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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 $\geq 30\%$ 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.

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3 **Conclusion:** The results suggest that BDD-NET has the potential to greatly improve
4 access to CBT, at least for low-risk individuals with moderately severe BDD symptoms
5 and reasonably good insight. A randomized controlled trial of BDD-NET is warranted.
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8 Clinicaltrials.gov registration ID: NCT01850433.
9

10 11 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

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

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3 time of work in order to attend therapy were also reported.[21 23] Therefore,
4 alternative ways of improving access to CBT are sorely needed.
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6 One way to increase access to CBT is to administer the treatment using the
7 Internet.[24 25] In the last decade, there has been a rapid development of Internet-
8 based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range
9 of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety
10 disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are
11 two main forms of ICBT: open access programs without any therapist guidance, and
12 programs with therapist support that try to closely mimic the process of face-to-face
13 CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of
14 modules accompanied by homework assignments, reflecting the content of a traditional
15 face-to-face therapy session. During the entire treatment, an identified therapist
16 provides guidance and gives feedback through a built-in e-mail system. Thus, the
17 therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in
18 traditional CBT, the only difference being the way care is delivered. There is evidence
19 that ICBT that incorporates therapist support may result in better treatment effects
20 when compared to ICBT provided without such guidance.[30-32] Furthermore, in a
21 recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there
22 was no significant difference between the two treatment modalities, suggesting non-
23 inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia,
24 ICBT has already been implemented as part of their regular health care systems.[34-36]

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

51 **Participants**

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55 The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD.
56 Participant demographics and clinical characteristics are presented in Table 1.
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3 Information about the study was posted on the official web page of the clinic
4 (www.internetpsykiatri.se), and flyers were distributed to mental health professionals.
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6 The study was also mentioned in a national newspaper that ran a three-part article
7 series about BDD. A total of 66 individuals were considered for eligibility (see Figure 1).
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9 To be eligible for the study participants had to be at least 18 years of age, outpatients,
10 and diagnosed with primary DSM-5 BDD. Exclusion criteria were psychotropic
11 medication changes within two months prior to enrolment, completed CBT for BDD
12 within the last 12 months, a score on the Yale-Brown Obsessive Compulsive Scale
13 Modified for Body Dysmorphic Disorder (BDD-YBOCS) of ≤ 16 , current substance
14 dependence, lifetime bipolar disorder or psychosis, acute suicidal ideation, a personality
15 disorder that could jeopardize treatment participation, or concurrent psychological
16 treatment. Participants who were taking psychotropic medication, and had been on a
17 stable dose for at least 2 months prior to enrolment were asked to not change their
18 medication during the study period. The regional ethical review board in Stockholm,
19 Sweden approved the study ID: 2013/117-31/2. Clinicaltrials.gov registration ID:
20 NCT01850433.
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31 <INSERT FIGURE 1 ABOUT HERE>

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33 34 35 36 37 **Procedure**

38 In the first stage of the recruitment process, potential participants were instructed to
39 complete an online screening consisting of Montgomery-Åsberg Depression Rating
40 Scale, Self-report (MADRS-S),[37] Alcohol Use Disorders Identification Test
41 (AUDIT),[38] Drug User Disorders Identification Test (DUDIT),[39] Dysmorphic
42 Concerns Questionnaire (DCQ),[40] and Body Dysmorphic Disorder Dimensional Scale
43 (BDD-D).[41] All participants who completed the screening were contacted by
44 telephone and assessed for BDD. Twenty-six individuals were invited to the clinic for an
45 in-person assessment by either a psychiatrist or a licensed psychologist. The Mini-
46 International Neuropsychiatric Interview (M.I.N.I.)[42] was used to determine the
47 presence of any DSM-IV-TR Axis-I disorders. A more in depth interview with the BDD
48 Diagnostic Module was conducted to establish the diagnosis of DSM-5 BDD.[43] The
49 questions used in this semi-structured interview were originally designed for DSM-IV-
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3 TR criteria and are similar to those used in the Structured Clinical Interview for DSM-IV
4 Axis I Disorders (SCID-I).[44] A question about the presence of repetitive behaviors was
5 added to reflect the DSM-5 criteria for BDD and the new DSM-5 insight specifiers were
6 also used to determine degree of insight regarding body dysmorphic beliefs (i.e., good or
7 fair insight, poor insight and absent insight/delusional beliefs). The assessors had
8 several years of experience administering structured interviews, such as the BDD-
9 YBOCS, and had undergone extensive training in using the M.I.N.I.
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15 16 17 **Measures**

18 Participants were assessed with both clinician and self-report measures at pre-
19 treatment, post-treatment and at the three-month follow-up. In addition, the BDD-D and
20 MADRS-S were administered weekly to monitor progress and suicide risk. The primary
21 outcome of interest was BDD symptom severity as measured with the BDD-YBOCS. The
22 self-report measures were administered online, a method which has previously been
23 shown to be as reliable and valid as pen-and-paper administration.[45-47]
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30 31 **Clinician-rated instruments**

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

33 The BDD-YBOCS[48] can be considered the gold standard for assessing symptom
34 severity and impairment associated with BDD. It is a clinician administered semi-
35 structured interview consisting of 12 items; each rated on a scale from 0-4, which
36 measures symptom severity during the last seven days, in the form of intrusive thoughts
37 (5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score
38 on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe
39 symptoms. BDD-YBOCS has shown high test-retest reliability ($r = .88$) and internal
40 consistency ($\alpha = .80$).[48] An empirically defined cut-off point of a 30 % reduction on the
41 BDD-YBOCS was used to determine responder status at post-treatment.[49] To
42 investigate specific effects on insight, the item of the BDD-YBOCS relating to insight was
43 also reported separately.
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53 *Clinical Global Impression (CGI)*

54 The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and
55 clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal)
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3 to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very
4 much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was
5 determined to indicate responder status in this study. CGI has shown good reliability
6 and validity for a range of psychiatric disorders.[51 52]
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10 11 *Global Assessment of Functioning (GAF)*

12 The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from
13 0 to 100 and is used to assess social, occupational, and psychological functioning, with a
14 higher score indicating better health. Overall reliability of the GAF are good, but
15 questions regarding its validity have been raised, see Aas 2010 for a review.[54]
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20 21 **Self-administered measures**

22 *Body Dysmorphic Dimensional Scale (BDD-D)*

23 The BDD-D[41] is a self report measure of symptom severity developed alongside the
24 DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and
25 repetitive behaviors, distress, control over symptoms, avoidance, and interference; each
26 rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20.
27 High internal consistency has been reported ($\alpha = .80$), though further validation work is
28 warranted.[41]
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37 *Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)*

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

54 As skin picking is common among persons diagnosed with BDD we used the SPS-R[57]
55 to assess skin picking severity and impairment. The SPS-R is a self-report measure that
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3 consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g.,
4 extreme). Good internal consistency ($\alpha = .83$) as well as discriminant and convergent
5 validity have been reported.[57]
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8 9 *Body Image Quality of Life Inventory (BIQLI)*

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

24 As mentioned earlier, participants with active suicidal ideation were not included in the
25 trial. However, suicidal ideation is common among patients diagnosed with BDD and the
26 following precautions were taken in order to detect patients that could deteriorate
27 during treatment. All participants underwent a structured clinical interview assessing
28 suicidal ideation before starting treatment. Throughout the entire treatment, MADRS-S
29 was administered weekly and participants who, at any time throughout the treatment
30 period, scored > 4 on item 9, which measures suicidal ideation, were immediately
31 contacted by their therapist. If the patient were in need of additional care, an
32 appointment was made with either a senior psychiatrist at the clinic, or at an emergency
33 psychiatric unit.
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42 Adverse events (AE) were recorded mid-treatment and at post-treatment in
43 accordance with guidelines presented by Rozental et al.[60]. AE were defined as
44 negative events that could have occurred due to treatment participation (e.g.,
45 deterioration of target symptoms, worse sleep, and general negative well-being such as
46 stress). Participants were asked if they had experienced any AE that they associated
47 with the intervention (yes/no). If yes, the participants were asked to describe the event
48 in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no
49 impact) to 3 (severely negative impact) at the time that the AE had occurred
50 (retrospective self-reports), and if the AE still had a negative impact on well-being at
51 present. A licensed psychologist reviewed the AE reported.
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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

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

32 RESULTS

36 Attrition

37 The participant flow throughout the trial is shown in Figure 1. One participant
38 terminated treatment during the first week due to reported personal problems and did
39 not complete any of the modules and was therefore regarded as a dropout, but was kept
40 in the primary analysis according to the ITT principles. The post-treatment and 3-month
41 follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants,
42 respectively. Self-rated questionnaires administered online were completed by 20 (87
43 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-
44 up.

54 Primary and secondary outcomes

55 Means, standard deviations, and within- group effect sizes, including confidence
56 intervals, for all assessment points with missing values replaced by multiple imputation
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3 are reported in Table 3. Paired t-tests showed significant changes on all measures from
4 pre- to post-treatment ($t(df = 13.72 - 20.15) = 3.10 - 7.54$, all p -values $< .01$), and from
5 pretreatment to follow-up ($t(df = 10.96 - 19.24) = 3.13 - 8.66$, all p -values $< .01$). On the
6 main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size
7 was $d = 2.01$, and the pre-treatment to follow-up effect size indicated sustained effects (d
8 = 2.04).
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13 At posttreatment, 82% of completers were responders ($\geq 30\%$ decrease on
14 the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to
15 posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).
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18 The significant pre- to post-treatment improvement on the BDD-YBOCS
19 insight item was in the large range ($t(18.44) = 4.30$, $p = < .001$, $d = 1.07$). Weekly scores
20 and follow-up data on the self-reported BDD-D are presented in Figure 2.
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25 <<INSERT FIGURE 2 ABOUT HERE>>
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28 The distribution of CGI-I scores for completers at posttreatment and follow-
29 up, respectively, was as follows: very much improved, 41 % and 52 %; much improved,
30 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At
31 posttreatment and follow-up, 64 % and 71 % were responders (very much or much
32 improved), respectively.
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35 On the other outcome measures, the within-group effect sizes from pretreatment to
36 posttreatment and pretreatment to follow-up were in the moderate to large range ($d =$
37 .55 – 1.82).
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46 47 **Adverse events**

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49 In total, 11 (48%) participants reported that they had experienced AE during the course
50 of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g.,
51 nightmares, depressive symptoms and worse sleep), followed by a deterioration of
52 symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus
53 on appearance), and general negative well-being (29%, e.g., stress). The AE reported
54 occurred mostly during the first part of the treatment, and most participants rated the
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3 negative impact of the AE as moderate ($Median = 2, M = 1.8, SD = 1.1$) when they
4 occurred, and as no longer having a negative impact at posttreatment ($Median = 0, M =$
5 $.7, SD = 1.6$) with the exception of one participant who reported that the treatment had
6 led to an increase in appearance concerns and more frequent intrusive thoughts
7 compared to baseline, and was classified as a non-responder at post-treatment. The
8 occurrence of AE during treatment was unrelated to responder status at post-treatment,
9 with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-
10 responders (Fisher's exact test = 0.59).

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16 During treatment, one participant became increasingly depressed and was
17 referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after
18 which treatment continued.
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22 23 **Treatment activity and acceptability**

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25 The mean number of messages that the participants sent to and received
26 from their therapist was 22.6 ($SD = 12.2$, range 0–47), and 30.2 ($SD = 11.3$, range 3–51),
27 respectively, and the therapists spent a weekly mean of 10.3 minutes ($SD = 6.7$, range
28 1.8–35.2), per participant. No significant differences were noted in time spent providing
29 support ($t(21) = 1.19, p = .25$), or in treatment effects between the two therapists ($t(21)$
30 $= -.60, p = .56$).
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35 In total, 19 (83%) participants completed the core components of the
36 treatment programme (modules 1–4), and six participants completed all eight of the
37 modules (26 %). The mean number of completed modules was 5.5 ($SD = 2.35$, range 0–
38 8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the
39 treatment, for example doing exercises in vivo and reading material online.
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43 At posttreatment, 6 (30%) of participants reported that they were very
44 pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was
45 somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was
46 somewhat displeased with the treatment provided. One participant did not answer the
47 satisfaction question.
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52 All participants on psychotropic medication had kept their dose stable
53 during treatment, and none had received any other type of psychological intervention. In
54 total, 5 (22%) participants reported that they had received additional care at the 3-
55 month follow-up. Of the participants receiving additional care, four were non-
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3 responders according to the CGI-I at post-treatment, and all endorsed a score above 20
4 on the BDD-YBOCS at follow-up. The other participant was classified as a responder at
5 post-treatment and follow-up, endorsing a score of 4 on the BDD-YBOCS. Two
6
7 participants had received one and five sessions of face-to-face CBT, respectively, two
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9 participants had been prescribed an SRI (of which one was prescribed for an indication
10 other than BDD), and one participant had increased the dose of current SRI.
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13 14 **DISCUSSION**

