., sexuality, emotional wellbeing, and relations). The total score ranges from -57 to +57. A positive score indicates that one's body image has a positive impact on quality of life, and vice versa. High test-retest (r = .79) and internal consistency (α = .94-95) have been reported.[58 59]

Safety procedures and adverse events

As mentioned earlier, participants with active suicidal ideation were not included in the trial. However, suicidal ideation is common among patients diagnosed with BDD and the following precautions were taken in order to detect patients that could deteriorate during treatment. All participants underwent a structured clinical interview assessing suicidal ideation before starting treatment. Throughout the entire treatment, MADRS-S was administered weekly and participants who, at any time throughout the treatment period, scored > 4 on item 9, which measures suicidal ideation, were immediately

contacted by their therapist. If the patient were in need of additional care, an appointment was made with either a senior psychiatrist at the clinic, or at an emergency psychiatric unit.

Adverse events (AE) were recorded mid-treatment and at post-treatment in accordance with guidelines presented by Rozental et al.[60]. AE were defined as negative events that could have occurred due to treatment participation (e.g., deterioration of target symptoms, worse sleep, and general negative well-being such as stress). Participants were asked if they had experienced any AE that they associated with the intervention (yes/no). If yes, the participants were asked to describe the event in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no impact) to 3 (severely negative impact) at the time that the AE had occurred (retrospective self-reports), and if the AE still had a negative impact on well-being at present. A licensed psychologist reviewed the AE reported.

Treatment

The BDD-NET program was delivered via a tailored online platform, using a dedicated server with encrypted traffic and a strong authentication login function in order to guarantee participant confidentiality. The user interface of the platform used for BDD-NET has been designed so that it can be used in any language. The 12-week long treatment was based on a CBT model for BDD, emphasizing the role of avoidance and safety behaviors as maintaining factors of BDD.[15] Most existing treatment protocols for BDD involve a larger number of face-to-face sessions, ranging from 12 to 22.[17 18] However, considering the format of ICBT (where therapists often make several contacts during the week), as well as previous ICBT research in OCD showing that 10 weeks of treatment yields the same results as 15 weeks of treatment, a 12-week long treatment was deemed appropriate.[26 61]

A central part of the treatment was a self-help text of 104 pages divided into 8 modules (with modules 1–4 containing the core treatment components). The self-help text underwent several revisions, and was reviewed by licensed psychologists with previous experience of either ICBT or obsessive-compulsive and related disorders. Each module was devoted to a special theme and included information and homework assignments. The participants were given consecutive access to the next module after correctly answering a quiz about the material that they had read, as well as filling out at

least one worksheet corresponding to the homework assignment given in the module. See Table 2 for a summary of the treatment modules and the number of participants completing each module. The participant had contact with an identified therapist throughout the whole treatment using a built-in e-mail system on the BDD-NET webpage. The two therapists providing the treatment were both licensed psychologists with several years of experience in treating obsessive-compulsive and related disorders. To ensure treatment integrity and adherence to protocol, a licensed psychologist monitored the messages sent by the therapists throughout the entire treatment. Participants had unlimited access to the therapist and could use the e-mail system at any time. The role of the therapist was mainly to guide and coach the participant through the treatment, provide feedback on homework assignments, answer questions from the participants, and consecutively grant access to the next treatment module. The therapist also acted proactively by sending e-mails to participants asking them to report on treatment progress. The participants were notified by an automated text-message (SMS) when they had a new e-mail in the treatment platform. All homework assignments and questions from the participants were reviewed and answered within 36 hours, except on weekends. Participants were randomised using random.org to one of two therapists, both licensed psychologists, with previous experience of treating obsessive-compulsive and related disorders. The duration of therapist contact was automatically recorded by the ICBT platform. None of the participants had face-to-face contact with a therapist.

<INSERT TABLE 2 ABOUT HERE>

Statistical analysis

The primary analyses were done according to intention-to-treat (ITT) including the full sample of 23 participants. Missing data at post-treatment and follow-up assessment were deemed to be missing at random (using logistic regression models, as well as inspecting correlations between indicator variables of missingness and other variables from the dataset that might predict missingness) and imputed using multiple imputation by chained equations.[62] All estimates with standard errors were pooled from five imputations using "Rubin's rules"[63] and the small sample correction for pooled degrees of freedom.[64] Paired *t*-tests were performed to assess if changes from pretreatment to post-treatment and pretreatment to follow-up were statistically

significant. Paired *t*-tests comparing post-treatm ent to follow-up were also performed to test for maintenance of the therapeutic gains. Within-group effect sizes were calculated by dividing the difference between pre-treatment and post-treatment scores by the within-group pooled standard deviation.[65] Fisher's exact test was used to examine weather there was an association between the occurrence of an AE and treatment responder status and independent *t*-tests were used to examine specific therapist effects. All data were analyzed with Stata statistical software, version 13.1[66] and the threshold for statistical significance set at the standard 5%.

RESULTS

Attrition

The participant flow throughout the trial is shown in Figure 1. One participant terminated treatment during the first week due to reported personal problems and did not complete any of the modules and was therefore regarded as a dropout, but was kept in the primary analysis according to the ITT principles. The post-treatment and 3-month follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants, respectively. Self-rated questionnaires administered online were completed by 20 (87 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-up.

Primary and secondary outcomes

Means, standard deviations, and within- group effect sizes, including confidence intervals, for all assessment points with missing values replaced by multiple imputation are reported in Table 3. Paired t-tests showed significant changes on all measures from pre- to post-treatment (t(df = 13.72 – 20.15) = 3.10 – 7.54, all p-values < .01), and from pretreatment to follow-up (t(df = 10.96 – 19.24) = 3.13 – 8.66, all p-values < .01). On the main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size was d = 2.01, and the pre-treatment to follow-up effect size indicated sustained effects (d = 2.04).

At posttreatment, 82% of completers were responders (≥ 30 % decrease on the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).

The significant pre- to post-treatment improvement on the BDD-YBOCS insight item was in the large range ($t(18.44) = 4.30$, p = < .001, $d = 1.07$). Weekly scores and follow-up data on the self-reported BDD-D are presented in Figure 2.

<<INSERT FIGURE 2 ABOUT HERE>>

The distribution of CGI-I scores for completers at posttreatment and follow-up, respectively, was as follows: very much improved, 41 % and 52 %; much improved, 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At posttreatment and follow-up, 64 % and 71 % were responders (very much or much improved), respectively.

On the other outcome measures, the within-group effect sizes from pretreatment to posttreatment and pretreatment to follow-up were in the moderate to large range ($d = .55 – 1.82$).

<INSERT TABLE 3 ABOUT HERE>

Adverse events

In total, 11 (48%) participants reported that they had experienced AE during the course of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g., nightmares, depressive symptoms and worse sleep), followed by a deterioration of symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus on appearance), and general negative well-being (29%, e.g., stress). The AE reported occurred mostly during the first part of the treatment, and most participants rated the negative impact of the AE as moderate (*Median* = 2, *M* = 1.8, *SD* = 1.1) when they occurred, and as no longer having a negative impact at posttreatment (*Median* = 0, *M* = .7, *SD* = 1.6) with the exception of one participant who reported that the treatment had led to an increase in appearance concerns and more frequent intrusive thoughts compared to baseline, and was classified as a non-responder at post-treatment. The occurrence of AE during treatment was unrelated to responder status at post-treatment, with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-responders (Fisher's exact test = 0.59).

During treatment, one participant became increasingly depressed and was referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after which treatment continued.

Treatment activity and acceptability

The mean number of messages that the participants sent to and received from their therapist was 22.6 (*SD* = 12.2, range 0–47), and 30.2 (*SD* = 11.3, range 3–51), respectively, and the therapists spent a weekly mean of 10.3 minutes (*SD* = 6.7, range 1.8–35.2), per participant. No significant differences were noted in time spent providing support ($t(21) = 1.19$, $p = .25$, $d = 0.5$ 95% CI -0.39-1.39), or in treatment effects between the two therapists ($t(21) = -.60$, $p = .56$, $d = -0.26$ 95% CI -1.11-0.60).

