Therapist guided internet based cognitive behavioural therapy for body dysmorphic disorder: single blind randomised controlled trial

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ABSTRACT

OBJECTIVES

To evaluate the efficacy of therapist guided internet based cognitive behavioural therapy (CBT) programme for body dysmorphic disorder (BDD-NET) compared with online supportive therapy.

DESIGN

A 12 week single blind parallel group randomised controlled trial.

SETTING

Academic medical centre.

PARTICIPANTS

94 self referred adult outpatients with a diagnosis of body dysmorphic disorder and a modified Yale-Brown obsessive compulsive scale (BDD-YBOCS) score of ≥20. Concurrent psychotropic drug treatment was permitted if the dose had been stable for at least two months before enrolment and remained unchanged during the trial.

INTERVENTIONS

Participants received either BDD-NET (n=47) or supportive therapy (n=47) delivered via the internet for 12 weeks.

MAIN OUTCOME MEASURES

The primary outcome was the BDD-YBOCS score after treatment and follow-up (three and six months from baseline) as evaluated by a masked assessor. Responder status was defined as a ≥30% reduction in symptoms on the scale.

Secondary outcomes were measures of depression (MADRS-S), global functioning (GAF), clinical global improvement (CGI-I), and quality of life (EQ5D). The six month follow-up time and all outcomes other than BDD-YBOCS and MADRS-S at 3 months were not pre-specified in the registration at clinicaltrials.gov because of an administrative error but were included in the original trial protocol approved by the regional ethics committee before the start of the trial.

RESULTS

BDD-NET was superior to supportive therapy and was associated with significant improvements in severity of symptoms of body dysmorphic disorder (BDD-YBOCS group difference –7.1 points, 95% confidence interval –9.8 to –4.4), depression (MADRS-S group difference –4.5 points, –7.5 to –1.4), and other secondary measures. At follow-up, 56% of those receiving BDD-NET were classed as responders, compared with 13% receiving supportive therapy. The number needed to treat was 2.34 (1.71 to 4.35). Self reported satisfaction was high.

CONCLUSIONS

CBT can be delivered safely via the internet to patients with body dysmorphic disorder. BDD-NET has the potential to increase access to evidence based psychiatric care for this mental disorder, in line with NICE priority recommendations. It could be particularly useful in a stepped care approach, in which general practitioner or other mental health professionals can offer treatment to people with mild to moderate symptoms at low risk of suicide.

TRIAL REGISTRATION

ClinicalTrials.gov ID: NCT02010619.

WHAT IS ALREADY KNOWN ON THIS TOPIC

The NICE guidelines recommend cognitive behavioural therapy (CBT) for body dysmorphic disorder but most affected people do not have access to this treatment

Internet based CBT is a burgeoning part of mental health aimed at increasing access to evidence based treatments for a range of mental disorders and other conditions

A pilot study suggested that therapist guided internet based CBT could be a highly acceptable, feasible, and potentially cost effective treatment option for body dysmorphic disorder

WHAT THIS STUDY ADDS

This large randomised controlled trial evaluated the efficacy of therapist guided internet based CBT for body dysmorphic disorder (BDD-NET)

BDD-NET was associated with significant improvements in symptom severity, despite no face to face contact with a therapist, and gains were maintained for at least three months after the end of treatment

Introduction

Body dysmorphic disorder (BDD) is a psychiatric disorder characterised by a pervasive preoccupation with perceived defects in physical appearance accompanied by avoidance and time consuming compulsive behaviours, such as mirror gazing and excessive camouflaging to hide perceived defects.[1] If left untreated, this is a chronic and unremitting disorder that is associated with functional impairment across multiple life domains, relatively high rates of psychiatric admissions to hospital, substance dependence, and suicidality.[2-4] Although the disorder is often underdetected and underdiagnosed within the mental health services,[5 6] epidemiological studies show that it is a common mental health problem, with a prevalence ranging from 0.7% to 2.2% in the general population.[7-10] It is common for those with body dysmorphic disorder to seek non-psychiatric care, such as dermatological treatment or plastic surgery, in an attempt to "fix" the perceived defects; however, such interventions rarely work and can lead to a deterioration of symptoms.[11 12]