15 This study explored the feasibility and acceptability of a novel therapist-guided ICBT
16 program designed to dramatically increase access to CBT for patients with BDD. In
17 general the participants felt that BDD-NET was highly acceptable. A significant
18 improvement was seen on the main outcome measure (clinician-rated BDD-YBOCS),
19 with a large effect size, and 82% of the participants classed as responders at post-
20 treatment. These treatment effects were maintained at the three-month follow-up.
21 Clinician-rated insight also improved from pre- to post-treatment. Secondary outcome
22 measures of depression, skin picking, global functioning and body image-related quality
23 of life showed significant improvements from pre- to post-treatment, and from pre-
24 treatment to follow-up, with moderate to large effect sizes.
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27 In general, the results are in line with other trials investigating the effects of
28 individual CBT for BDD delivered in specialized clinic settings.[16-18] However, direct
29 comparisons with previous trials should be made with caution, because ours was a self-
30 referred and moderately ill patient group with relatively good insight. Some research
31 has shown that the source of patient referral may have a bearing on the types of patients
32 seen and the degree of clinical improvement with computerized or internet-based
33 therapies, with patients referred by mental health professionals having more
34 comorbidity, being less motivated for treatment and achieving more modest outcomes,
35 compared to self-referrals or referrals from general practitioners.[66]
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38 A comparison of the demographic and clinical characteristics of our sample
39 with those of two recently published RCTs appears in Table 4. Despite having moderate
40 to severe BDD symptoms, our predominantly female, self-referred sample might have
41 been particularly motivated to engage in psychological treatment, compared to the
42 average BDD patient seen in specialist settings. The proportion of patients with absent
43 or delusional insight also appears to be lower in this sample compared to the
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3 proportions seen in specialist clinic samples. Furthermore, though the rates of comorbid
4 disorders were similar, on average, our participants endorsed mild depressive
5 symptoms, compared to the moderate to severe depressive symptoms reported in the
6 trials published by Wilhelm et al.[17] and Veale et al.[18].
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10 ICBT should not be seen as a substitute for traditional face-to-face
11 treatment but, rather, a clinician extender that may substantially increase access to
12 evidence based treatment for a large proportion of sufferers who are not currently
13 receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input
14 will be required for complex patients who have poor insight and high suicide risk. In this
15 regard, BDD-NET may be particularly useful in the context of stepped-care for BDD,
16 where low-risk patients with reasonably good insight are offered ICBT and non-
17 responders or more complex and risky patients are offered more intensive, clinic based
18 CBT alone or in combination with medication.
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30 Participants in this trial made marked improvements despite no face-to-
31 face contact, beyond the baseline, post-treatment and follow-up assessments. Although
32 the treatment is Internet-based, the mechanisms of change may be the same as in
33 traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still
34 instructed to expose him or herself to feared stimuli in vivo without using maladaptive
35 coping strategies. Each participant had the same identified therapist throughout the
36 entire treatment, and although therapist contact was only around 10 minutes per
37 participant and week, the therapist sent a mean number of 30.2 messages per
38 participant, which averages out to 2-3 contacts per week. Messages sent from the
39 therapist were usually short, with prompts to the participant to engage in ERP and
40 report the outcome, allowing for adjustment of exposure strategies when needed. Thus,
41 the therapist was proactive and had shorter, but more frequent contact with
42 participants compared to traditional CBT, where sessions usually are held once a week.
43 Despite minimal therapist contact, participants often report the feeling of a therapist
44 presence; the therapists' frequent encouragement to engage in daily ERP may be a
45 critical component of the intervention.[32]
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3 In total, 48% of the participants experienced an adverse event during
4 treatment. However, the adverse events were mostly mild, and non-enduring, and a vast
5 majority of participants were very pleased or pleased with the treatment provided. Most
6 (83%) of the participants completed all of the core treatment components and engaged
7 in ERP, suggesting that the treatment was engaging and highly acceptable. The
8 treatment completion rate is in line with previous ICBT studies of various disorders,
9 suggesting that ICBT is as acceptable for patients with BDD as it is for other patient
10 groups (e.g., OCD, SAD, and MDD).[26 27]

11
12 Stigma, shame and logistic barriers can be a hindrance for persons with
13 BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is
14 online; this could reduce initial shame and stigma associated with openly talking about
15 one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the
16 clinic while receiving CBT and has the potential to minimize logistic barriers and
17 increase access to evidence-based care in rural areas or where trained therapists are not
18 available. Furthermore, one therapist can have more patients in treatment at the same
19 time compared to face-to-face therapy, while spending less time per patient as the
20 routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT
21 format has the potential to lower the severity threshold for people with BDD to seek and
22 receive adequate treatment. Expert clinicians can dedicate more time and resources to
23 complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is
24 protocol based and delivered as a series of modules online. This greatly reduces the risk
25 of therapist drift,[67] and ensures that all patients receive exactly the same treatment.
26 The control over content delivered also opens up for dismantling studies, as modules
27 can easily be added or taken out to test the specific effect of a treatment component, as
28 shown by Ljótsson et al.[68] where the specific effect of systematic exposure on Irritable
29 Bowel Syndrome symptoms was tested.

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

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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

Measure	Pre-treatment		Post-treatment		3-month follow-up ^a		Within-group effect size <i>d</i>								
							Pre to post ^a			Pre to follow-up ^a			Post to follow-up ^a		
	M	SD	M	SD	M	SD	<i>d</i>	CI-	CI+	<i>d</i>	CI-	CI+	<i>d</i>	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 \pm 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

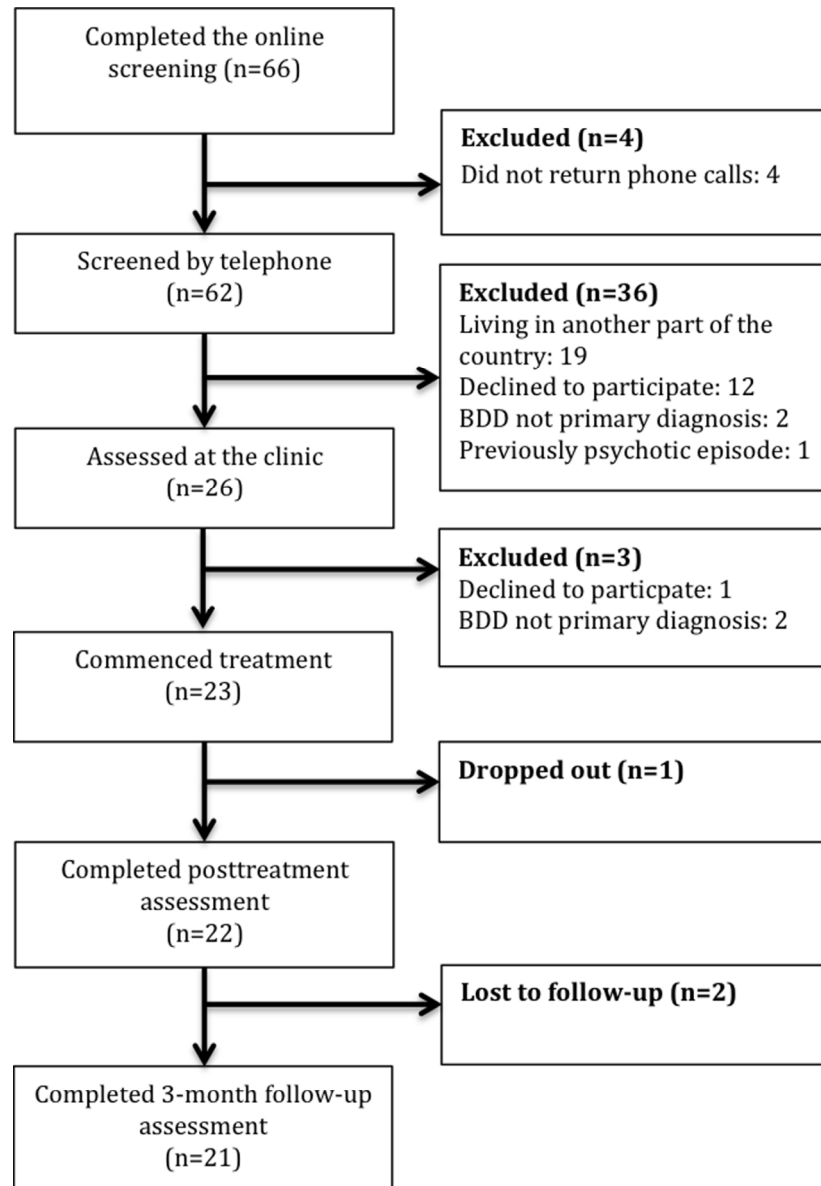
JE was the project manager and participated in designing the study, analyzing data, providing treatment, and drafting the manuscript and the treatment manual. VI participated in designing the study, providing treatment and drafting the manuscript and the treatment manual. EA participated in designing 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.

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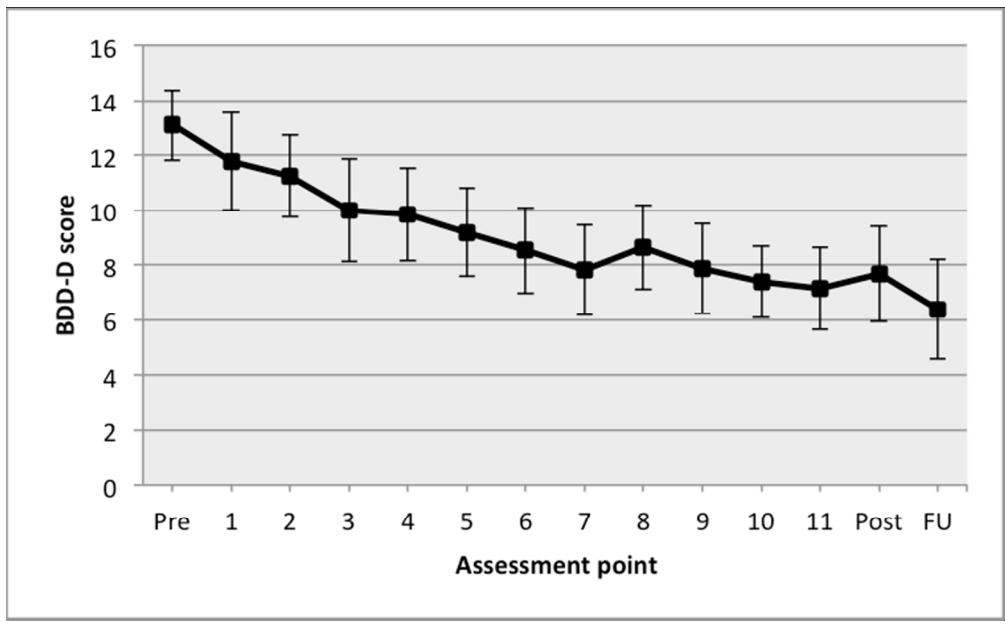
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11 **COMPETING INTERESTS**

12 None declared.
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Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study

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Title

Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dismorphic 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 $\geq 30\%$ 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.

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3 **Conclusion:** The results suggest that BDD-NET has the potential to greatly improve
4 access to CBT, at least for low-risk individuals with moderately severe BDD symptoms
5 and reasonably good insight. A randomized controlled trial of BDD-NET is warranted.
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10 **Clinicaltrials.gov registration ID:** NCT01850433.
11

12 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 14
15 • This study is the first to explore the feasibility and acceptability of a novel
16 therapist-guided Internet-based (ICBT) program designed to dramatically
17 increase access to CBT for patients with BDD.
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21 • BDD-NET may be particularly useful in the context of stepped-care for BDD,
22 where low-risk patients with reasonably good insight are offered ICBT and non-
23 responders or more complex and risky patients are offered more intensive, clinic
24 based CBT alone or in combination with medication.
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28 • This was an uncontrolled trial. This limits the possibilities to make causal
29 inferences as to what caused the observed changes.
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33 • There is also bias in this study as participants were self-referred.
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37 • Despite the limitations of this uncontrolled trial, the results suggest that BDD-
38 NET has the potential to reduce symptoms and increase access to CBT for
39 patients with BDD who are motivated to receive treatment.
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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 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 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

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3 time of work in order to attend therapy were also reported.[21 23] Therefore,
4 alternative ways of improving access to CBT are sorely needed.
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6 One way to increase access to CBT is to administer the treatment using the
7 Internet.[24 25] In the last decade, there has been a rapid development of Internet-
8 based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range
9 of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety
10 disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are
11 two main forms of ICBT: open access programs without any therapist guidance, and
12 programs with therapist support that try to closely mimic the process of face-to-face
13 CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of
14 modules accompanied by homework assignments, reflecting the content of a traditional
15 face-to-face therapy session. During the entire treatment, an identified therapist
16 provides guidance and gives feedback through a built-in e-mail system. Thus, the
17 therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in
18 traditional CBT, the only difference being the way care is delivered. There is evidence
19 that ICBT that incorporates therapist support may result in better treatment effects
20 when compared to ICBT provided without such guidance.[30-32] Furthermore, in a
21 recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there
22 was no significant difference between the two treatment modalities, suggesting non-
23 inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia,
24 ICBT has already been implemented as part of their regular health care systems.[34-36]
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26 With the primary aim to increase access to evidence based treatment for
27 BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT
28 program based on existing manuals,[15 19] and tested its feasibility and efficacy in an
29 uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to
30 patients, lead to a reduction of BDD and other psychiatric symptoms, and require
31 minimal therapist input.
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33 **METHOD**

34 **Participants**

35 The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD.
36 Participant demographics and clinical characteristics are presented in Table 1.
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3 Information about the study was posted on the official web page of the clinic
4 (www.internetpsykiatri.se), and flyers were distributed to mental health professionals.
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6 The study was also mentioned in a national newspaper that ran a three-part article
7 series about BDD. A total of 66 individuals were considered for eligibility (see Figure 1).
8
9 To be eligible for the study participants had to be at least 18 years of age, outpatients,
10 and diagnosed with primary DSM-5 BDD. Exclusion criteria were psychotropic
11 medication changes within two months prior to enrolment, completed CBT for BDD
12 within the last 12 months, a score on the Yale-Brown Obsessive Compulsive Scale
13 Modified for Body Dysmorphic Disorder (BDD-YBOCS) of ≤ 16 , current substance
14 dependence, lifetime bipolar disorder or psychosis, acute suicidal ideation, a personality
15 disorder that could jeopardize treatment participation, or concurrent psychological
16 treatment. Participants who were taking psychotropic medication, and had been on a
17 stable dose for at least 2 months prior to enrolment were asked to not change their
18 medication during the study period. The regional ethical review board in Stockholm,
19 Sweden approved the study ID: 2013/117-31/2. Clinicaltrials.gov registration ID:
20 NCT01850433.
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31 <INSERT FIGURE 1 ABOUT HERE>