In total, 19 (83%) participants completed the core components of the treatment programme (modules 1–4), and six participants completed all eight of the modules (26 %). The mean number of completed modules was 5.5 (*SD* = 2.35, range 0–8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the treatment, for example doing exercises in vivo and reading material online.

At posttreatment, 6 (30%) participants reported that they were very pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was somewhat displeased with the treatment provided. One participant did not answer the satisfaction question.

All participants on psychotropic medication prior to treatment had kept their dose stable during treatment, and none had received any other type of psychological intervention. In total, 5 (22%) participants reported that they had received additional care at the 3-month follow-up. Of the participants receiving additional care, four were non-responders according to the CGI-I at post-treatment, and all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT, respectively, two participants had been prescribed an SRI (of which one was prescribed for an indication other than BDD), and one participant had increased the dose of current SRI.

DISCUSSION

This study explored the feasibility and acceptability of a novel therapist-guided ICBT program designed to increase access to CBT for patients with BDD. In general the participants felt that BDD-NET was highly acceptable. A significant improvement was seen on the main outcome measure (clinician-rated BDD-YBOCS), with a large effect size, and 82% of the participants classed as responders at post-treatment. These treatment effects were maintained at the three-month follow-up. Clinician-rated insight also improved from pre- to post-treatment. Secondary outcome measures of depression, skin picking, global functioning and body image-related quality of life showed significant improvements from pre- to post-treatment, and from pre-treatment to follow-up, with moderate to large effect sizes.

In general, the results are in line with other trials investigating the effects of individual CBT for BDD delivered in specialized clinic settings.[16-18] However, direct comparisons with previous trials should be made with caution, because ours was a self-referred and moderately ill patient group with relatively good insight. Some research has shown that the source of patient referral may have a bearing on the types of patients seen and the degree of clinical improvement with computerized or internet-based therapies, with patients referred by mental health professionals having more comorbidity, being less motivated for treatment and achieving more modest outcomes, compared to self-referrals or referrals from general practitioners.[67]

A comparison of the demographic and clinical characteristics of our sample with those of two recently published RCTs appears in Table 4. A cut-off of 16 on the BDD-YBOCS was used for entry into the study, which would represent minimal symptoms. However, only one participant had a score on the BDD-YBOCS below 22, and the range of baseline BDD-YBOCS scores was 16-42, and the score median was 30. Thus, our sample had moderate to severe symptoms. Despite having moderate to severe BDD symptoms, our predominantly female, self-referred sample might have been particularly motivated to engage in psychological treatment, compared to the average BDD patient seen in specialist settings. The proportion of patients with absent or delusional insight also appears to be lower in this sample compared to the proportions seen in specialist clinic samples. Furthermore, though the rates of comorbid disorders were similar, on average, our participants endorsed mild depressive symptoms, compared to the

moderate to severe depressive symptoms reported in the trials published by Wilhelm et al.[17] and Veale et al.[18].

ICBT should not be seen as a substitute for traditional face-to-face treatment but, rather, a clinician extender that may substantially increase access to evidence based treatment for a large proportion of sufferers who are not currently receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input will be required for complex patients who have poor insight and high suicide risk. In this regard, BDD-NET may be particularly useful in the context of stepped-care for BDD, where low-risk patients with reasonably good insight are offered ICBT and non-responders or more complex and risky patients are offered more intensive, clinic based CBT alone or in combination with medication.

<INSERT TABLE 4 ABOUT HERE>

Participants in this trial made marked improvements despite no face-to-face contact, beyond the baseline, post-treatment and follow-up assessments. Although the treatment is Internet-based, the mechanisms of change may be the same as in traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still instructed to expose him or herself to feared stimuli in vivo without using maladaptive coping strategies. Each participant had the same identified therapist throughout the entire treatment, and although therapist contact was only around 10 minutes per participant and week, the therapist sent a mean number of 30.2 messages per participant, which averages out to 2-3 contacts per week. Messages sent from the therapist were usually short, with prompts to the participant to engage in ERP and report the outcome, allowing for adjustment of exposure strategies when needed. Thus, the therapist was proactive and had shorter, but more frequent contact with participants compared to traditional CBT, where sessions usually are held once a week. Despite minimal therapist contact, participants often report the feeling of a therapist presence; the therapists' frequent encouragement to engage in daily ERP may be a critical component of the intervention.[32]

In total, 48% of the participants experienced an adverse event during treatment. However, the adverse events were mostly mild, and non-enduring, and a vast majority of participants were very pleased or pleased with the treatment provided. Most

(83%) of the participants completed all of the core treatment components and engaged in ERP, suggesting that the treatment was engaging and highly acceptable. The treatment completion rate is in line with previous ICBT studies of various disorders, suggesting that ICBT is as acceptable for patients with BDD as it is for other patient groups (e.g., OCD, SAD, and MDD).[26 27]

Stigma, shame and logistic barriers can be a hindrance for persons with BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is online; this could reduce initial shame and stigma associated with openly talking about one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the clinic while receiving CBT and has the potential to minimize logistic barriers and increase access to evidence-based care in rural areas or where trained therapists are not available. Furthermore, one therapist can have more patients in treatment at the same time compared to face-to-face therapy, while spending less time per patient as the routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT format has the potential to lower the severity threshold for people with BDD to seek and receive adequate treatment. Expert clinicians can dedicate more time and resources to complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is protocol based and delivered as a series of modules online. This greatly reduces the risk of therapist drift,[68] and ensures that all patients receive exactly the same treatment. The control over content delivered also opens up for dismantling studies, as modules can easily be added or taken out to test the specific effect of a treatment component, as shown by Ljótsson et al.[69] where the specific effect of systematic exposure on Irritable Bowel Syndrome symptoms was tested.

This study has several limitations that need to be considered when interpreting the results. First and foremost, this was an uncontrolled trial. This limits the possibilities to make causal inferences as to what caused the observed changes. The improvements observed over the course of treatment could have been due to the mere passage of time. However, when considering the chronicity of BDD,[8 70] we regard it as unlikely that the treatment effects in this trial could be entirely explained by spontaneous remission. Furthermore, the improvements observed could also be due to unspecific factors, such as caregiver attention. However, the maintenance of improvement from post-treatment to follow-up indicates that treatment gains were temporally stable, and the majority of participants did not receive any further treatment.

Due to safety concerns, the presence of severe suicidal ideation and substance dependence, both of which are common comorbidities in BDD, were criteria for exclusion. Thus, it is unknown if BDD-NET would be appropriate for patients with these comorbidities. The insight item on the BDD-YBOCS was used to assess change in insight before and after treatment; other available instruments such as the Brown Assessment of Beliefs Scale (BABS)[71] may have provided a more precise and sensitive measure of overvalued ideation. Both therapists in the study had previous experience of treating BDD, and although the essential components of the treatment are delivered as online modules, there could be a specific therapist factor as the therapists answered questions and gave treatment guidance through the integrated e-mail system. It is unknown if the same outcomes would be obtained with less experienced therapists.

Despite the limitations of this uncontrolled trial, the results suggest that BDD-NET has the potential to reduce symptoms and increase access to CBT for a large majority of moderately ill patients with BDD who are motivated to receive treatment. A randomized controlled trial of BDD-NET is warranted.

ACKNOWLEDGEMENTS

We would like to thank Monica Hellberg, Sofia Eriksson, Vania Panes Lundmark and Kayoko Isomura for their invaluable help.

AUTHOR'S CONTRIBUTIONS

JE was the project manager and participated in designing the study, analyzing data, providing treatment, and drafting the manuscript and the treatment manual. VI participated in designing the study, providing treatment and drafting the manuscript and the treatment manual. EA participated in designing the study and drafting the manuscript and the treatment manual. DMC participated in drafting the manuscript and designing the study. BL participated in designing the study, analyzing data and drafting the manuscript and the treatment manual. CR participated in designing the study and drafting the treatment manual and the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

None declared.