Evidence based treatments for body dysmorphic disorder include psychopharmacological treatment and

cognitive behaviour therapy (CBT).[13-16] Guidance from the National Institute for Health and Clinical Excellence (NICE) recommends that adults should be offered the choice of either a course of a selective serotonin response inhibitor or specialised CBT that deals with the key features of the disorder.[17] There is, however, a gap between supply and demand of CBT because of various factors, such as a lack of trained therapists, direct and indirect costs associated with treatment, and geographical barriers that prevent people with body dysmorphic disorder from receiving specialised CBT.[18-20] In two surveys, only 10-17% of people with body dysmorphic concerns reported that they had received an empirically supported psychotherapy (such as CBT), and 19-34% reported that they had received an SSRI.[19 20] Thus, one of NICE's key priorities for implementation—namely, that each primary care trust, mental healthcare trust, and children's trust that provides mental health services should have access to a specialist multidisciplinary team offering age appropriate care—is currently far from reality.[17] The growth in demand for mental healthcare exceeds available National Health Service (NHS) resources in the United Kingdom, and this gap is likely to increase up to 2020.[21] Cost pressures require that providers find innovative ways to deliver services. The UK government's mental health strategy "no health without mental health"[22] recommends the increased use of information and communication technology to improve care and access to services. UK government initiatives such as "Digital First" aim to reduce unnecessary face to face contact between patients and healthcare professionals.[21] Many people with body dysmorphic disorder report that one important reason for not seeking treatment is related to feelings of shame and stigma associated with their concerns about appearance, making telecare options potentially suitable.[19 20]

Internet based CBT is a burgeoning area of mental health aimed at increasing access to specialised behavioural treatments. In some countries (such as Sweden, Australia, and the Netherlands) internet based CBT has been implemented as part of the regular healthcare system and is efficacious and cost effective for a wide range of mental health disorders.[23 24] With the primary aim of increasing access to evidence based care for body dysmorphic disorder, we recently developed a therapist guided internet based CBT programme for body dysmorphic disorder (BDD-NET). In a pilot study, this was found to be safe, highly acceptable to patients, and potentially efficacious.[25] Crucially, the treatment required only a fraction of the therapist time associated with regular CBT.

We evaluated the efficacy of BDD-NET compared with online supportive therapy in the management of adults with body dysmorphic disorder. Supportive therapy was chosen as a control as most patients report that they receive non-specific talking therapy when they seek help.[19] We hypothesised that BDD-NET would be superior to online supportive therapy in reducing symptoms, as well as other psychiatric symptoms, and improve quality of life.

Method

Trial design

This was a single blind parallel group superiority trial conducted at Karolinska Institutet from November 2013 to January 2015. Participants were randomly assigned to 12 weeks of BDD-NET (n=47) or online supportive therapy (n=47) in a 1:1 ratio without restriction. Both groups were followed for three months after the end of treatment (six months from baseline). This follow-up point was not included in the trial registration (clinicaltrials.gov) because of an administrative error but was included in the original study protocol. Participants randomised to supportive therapy were offered BDD-NET after the six month follow-up assessments. No changes to methods were made after the trial started. The study is reported in accordance to the Consolidated Standards for Reporting Trials (CONSORT) statement for non-pharmacological treatments.[26]

Participants

Eligible participants were individuals with access to the internet, aged 18 or over, and with a principal diagnosis of body dysmorphic disorder according to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5),[1] with a score of at least 20 on the modified Yale-Brown obsessive-compulsive scale (BDD-YBOCS).[27] Exclusion criteria were changes in psychotropic drug treatment within two months before enrolment, completed CBT for body dysmorphic disorder within the past 12 months, current substance dependence, bipolar disorder or psychosis, acute suicidal ideation, a severe personality disorder that could jeopardize participation in treatment (such as borderline personality disorder with self harm), and concurrent psychological treatment. Participants who were taking psychotropic drugs and had been taking a stable dose for at least two months before enrolment were asked to keep their dose stable during the study period.