32 <INSERT TABLE 1 ABOUT HERE>

33 34 35 36 37 **Procedure**

38 In the first stage of the recruitment process, potential participants were instructed to
39 complete an online screening consisting of Montgomery-Åsberg Depression Rating
40 Scale, Self-report (MADRS-S),[37] Alcohol Use Disorders Identification Test
41 (AUDIT),[38] Drug User Disorders Identification Test (DUDIT),[39] Dysmorphic
42 Concerns Questionnaire (DCQ),[40] and Body Dysmorphic Disorder Dimensional Scale
43 (BDD-D).[41] All participants who completed the screening were contacted by
44 telephone and assessed for BDD. Twenty-six individuals were invited to the clinic for an
45 in-person assessment by either a psychiatrist or a licensed psychologist. The Mini-
46 International Neuropsychiatric Interview (M.I.N.I.)[42] was used to determine the
47 presence of any DSM-IV-TR Axis-I disorders. A more in depth interview with the BDD
48 Diagnostic Module was conducted to establish the diagnosis of DSM-5 BDD.[43] The
49 questions used in this semi-structured interview were originally designed for DSM-IV-
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3 TR criteria and are similar to those used in the Structured Clinical Interview for DSM-IV
4 Axis I Disorders (SCID-I).[44] A question about the presence of repetitive behaviors was
5 added to reflect the DSM-5 criteria for BDD and the new DSM-5 insight specifiers were
6 also used to determine degree of insight regarding body dysmorphic beliefs (i.e., good or
7 fair insight, poor insight and absent insight/delusional beliefs). The assessors had
8 several years of experience administering structured interviews, such as the BDD-
9 YBOCS, and had undergone extensive training in using the M.I.N.I.
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16 **Measures**

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

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

32 The BDD-YBOCS[48] can be considered the gold standard for assessing symptom
33 severity and impairment associated with BDD. It is a clinician administered semi-
34 structured interview consisting of 12 items; each rated on a scale from 0-4, which
35 measures symptom severity during the last seven days, in the form of intrusive thoughts
36 (5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score
37 on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe
38 symptoms. BDD-YBOCS has shown high test-retest reliability ($r = .88$) and internal
39 consistency ($\alpha = .80$).[48] An empirically defined cut-off point of a 30 % reduction on the
40 BDD-YBOCS was used to determine responder status at post-treatment.[49] To
41 investigate specific effects on insight, the item of the BDD-YBOCS relating to insight was
42 also reported separately.
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53 *Clinical Global Impression (CGI)*

54 The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and
55 clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal)
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3 to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very
4 much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was
5 determined to indicate responder status in this study. CGI has shown good reliability
6 and validity for a range of psychiatric disorders.[51 52]
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10 11 *Global Assessment of Functioning (GAF)*

12 The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from
13 0 to 100 and is used to assess social, occupational, and psychological functioning, with a
14 higher score indicating better health. Overall reliability of the GAF are good, but
15 questions regarding its validity have been raised, see Aas 2010 for a review.[54]
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20 21 **Self-administered measures**

22 *Body Dysmorphic Dimensional Scale (BDD-D)*

23 The BDD-D[41] is a self report measure of symptom severity developed alongside the
24 DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and
25 repetitive behaviors, distress, control over symptoms, avoidance, and interference; each
26 rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20.
27 High internal consistency has been reported ($\alpha = .80$), though further validation work is
28 warranted.[41]
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37 *Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)*

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

54 As skin picking is common among persons diagnosed with BDD we used the SPS-R[57]
55 to assess skin picking severity and impairment. The SPS-R is a self-report measure that
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3 consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g.,
4 extreme). Good internal consistency ($\alpha = .83$) as well as discriminant and convergent
5 validity have been reported.[57]
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8 9 *Body Image Quality of Life Inventory (BIQLI)*

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

24 As mentioned earlier, participants with active suicidal ideation were not included in the
25 trial. However, suicidal ideation is common among patients diagnosed with BDD and the
26 following precautions were taken in order to detect patients that could deteriorate
27 during treatment. All participants underwent a structured clinical interview assessing
28 suicidal ideation before starting treatment. Throughout the entire treatment, MADRS-S
29 was administered weekly and participants who, at any time throughout the treatment
30 period, scored > 4 on item 9, which measures suicidal ideation, were immediately
31 contacted by their therapist. If the patient were in need of additional care, an
32 appointment was made with either a senior psychiatrist at the clinic, or at an emergency
33 psychiatric unit.
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42 Adverse events (AE) were recorded mid-treatment and at post-treatment in
43 accordance with guidelines presented by Rozental et al.[60]. AE were defined as
44 negative events that could have occurred due to treatment participation (e.g.,
45 deterioration of target symptoms, worse sleep, and general negative well-being such as
46 stress). Participants were asked if they had experienced any AE that they associated
47 with the intervention (yes/no). If yes, the participants were asked to describe the event
48 in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no
49 impact) to 3 (severely negative impact) at the time that the AE had occurred
50 (retrospective self-reports), and if the AE still had a negative impact on well-being at
51 present. A licensed psychologist reviewed the AE reported.
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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

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

32 RESULTS

37 Attrition

38 The participant flow throughout the trial is shown in Figure 1. One participant
39 terminated treatment during the first week due to reported personal problems and did
40 not complete any of the modules and was therefore regarded as a dropout, but was kept
41 in the primary analysis according to the ITT principles. The post-treatment and 3-month
42 follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants,
43 respectively. Self-rated questionnaires administered online were completed by 20 (87
44 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-
45 up.

54 Primary and secondary outcomes

55 Means, standard deviations, and within- group effect sizes, including confidence
56 intervals, for all assessment points with missing values replaced by multiple imputation
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3 are reported in Table 3. Paired t-tests showed significant changes on all measures from
4 pre- to post-treatment ($t(df = 13.72 - 20.15) = 3.10 - 7.54$, all p -values $< .01$), and from
5 pretreatment to follow-up ($t(df = 10.96 - 19.24) = 3.13 - 8.66$, all p -values $< .01$). On the
6 main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size
7 was $d = 2.01$, and the pre-treatment to follow-up effect size indicated sustained effects (d
8 = 2.04).
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13 At posttreatment, 82% of completers were responders ($\geq 30\%$ decrease on
14 the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to
15 posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).
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17
18 The significant pre- to post-treatment improvement on the BDD-YBOCS
19 insight item was in the large range ($t(18.44) = 4.30$, $p = < .001$, $d = 1.07$). Weekly scores
20 and follow-up data on the self-reported BDD-D are presented in Figure 2.
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25 <<INSERT FIGURE 2 ABOUT HERE>>
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27
28 The distribution of CGI-I scores for completers at posttreatment and follow-
29 up, respectively, was as follows: very much improved, 41 % and 52 %; much improved,
30 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At
31 posttreatment and follow-up, 64 % and 71 % were responders (very much or much
32 improved), respectively.
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34
35 On the other outcome measures, the within-group effect sizes from pretreatment to
36 posttreatment and pretreatment to follow-up were in the moderate to large range ($d =$
37 .55 – 1.82).
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46 47 **Adverse events**

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49 In total, 11 (48%) participants reported that they had experienced AE during the course
50 of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g.,
51 nightmares, depressive symptoms and worse sleep), followed by a deterioration of
52 symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus
53 on appearance), and general negative well-being (29%, e.g., stress). The AE reported
54 occurred mostly during the first part of the treatment, and most participants rated the
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3 negative impact of the AE as moderate ($Median = 2, M = 1.8, SD = 1.1$) when they
4 occurred, and as no longer having a negative impact at posttreatment ($Median = 0, M =$
5 $.7, SD = 1.6$) with the exception of one participant who reported that the treatment had
6 led to an increase in appearance concerns and more frequent intrusive thoughts
7 compared to baseline, and was classified as a non-responder at post-treatment. The
8 occurrence of AE during treatment was unrelated to responder status at post-treatment,
9 with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-
10 responders (Fisher's exact test = 0.59).

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16 During treatment, one participant became increasingly depressed and was
17 referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after
18 which treatment continued.
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22 23 **Treatment activity and acceptability**

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25 The mean number of messages that the participants sent to and received
26 from their therapist was 22.6 ($SD = 12.2$, range 0–47), and 30.2 ($SD = 11.3$, range 3–51),
27 respectively, and the therapists spent a weekly mean of 10.3 minutes ($SD = 6.7$, range
28 1.8–35.2), per participant. No significant differences were noted in time spent providing
29 support ($t(21) = 1.19, p = .25$), or in treatment effects between the two therapists ($t(21)$
30 $= -.60, p = .56$).

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35 In total, 19 (83%) participants completed the core components of the
36 treatment programme (modules 1–4), and six participants completed all eight of the
37 modules (26 %). The mean number of completed modules was 5.5 ($SD = 2.35$, range 0–
38 8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the
39 treatment, for example doing exercises in vivo and reading material online.
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44 At posttreatment, 6 (30%) of participants reported that they were very
45 pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was
46 somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was
47 somewhat displeased with the treatment provided. One participant did not answer the
48 satisfaction question.
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53 All participants on psychotropic medication had kept their dose stable
54 during treatment, and none had received any other type of psychological intervention. In
55 total, 5 (22%) participants reported that they had received additional care at the 3-
56 month follow-up. Of the participants receiving additional care, four were non-
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3 responders according to the CGI-I at post-treatment, and all endorsed a score above 20
4 on the BDD-YBOCS at follow-up. The other participant was classified as a responder at
5 post-treatment and follow-up, endorsing a score of 4 on the BDD-YBOCS. Two
6
7 participants had received one and five sessions of face-to-face CBT, respectively, two
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9 participants had been prescribed an SRI (of which one was prescribed for an indication
10 other than BDD), and one participant had increased the dose of current SRI.
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13 14 **DISCUSSION**

15 This study explored the feasibility and acceptability of a novel therapist-guided ICBT
16 program designed to dramatically increase access to CBT for patients with BDD. In
17 general the participants felt that BDD-NET was highly acceptable. A significant
18 improvement was seen on the main outcome measure (clinician-rated BDD-YBOCS),
19 with a large effect size, and 82% of the participants classed as responders at post-
20 treatment. These treatment effects were maintained at the three-month follow-up.
21 Clinician-rated insight also improved from pre- to post-treatment. Secondary outcome
22 measures of depression, skin picking, global functioning and body image-related quality
23 of life showed significant improvements from pre- to post-treatment, and from pre-
24 treatment to follow-up, with moderate to large effect sizes.
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27 In general, the results are in line with other trials investigating the effects of
28 individual CBT for BDD delivered in specialized clinic settings.[16-18] However, direct
29 comparisons with previous trials should be made with caution, because ours was a self-
30 referred and moderately ill patient group with relatively good insight. Some research
31 has shown that the source of patient referral may have a bearing on the types of patients
32 seen and the degree of clinical improvement with computerized or internet-based
33 therapies, with patients referred by mental health professionals having more
34 comorbidity, being less motivated for treatment and achieving more modest outcomes,
35 compared to self-referrals or referrals from general practitioners.[66]
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38 A comparison of the demographic and clinical characteristics of our sample
39 with those of two recently published RCTs appears in Table 4. Despite having moderate
40 to severe BDD symptoms, our predominantly female, self-referred sample might have
41 been particularly motivated to engage in psychological treatment, compared to the
42 average BDD patient seen in specialist settings. The proportion of patients with absent
43 or delusional insight also appears to be lower in this sample compared to the
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3 proportions seen in specialist clinic samples. Furthermore, though the rates of comorbid
4 disorders were similar, on average, our participants endorsed mild depressive
5 symptoms, compared to the moderate to severe depressive symptoms reported in the
6 trials published by Wilhelm et al.[17] and Veale et al.[18].
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10 ICBT should not be seen as a substitute for traditional face-to-face
11 treatment but, rather, a clinician extender that may substantially increase access to
12 evidence based treatment for a large proportion of sufferers who are not currently
13 receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input
14 will be required for complex patients who have poor insight and high suicide risk. In this
15 regard, BDD-NET may be particularly useful in the context of stepped-care for BDD,
16 where low-risk patients with reasonably good insight are offered ICBT and non-
17 responders or more complex and risky patients are offered more intensive, clinic based
18 CBT alone or in combination with medication.
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30 Participants in this trial made marked improvements despite no face-to-
31 face contact, beyond the baseline, post-treatment and follow-up assessments. Although
32 the treatment is Internet-based, the mechanisms of change may be the same as in
33 traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still
34 instructed to expose him or herself to feared stimuli in vivo without using maladaptive
35 coping strategies. Each participant had the same identified therapist throughout the
36 entire treatment, and although therapist contact was only around 10 minutes per
37 participant and week, the therapist sent a mean number of 30.2 messages per
38 participant, which averages out to 2-3 contacts per week. Messages sent from the
39 therapist were usually short, with prompts to the participant to engage in ERP and
40 report the outcome, allowing for adjustment of exposure strategies when needed. Thus,
41 the therapist was proactive and had shorter, but more frequent contact with
42 participants compared to traditional CBT, where sessions usually are held once a week.
43 Despite minimal therapist contact, participants often report the feeling of a therapist
44 presence; the therapists' frequent encouragement to engage in daily ERP may be a
45 critical component of the intervention.[32]
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3 In total, 48% of the participants experienced an adverse event during
4 treatment. However, the adverse events were mostly mild, and non-enduring, and a vast
5 majority of participants were very pleased or pleased with the treatment provided. Most
6 (83%) of the participants completed all of the core treatment components and engaged
7 in ERP, suggesting that the treatment was engaging and highly acceptable. The
8 treatment completion rate is in line with previous ICBT studies of various disorders,
9 suggesting that ICBT is as acceptable for patients with BDD as it is for other patient
10 groups (e.g., OCD, SAD, and MDD).[26 27]

11
12 Stigma, shame and logistic barriers can be a hindrance for persons with
13 BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is
14 online; this could reduce initial shame and stigma associated with openly talking about
15 one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the
16 clinic while receiving CBT and has the potential to minimize logistic barriers and
17 increase access to evidence-based care in rural areas or where trained therapists are not
18 available. Furthermore, one therapist can have more patients in treatment at the same
19 time compared to face-to-face therapy, while spending less time per patient as the
20 routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT
21 format has the potential to lower the severity threshold for people with BDD to seek and
22 receive adequate treatment. Expert clinicians can dedicate more time and resources to
23 complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is
24 protocol based and delivered as a series of modules online. This greatly reduces the risk
25 of therapist drift,[67] and ensures that all patients receive exactly the same treatment.
26 The control over content delivered also opens up for dismantling studies, as modules
27 can easily be added or taken out to test the specific effect of a treatment component, as
28 shown by Ljótsson et al.[68] where the specific effect of systematic exposure on Irritable
29 Bowel Syndrome symptoms was tested.