FUNDING

Financial support was provided through the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet. The Swedish Research Council and the Swedish Society of Medicine (Söderströmska Königska sjukhemmet) provided funding for this study.

DATA SHARING

No additional data available.

FIGURE LEGEND

Figure 1: Participant flow through the study

Figure 2: Weekly scores on the self-administered Body Dysmorphic Disorder Dimensional Scale, BDD-D (including 95 % confidence intervals)

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Table 1. Socio-demographic and clinical characteristics of the sample (*N* = 23)

Variable	Mean/*n*	SD/%
Age in years (Mean, *SD*)	30.3	(6.3)
Female (*n*, %)	16	(70%)
Employment status (*n*, %)		
Employed	14	(61%)
Unemployed	4	(17%)
Student	5	(22%)
Married (*n*, %)	7	(30%)
Education (*n*, %)		
High school	16	(70%)
University college	7	(30%)
Previous psychological treatment (*n*, %)	12	(52%)
Previous use of psychotropic medication (*n*, %)	11	(48%)
Current use of psychotropic medication (*n*, %)	7	(30%)
Years with BDD symptoms (Mean, *SD*)	15.3	(8.1)
Number of body areas of concern (Mean, *SD*)	6	(3)
BDD-5 insight specifier (*n*, %)		
Good or fair insight	10	43%
Poor insight	11	(48%)
Absent/delusional beliefs	2	(9%)
Current comorbidity (*n*, %)		
Major depressive disorder	10	(43%)
Panic disorder	1	(4%)
Social anxiety disorder	5	(22%)
Obsessive-compulsive disorder	2	(9%)
Bulimia nervosa	2	(9%)
Generalized anxiety disorder	1	(4%)

Table 2. Description of consecutive treatment modules and the number of participants completing each module

Module	Contents	No. of participants[a]
1.	Psychoeducation: Introduction the treatment and information about BDD such as prevalence, known etiology, and common symptoms. Different fictional patient characters are introduced and used as examples to help clarify the treatment components throughout the treatment. Participants begin to register BDD-related behaviors and thoughts in an online diary.	22 (96%)
2.	A cognitive-behavior conceptualization: Explanation of how self-defeating thoughts and BDD related avoidance and safety behaviors maintain appearance concerns and fears. Participants learn how to conduct a functional analysis of how their own BDD symptoms are maintained.	21 (91%)
3.	Cognitive restructuring: A more in-depth rationale for how self-defeating thoughts and maladaptive thinking maintains BDD symptoms. Participants evaluate negative thoughts and engage in cognitive restructuring using online worksheets.	21 (91%)
4.	Exposure and response prevention (ERP): Explanation of exposure and different strategies for conducting response prevention is presented. Participants set treatment goals and conduct their first in vivo ERP exercise. ERP continues during the remainder of treatment, and participants continuously assess outcome of ERP using an online worksheet.	19 (83%)
5.	More on ERP: Different aspects of ERP are highlighted and a more in-depth explanation is given on how to work with ERP over time.	14 (61%)
6.	Values-based behavior change: Participants identify values-based long-term goals within the domains of relationships, career, and leisure activities. An accepting stance towards negative thoughts and experiences is proposed as an alternative to attempts to control these experiences, while at the same time engaging in meaningful values-based activities.	13 (57%)
7.	Difficulties during treatment: Commonly encountered difficulties during treatment such as loss of motivation and problems integrating exercises into daily schedule are presented and discussed, as well as common obstacles associated with ERP and how to overcome them.	10 (44%)
8.	Relapse prevention: How to handle relapses into avoidance behaviors and repetitive behavior. The participants also summarize the main lessons learned, what has been gained through the treatment and their future plans.	6 (27%)

Note. [a] *Defined as doing the homework associated with each module.*

Table 3. Primary and secondary outcome measures

							Within-group effect size *d*								
	Pre-treatment		Post-treatment		3-month follow-up[a]		Pre to post[a]			Pre to follow-up[a]			Post to follow-up[a]		
Measure	M	SD	M	SD	M	SD	*d*	CI-	CI+	*d*	CI-	CI+	*d*	CI-	CI+
BDD-YBOCS	30.78	6.24	15.70	8.48	13.85	9.57	**2.01**	1.05	2.97	**2.04**	1.18	2.91	**0.20**	-0.14	0.54
BDD-YBOCS i	2.17	0.89	1.42	0.83	1.22	0.91	**0.88**	0.34	1.42	**1.07**	0.39	1.74	**0.23**	-0.24	0.70
BDD-D	13.09	3	7.67	4.03	6.38	4.19	**1.51**	0.62	2.41	**1.82**	0.96	2.68	**0.31**	0.01	0.61
MADRS-S	17.91	8.22	10.23	7.52	11.74	10.17	**0.97**	0.47	1.48	**0.65**	0.18	1.11	**-0.15**	-0.42	0.11
SPS-R	8.83	7.31	4.91	6.78	4.53	6.31	**0.55**	0.15	0.96	**0.63**	0.18	1.07	**0.06**	-0.14	0.25
BIQLI[b]	-27.26	13.38	-10.83	17.36	-11.11	19.66	**1.05**	0.35	1.75	**0.96**	0.17	1.75	**-0.02**	-0.32	0.29
GAF	49.87	7.23	61.75	8.85	63.21	9.05	**1.47**	0.69	2.25	**1.62**	0.90	2.33	**0.16**	-0.09	0.42

Note. BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD. BDD-YBOCS i, Yale-Brown Obsessive Compulsive Scale Modified for BDD insight item. BDD-D, Body Dysmorphic Disorder Dimensional Scale. MADRS-S, Montgomery-Åsberg Depression Rating Scale, self-report. SPS-R, Skin Picking Scale Revised. BIQLI, Body Image Quality of Life Inventory. GAF, Global Assessment of Functioning Scale. Effect sizes are reported with 95% confidence intervals.

[a] Pooled estimates based on multiple imputation.

[b] Higher scores indicate better health. Sign of effect sizes changed for clarity.

Table 4. Baseline characteristics of patients in the current study, compared to two recent RCTs of CBT for BDD

Variable	BDD-NET	Veale et al. 2014	Wilhelm et al. 2014[a]
Age in years	30.3 (6.3)	Median = 30	33.2 (11.4)
Female	70%	57%	53%
Employed	61%	46%	65%
Referral	Self-referred	Primary or secondary care	Self-referred
BDD-YBOCS	30.78 (6.24)	35.48 (6.61)[a]	32.5 (3.2)
Delusional BDD	9%	54%	n/a
BABS	n/a	18.24 (4.68)[a]	14.1 (3.9)
MADRS	17.91 (8.22)	28.57 (10.69)[a]	n/a
BDI	n/a	n/a	22.4 (14)
Current comorbidity			
MDD	43%	44%	47%
SAD	22%	11%	24%
OCD	9%	4%	6%
Current use of medications	30%	46%	71%

Note. Values denote means ± SD unless otherwise specified.

BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD; BABS, Brown Assessment of Beliefs Scale; MADRS, Montgomery-Åsberg Depression Rating Scale; BDI, Beck Depression Inventory.

[a] Participant characteristics of those randomised to CBT.

Title

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

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Running title

Internet-based CBT for BDD: A feasibility study

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Keywords

BDD, OCD, CBT, Internet, treatment

ABSTRACT

Objectives: Cognitive behavioral therapy (CBT) is an effective treatment for body dysmorphic disorder (BDD). However, most sufferers do not have access to this treatment. One way to increase access to CBT is to administer the treatment remotely via the Internet. This study piloted a novel therapist-supported, Internet-based CBT program for BDD (BDD-NET).

Design: Uncontrolled clinical trial.

Participants: Patients (*N*=23) were recruited through self-referral and assessed face-to-face at a clinic specializing in obsessive-compulsive and related disorders. Suitable patients were offered secure access to BDD-NET.