Recruitment and determination of eligibility

Participants were recruited from all over Sweden. Flyers were distributed to psychiatrists and general practitioners throughout Sweden with information about the study. In addition, the study was advertised in national newspapers. Interested applicants had to register on the study's secure website and complete an online screening consisting of the Montgomery-Åsberg depression rating scale self report (MADRS-S),[28] alcohol use disorders identification test,[29] drug user disorders identification test,[30] body dysmorphic disorder questionnaire,[31] and general background information. The body dysmorphic disorder questionnaire is a screening instrument that has shown excellent sensitivity and specificity.[31] Potentially suitable participants underwent a structured diagnostic interview with a clinical psychologist or with a trained student in the final semester of a five year clinical psychology programme. The interviews were conducted over telephone, which is a reliable administration format for structured

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psychiatric assessments.[32] To establish a diagnosis of body dysmorphic disorder, we used the structured clinical interview for DSM-IV axis I disorders, with an added question about the presence of repetitive behaviours to reflect the updates made to the diagnostic criteria of body dysmorphic disorder in DSM-5. The mini-international neuropsychiatric interview was used to determine the presence of other comorbid psychiatric disorders.[33] All assessors had received extensive training in structured diagnostic interviews. To ensure reliability of diagnostic procedure and eligibility criteria, a consultant psychiatrist reviewed each case and made the final decision on enrolment.

Interventions

BDD-NET

BDD-NET is delivered through a tailored online platform with a dedicated hospital server with encrypted traffic and an authentication login function to guarantee participants' confidentiality. Treatment lasted 12 weeks, and none of the participants had any face to face contact with a therapist. The treatment protocol is based on a CBT model for body dysmorphic disorder, emphasising the role of negatively reinforced avoidance and safety seeking behaviours (such as mirror checking and camouflaging perceived physical defects) as maintaining factors of body dysmorphic disorder. The treatment protocol has been validated in a previous trial, and the treatment effects are comparable with those gained in traditional face to face CBT.[25] The main intervention in BDD-NET is systematic exposure to fear eliciting situations or events combined with response prevention until anxiety and urges to ritualise subside (such as leaving home and refraining from compulsive mirror checking).

In total, BDD-NET consists of eight interactive modules delivered over 12 weeks, with the first five modules containing the core treatment components.[23] Each module is devoted to a special theme and covers psychoeducation, a cognitive behaviour conceptualisation of body dysmorphic disorder, cognitive restructuring, exposure and response prevention, more on exposure and response prevention, values based behaviour change, difficulties encountered during treatment, and prevention of relapse. To progress to the next module participants have to complete homework assignments (such as reading text material, answering a quiz at the end of each module, filling out worksheets, or doing exposure and response prevention) and report to their therapist. The participants had contact with an identified therapist throughout the entire treatment using a built-in email system on the BDD-NET webpage. Participants could log in and send emails at any time. All homework assignments and questions from the participants were reviewed and answered within 36 hours, except on weekends. The role of the therapist was mainly to guide and coach the participant throughout the treatment, provide feedback on homework assignments, answer questions from the participants, and consecutively grant access to the next treatment module. The participants were notified by an automated text message (SMS) when they had a new email in the treatment platform from their therapist.

The therapists guiding the participants through the treatment were four clinical psychology students who had completed their basic clinical training (320 hours) and had provided therapy in milder cases under the supervision of a senior psychologist. The clinical psychology students had no prior experience of treating body dysmorphic disorder but were closely supervised by the lead author (JE) with weekly meetings throughout the trial. The duration of therapist contact and sent emails was automatically recorded by the BDD-NET platform. Median therapist time spent weekly per participant reading and answering emails was 13.2 minutes. To ensure treatment integrity and adherence to protocol, the lead author monitored the messages sent by the therapists throughout the entire treatment, and provided supervision. Appendix 1 shows a screenshot of BDD-NET.

Online supportive therapy

Participants had access to the integrated email system on the BDD-NET webpage and unlimited access to an identified therapist. They were given the opportunity to talk freely about their experiences, thoughts, and feelings about body dysmorphic disorder and how it affected their life. The therapist sent an email at least once a week, encouraging the participant to discuss distressing life events and to promote problem solving. The therapists used skills drawn from counselling techniques and included minimal encouragers, reflecting, empathising, and summarising. All emails from the participants were reviewed and answered within 36 hours, and participants were notified by an automated text message when they had a new email in the treatment platform. Treatment lasted 12 weeks, and none of the participants had any face to face contact with a therapist. Non-directive supportive therapy delivered via the internet has been shown to reduce symptoms associated with obsessive compulsive disorder,[34] though there are no reports of its efficacy for body dysmorphic disorder. The supportive therapy served as a control for caregiver attention and the possible anxiety alleviating effect of sharing one's distress with a therapist. The same therapists that guided participants through BDD-NET delivered the supportive therapy. Therapists spent a median of 6.3 minutes per participant per week reading and answering emails. To ensure treatment integrity, the lead author monitored the messages sent by the therapists throughout the entire treatment and provided supervision. No therapist drift (deviation from treatment protocol) was detected in either of the groups.