30
31 This study has several limitations that need to be considered when
32 interpreting the results. First and foremost, this was an uncontrolled trial. This limits the
33 possibilities to make causal inferences as to what caused the observed changes. The
34 improvements observed over the course of treatment could have been due to the mere
35 passage of time. However, when considering the chronicity of BDD,[8 69] we regard it as
36 unlikely that the treatment effects in this trial could be entirely explained by
37 spontaneous remission. Furthermore, the improvements observed could also be due to
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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.

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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.

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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

Measure	Pre-treatment		Post-treatment		3-month follow-up ^a		Within-group effect size <i>d</i>								
							Pre to post ^a			Pre to follow-up ^a			Post to follow-up ^a		
	M	SD	M	SD	M	SD	<i>d</i>	CI-	CI+	<i>d</i>	CI-	CI+	<i>d</i>	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 \pm 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 $\geq 30\%$ 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.

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3 **Conclusion:** The results suggest that BDD-NET has the potential to greatly increase
4 access to CBT, at least for low-risk individuals with moderately severe BDD symptoms
5 and reasonably good insight. A randomized controlled trial of BDD-NET is warranted.
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8 Clinicaltrials.gov registration ID: NCT01850433.
9

10 11 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

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

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

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7 One way to increase access to CBT is to administer the treatment using the
8
9 Internet.[24 25] In the last decade, there has been a rapid development of Internet-
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11 based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range
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13 of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety
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15 disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are
16
17 two main forms of ICBT: open access programs without any therapist guidance, and
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19 programs with therapist support that try to closely mimic the process of face-to-face
20
21 CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of
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23 modules accompanied by homework assignments, reflecting the content of a traditional
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25 face-to-face therapy session. During the entire treatment, an identified therapist
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27 provides guidance and gives feedback through a built-in e-mail system. Thus, the
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29 therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in
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31 traditional CBT, the only difference being the way care is delivered. There is evidence
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33 that ICBT that incorporates therapist support may result in better treatment effects
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35 when compared to ICBT provided without such guidance.[30-32] Furthermore, in a
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37 recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there
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39 was no significant difference between the two treatment modalities, suggesting non-
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41 inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia,
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43 ICBT has already been implemented as part of their regular health care systems.[34-36]

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45 With the primary aim to increase access to evidence based treatment for
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47 BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT
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49 program based on existing manuals,[15 19] and tested its feasibility and efficacy in an
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51 uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to
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53 patients, lead to a reduction of BDD and other psychiatric symptoms, and require
54
55 minimal therapist input.

56 57 **METHOD**

58 59 **Participants**

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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 originally 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 reliability 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

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3 (5 items), compulsions (5 items), insight (1 item) and avoidance (1 item). The total score
4 on the BDD-YBOCS ranges from 0-48, with a higher score indicating more severe
5 symptoms. BDD-YBOCS has shown high test-retest reliability ($r = .88$) and internal
6 consistency ($\alpha = .80$).[48] An empirically defined cut-off point of a 30 % reduction on the
7 BDD-YBOCS was used to determine responder status at post-treatment.[49] To
8 investigate specific [treatment](#) effects on insight, the item of the BDD-YBOCS relating to
9 insight was also reported separately.
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15 16 17 *Clinical Global Impression (CGI)*

18 The CGI[50] is a clinician rated measure of clinical global severity of illness (CGI-S), and
19 clinical global improvement (CGI-I). The CGI-S scores range from 1 (not at all ill, normal)
20 to 7 (extremely ill), and the CGI-I scores range from 1 (very much improved) to 7 (very
21 much worse) and a score of 4 means unchanged. A score of 1 or 2 on the CGI-I was
22 determined to indicate responder status in this study. CGI has shown good reliability
23 and validity for a range of psychiatric disorders.[51 52]
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30 31 *Global Assessment of Functioning (GAF)*

32 The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from
33 0 to 100 and is used to assess social, occupational, and psychological functioning, with a
34 higher score indicating better health. Overall reliability of the GAF [is](#) good, but questions
35 regarding its validity have been raised; see Aas 2010 for a review.[54]
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40 **Self-administered measures**

41 42 *Body Dysmorphic Dimensional Scale (BDD-D)*

43 The BDD-D[41] is a self report measure of symptom severity developed alongside the
44 DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and
45 repetitive behaviors, distress, control over symptoms, avoidance, and interference; each
46 rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20.
47 High internal consistency has been reported ($\alpha = .80$), though further validation work is
48 warranted.[41]
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55 56 *Montgomery-Åsberg Depression Rating Scale, self-report (MADRS-S)*

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3 The MADRS-S[37] is the self-report version of the Montgomery-Åsberg Depression
4 Rating Scale (MADRS)[55], and measures severity of depression. The scale consists of 9
5 items, each measuring a different symptom (mood, feelings of unease, sleep, appetite,
6 ability to concentrate, initiative, emotional involvement, pessimism, and suicidal
7 ideation) on a seven-point scale with a total score ranging from 0 to 54. Good to
8 excellent test-retest reliability have been reported ($r = .80 - .94$)[37], as well as a high
9 correlation ($r = .87$) between the MADRS-S and the Beck Depression Inventory in a
10 comparative study.[56]
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17 18 *Skin Picking Scale-Revised (SPS-R)*

19 As skin picking is common among persons diagnosed with BDD we used the SPS-R[57]
20 to assess skin picking severity and impairment. The SPS-R is a self-report measure that
21 consists of 8 items that are rated on a 5-point scale from 0 (e.g., none) to 4 (e.g.,
22 extreme). Good internal consistency ($\alpha = .83$) as well as discriminant and convergent
23 validity have been reported.[57]
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30 31 *Body Image Quality of Life Inventory (BIQLI)*

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

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

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6 Adverse events (AE) were recorded mid-treatment and at post-treatment in
7 accordance with guidelines presented by Rozental et al.[60]. AE were defined as
8 negative events that could have occurred due to treatment participation (e.g.,
9 deterioration of target symptoms, worse sleep, and general negative well-being such as
10 stress). Participants were asked if they had experienced any AE that they associated
11 with the intervention (yes/no). If yes, the participants were asked to describe the event
12 in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no
13 impact) to 3 (severely negative impact) at the time that the AE had occurred
14 (retrospective self-reports), and if the AE still had a negative impact on well-being at
15 present. A licensed psychologist reviewed the AE reported.
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24 25 Treatment

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

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_____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

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

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40 The primary analyses were done according to intention-to-treat (ITT) including the full
41 sample of 23 participants. Missing data at post-treatment and follow-up assessment
42 were deemed to be missing at random (using logistic regression models, as well as
43 inspecting correlations between indicator variables of missingness and other variables
44 from the dataset that might predict missingness) and imputed using multiple imputation
45 by chained equations.[62] All estimates with standard errors were pooled from five
46 imputations using “Rubin’s rules”[63] and the small sample correction for pooled
47 degrees of freedom.[64] Paired *t*-tests were performed to assess if changes from
48 pretreatment to post-treatment and pretreatment to follow-up were statistically
49 significant. Paired *t*-tests comparing post-treatment to follow-up were also performed to
50 test for maintenance of the therapeutic gains. Within-group effect sizes were calculated
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3 by dividing the difference between pre-treatment and post-treatment scores by the
4 within-group pooled standard deviation.[65] Fisher's exact test was used to examine
5 whether there was an association between the occurrence of an AE and treatment
6 responder status and independent *t*-tests were used to examine specific therapist
7 effects. All data were analyzed with Stata statistical software, version 13.1[66] and the
8 threshold for statistical significance set at the standard 5%.
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13 14 15 **RESULTS**

16 17 18 **Attrition**

19 The participant flow throughout the trial is shown in Figure 1. One participant
20 terminated treatment during the first week due to reported personal problems and did
21 not complete any of the modules and was therefore regarded as a dropout, but was kept
22 in the primary analysis according to the ITT principles. The post-treatment and 3-month
23 follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants,
24 respectively. Self-rated questionnaires administered online were completed by 20 (87
25 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-
26 up.
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35 36 **Primary and secondary outcomes**

37 Means, standard deviations, and within- group effect sizes, including confidence
38 intervals, for all assessment points with missing values replaced by multiple imputation
39 are reported in Table 3. Paired *t*-tests showed significant changes on all measures from
40 pre- to post-treatment ($t(df = 13.72 - 20.15) = 3.10 - 7.54$, all *p*-values < .01), and from
41 pretreatment to follow-up ($t(df = 10.96 - 19.24) = 3.13 - 8.66$, all *p*-values < .01). On the
42 main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size
43 was $d = 2.01$, and the pre-treatment to follow-up effect size indicated sustained effects (d
44 = 2.04).
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50 At posttreatment, 82% of completers were responders (≥ 30 % decrease on
51 the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to
52 posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).
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3 The significant pre- to post-treatment improvement on the BDD-YBOCS
4 insight item was in the large range ($t(18.44) = 4.30, p = <.001, d = 1.07$). Weekly scores
5 and follow-up data on the self-reported BDD-D are presented in Figure 2.
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10 <<INSERT FIGURE 2 ABOUT HERE>>
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13 The distribution of CGI-I scores for completers at posttreatment and follow-
14 up, respectively, was as follows: very much improved, 41 % and 52 %; much improved,
15 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At
16 posttreatment and follow-up, 64 % and 71 % were responders (very much or much
17 improved), respectively.
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21 On the other outcome measures, the within-group effect sizes from
22 pretreatment to posttreatment and pretreatment to follow-up were in the moderate to
23 large range ($d = .55 - 1.82$).
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31 **Adverse events**

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33 In total, 11 (48%) participants reported that they had experienced AE during the course
34 of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g.,
35 nightmares, depressive symptoms and worse sleep), followed by a deterioration of
36 symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus
37 on appearance), and general negative well-being (29%, e.g., stress). The AE reported
38 occurred mostly during the first part of the treatment, and most participants rated the
39 negative impact of the AE as moderate ($Median = 2, M = 1.8, SD = 1.1$) when they
40 occurred, and as no longer having a negative impact at posttreatment ($Median = 0, M =$
41 $.7, SD = 1.6$) with the exception of one participant who reported that the treatment had
42 led to an increase in appearance concerns and more frequent intrusive thoughts
43 compared to baseline, and was classified as a non-responder at post-treatment. The
44 occurrence of AE during treatment was unrelated to responder status at post-treatment,
45 with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-
46 responders (Fisher's exact test = 0.59).
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3 During treatment, one participant became increasingly depressed and was
4 referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after
5 which treatment continued.
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8 9 10 **Treatment activity and acceptability**

11 The mean number of messages that the participants sent to and received
12 from their therapist was 22.6 ($SD = 12.2$, range 0–47), and 30.2 ($SD = 11.3$, range 3–51),
13 respectively, and the therapists spent a weekly mean of 10.3 minutes ($SD = 6.7$, range
14 1.8–35.2), per participant. No significant differences were noted in time spent providing
15 support ($t(21) = 1.19$, $p = .25$, $d = 0.5$ 95% CI -0.39-1.39), or in treatment effects between
16 the two therapists ($t(21) = -.60$, $p = .56$, $d = -0.26$ 95% CI -1.11-0.60).
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19 In total, 19 (83%) participants completed the core components of the
20 treatment programme (modules 1–4), and six participants completed all eight of the
21 modules (26 %). The mean number of completed modules was 5.5 ($SD = 2.35$, range 0–
22 8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the
23 treatment, for example doing exercises in vivo and reading material online.
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26 At posttreatment, 6 (30%) participants reported that they were very
27 pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was
28 somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was
29 somewhat displeased with the treatment provided. One participant did not answer the
30 satisfaction question.
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33 All participants on psychotropic medication prior to treatment had kept
34 their dose stable during treatment, and none had received any other type of
35 psychological intervention. In total, 5 (22%) participants reported that they had
36 received additional care at the 3-month follow-up. Of the participants receiving
37 additional care, four were non-responders according to the CGI-I at post-treatment, and
38 all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was
39 classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the
40 BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT,
41 respectively, two participants had been prescribed an SRI (of which one was prescribed
42 for an indication other than BDD), and one participant had increased the dose of current
43 SRI.
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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