Intervention: BDD-NET is a 12-week treatment program based on current psychological models of BDD that includes psycho-education, functional analysis, cognitive restructuring, exposure and response prevention, and relapse prevention modules. A dedicated therapist provides active guidance and feedback throughout the entire process.

Main outcome measure: The clinician-administered Yale-Brown Obsessive Compulsive Scale for BDD (BDD-YBOCS). Symptom severity was assessed pre-treatment, post-treatment and at the 3-month follow-up.

Results: BDD-NET was deemed highly acceptable by patients and led to significant improvements on the BDD-YBOCS (p = < .001) with a large within-group effect size (Cohen's d = 2.01, 95% CI 1.05-2.97). At post-treatment, 82% of the patients were classified as responders (defined as ≥30% improvement on the BDD-YBOCS). These gains were maintained at the 3-month follow-up. Secondary outcome measures of depression, global functioning and quality of life also showed significant improvements with moderate to large effect sizes. On average, therapists spent 10 minutes per patient per week providing support.

Conclusion: The results suggest that BDD-NET has the potential to greatly increase access to CBT, at least for low-risk individuals with moderately severe BDD symptoms and reasonably good insight. A randomized controlled trial of BDD-NET is warranted. Clinicaltrials.gov registration ID: NCT01850433.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is the first to explore the feasibility and acceptability of a novel therapist-guided Internet-based (ICBT) program designed to dramatically increase access to CBT for patients with BDD.
- The uncontrolled nature of the study limits the possibility to make causal inferences as to what caused the observed changes.
- All participants were self-referred and hence particularly motivated for treatment.

INTRODUCTION

Body dysmorphic disorder (BDD) is characterized by an intense preoccupation with perceived defects in physical appearance that is accompanied, at some point during the occurrence of the disorder, by repetitive behaviors or mental acts, such as excessive mirror checking, in response to the appearance concerns. These concerns cause clinically significant distress or functional impairment and are not better explained by an eating disorder.[1] BDD is common, debilitating, associated with relatively high rates of psychiatric hospitalization and suicidality, and has a chronic and unremitting course if left untreated.[2-8] People suffering from BDD often seek non-psychiatric care due to perceived appearance flaws, such as dermatological treatment or plastic surgery.[9] However, these treatments rarely work, and can even result in the deterioration of the BDD symptoms.[9 10]

One treatment modality that has shown promise for BDD is cognitive behavioral therapy (CBT).[11 12] To our knowledge, only four randomized controlled trials (RCT) have been published to date. In the mid-90s, Rosen et al.[13] investigated the effect of group CBT, and Veale et al.[14] conducted a study of individual CBT for BDD with response rates of 81.5% and 78%, respectively. Recently, Wilhelm et al.[15] developed and published a multimodal treatment manual specifically designed for BDD that has been tested in one open trial and one wait-list controlled trial with large within-group effect sizes and response rates around 80-81%.[16 17] In the only RCT to employ a an active comparison group, Veale et al.[18] recently reported superiority of CBT compared to anxiety management, a credible psychological intervention primarily consisting of progressive muscle relaxation and breathing techniques, and a 52% response rate for CBT after 16 therapy sessions.

Despite the growing support for CBT and readily available treatment manuals,[15 19] numerous barriers to treatment exist. One of the biggest challenges of CBT is the restricted access, partly due to a lack of trained therapists, but also due to the direct and indirect costs associated with treatment.[20-22] In two online surveys, only 10 to 17% of people with body dysmorphic concerns reported that they had received an empirically supported psychotherapy (i.e. CBT), with a majority reporting that a major contributing factor for not seeking help was shame associated with talking openly about one's appearance concerns.[21 23] Furthermore, treatment barriers such as a lack of a specialised health care provider close by and logistic problems such as having to take

time off work in order to attend therapy were also reported.[21 23] Therefore, alternative ways of improving access to CBT are sorely needed.

One way to increase access to CBT is to administer the treatment using the Internet.[24 25] In the last decade, there has been a rapid development of Internet-based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are two main forms of ICBT: open access programs without any therapist guidance, and programs with therapist support that try to closely mimic the process of face-to-face CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of modules accompanied by homework assignments, reflecting the content of a traditional face-to-face therapy session. During the entire treatment, an identified therapist provides guidance and gives feedback through a built-in e-mail system. Thus, the therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in traditional CBT, the only difference being the way care is delivered. There is evidence that ICBT that incorporates therapist support may result in better treatment effects when compared to ICBT provided without such guidance.[30-32] Furthermore, in a recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there was no significant difference between the two treatment modalities, suggesting non-inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia, ICBT has already been implemented as part of their regular health care systems.[34-36]

With the primary aim to increase access to evidence based treatment for BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT program based on existing manuals,[15 19] and tested its feasibility and efficacy in an uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to patients, lead to a reduction of BDD and other psychiatric symptoms, and require minimal therapist input.

METHOD

Participants

The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD. Participant demographics and clinical characteristics are presented in Table 1. The most

common body areas of concern reported by at least 50% of the participants at baseline included: face (i.e., shape or size) 18 (78%), skin 14 (61%), part of the face (e.g., nose, ears, eyes) 14 (61%), hair 13 (57%), and weight 12 (52%).

Information about the study was posted on the official web page of the clinic (www.internetpsykiatri.se), and flyers were distributed to mental health professionals. The study was also mentioned in a national newspaper that ran a three-part article series about BDD. A total of 66 individuals were considered for eligibility (see Figure 1). To be eligible for the study participants had to be at least 18 years of age, outpatients, and diagnosed with primary DSM-5 BDD, and currently living in Stockholm or Uppsala county. As this was a pilot study exploring the feasibility of BDD-NET, geographic proximity was required to facilitate in person assessments, and the opportunity to intervene in case of safety concerns.

Exclusion criteria were psychotropic medication changes within two months prior to enrolment, completed CBT for BDD within the last 12 months, a score on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder (BDD-YBOCS) of ≤ 16, current substance dependence, lifetime bipolar disorder or psychosis, acute suicidal ideation, a personality disorder that could jeopardize treatment participation (e.g., borderline personality disorder with self-harm), or concurrent psychological treatment. Participants who were taking psychotropic medication, and had been on a stable dose for at least 2 months prior to enrolment were asked to not change their medication during the study period. After a complete description of the study, written informed consent was obtained from all the participants. The regional ethical review board in Stockholm, Sweden approved the study ID: 2013/117-31/2. Clinicaltrials.gov registration ID: NCT01850433.

<INSERT FIGURE 1 ABOUT HERE>

<INSERT TABLE 1 ABOUT HERE>

Procedure

In the first stage of the recruitment process, potential participants were instructed to complete an online screening consisting of Montgomery-Åsberg Depression Rating Scale, Self-report (MADRS-S),[37] Alcohol Use Disorders Identification Test

(AUDIT),[38] Drug User Disorders Identification Test (DUDIT),[39] Dysmorphic Concerns Questionnaire (DCQ),[40] and Body Dysmorphic Disorder Dimensional Scale (BDD-D).[41] All participants who completed the screening were contacted by telephone and assessed for BDD. Twenty-six individuals were invited to the clinic for an in-person assessment by either a psychiatrist or a licensed psychologist. The Mini-International Neuropsychiatric Interview (M.I.N.I.)[42] was used to determine the presence of any DSM-IV-TR Axis-I disorders. A more in depth interview with the BDD Diagnostic Module was conducted to establish the diagnosis of DSM-5 BDD.[43] The questions used in this semi-structured interview were orignially designed for DSM-IV-TR criteria and are similar to those used in the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I).[44] A question about the presence of repetitive behaviors was added to reflect the DSM-5 criteria for BDD and the new DSM-5 insight specifiers was also used to determine degree of insight regarding body dysmorphic beliefs (i.e., good or fair insight, poor insight and absent insight/delusional beliefs). The assessors had several years of experience administering structured interviews, such as the BDD-YBOCS, and had undergone extensive training in using the M.I.N.I. However, inter-rater reliablity of the BDD-YBOCS was not established in this study.