Randomisation and masking

Participants were randomised on a 1:1 ratio with simple randomisation with no constraints. To prevent potential selection bias related to the randomisation procedure, an external party not involved in the inclusion process used

a true number service (www.random.org). Allocation concealment was ensured through randomisation after the decision to include each participant had been made. Immediately after randomisation, participants received information about which treatment they had been allocated to and how they could log on to the secure website. Assessors in the trial remained masked to treatment allocation at baseline and three and six month follow-up. Because of the nature of the intervention, participants and therapists were not blinded to treatment.

Assessment points and outcomes

All participants were assessed at baseline and then received 12 weeks of treatment. Follow-up times were three and six months from baseline (after treatment and three months after treatment, respectively). After the six month follow-up, participants in the supportive therapy group were offered BDD-NET and reassessed after receiving 12 weeks of additional treatment with BDD-NET. Participants also completed online self report measures at these time points, a method that has been shown to be as reliable and as valid as written administration.[35 36]

The primary outcome was change in severity of symptoms of body dysmorphic disorder assessed with the BDD-YBOCS administered by a clinician.[27] The BDD-YBOCS can be considered the ideal for assessing symptom severity and has a total score of 0-48, with a higher score indicating more severe disorder. To ensure quality of assessments, clinicians in this trial practiced together on case examples with excellent reliability between raters (intraclass correlation 0.95, 95% confidence interval 0.89 to 0.98).

Secondary outcomes included responder status defined as an empirically derived cut off point of ≥30% reduction from baseline on the BDD-YBOCS.[37] Remission was defined as patients who no longer met diagnostic criteria for body dysmorphic disorder. Depressive symptoms were assessed with the MADRS-S.[28] Clinician rated global functioning and improvement was assessed with the global assessment of functioning scale (GAF)[38] and the clinical global improvement scale (CGI-I).[39] Quality of life was assessed with the EQ5D EuroQol (EQ5D).[40]

All outcomes other than BDD-YBOCS and MADRS-S at three months were not pre-specified in the registration at clinicaltrials.gov because of an administrative error but were included in the original trial protocol approved by the regional ethics committee before the start of the trial.

The occurrences of adverse events were recorded mid-treatment and after treatment with a self report form.[41] Treatment credibility and expectancy of improvement were recorded at week two with the C scale (included post hoc after trial registration).[42]

Patient involvement

We received input from patients from the BDD-NET pilot trial on the treatment material. No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for recruitment, design, or implementation of the study. No patients were asked to advise on interpretation or writing up of results. We carefully assessed the burden of the trial interventions on the patients by collecting information about adverse events, quality of life, and time spent on the treatment. We plan to disseminate the results of the research to study participants and to the Swedish OCD Foundation.

Power calculation and statistical analysis

We powered the study to be able to detect at least a medium standardised effect size (Cohen's d). We based power calculations on a previous pilot trial of BDD-NET and the efficacy of online supportive therapy for obsessive compulsive disorder.[25 34] A sample size of 39 per group was required to give 80% power and a two sided 5% significance for detecting a mean difference between groups of at least 4 and a standard deviation of 6.24 on the BDD-YBOCS between BDD-NET and supportive therapy. We anticipated a potential 10% dropout rate, giving a planned sample size of at least 44 per group, or 88 in total. There were no planned interim analyses or rules for stopping.

Analyses were by intention to treat, with participants analysed in the group to which they had been randomised. Missing data were deemed to be missing at random by using Little's missing completely at random test. Linear mixed models with maximum likelihood estimations were used to evaluate the effect of treatment group on the different outcomes. Such models take into account the differences in rate of change and differences in trajectories of change between individuals with repeated responses and use all the available data for each participant.[43] The fixed part of the model included a treatment indicator variable (supportive therapy/BDD-NET), a time indicator variable (three or six months), and an interaction effect of treatment × time to allow for differential change between the two groups from the three to the six month follow-up. Baseline (before treatment) scores on each outcome measure were included as covariates. Participant varying intercepts were included as a random effect in the model. As therapist support time varied between the two treatment arms, it was included as an additional covariate in the model. Because it did not predict outcome, however, (P=0.11-0.98) it was dropped from the final model. We used χ^2 tests for categorical data and independent *t* tests for assessing differences between groups when time was not a factor on the outcome variable. We carried out post hoc analysis of participants in the supportive therapy arm who later crossed over to BDD-NET after the six month follow-up using paired *t* tests. Effect sizes within and between groups were calculated as Cohen's d. All statistical analyses were done in STATA 13.1.