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

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6 ICBT should not be seen as a substitute for traditional face-to-face
7 treatment but, rather, a clinician extender that may substantially increase access to
8 evidence based treatment for a large proportion of sufferers who are not currently
9 receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input
10 will be required for complex patients who have poor insight and high suicide risk. In this
11 regard, BDD-NET may be particularly useful in the context of stepped-care for BDD,
12 where low-risk patients with reasonably good insight are offered ICBT and non-
13 responders or more complex and risky patients are offered more intensive, clinic based
14 CBT alone or in combination with medication.
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23 <INSERT TABLE 4 ABOUT HERE>
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27 Participants in this trial made marked improvements despite no face-to-
28 face contact, beyond the baseline, post-treatment and follow-up assessments. Although
29 the treatment is Internet-based, the mechanisms of change may be the same as in
30 traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still
31 instructed to expose him or herself to feared stimuli in vivo without using maladaptive
32 coping strategies. Each participant had the same identified therapist throughout the
33 entire treatment, and although therapist contact was only around 10 minutes per
34 participant and week, the therapist sent a mean number of 30.2 messages per
35 participant, which averages out to 2-3 contacts per week. Messages sent from the
36 therapist were usually short, with prompts to the participant to engage in ERP and
37 report the outcome, allowing for adjustment of exposure strategies when needed. Thus,
38 the therapist was proactive and had shorter, but more frequent contact with
39 participants compared to traditional CBT, where sessions usually are held once a week.
40 Despite minimal therapist contact, participants often report the feeling of a therapist
41 presence; the therapists' frequent encouragement to engage in daily ERP may be a
42 critical component of the intervention.[32]
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54 In total, 48% of the participants experienced an adverse event during
55 treatment. However, the adverse events were mostly mild, and non-enduring, and a vast
56 majority of participants were very pleased or pleased with the treatment provided. Most
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3 (83%) of the participants completed all of the core treatment components and engaged
4 in ERP, suggesting that the treatment was engaging and highly acceptable. The
5 treatment completion rate is in line with previous ICBT studies of various disorders,
6 suggesting that ICBT is as acceptable for patients with BDD as it is for other patient
7 groups (e.g., OCD, SAD, and MDD).[26 27]
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11 Stigma, shame and logistic barriers can be a hindrance for persons with
12 BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is
13 online; this could reduce initial shame and stigma associated with openly talking about
14 one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the
15 clinic while receiving CBT and has the potential to minimize logistic barriers and
16 increase access to evidence-based care in rural areas or where trained therapists are not
17 available. Furthermore, one therapist can have more patients in treatment at the same
18 time compared to face-to-face therapy, while spending less time per patient as the
19 routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT
20 format has the potential to lower the severity threshold for people with BDD to seek and
21 receive adequate treatment. Expert clinicians can dedicate more time and resources to
22 complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is
23 protocol based and delivered as a series of modules online. This greatly reduces the risk
24 of therapist drift,[68] and ensures that all patients receive exactly the same treatment.
25 The control over content delivered also opens up for dismantling studies, as modules
26 can easily be added or taken out to test the specific effect of a treatment component, as
27 shown by Ljótsson et al.[69] where the specific effect of systematic exposure on Irritable
28 Bowel Syndrome symptoms was tested.
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32 This study has several limitations that need to be considered when
33 interpreting the results. First and foremost, this was an uncontrolled trial. This limits the
34 possibilities to make causal inferences as to what caused the observed changes. The
35 improvements observed over the course of treatment could have been due to the mere
36 passage of time. However, when considering the chronicity of BDD,[8 70] we regard it as
37 unlikely that the treatment effects in this trial could be entirely explained by
38 spontaneous remission. Furthermore, the improvements observed could also be due to
39 unspecific factors, such as caregiver attention. However, the maintenance of
40 improvement from post-treatment to follow-up indicates that treatment gains were
41 temporally stable, and the majority of participants did not receive any further treatment.
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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.

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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.

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DATA SHARING

No additional data available.

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For peer review only

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

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

Measure	Pre-treatment		Post-treatment		3-month follow-up ^a		Within-group effect size <i>d</i>								
							Pre to post ^a			Pre to follow-up ^a			Post to follow-up ^a		
	M	SD	M	SD	M	SD	<i>d</i>	CI-	CI+	<i>d</i>	CI-	CI+	<i>d</i>	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 \pm 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.

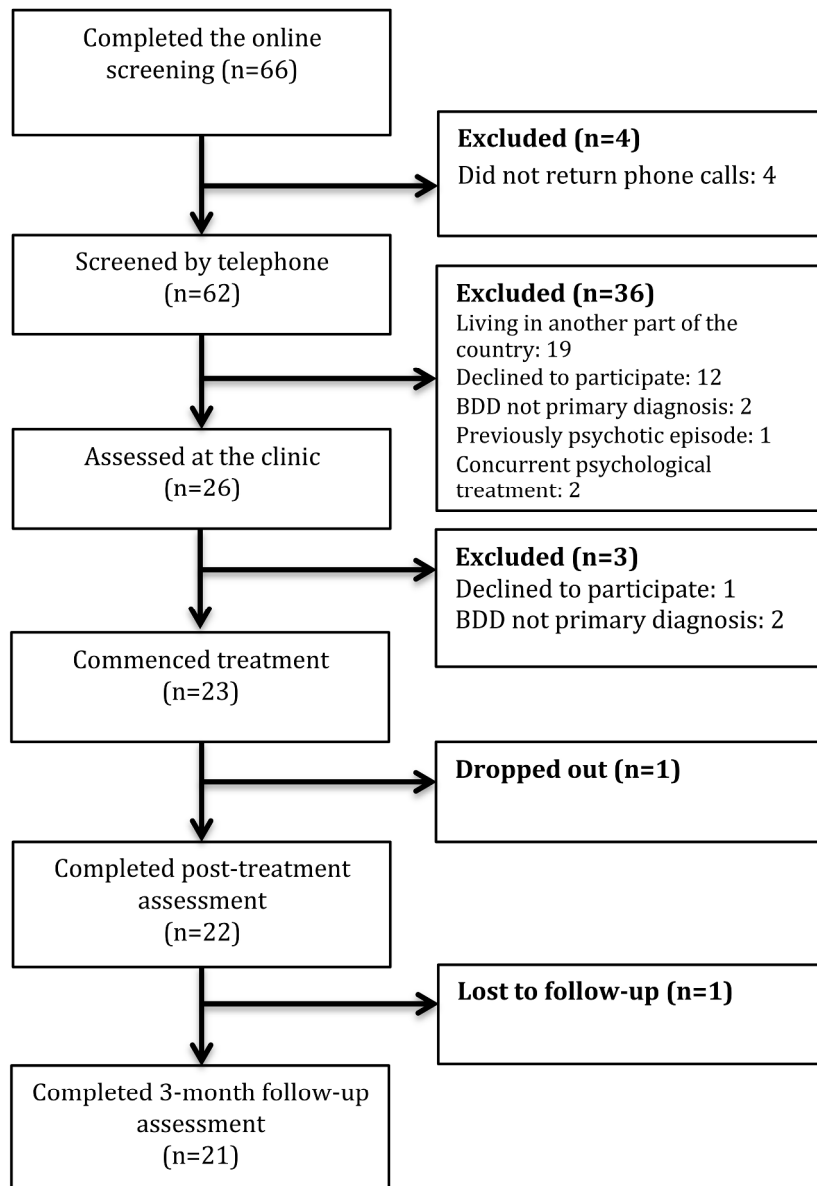
^a Participant characteristics of those randomised to CBT.

FIGURE LEGEND

Figure 1: Participant flow through the study

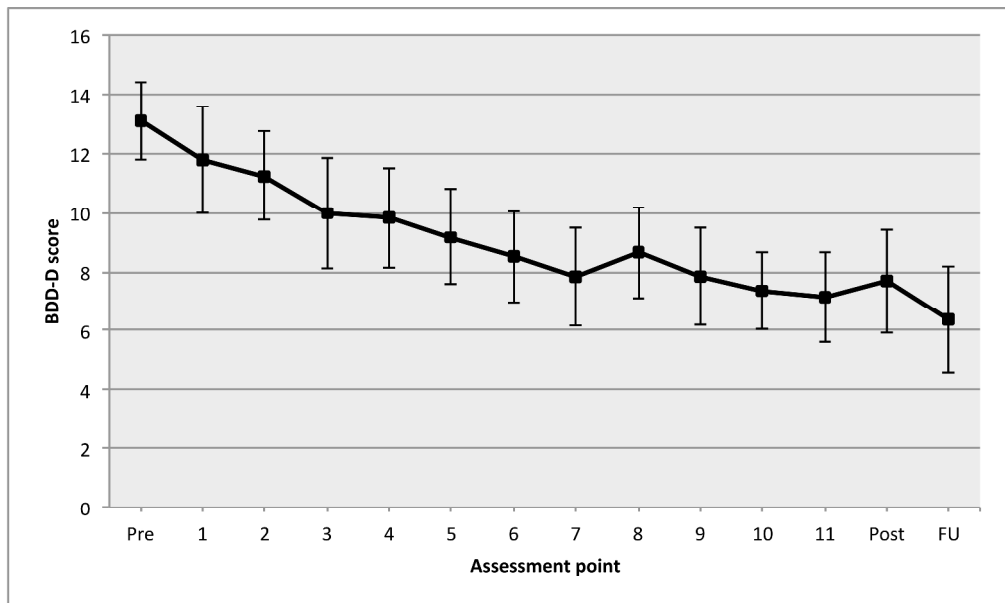
Figure 2: Weekly scores on the self-administered Body Dysmorphic Disorder Dimensional Scale, BDD-D (including 95 % confidence intervals)

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Participant flow through the study.

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

review only

BMJ Open

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

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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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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 $\geq 30\%$ 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.

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3 **Conclusion:** The results suggest that BDD-NET has the potential to greatly increase
4 access to CBT, at least for low-risk individuals with moderately severe BDD symptoms
5 and reasonably good insight. A randomized controlled trial of BDD-NET is warranted.
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10 **Clinicaltrials.gov registration ID:** NCT01850433.
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12 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

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

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3 time off work in order to attend therapy were also reported.[21 23] Therefore,
4 alternative ways of improving access to CBT are sorely needed.
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6 One way to increase access to CBT is to administer the treatment using the
7 Internet.[24 25] In the last decade, there has been a rapid development of Internet-
8 based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range
9 of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety
10 disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are
11 two main forms of ICBT: open access programs without any therapist guidance, and
12 programs with therapist support that try to closely mimic the process of face-to-face
13 CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of
14 modules accompanied by homework assignments, reflecting the content of a traditional
15 face-to-face therapy session. During the entire treatment, an identified therapist
16 provides guidance and gives feedback through a built-in e-mail system. Thus, the
17 therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in
18 traditional CBT, the only difference being the way care is delivered. There is evidence
19 that ICBT that incorporates therapist support may result in better treatment effects
20 when compared to ICBT provided without such guidance.[30-32] Furthermore, in a
21 recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there
22 was no significant difference between the two treatment modalities, suggesting non-
23 inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia,
24 ICBT has already been implemented as part of their regular health care systems.[34-36]

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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

1
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3 common body areas of concern reported by at least 50% of the participants at baseline
4 included: face (i.e., shape or size) 18 (78%), skin 14 (61%), part of the face (e.g., nose,
5 ears, eyes) 14 (61%), hair 13 (57%), and weight 12 (52%).
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8 Information about the study was posted on the official web page of the
9 clinic (www.internetpsykiatri.se), and flyers were distributed to mental health
10 professionals. The study was also mentioned in a national newspaper that ran a three-
11 part article series about BDD. A total of 66 individuals were considered for eligibility
12 (see Figure 1). To be eligible for the study participants had to be at least 18 years of age,
13 outpatients, and diagnosed with primary DSM-5 BDD, and currently living in Stockholm
14 or Uppsala county. As this was a pilot study exploring the feasibility of BDD-NET,
15 geographic proximity was required to facilitate in person assessments, and the
16 opportunity to intervene in case of safety concerns.
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23 Exclusion criteria were psychotropic medication changes within two
24 months prior to enrolment, completed CBT for BDD within the last 12 months, a score
25 on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder
26 (BDD-YBOCS) of ≤ 16 , current substance dependence, lifetime bipolar disorder or
27 psychosis, acute suicidal ideation, a personality disorder that could jeopardize treatment
28 participation (e.g., borderline personality disorder with self-harm), or concurrent
29 psychological treatment. Participants who were taking psychotropic medication, and
30 had been on a stable dose for at least 2 months prior to enrolment were asked to not
31 change their medication during the study period. After a complete description of the
32 study, written informed consent was obtained from all the participants. The regional
33 ethical review board in Stockholm, Sweden approved the study ID: 2013/117-31/2.
34 Clinicaltrials.gov registration ID: NCT01850433.
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51 Procedure

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

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

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

34 The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from
35 0 to 100 and is used to assess social, occupational, and psychological functioning, with a
36 higher score indicating better health. Overall reliability of the GAF is good, but questions
37 regarding its validity have been raised; see Aas 2010 for a review.[54]
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43 **Self-administered measures**

44 *Body Dysmorphic Dimensional Scale (BDD-D)*

45 The BDD-D[41] is a self report measure of symptom severity developed alongside the
46 DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and
47 repetitive behaviors, distress, control over symptoms, avoidance, and interference; each
48 rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20.
49 High internal consistency has been reported ($\alpha = .80$), though further validation work is
50 warranted.[41]
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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 ($\alpha = .83$) 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 ($\alpha = .94-95$) 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

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3 contacted by their therapist. If the patient were in need of additional care, an
4 appointment was made with either a senior psychiatrist at the clinic, or at an emergency
5 psychiatric unit.
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8 Adverse events (AE) were recorded mid-treatment and at post-treatment in
9 accordance with guidelines presented by Rozental et al.[60]. AE were defined as
10 negative events that could have occurred due to treatment participation (e.g.,
11 deterioration of target symptoms, worse sleep, and general negative well-being such as
12 stress). Participants were asked if they had experienced any AE that they associated
13 with the intervention (yes/no). If yes, the participants were asked to describe the event
14 in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no
15 impact) to 3 (severely negative impact) at the time that the AE had occurred
16 (retrospective self-reports), and if the AE still had a negative impact on well-being at
17 present. A licensed psychologist reviewed the AE reported.
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27 **Treatment**