Measures

Participants were assessed with both clinician and self-report measures at pre-treatment, post-treatment and at the three-month follow-up. In addition, the BDD-D and MADRS-S were administered weekly to monitor progress and suicide risk.

Questionnaires used in this trial have previously been translated into Swedish and gone through a rigorous back-translation process to check for any inconsistencies.

The primary outcome of interest was BDD symptom severity as measured with the clinician-administered BDD-YBOCS. The self-report measures were administered online, a method which has previously been shown to be as reliable and valid as pen-and-paper administration.[45-47]

Clinician-rated instruments

Yale-Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS)

The BDD-YBOCS[48] can be considered the gold standard for assessing symptom severity and impairment associated with BDD. It is a clinician administered semi-

structured interview consisting of 12 items; each rated on a scale from 0-4, which measures symptom severity during the last seven days, in the form of intrusive thoughts (5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe symptoms. BDD-YBOCS has shown high test-retest reliability (r = .88) and internal consistency (α = .80).[48] An empirically defined cut-off point of a 30 % reduction on the BDD-YBOCS was used to determine responder status at post-treatment.[49] To investigate specific treatment effects on insight, the item of the BDD-YBOCS relating to insight was also reported separately.

Clinical Global Impression (CGI)

The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal) to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was determined to indicate responder status in this study. CGI has shown good reliability and validity for a range of psychiatric disorders.[51 52]

Global Assessment of Functioning (GAF)

The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from 0 to 100 and is used to assess social, occupational, and psychological functioning, with a higher score indicating better health. Overall reliability of the GAF is good, but questions regarding its validity have been raised; see Aas 2010 for a review.[54]

Self-administered measures

Body Dysmorphic Dimensional Scale (BDD-D)

The BDD-D[41] is a self report measure of symptom severity developed alongside the DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and repetitive behaviors, distress, control over symptoms, avoidance, and interference; each rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20. High internal consistency has been reported (α = .80), though further validation work is warranted.[41]

Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)

The MADRS-S[37] is the self-report version of the Montgomery-Åsberg Depression Rating Scale (MADRS)[55], and measures severity of depression. The scale consists of 9 items, each measuring a different symptom (mood, feelings of unease, sleep, appetite, ability to concentrate, initiative, emotional involvement, pessimism, and suicidal ideation) on a seven-point scale with a total score ranging from 0 to 54. Good to excellent test-retest reliability have been reported (r = .80 - .94)[37], as well as a high correlation (r = .87) between the MADRS-S and the Beck Depression Inventory in a comparative study.[56]

Skin Picking Scale-Revised (SPS-R)

As skin picking is common among persons diagnosed with BDD we used the SPS-R[57] to assess skin picking severity and impairment. The SPS-R is a self-report measure that consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g., extreme). Good internal consistency (α = .83) as well as discriminant and convergent validity have been reported.[57]

Body Image Quality of Life Inventory (BIQLI)

The BIQLI[58] is a self-report measure that consists of 19 items with a 7-point scale ranging from -3 (very negative effect) to +3 (very positive effect) that assesses the impact of body image on various aspects of life (e.g., sexuality, emotional wellbeing, and relations). The total score ranges from -57 to +57. A positive score indicates that one's body image has a positive impact on quality of life, and vice versa. High test-retest (r = .79) and internal consistency (α = .94-95) have been reported.[58 59]

Safety procedures and adverse events

As mentioned earlier, participants with active suicidal ideation were not included in the trial. However, suicidal ideation is common among patients diagnosed with BDD and the following precautions were taken in order to detect patients that could deteriorate during treatment. All participants underwent a structured clinical interview assessing suicidal ideation before starting treatment. Throughout the entire treatment, MADRS-S was administered weekly and participants who, at any time throughout the treatment period, scored > 4 on item 9, which measures suicidal ideation, were immediately

contacted by their therapist. If the patient were in need of additional care, an appointment was made with either a senior psychiatrist at the clinic, or at an emergency psychiatric unit.

Adverse events (AE) were recorded mid-treatment and at post-treatment in accordance with guidelines presented by Rozental et al.[60]. AE were defined as negative events that could have occurred due to treatment participation (e.g., deterioration of target symptoms, worse sleep, and general negative well-being such as stress). Participants were asked if they had experienced any AE that they associated with the intervention (yes/no). If yes, the participants were asked to describe the event in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no impact) to 3 (severely negative impact) at the time that the AE had occurred (retrospective self-reports), and if the AE still had a negative impact on well-being at present. A licensed psychologist reviewed the AE reported.

Treatment

The BDD-NET program was delivered via a tailored online platform, using a dedicated server with encrypted traffic and a strong authentication login function in order to guarantee participant confidentiality. The user interface of the platform used for BDD-NET has been designed so that it can be used in any language. The 12-week long treatment was based on a CBT model for BDD, emphasizing the role of avoidance and safety behaviors as maintaining factors of BDD.[15] Most existing treatment protocols for BDD involve a larger number of face-to-face sessions, ranging from 12 to 22.[17 18] However, considering the format of ICBT (where therapists often make several contacts during the week), as well as previous ICBT research in OCD showing that 10 weeks of treatment yields the same results as 15 weeks of treatment, a 12-week long treatment was deemed appropriate.[26 61]

A central part of the treatment was a self-help text of 104 pages divided into 8 modules (with modules 1–4 containing the core treatment components). The self-help text underwent several revisions, and was reviewed by licensed psychologists with previous experience of either ICBT or obsessive-compulsive and related disorders. Each module was devoted to a special theme and included information and homework assignments. The participants were given consecutive access to the next module after correctly answering a quiz about the material that they had read, as well as filling out at

least one worksheet corresponding to the homework assignment given in the module. See Table 2 for a summary of the treatment modules and the number of participants completing each module. The participant had contact with an identified therapist throughout the whole treatment using a built-in e-mail system on the BDD-NET webpage. The two therapists providing the treatment were both licensed psychologists with several years of experience in treating obsessive-compulsive and related disorders. To ensure treatment integrity and adherence to protocol, a licensed psychologist monitored the messages sent by the therapists throughout the entire treatment. Participants had unlimited access to the therapist and could use the e-mail system at any time. The role of the therapist was mainly to guide and coach the participant through the treatment, provide feedback on homework assignments, answer questions from the participants, and consecutively grant access to the next treatment module. The therapist also acted proactively by sending e-mails to participants asking them to report on treatment progress. The participants were notified by an automated text-message (SMS) when they had a new e-mail in the treatment platform. All homework assignments and questions from the participants were reviewed and answered within 36 hours, except on weekends. Participants were randomised using random.org to one of two therapists, both licensed psychologists, with previous experience of treating obsessive-compulsive and related disorders. The duration of therapist contact was automatically recorded by the ICBT platform. None of the participants had face-to-face contact with a therapist.

<INSERT TABLE 2 ABOUT HERE>

Statistical analysis

The primary analyses were done according to intention-to-treat (ITT) including the full sample of 23 participants. Missing data at post-treatment and follow-up assessment were deemed to be missing at random (using logistic regression models, as well as inspecting correlations between indicator variables of missingness and other variables from the dataset that might predict missingness) and imputed using multiple imputation by chained equations.[62] All estimates with standard errors were pooled from five imputations using "Rubin's rules"[63] and the small sample correction for pooled degrees of freedom.[64] Paired *t*-tests were performed to assess if changes from pretreatment to post-treatment and pretreatment to follow-up were statistically

significant. Paired *t*-tests comparing post-treatm ent to follow-up were also performed to test for maintenance of the therapeutic gains. Within-group effect sizes were calculated by dividing the difference between pre-treatment and post-treatment scores by the within-group pooled standard deviation.[65] Fisher's exact test was used to examine weather there was an association between the occurrence of an AE and treatment responder status and independent *t*-tests were used to examine specific therapist effects. All data were analyzed with Stata statistical software, version 13.1[66] and the threshold for statistical significance set at the standard 5%.