28 The BDD-NET program was delivered via a tailored online platform, using a dedicated
29 server with encrypted traffic and a strong authentication login function in order to
30 guarantee participant confidentiality. The user interface of the platform used for BDD-
31 NET has been designed so that it can be used in any language. The 12-week long
32 treatment was based on a CBT model for BDD, emphasizing the role of avoidance and
33 safety behaviors as maintaining factors of BDD.[15] Most existing treatment protocols
34 for BDD involve a larger number of face-to-face sessions, ranging from 12 to 22.[17 18]
35 However, considering the format of ICBT (where therapists often make several contacts
36 during the week), as well as previous ICBT research in OCD showing that 10 weeks of
37 treatment yields the same results as 15 weeks of treatment, a 12-week long treatment
38 was deemed appropriate.[26 61]
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47 A central part of the treatment was a self-help text of 104 pages divided
48 into 8 modules (with modules 1–4 containing the core treatment components). The self-
49 help text underwent several revisions, and was reviewed by licensed psychologists with
50 previous experience of either ICBT or obsessive-compulsive and related disorders. Each
51 module was devoted to a special theme and included information and homework
52 assignments. The participants were given consecutive access to the next module after
53 correctly answering a quiz about the material that they had read, as well as filling out at
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3 least one worksheet corresponding to the homework assignment given in the module.
4 See Table 2 for a summary of the treatment modules and the number of participants
5 completing each module. The participant had contact with an identified therapist
6 throughout the whole treatment using a built-in e-mail system on the BDD-NET
7 webpage. The two therapists providing the treatment were both licensed psychologists
8 with several years of experience in treating obsessive-compulsive and related disorders.
9 To ensure treatment integrity and adherence to protocol, a licensed psychologist
10 monitored the messages sent by the therapists throughout the entire treatment.
11 Participants had unlimited access to the therapist and could use the e-mail system at any
12 time. The role of the therapist was mainly to guide and coach the participant through the
13 treatment, provide feedback on homework assignments, answer questions from the
14 participants, and consecutively grant access to the next treatment module. The therapist
15 also acted proactively by sending e-mails to participants asking them to report on
16 treatment progress. The participants were notified by an automated text-message (SMS)
17 when they had a new e-mail in the treatment platform. All homework assignments and
18 questions from the participants were reviewed and answered within 36 hours, except
19 on weekends. Participants were randomised using random.org to one of two therapists,
20 both licensed psychologists, with previous experience of treating obsessive-compulsive
21 and related disorders. The duration of therapist contact was automatically recorded by
22 the ICBT platform. None of the participants had face-to-face contact with a therapist.
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42 **Statistical analysis**

43 The primary analyses were done according to intention-to-treat (ITT) including the full
44 sample of 23 participants. Missing data at post-treatment and follow-up assessment
45 were deemed to be missing at random (using logistic regression models, as well as
46 inspecting correlations between indicator variables of missingness and other variables
47 from the dataset that might predict missingness) and imputed using multiple imputation
48 by chained equations.[62] All estimates with standard errors were pooled from five
49 imputations using “Rubin’s rules”[63] and the small sample correction for pooled
50 degrees of freedom.[64] Paired *t*-tests were performed to assess if changes from
51 pretreatment to post-treatment and pretreatment to follow-up were statistically
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3 significant. Paired *t*-tests comparing post-treatment to follow-up were also performed
4 to test for maintenance of the therapeutic gains. Within-group effect sizes were
5 calculated by dividing the difference between pre-treatment and post-treatment scores
6 by the within-group pooled standard deviation.[65] Fisher's exact test was used to
7 examine whether there was an association between the occurrence of an AE and
8 treatment responder status and independent *t*-tests were used to examine specific
9 therapist effects. All data were analyzed with Stata statistical software, version 13.1[66]
10 and the threshold for statistical significance set at the standard 5%.

11 12 13 14 15 16 17 18 **RESULTS**

19 20 21 **Attrition**

22 The participant flow throughout the trial is shown in Figure 1. One participant
23 terminated treatment during the first week due to reported personal problems and did
24 not complete any of the modules and was therefore regarded as a dropout, but was kept
25 in the primary analysis according to the ITT principles. The post-treatment and 3-month
26 follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants,
27 respectively. Self-rated questionnaires administered online were completed by 20 (87
28 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-
29 up.

30 31 32 33 34 35 36 37 38 **Primary and secondary outcomes**

39 Means, standard deviations, and within- group effect sizes, including confidence
40 intervals, for all assessment points with missing values replaced by multiple imputation
41 are reported in Table 3. Paired *t*-tests showed significant changes on all measures from
42 pre- to post-treatment ($t(df = 13.72 - 20.15) = 3.10 - 7.54$, all *p*-values < .01), and from
43 pretreatment to follow-up ($t(df = 10.96 - 19.24) = 3.13 - 8.66$, all *p*-values < .01). On the
44 main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size
45 was $d = 2.01$, and the pre-treatment to follow-up effect size indicated sustained effects (d
46 = 2.04).

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

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3 The significant pre- to post-treatment improvement on the BDD-YBOCS
4 insight item was in the large range ($t(18.44) = 4.30, p = <.001, d = 1.07$). Weekly scores
5 and follow-up data on the self-reported BDD-D are presented in Figure 2.
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13 The distribution of CGI-I scores for completers at posttreatment and follow-
14 up, respectively, was as follows: very much improved, 41 % and 52 %; much improved,
15 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At
16 posttreatment and follow-up, 64 % and 71 % were responders (very much or much
17 improved), respectively.
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21 On the other outcome measures, the within-group effect sizes from
22 pretreatment to posttreatment and pretreatment to follow-up were in the moderate to
23 large range ($d = .55 - 1.82$).
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31 **Adverse events**

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33 In total, 11 (48%) participants reported that they had experienced AE during the course
34 of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g.,
35 nightmares, depressive symptoms and worse sleep), followed by a deterioration of
36 symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus
37 on appearance), and general negative well-being (29%, e.g., stress). The AE reported
38 occurred mostly during the first part of the treatment, and most participants rated the
39 negative impact of the AE as moderate ($Median = 2, M = 1.8, SD = 1.1$) when they
40 occurred, and as no longer having a negative impact at posttreatment ($Median = 0, M =$
41 $.7, SD = 1.6$) with the exception of one participant who reported that the treatment had
42 led to an increase in appearance concerns and more frequent intrusive thoughts
43 compared to baseline, and was classified as a non-responder at post-treatment. The
44 occurrence of AE during treatment was unrelated to responder status at post-treatment,
45 with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-
46 responders (Fisher's exact test = 0.59).
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3 During treatment, one participant became increasingly depressed and was
4 referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after
5 which treatment continued.
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8 9 10 **Treatment activity and acceptability**

11 The mean number of messages that the participants sent to and received
12 from their therapist was 22.6 ($SD = 12.2$, range 0–47), and 30.2 ($SD = 11.3$, range 3–51),
13 respectively, and the therapists spent a weekly mean of 10.3 minutes ($SD = 6.7$, range
14 1.8–35.2), per participant. No significant differences were noted in time spent providing
15 support ($t(21) = 1.19$, $p = .25$, $d = 0.5$ 95% CI -0.39-1.39), or in treatment effects between
16 the two therapists ($t(21) = -.60$, $p = .56$, $d = -0.26$ 95% CI -1.11-0.60).
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19 In total, 19 (83%) participants completed the core components of the
20 treatment programme (modules 1–4), and six participants completed all eight of the
21 modules (26 %). The mean number of completed modules was 5.5 ($SD = 2.35$, range 0–
22 8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the
23 treatment, for example doing exercises in vivo and reading material online.
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26 At posttreatment, 6 (30%) participants reported that they were very
27 pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was
28 somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was
29 somewhat displeased with the treatment provided. One participant did not answer the
30 satisfaction question.
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33 All participants on psychotropic medication prior to treatment had kept
34 their dose stable during treatment, and none had received any other type of
35 psychological intervention. In total, 5 (22%) participants reported that they had
36 received additional care at the 3-month follow-up. Of the participants receiving
37 additional care, four were non-responders according to the CGI-I at post-treatment, and
38 all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was
39 classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the
40 BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT,
41 respectively, two participants had been prescribed an SRI (of which one was prescribed
42 for an indication other than BDD), and one participant had increased the dose of current
43 SRI.
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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

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

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6 ICBT should not be seen as a substitute for traditional face-to-face
7 treatment but, rather, a clinician extender that may substantially increase access to
8 evidence based treatment for a large proportion of sufferers who are not currently
9 receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input
10 will be required for complex patients who have poor insight and high suicide risk. In this
11 regard, BDD-NET may be particularly useful in the context of stepped-care for BDD,
12 where low-risk patients with reasonably good insight are offered ICBT and non-
13 responders or more complex and risky patients are offered more intensive, clinic based
14 CBT alone or in combination with medication.
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27 Participants in this trial made marked improvements despite no face-to-
28 face contact, beyond the baseline, post-treatment and follow-up assessments. Although
29 the treatment is Internet-based, the mechanisms of change may be the same as in
30 traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still
31 instructed to expose him or herself to feared stimuli in vivo without using maladaptive
32 coping strategies. Each participant had the same identified therapist throughout the
33 entire treatment, and although therapist contact was only around 10 minutes per
34 participant and week, the therapist sent a mean number of 30.2 messages per
35 participant, which averages out to 2-3 contacts per week. Messages sent from the
36 therapist were usually short, with prompts to the participant to engage in ERP and
37 report the outcome, allowing for adjustment of exposure strategies when needed. Thus,
38 the therapist was proactive and had shorter, but more frequent contact with
39 participants compared to traditional CBT, where sessions usually are held once a week.
40 Despite minimal therapist contact, participants often report the feeling of a therapist
41 presence; the therapists' frequent encouragement to engage in daily ERP may be a
42 critical component of the intervention.[32]
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54 In total, 48% of the participants experienced an adverse event during
55 treatment. However, the adverse events were mostly mild, and non-enduring, and a vast
56 majority of participants were very pleased or pleased with the treatment provided. Most
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3 (83%) of the participants completed all of the core treatment components and engaged
4 in ERP, suggesting that the treatment was engaging and highly acceptable. The
5 treatment completion rate is in line with previous ICBT studies of various disorders,
6 suggesting that ICBT is as acceptable for patients with BDD as it is for other patient
7 groups (e.g., OCD, SAD, and MDD).[26 27]

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

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

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3 Due to safety concerns, the presence of severe suicidal ideation and
4 substance dependence, both of which are common comorbidities in BDD, were criteria
5 for exclusion. Thus, it is unknown if BDD-NET would be appropriate for patients with
6 these comorbidities. The insight item on the BDD-YBOCS was used to assess change in
7 insight before and after treatment; other available instruments such as the Brown
8 Assessment of Beliefs Scale (BABS)[71] may have provided a more precise and sensitive
9 measure of overvalued ideation. Both therapists in the study had previous experience of
10 treating BDD, and although the essential components of the treatment are delivered as
11 online modules, there could be a specific therapist factor as the therapists answered
12 questions and gave treatment guidance through the integrated e-mail system. It is
13 unknown if the same outcomes would be obtained with less experienced therapists.
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22 Despite the limitations of this uncontrolled trial, the results suggest that
23 BDD-NET has the potential to reduce symptoms and increase access to CBT for a large
24 majority of moderately ill patients with BDD who are motivated to receive treatment. A
25 randomized controlled trial of BDD-NET is warranted.
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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.

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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, <i>SD</i>)	30.3	(6.3)
Female (<i>n</i> , %)	16	(70%)
Employment status (<i>n</i> , %)		
Employed	14	(61%)
Unemployed	4	(17%)
Student	5	(22%)
Married (<i>n</i> , %)	7	(30%)
Education (<i>n</i> , %)		
High school	16	(70%)
University college	7	(30%)
Previous psychological treatment (<i>n</i> , %)	12	(52%)
Previous use of psychotropic medication (<i>n</i> , %)	11	(48%)
Current use of psychotropic medication (<i>n</i> , %)	7	(30%)
Years with BDD symptoms (Mean, <i>SD</i>)	15.3	(8.1)
Number of body areas of concern (Mean, <i>SD</i>)	6	(3)
BDD-5 insight specifier (<i>n</i> , %)		
Good or fair insight	10	43%
Poor insight	11	(48%)
Absent/delusional beliefs	2	(9%)
Current comorbidity (<i>n</i> , %)		
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

Measure	Pre-treatment		Post-treatment		3-month follow-up ^a		Within-group effect size <i>d</i>								
							Pre to post ^a			Pre to follow-up ^a			Post to follow-up ^a		
	M	SD	M	SD	M	SD	<i>d</i>	CI-	CI+	<i>d</i>	CI-	CI+	<i>d</i>	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 \pm 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 $\geq 30\%$ 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.