RESULTS

Attrition

The participant flow throughout the trial is shown in Figure 1. One participant terminated treatment during the first week due to reported personal problems and did not complete any of the modules and was therefore regarded as a dropout, but was kept in the primary analysis according to the ITT principles. The post-treatment and 3-month follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants, respectively. Self-rated questionnaires administered online were completed by 20 (87 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-up.

Primary and secondary outcomes

Means, standard deviations, and within- group effect sizes, including confidence intervals, for all assessment points with missing values replaced by multiple imputation are reported in Table 3. Paired t-tests showed significant changes on all measures from pre- to post-treatment (t(df = 13.72 – 20.15) = 3.10 – 7.54, all p-values < .01), and from pretreatment to follow-up (t(df = 10.96 – 19.24) = 3.13 – 8.66, all p-values < .01). On the main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size was d = 2.01, and the pre-treatment to follow-up effect size indicated sustained effects (d = 2.04).

At posttreatment, 82% of completers were responders (≥ 30 % decrease on the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).

The significant pre- to post-treatment improvement on the BDD-YBOCS insight item was in the large range ($t(18.44) = 4.30$, p = < .001, $d = 1.07$). Weekly scores and follow-up data on the self-reported BDD-D are presented in Figure 2.

<<INSERT FIGURE 2 ABOUT HERE>>

The distribution of CGI-I scores for completers at posttreatment and follow-up, respectively, was as follows: very much improved, 41 % and 52 %; much improved, 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At posttreatment and follow-up, 64 % and 71 % were responders (very much or much improved), respectively.

On the other outcome measures, the within-group effect sizes from pretreatment to posttreatment and pretreatment to follow-up were in the moderate to large range (d = .55 – 1.82).

<INSERT TABLE 3 ABOUT HERE>

Adverse events

In total, 11 (48%) participants reported that they had experienced AE during the course of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g., nightmares, depressive symptoms and worse sleep), followed by a deterioration of symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus on appearance), and general negative well-being (29%, e.g., stress). The AE reported occurred mostly during the first part of the treatment, and most participants rated the negative impact of the AE as moderate (*Median* = 2, *M* = 1.8, *SD* = 1.1) when they occurred, and as no longer having a negative impact at posttreatment (*Median* = 0, *M* = .7, *SD* = 1.6) with the exception of one participant who reported that the treatment had led to an increase in appearance concerns and more frequent intrusive thoughts compared to baseline, and was classified as a non-responder at post-treatment. The occurrence of AE during treatment was unrelated to responder status at post-treatment, with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-responders (Fisher's exact test = 0.59).

During treatment, one participant became increasingly depressed and was referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after which treatment continued.

Treatment activity and acceptability

The mean number of messages that the participants sent to and received from their therapist was 22.6 (*SD* = 12.2, range 0–47), and 30.2 (*SD* = 11.3, range 3–51), respectively, and the therapists spent a weekly mean of 10.3 minutes (*SD* = 6.7, range 1.8–35.2), per participant. No significant differences were noted in time spent providing support ($t(21) = 1.19$, $p = .25$, $d = 0.5$ 95% CI -0.39-1.39), or in treatment effects between the two therapists ($t(21) = -.60$, $p = .56$, $d = -0.26$ 95% CI -1.11-0.60).

In total, 19 (83%) participants completed the core components of the treatment programme (modules 1–4), and six participants completed all eight of the modules (26 %). The mean number of completed modules was 5.5 (*SD* = 2.35, range 0–8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the treatment, for example doing exercises in vivo and reading material online.

At posttreatment, 6 (30%) participants reported that they were very pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was somewhat displeased with the treatment provided. One participant did not answer the satisfaction question.

All participants on psychotropic medication prior to treatment had kept their dose stable during treatment, and none had received any other type of psychological intervention. In total, 5 (22%) participants reported that they had received additional care at the 3-month follow-up. Of the participants receiving additional care, four were non-responders according to the CGI-I at post-treatment, and all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT, respectively, two participants had been prescribed an SRI (of which one was prescribed for an indication other than BDD), and one participant had increased the dose of current SRI.

DISCUSSION

This study explored the feasibility and acceptability of a novel therapist-guided ICBT program designed to increase access to CBT for patients with BDD. In general the participants felt that BDD-NET was highly acceptable. A significant improvement was seen on the main outcome measure (clinician-rated BDD-YBOCS), with a large effect size, and 82% of the participants classed as responders at post-treatment. These treatment effects were maintained at the three-month follow-up. Clinician-rated insight also improved from pre- to post-treatment. Secondary outcome measures of depression, skin picking, global functioning and body image-related quality of life showed significant improvements from pre- to post-treatment, and from pre-treatment to follow-up, with moderate to large effect sizes.

In general, the results are in line with other trials investigating the effects of individual CBT for BDD delivered in specialized clinic settings.[16-18] However, direct comparisons with previous trials should be made with caution, because ours was a self-referred and moderately ill patient group with relatively good insight. Some research has shown that the source of patient referral may have a bearing on the types of patients seen and the degree of clinical improvement with computerized or internet-based therapies, with patients referred by mental health professionals having more comorbidity, being less motivated for treatment and achieving more modest outcomes, compared to self-referrals or referrals from general practitioners.[67]

A comparison of the demographic and clinical characteristics of our sample with those of two recently published RCTs appears in Table 4. A cut-off of 16 on the BDD-YBOCS was used for entry into the study, which would represent minimal symptoms. However, only one participant had a score on the BDD-YBOCS below 22, and the range of baseline BDD-YBOCS scores was 16-42, and the score median was 30. Thus, our sample had moderate to severe symptoms. Despite having moderate to severe BDD symptoms, our predominantly female, self-referred sample might have been particularly motivated to engage in psychological treatment, compared to the average BDD patient seen in specialist settings. The proportion of patients with absent or delusional insight also appears to be lower in this sample compared to the proportions seen in specialist clinic samples. Furthermore, though the rates of comorbid disorders were similar, on average, our participants endorsed mild depressive symptoms, compared to the

moderate to severe depressive symptoms reported in the trials published by Wilhelm et al.[17] and Veale et al.[18].

ICBT should not be seen as a substitute for traditional face-to-face treatment but, rather, a clinician extender that may substantially increase access to evidence based treatment for a large proportion of sufferers who are not currently receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input will be required for complex patients who have poor insight and high suicide risk. In this regard, BDD-NET may be particularly useful in the context of stepped-care for BDD, where low-risk patients with reasonably good insight are offered ICBT and non-responders or more complex and risky patients are offered more intensive, clinic based CBT alone or in combination with medication.

<INSERT TABLE 4 ABOUT HERE>

Participants in this trial made marked improvements despite no face-to-face contact, beyond the baseline, post-treatment and follow-up assessments. Although the treatment is Internet-based, the mechanisms of change may be the same as in traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still instructed to expose him or herself to feared stimuli in vivo without using maladaptive coping strategies. Each participant had the same identified therapist throughout the entire treatment, and although therapist contact was only around 10 minutes per participant and week, the therapist sent a mean number of 30.2 messages per participant, which averages out to 2-3 contacts per week. Messages sent from the therapist were usually short, with prompts to the participant to engage in ERP and report the outcome, allowing for adjustment of exposure strategies when needed. Thus, the therapist was proactive and had shorter, but more frequent contact with participants compared to traditional CBT, where sessions usually are held once a week. Despite minimal therapist contact, participants often report the feeling of a therapist presence; the therapists' frequent encouragement to engage in daily ERP may be a critical component of the intervention.[32]

In total, 48% of the participants experienced an adverse event during treatment. However, the adverse events were mostly mild, and non-enduring, and a vast majority of participants were very pleased or pleased with the treatment provided. Most

(83%) of the participants completed all of the core treatment components and engaged in ERP, suggesting that the treatment was engaging and highly acceptable. The treatment completion rate is in line with previous ICBT studies of various disorders, suggesting that ICBT is as acceptable for patients with BDD as it is for other patient groups (e.g., OCD, SAD, and MDD).[26 27]

Stigma, shame and logistic barriers can be a hindrance for persons with BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is online; this could reduce initial shame and stigma associated with openly talking about one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the clinic while receiving CBT and has the potential to minimize logistic barriers and increase access to evidence-based care in rural areas or where trained therapists are not available. Furthermore, one therapist can have more patients in treatment at the same time compared to face-to-face therapy, while spending less time per patient as the routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT format has the potential to lower the severity threshold for people with BDD to seek and receive adequate treatment. Expert clinicians can dedicate more time and resources to complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is protocol based and delivered as a series of modules online. This greatly reduces the risk of therapist drift,[68] and ensures that all patients receive exactly the same treatment. The control over content delivered also opens up for dismantling studies, as modules can easily be added or taken out to test the specific effect of a treatment component, as shown by Ljótsson et al.[69] where the specific effect of systematic exposure on Irritable Bowel Syndrome symptoms was tested.