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3 **Conclusion:** The results suggest that BDD-NET has the potential to greatly increase
4 access to CBT, at least for low-risk individuals with moderately severe BDD symptoms
5 and reasonably good insight. A randomized controlled trial of BDD-NET is warranted.
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8 Clinicaltrials.gov registration ID: NCT01850433.
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10 11 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

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

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3 time off work in order to attend therapy were also reported.[21 23] Therefore,
4 alternative ways of improving access to CBT are sorely needed.
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6 One way to increase access to CBT is to administer the treatment using the
7 Internet.[24 25] In the last decade, there has been a rapid development of Internet-
8 based CBT (ICBT) programs, with over 100 published RCTs since 2001 for a wide range
9 of psychiatric disorders, such as obsessive-compulsive disorder (OCD), social anxiety
10 disorder (SAD), major depressive disorder (MDD) and panic disorder.[26-28] There are
11 two main forms of ICBT: open access programs without any therapist guidance, and
12 programs with therapist support that try to closely mimic the process of face-to-face
13 CBT.[29] In the latter modality of ICBT, the treatment is presented online as a series of
14 modules accompanied by homework assignments, reflecting the content of a traditional
15 face-to-face therapy session. During the entire treatment, an identified therapist
16 provides guidance and gives feedback through a built-in e-mail system. Thus, the
17 therapeutic aim of ICBT is to cultivate new behaviors and thinking patterns, just as in
18 traditional CBT, the only difference being the way care is delivered. There is evidence
19 that ICBT that incorporates therapist support may result in better treatment effects
20 when compared to ICBT provided without such guidance.[30-32] Furthermore, in a
21 recent meta-analysis of 13 RCTs directly comparing ICBT against face-to-face CBT there
22 was no significant difference between the two treatment modalities, suggesting non-
23 inferiority of ICBT.[33] In some countries like Sweden, the Netherlands and Australia,
24 ICBT has already been implemented as part of their regular health care systems.[34-36]
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26 With the primary aim to increase access to evidence based treatment for
27 BDD, we developed BDD-NET, a structured and interactive therapist-supported ICBT
28 program based on existing manuals,[15 19] and tested its feasibility and efficacy in an
29 uncontrolled clinical trial. We hypothesized that BDD-NET would be acceptable to
30 patients, lead to a reduction of BDD and other psychiatric symptoms, and require
31 minimal therapist input.
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33 **METHOD**

34 **Participants**

35 The study included 23 self-referred adults with a primary DSM-5 diagnosis of BDD.
36 Participant demographics and clinical characteristics are presented in Table 1. The most
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3 common body areas of concern reported by at least 50% of the participants at baseline
4 included: face (i.e., shape or size) 18 (78%), skin 14 (61%), part of the face (e.g., nose,
5 ears, eyes) 14 (61%), hair 13 (57%), and weight 12 (52%).
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8 Information about the study was posted on the official web page of the
9 clinic (www.internetpsykiatri.se), and flyers were distributed to mental health
10 professionals. The study was also mentioned in a national newspaper that ran a three-
11 part article series about BDD. A total of 66 individuals were considered for eligibility
12 (see Figure 1). To be eligible for the study participants had to be at least 18 years of age,
13 outpatients, and diagnosed with primary DSM-5 BDD, and currently living in Stockholm
14 or Uppsala county. As this was a pilot study exploring the feasibility of BDD-NET,
15 geographic proximity was required to facilitate in person assessments, and the
16 opportunity to intervene in case of safety concerns.
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23 Exclusion criteria were psychotropic medication changes within two
24 months prior to enrolment, completed CBT for BDD within the last 12 months, a score
25 on the Yale-Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder
26 (BDD-YBOCS) of ≤ 16 , current substance dependence, lifetime bipolar disorder or
27 psychosis, acute suicidal ideation, a personality disorder that could jeopardize treatment
28 participation (e.g., borderline personality disorder with self-harm), or concurrent
29 psychological treatment. Participants who were taking psychotropic medication, and
30 had been on a stable dose for at least 2 months prior to enrolment were asked to not
31 change their medication during the study period. After a complete description of the
32 study, written informed consent was obtained from all the participants. The regional
33 ethical review board in Stockholm, Sweden approved the study ID: 2013/117-31/2.
34 Clinicaltrials.gov registration ID: NCT01850433.
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51 Procedure

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

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

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

34 The GAF[53] is a clinician rated measure consisting of a numeric scale that ranges from
35 0 to 100 and is used to assess social, occupational, and psychological functioning, with a
36 higher score indicating better health. Overall reliability of the GAF is good, but questions
37 regarding its validity have been raised; see Aas 2010 for a review.[54]
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43 **Self-administered measures**

44 *Body Dysmorphic Dimensional Scale (BDD-D)*

45 The BDD-D[41] is a self report measure of symptom severity developed alongside the
46 DSM-5 criteria for BDD. It consists of 5 items measuring time occupied by thoughts and
47 repetitive behaviors, distress, control over symptoms, avoidance, and interference; each
48 rated on a scale from 0 (none) to 4 (extreme), with a total score ranging from 0 to 20.
49 High internal consistency has been reported ($\alpha = .80$), though further validation work is
50 warranted.[41]
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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 ($\alpha = .83$) 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 ($\alpha = .94-95$) 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

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3 contacted by their therapist. If the patient were in need of additional care, an
4 appointment was made with either a senior psychiatrist at the clinic, or at an emergency
5 psychiatric unit.
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8 Adverse events (AE) were recorded mid-treatment and at post-treatment in
9 accordance with guidelines presented by Rozental et al.[60]. AE were defined as
10 negative events that could have occurred due to treatment participation (e.g.,
11 deterioration of target symptoms, worse sleep, and general negative well-being such as
12 stress). Participants were asked if they had experienced any AE that they associated
13 with the intervention (yes/no). If yes, the participants were asked to describe the event
14 in their own words, and rate the impact of the AE on a 4-point scale ranging from 0 (no
15 impact) to 3 (severely negative impact) at the time that the AE had occurred
16 (retrospective self-reports), and if the AE still had a negative impact on well-being at
17 present. A licensed psychologist reviewed the AE reported.
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26 Treatment

27 The BDD-NET program was delivered via a tailored online platform, using a dedicated
28 server with encrypted traffic and a strong authentication login function in order to
29 guarantee participant confidentiality. The user interface of the platform used for BDD-
30 NET has been designed so that it can be used in any language. The 12-week long
31 treatment was based on a CBT model for BDD, emphasizing the role of avoidance and
32 safety behaviors as maintaining factors of BDD.[15] Most existing treatment protocols
33 for BDD involve a larger number of face-to-face sessions, ranging from 12 to 22.[17 18]
34 However, considering the format of ICBT (where therapists often make several contacts
35 during the week), as well as previous ICBT research in OCD showing that 10 weeks of
36 treatment yields the same results as 15 weeks of treatment, a 12-week long treatment
37 was deemed appropriate.[26 61]
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47 A central part of the treatment was a self-help text of 104 pages divided
48 into 8 modules (with modules 1–4 containing the core treatment components). The self-
49 help text underwent several revisions, and was reviewed by licensed psychologists with
50 previous experience of either ICBT or obsessive-compulsive and related disorders. Each
51 module was devoted to a special theme and included information and homework
52 assignments. The participants were given consecutive access to the next module after
53 correctly answering a quiz about the material that they had read, as well as filling out at
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3 least one worksheet corresponding to the homework assignment given in the module.
4 See Table 2 for a summary of the treatment modules and the number of participants
5 completing each module. The participant had contact with an identified therapist
6 throughout the whole treatment using a built-in e-mail system on the BDD-NET
7 webpage. The two therapists providing the treatment were both licensed psychologists
8 with several years of experience in treating obsessive-compulsive and related disorders.
9 To ensure treatment integrity and adherence to protocol, a licensed psychologist
10 monitored the messages sent by the therapists throughout the entire treatment.
11 Participants had unlimited access to the therapist and could use the e-mail system at any
12 time. The role of the therapist was mainly to guide and coach the participant through the
13 treatment, provide feedback on homework assignments, answer questions from the
14 participants, and consecutively grant access to the next treatment module. The therapist
15 also acted proactively by sending e-mails to participants asking them to report on
16 treatment progress. The participants were notified by an automated text-message (SMS)
17 when they had a new e-mail in the treatment platform. All homework assignments and
18 questions from the participants were reviewed and answered within 36 hours, except
19 on weekends. Participants were randomised using random.org to one of two therapists,
20 both licensed psychologists, with previous experience of treating obsessive-compulsive
21 and related disorders. The duration of therapist contact was automatically recorded by
22 the ICBT platform. None of the participants had face-to-face contact with a therapist.
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41 **Statistical analysis**

42 The primary analyses were done according to intention-to-treat (ITT) including the full
43 sample of 23 participants. Missing data at post-treatment and follow-up assessment
44 were deemed to be missing at random (using logistic regression models, as well as
45 inspecting correlations between indicator variables of missingness and other variables
46 from the dataset that might predict missingness) and imputed using multiple imputation
47 by chained equations.[62] All estimates with standard errors were pooled from five
48 imputations using “Rubin’s rules”[63] and the small sample correction for pooled
49 degrees of freedom.[64] Paired *t*-tests were performed to assess if changes from
50 pretreatment to post-treatment and pretreatment to follow-up were statistically
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3 | significant. Paired *t*-tests comparing post-treatment to follow-up were also performed
4 to test for maintenance of the therapeutic gains. Within-group effect sizes were
5 calculated by dividing the difference between pre-treatment and post-treatment scores
6 by the within-group pooled standard deviation.[65] Fisher's exact test was used to
7 examine whether there was an association between the occurrence of an AE and
8 treatment responder status and independent *t*-tests were used to examine specific
9 therapist effects. All data were analyzed with Stata statistical software, version 13.1[66]
10 and the threshold for statistical significance set at the standard 5%.

17 18 **RESULTS**

21 **Attrition**

22 The participant flow throughout the trial is shown in Figure 1. One participant
23 terminated treatment during the first week due to reported personal problems and did
24 not complete any of the modules and was therefore regarded as a dropout, but was kept
25 in the primary analysis according to the ITT principles. The post-treatment and 3-month
26 follow-up assessments were completed by 22 (96 %) and 21 (91 %) participants,
27 respectively. Self-rated questionnaires administered online were completed by 20 (87
28 %) participants at posttreatment, and by 19 (83 %) participants at the 3-month follow-
29 up.
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38 **Primary and secondary outcomes**

39 Means, standard deviations, and within- group effect sizes, including confidence
40 intervals, for all assessment points with missing values replaced by multiple imputation
41 are reported in Table 3. Paired *t*-tests showed significant changes on all measures from
42 pre- to post-treatment ($t(df = 13.72 - 20.15) = 3.10 - 7.54$, all *p*-values < .01), and from
43 pretreatment to follow-up ($t(df = 10.96 - 19.24) = 3.13 - 8.66$, all *p*-values < .01). On the
44 main outcome measure (BDD-YBOCS), the pretreatment to post-treatment effect size
45 was $d = 2.01$, and the pre-treatment to follow-up effect size indicated sustained effects (d
46 = 2.04).
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54 At posttreatment, 82% of completers were responders (≥ 30 % decrease on
55 the BDD-YBOCS), and the mean decrease of the BDD-YBOCS score from pretreatment to
56 posttreatment was 51% (Mean difference = 15.08, 95% CI 10.86–19.30).
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3 The significant pre- to post-treatment improvement on the BDD-YBOCS
4 insight item was in the large range ($t(18.44) = 4.30, p = <.001, d = 1.07$). Weekly scores
5 and follow-up data on the self-reported BDD-D are presented in Figure 2.
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10 <<INSERT FIGURE 2 ABOUT HERE>>
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13 The distribution of CGI-I scores for completers at posttreatment and follow-
14 up, respectively, was as follows: very much improved, 41 % and 52 %; much improved,
15 23% and 19 %; minimally improved, 27 % and 19 %; no change, 5 % and 10 %. At
16 posttreatment and follow-up, 64 % and 71 % were responders (very much or much
17 improved), respectively.
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21 On the other outcome measures, the within-group effect sizes from
22 pretreatment to posttreatment and pretreatment to follow-up were in the moderate to
23 large range ($d = .55 - 1.82$).
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31 **Adverse events**

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33 In total, 11 (48%) participants reported that they had experienced AE during the course
34 of treatment. The most frequent side effect was emergence of new symptoms (43%, e.g.,
35 nightmares, depressive symptoms and worse sleep), followed by a deterioration of
36 symptoms (29%, e.g., more frequent negative thoughts about appearance and/or focus
37 on appearance), and general negative well-being (29%, e.g., stress). The AE reported
38 occurred mostly during the first part of the treatment, and most participants rated the
39 negative impact of the AE as moderate ($Median = 2, M = 1.8, SD = 1.1$) when they
40 occurred, and as no longer having a negative impact at posttreatment ($Median = 0, M =$
41 $.7, SD = 1.6$) with the exception of one participant who reported that the treatment had
42 led to an increase in appearance concerns and more frequent intrusive thoughts
43 compared to baseline, and was classified as a non-responder at post-treatment. The
44 occurrence of AE during treatment was unrelated to responder status at post-treatment,
45 with 8 (44%) of the responders reporting an AE compared to 3 (75%) of the non-
46 responders (Fisher's exact test = 0.59).
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3 During treatment, one participant became increasingly depressed and was
4 referred for a detailed psychiatric evaluation and was prescribed an SSRI (week 9), after
5 which treatment continued.
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8 9 10 **Treatment activity and acceptability**