This study has several limitations that need to be considered when interpreting the results. First and foremost, this was an uncontrolled trial. This limits the possibilities to make causal inferences as to what caused the observed changes. The improvements observed over the course of treatment could have been due to the mere passage of time. However, when considering the chronicity of BDD,[8 70] we regard it as unlikely that the treatment effects in this trial could be entirely explained by spontaneous remission. Furthermore, the improvements observed could also be due to unspecific factors, such as caregiver attention. However, the maintenance of improvement from post-treatment to follow-up indicates that treatment gains were temporally stable, and the majority of participants did not receive any further treatment.

Due to safety concerns, the presence of severe suicidal ideation and substance dependence, both of which are common comorbidities in BDD, were criteria for exclusion. Thus, it is unknown if BDD-NET would be appropriate for patients with these comorbidities. The insight item on the BDD-YBOCS was used to assess change in insight before and after treatment; other available instruments such as the Brown Assessment of Beliefs Scale (BABS)[71] may have provided a more precise and sensitive measure of overvalued ideation. Both therapists in the study had previous experience of treating BDD, and although the essential components of the treatment are delivered as online modules, there could be a specific therapist factor as the therapists answered questions and gave treatment guidance through the integrated e-mail system. It is unknown if the same outcomes would be obtained with less experienced therapists.

Despite the limitations of this uncontrolled trial, the results suggest that BDD-NET has the potential to reduce symptoms and increase access to CBT for a large majority of moderately ill patients with BDD who are motivated to receive treatment. A randomized controlled trial of BDD-NET is warranted.

ACKNOWLEDGEMENTS

We would like to thank Monica Hellberg, Sofia Eriksson, Vania Panes Lundmark and Kayoko Isomura for their invaluable help.

AUTHOR'S CONTRIBUTIONS

JE was the project manager and participated in designing the study, analyzing data, providing treatment, and drafting the manuscript and the treatment manual. VI participated in designing the study, providing treatment and drafting the manuscript and the treatment manual. EA participated in designing the study and drafting the manuscript and the treatment manual. DMC participated in drafting the manuscript and designing the study. BL participated in designing the study, analyzing data and drafting the manuscript and the treatment manual. CR participated in designing the study and drafting the treatment manual and the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

None declared.

FUNDING

Financial support was provided through the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet. The Swedish Research Council and the Swedish Society of Medicine (Söderströmska Königska sjukhemmet) provided funding for this study.

DATA SHARING

No additional data available.

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Table 1. Socio-demographic and clinical characteristics of the sample (*N* = 23)

Variable	Mean/*n*	SD/%
Age in years (Mean, *SD*)	30.3	(6.3)
Female (*n*, %)	16	(70%)
Employment status (*n*, %)		
Employed	14	(61%)
Unemployed	4	(17%)
Student	5	(22%)
Married (*n*, %)	7	(30%)
Education (*n*, %)		
High school	16	(70%)
University college	7	(30%)
Previous psychological treatment (*n*, %)	12	(52%)
Previous use of psychotropic medication (*n*, %)	11	(48%)
Current use of psychotropic medication (*n*, %)	7	(30%)
Years with BDD symptoms (Mean, *SD*)	15.3	(8.1)
Number of body areas of concern (Mean, *SD*)	6	(3)
BDD-5 insight specifier (*n*, %)		
Good or fair insight	10	43%
Poor insight	11	(48%)
Absent/delusional beliefs	2	(9%)
Current comorbidity (*n*, %)		
Major depressive disorder	10	(43%)
Panic disorder	1	(4%)
Social anxiety disorder	5	(22%)
Obsessive-compulsive disorder	2	(9%)
Bulimia nervosa	2	(9%)
Generalized anxiety disorder	1	(4%)

Table 2. Description of consecutive treatment modules and the number of participants completing each module

Module	Contents	No. of participants[a]
1.	Psychoeducation: Introduction the treatment and information about BDD such as prevalence, known etiology, and common symptoms. Different fictional patient characters are introduced and used as examples to help clarify the treatment components throughout the treatment. Participants begin to register BDD-related behaviors and thoughts in an online diary.	22 (96%)
2.	A cognitive-behavior conceptualization: Explanation of how self-defeating thoughts and BDD related avoidance and safety behaviors maintain appearance concerns and fears. Participants learn how to conduct a functional analysis of how their own BDD symptoms are maintained.	21 (91%)
3.	Cognitive restructuring: A more in-depth rationale for how self-defeating thoughts and maladaptive thinking maintains BDD symptoms. Participants evaluate negative thoughts and engage in cognitive restructuring using online worksheets.	21 (91%)
4.	Exposure and response prevention (ERP): Explanation of exposure and different strategies for conducting response prevention is presented. Participants set treatment goals and conduct their first in vivo ERP exercise. ERP continues during the remainder of treatment, and participants continuously assess outcome of ERP using an online worksheet.	19 (83%)
5.	More on ERP: Different aspects of ERP are highlighted and a more in-depth explanation is given on how to work with ERP over time.	14 (61%)
6.	Values-based behavior change: Participants identify values-based long-term goals within the domains of relationships, career, and leisure activities. An accepting stance towards negative thoughts and experiences is proposed as an alternative to attempts to control these experiences, while at the same time engaging in meaningful values-based activities.	13 (57%)
7.	Difficulties during treatment: Commonly encountered difficulties during treatment such as loss of motivation and problems integrating exercises into daily schedule are presented and discussed, as well as common obstacles associated with ERP and how to overcome them.	10 (44%)
8.	Relapse prevention: How to handle relapses into avoidance behaviors and repetitive behavior. The participants also summarize the main lessons learned, what has been gained through the treatment and their future plans.	6 (27%)

Note. [a] *Defined as doing the homework associated with each module.*

Table 3. Primary and secondary outcome measures

							Within-group effect size *d*								
	Pre-treatment		Post-treatment		3-month follow-up[a]		Pre to post[a]			Pre to follow-up[a]			Post to follow-up[a]		
Measure	M	SD	M	SD	M	SD	*d*	CI-	CI+	*d*	CI-	CI+	*d*	CI-	CI+
BDD-YBOCS	30.78	6.24	15.70	8.48	13.85	9.57	**2.01**	1.05	2.97	**2.04**	1.18	2.91	**0.20**	-0.14	0.54
BDD-YBOCS i	2.17	0.89	1.42	0.83	1.22	0.91	**0.88**	0.34	1.42	**1.07**	0.39	1.74	**0.23**	-0.24	0.70
BDD-D	13.09	3	7.67	4.03	6.38	4.19	**1.51**	0.62	2.41	**1.82**	0.96	2.68	**0.31**	0.01	0.61
MADRS-S	17.91	8.22	10.23	7.52	11.74	10.17	**0.97**	0.47	1.48	**0.65**	0.18	1.11	**-0.15**	-0.42	0.11
SPS-R	8.83	7.31	4.91	6.78	4.53	6.31	**0.55**	0.15	0.96	**0.63**	0.18	1.07	**0.06**	-0.14	0.25
BIQLI[b]	-27.26	13.38	-10.83	17.36	-11.11	19.66	**1.05**	0.35	1.75	**0.96**	0.17	1.75	**-0.02**	-0.32	0.29
GAF	49.87	7.23	61.75	8.85	63.21	9.05	**1.47**	0.69	2.25	**1.62**	0.90	2.33	**0.16**	-0.09	0.42

Note. BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD. BDD-YBOCS i, Yale-Brown Obsessive Compulsive Scale Modified for BDD insight item. BDD-D, Body Dysmorphic Disorder Dimensional Scale. MADRS-S, Montgomery-Åsberg Depression Rating Scale, self-report. SPS-R, Skin Picking Scale Revised. BIQLI, Body Image Quality of Life Inventory. GAF, Global Assessment of Functioning Scale. Effect sizes are reported with 95% confidence intervals.