11 The mean number of messages that the participants sent to and received
12 from their therapist was 22.6 ($SD = 12.2$, range 0–47), and 30.2 ($SD = 11.3$, range 3–51),
13 respectively, and the therapists spent a weekly mean of 10.3 minutes ($SD = 6.7$, range
14 1.8–35.2), per participant. No significant differences were noted in time spent providing
15 support ($t(21) = 1.19$, $p = .25$, $d = 0.5$ 95% CI -0.39-1.39), or in treatment effects between
16 the two therapists ($t(21) = -.60$, $p = .56$, $d = -0.26$ 95% CI -1.11-0.60).
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19 In total, 19 (83%) participants completed the core components of the
20 treatment programme (modules 1–4), and six participants completed all eight of the
21 modules (26 %). The mean number of completed modules was 5.5 ($SD = 2.35$, range 0–
22 8). Most participants spent 2 to 7 hours/per week (retrospective self reports) on the
23 treatment, for example doing exercises in vivo and reading material online.
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26 At posttreatment, 6 (30%) participants reported that they were very
27 pleased with the treatment provided; 11 (55%) that they were pleased; 1 (5%) was
28 somewhat pleased; 1 (5 %) was neither pleased nor displeased; and 1 (5%) was
29 somewhat displeased with the treatment provided. One participant did not answer the
30 satisfaction question.
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33 All participants on psychotropic medication prior to treatment had kept
34 their dose stable during treatment, and none had received any other type of
35 psychological intervention. In total, 5 (22%) participants reported that they had
36 received additional care at the 3-month follow-up. Of the participants receiving
37 additional care, four were non-responders according to the CGI-I at post-treatment, and
38 all endorsed a score above 20 on the BDD-YBOCS at follow-up. The other participant was
39 classified as a responder at post-treatment and follow-up, endorsing a score of 4 on the
40 BDD-YBOCS. Two participants had received one and five sessions of face-to-face CBT,
41 respectively, two participants had been prescribed an SRI (of which one was prescribed
42 for an indication other than BDD), and one participant had increased the dose of current
43 SRI.
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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

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

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6 ICBT should not be seen as a substitute for traditional face-to-face
7 treatment but, rather, a clinician extender that may substantially increase access to
8 evidence based treatment for a large proportion of sufferers who are not currently
9 receiving it. Clearly, ICBT will not be indicated for all BDD patients and specialist input
10 will be required for complex patients who have poor insight and high suicide risk. In this
11 regard, BDD-NET may be particularly useful in the context of stepped-care for BDD,
12 where low-risk patients with reasonably good insight are offered ICBT and non-
13 responders or more complex and risky patients are offered more intensive, clinic based
14 CBT alone or in combination with medication.
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27 Participants in this trial made marked improvements despite no face-to-
28 face contact, beyond the baseline, post-treatment and follow-up assessments. Although
29 the treatment is Internet-based, the mechanisms of change may be the same as in
30 traditional CBT (i.e., behavior change/habituation through ERP) as the participant is still
31 instructed to expose him or herself to feared stimuli in vivo without using maladaptive
32 coping strategies. Each participant had the same identified therapist throughout the
33 entire treatment, and although therapist contact was only around 10 minutes per
34 participant and week, the therapist sent a mean number of 30.2 messages per
35 participant, which averages out to 2-3 contacts per week. Messages sent from the
36 therapist were usually short, with prompts to the participant to engage in ERP and
37 report the outcome, allowing for adjustment of exposure strategies when needed. Thus,
38 the therapist was proactive and had shorter, but more frequent contact with
39 participants compared to traditional CBT, where sessions usually are held once a week.
40 Despite minimal therapist contact, participants often report the feeling of a therapist
41 presence; the therapists' frequent encouragement to engage in daily ERP may be a
42 critical component of the intervention.[32]
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54 In total, 48% of the participants experienced an adverse event during
55 treatment. However, the adverse events were mostly mild, and non-enduring, and a vast
56 majority of participants were very pleased or pleased with the treatment provided. Most
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3 (83%) of the participants completed all of the core treatment components and engaged
4 in ERP, suggesting that the treatment was engaging and highly acceptable. The
5 treatment completion rate is in line with previous ICBT studies of various disorders,
6 suggesting that ICBT is as acceptable for patients with BDD as it is for other patient
7 groups (e.g., OCD, SAD, and MDD).[26 27]
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11 Stigma, shame and logistic barriers can be a hindrance for persons with
12 BDD to seek treatment.[21 23] An advantage of BDD-NET is that all therapist contact is
13 online; this could reduce initial shame and stigma associated with openly talking about
14 one's appearance concerns. BDD-NET also eliminates the need for weekly visits to the
15 clinic while receiving CBT and has the potential to minimize logistic barriers and
16 increase access to evidence-based care in rural areas or where trained therapists are not
17 available. Furthermore, one therapist can have more patients in treatment at the same
18 time compared to face-to-face therapy, while spending less time per patient as the
19 routine aspects of treatment are delegated to the computerized platform. Thus, the ICBT
20 format has the potential to lower the severity threshold for people with BDD to seek and
21 receive adequate treatment. Expert clinicians can dedicate more time and resources to
22 complex, e.g., suicidal, cases. Another advantage of BDD-NET is that the treatment is
23 protocol based and delivered as a series of modules online. This greatly reduces the risk
24 of therapist drift,[68] and ensures that all patients receive exactly the same treatment.
25 The control over content delivered also opens up for dismantling studies, as modules
26 can easily be added or taken out to test the specific effect of a treatment component, as
27 shown by Ljótsson et al.[69] where the specific effect of systematic exposure on Irritable
28 Bowel Syndrome symptoms was tested.
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42 This study has several limitations that need to be considered when
43 interpreting the results. First and foremost, this was an uncontrolled trial. This limits the
44 possibilities to make causal inferences as to what caused the observed changes. The
45 improvements observed over the course of treatment could have been due to the mere
46 passage of time. However, when considering the chronicity of BDD,[8 70] we regard it as
47 unlikely that the treatment effects in this trial could be entirely explained by
48 spontaneous remission. Furthermore, the improvements observed could also be due to
49 unspecific factors, such as caregiver attention. However, the maintenance of
50 improvement from post-treatment to follow-up indicates that treatment gains were
51 temporally stable, and the majority of participants did not receive any further treatment.
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3 Due to safety concerns, the presence of severe suicidal ideation and
4 substance dependence, both of which are common comorbidities in BDD, were criteria
5 for exclusion. Thus, it is unknown if BDD-NET would be appropriate for patients with
6 these comorbidities. The insight item on the BDD-YBOCS was used to assess change in
7 insight before and after treatment; other available instruments such as the Brown
8 Assessment of Beliefs Scale (BABS)[71] may have provided a more precise and sensitive
9 measure of overvalued ideation. Both therapists in the study had previous experience of
10 treating BDD, and although the essential components of the treatment are delivered as
11 online modules, there could be a specific therapist factor as the therapists answered
12 questions and gave treatment guidance through the integrated e-mail system. It is
13 unknown if the same outcomes would be obtained with less experienced therapists.
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22 Despite the limitations of this uncontrolled trial, the results suggest that
23 BDD-NET has the potential to reduce symptoms and increase access to CBT for a large
24 majority of moderately ill patients with BDD who are motivated to receive treatment. A
25 randomized controlled trial of BDD-NET is warranted.
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32 Kayoko Isomura for their invaluable help.
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37 **AUTHOR'S CONTRIBUTIONS**

38 JE was the project manager and participated in designing the study, analyzing data,
39 providing treatment, and drafting the manuscript and the treatment manual. VI
40 participated in designing the study, providing treatment and drafting the manuscript
41 and the treatment manual. EA participated in designing the study and drafting the
42 manuscript and the treatment manual. DMC participated in drafting the manuscript and
43 designing the study. BL participated in designing the study, analyzing data and drafting
44 the manuscript and the treatment manual. CR participated in designing the study and
45 drafting the treatment manual and the manuscript. All authors read and approved the
46 final manuscript.
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55 **COMPETING INTERESTS**

56 None declared.
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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, <i>SD</i>)	30.3	(6.3)
Female (<i>n</i> , %)	16	(70%)
Employment status (<i>n</i> , %)		
Employed	14	(61%)
Unemployed	4	(17%)
Student	5	(22%)
Married (<i>n</i> , %)	7	(30%)
Education (<i>n</i> , %)		
High school	16	(70%)
University college	7	(30%)
Previous psychological treatment (<i>n</i> , %)	12	(52%)
Previous use of psychotropic medication (<i>n</i> , %)	11	(48%)
Current use of psychotropic medication (<i>n</i> , %)	7	(30%)
Years with BDD symptoms (Mean, <i>SD</i>)	15.3	(8.1)
Number of body areas of concern (Mean, <i>SD</i>)	6	(3)
BDD-5 insight specifier (<i>n</i> , %)		
Good or fair insight	10	43%
Poor insight	11	(48%)
Absent/delusional beliefs	2	(9%)
Current comorbidity (<i>n</i> , %)		
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

Measure	Pre-treatment		Post-treatment		3-month follow-up ^a		Within-group effect size <i>d</i>								
							Pre to post ^a			Pre to follow-up ^a			Post to follow-up ^a		
	M	SD	M	SD	M	SD	<i>d</i>	CI-	CI+	<i>d</i>	CI-	CI+	<i>d</i>	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 \pm SD unless otherwise specified.

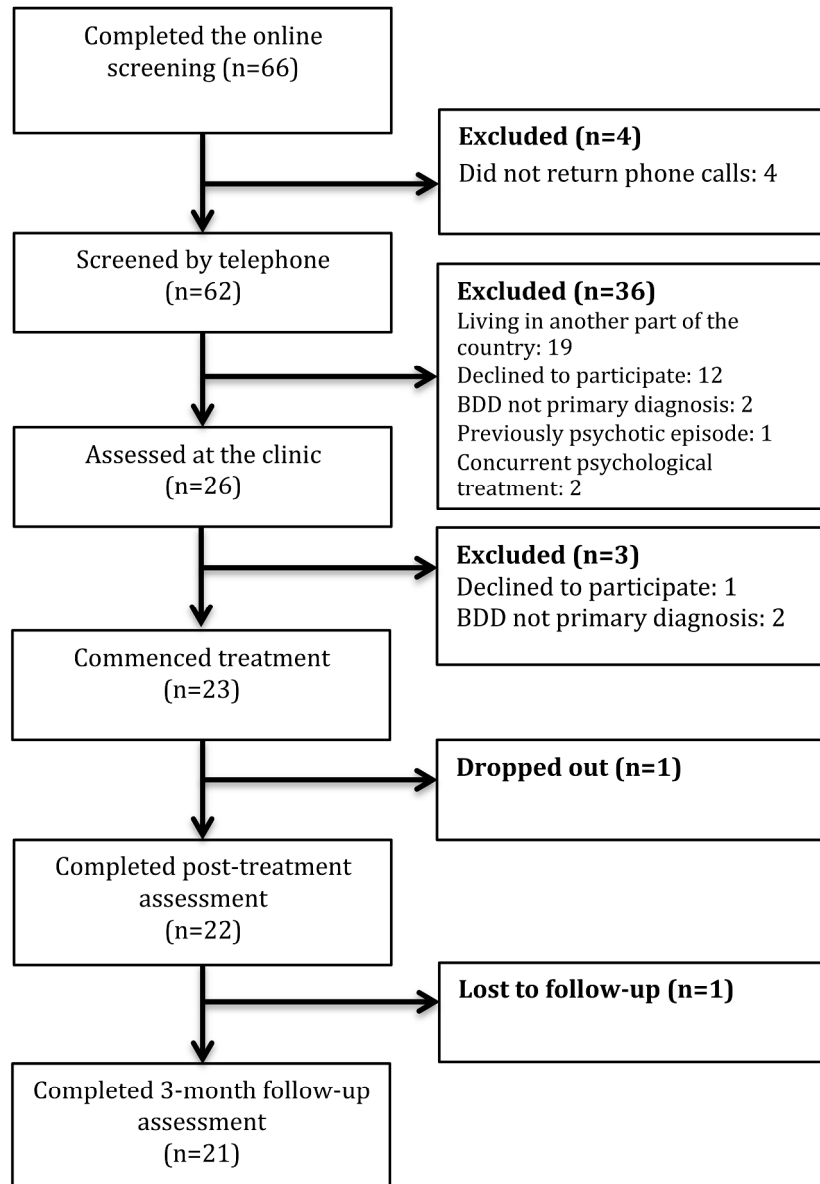
BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD; BABS, Brown Assessment of Beliefs Scale; MADRS, Montgomery-Åsberg Depression Rating Scale; BDI, Beck Depression Inventory.

^a Participant characteristics of those randomised to CBT.

FIGURE LEGEND

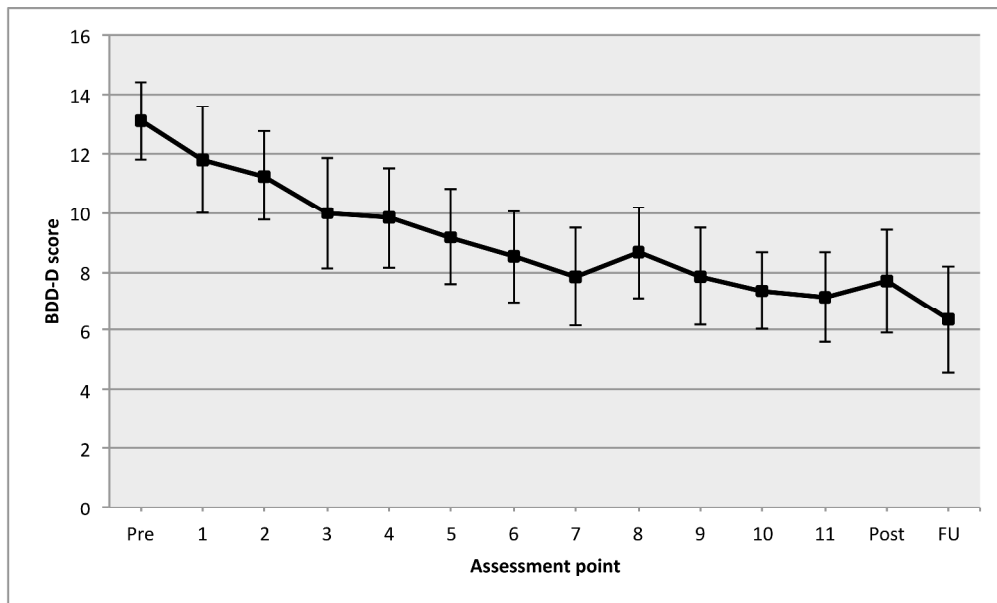
Figure 1: Participant flow through the study

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



Participant flow through the study.

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

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