[a] Pooled estimates based on multiple imputation.

[b] Higher scores indicate better health. Sign of effect sizes changed for clarity.

Table 4. Baseline characteristics of patients in the current study, compared to two recent RCTs of CBT for BDD

Variable	BDD-NET	Veale et al. 2014	Wilhelm et al. 2014[a]
Age in years	30.3 (6.3)	Median = 30	33.2 (11.4)
Female	70%	57%	53%
Employed	61%	46%	65%
Referral	Self-referred	Primary or secondary care	Self-referred
BDD-YBOCS	30.78 (6.24)	35.48 (6.61)[a]	32.5 (3.2)
Delusional BDD	9%	54%	n/a
BABS	n/a	18.24 (4.68)[a]	14.1 (3.9)
MADRS	17.91 (8.22)	28.57 (10.69)[a]	n/a
BDI	n/a	n/a	22.4 (14)
Current comorbidity			
MDD	43%	44%	47%
SAD	22%	11%	24%
OCD	9%	4%	6%
Current use of medications	30%	46%	71%

Note. Values denote means ± SD unless otherwise specified.

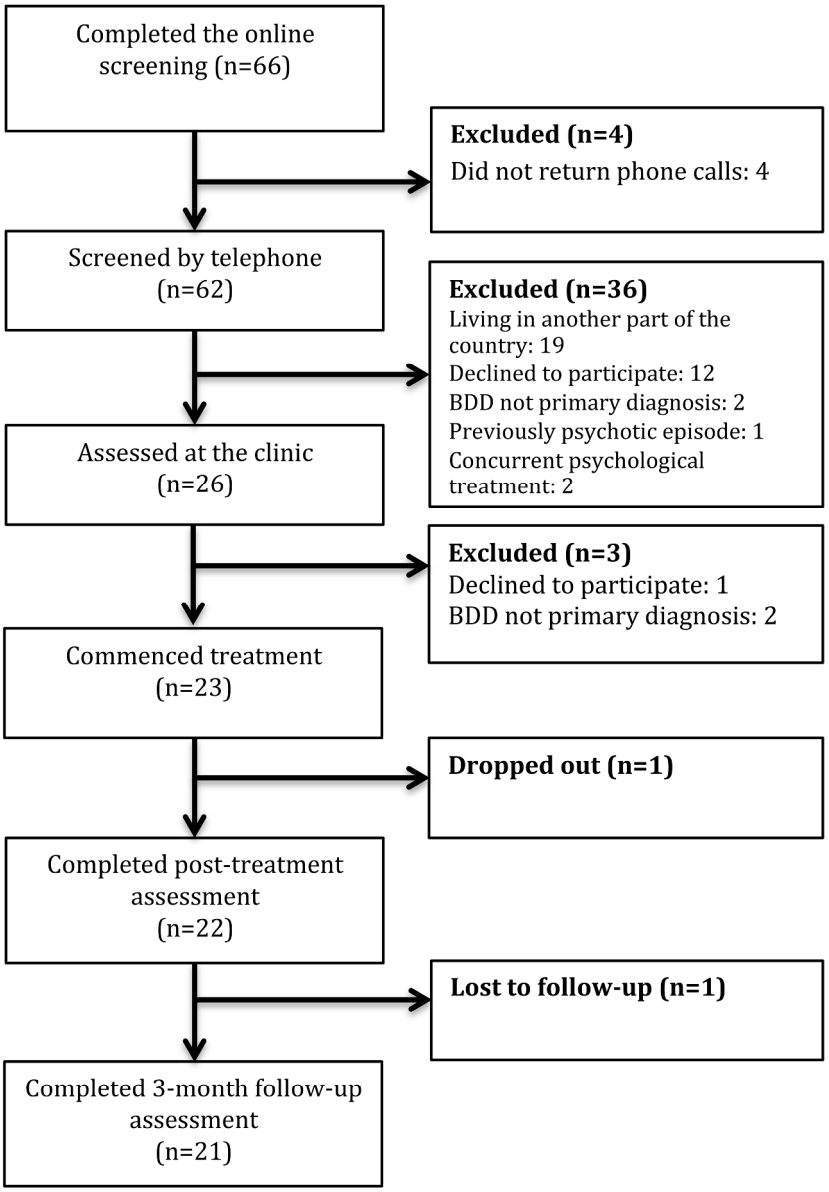
BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD; BABS, Brown Assessment of Beliefs Scale; MADRS, Montgomery-Åsberg Depression Rating Scale; BDI, Beck Depression Inventory.

[a] Participant characteristics of those randomised to CBT.

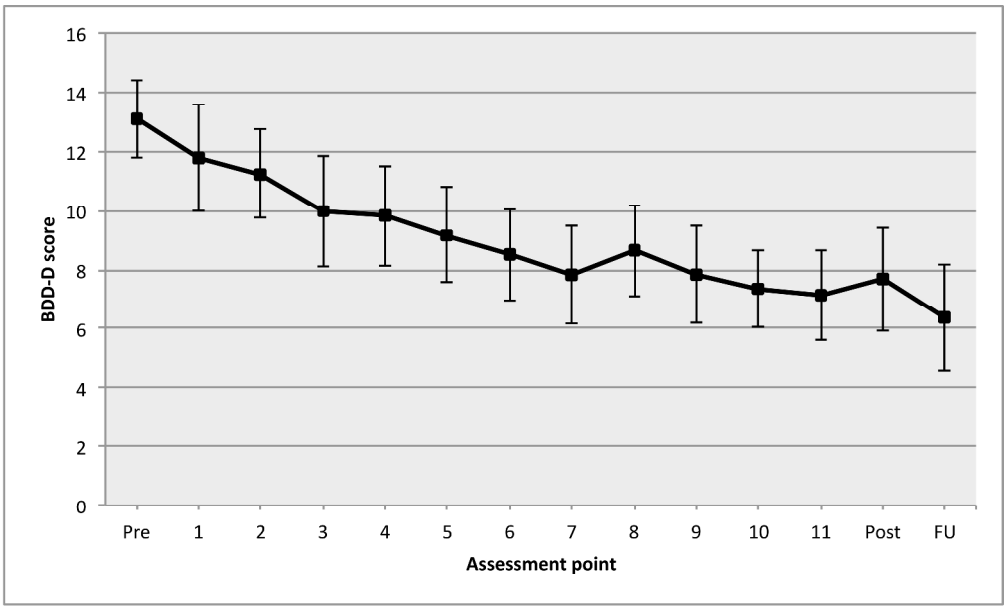
FIGURE LEGEND

Figure 1: Participant flow through the study

Figure 2: Weekly scores on the self-administered Body Dysmorphic Disorder Dimensional Scale, BDD-D (including 95 % confidence intervals)



Participant flow through the study.



Weekly scores on the self-administered Body Dysmorphic Disorder Dimensional Scale, BDD-D (including 95 % confidence intervals)