Results

Figure 1 shows the flow of participants through the trial. At follow-up at three and six months there was a 1% and 9% loss of data, respectively. Little's test suggested that the missing data met the assumption for missing at random (χ^2=42.57, df=52, P=0.82). There were no significant differences in dropout rates across conditions at after treatment (χ^2=1.01, df=1, P=0.32) or at the six month

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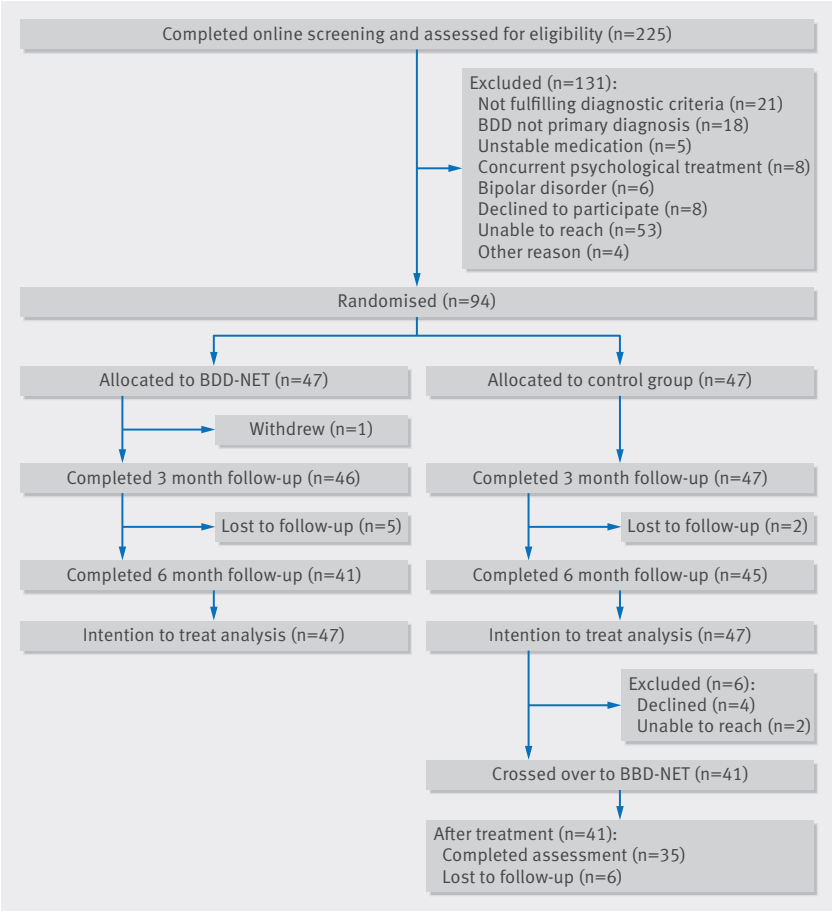

Fig 1 | **Flow of participants with body dysmorphic disorder (BDD) through study of therapist guided internet based cognitive behavioural therapy (BDD-NET)**

Table 1 | **Sociodemographic characteristics of participants with body dysmorphic disorder according to allocation to internet based cognitive behavioural therapy (BDD-NET) or supportive therapy. Figures are number (percentage) of participants unless stated otherwise**

Variable	BDD-NET (n=47)	Supportive therapy (n=47)
Women	39 (83)	41 (87)
Men	8 (17)	6 (13)
Age (years):		
Mean age (SD)	34 (14)	31 (11)
Min-max	18-72	19-66
Highest education:		
Primary school	4 (9)	6 (13)
High school	31 (66)	23 (49)
College/university	11 (23)	17 (36)
Doctorate	1 (2)	1 (2)
Occupational status:		
Working	25 (53)	28 (60)
Student	13 (28)	10 (21)
Retired	2 (4)	1 (2)
Unemployed	7 (15)	6 (13)
Disability pension	0	2 (4)

follow-up (χ^2=1.11, df=1, P=0.29), and dropouts did not significantly differ from completers on baseline demographics or on symptom measures. The two groups did not significantly differ on any baseline characteristics (P=0.08-1.00; tables 1 and 2).

Primary outcome

BDD-YBOCS scores were significantly lower for BDD-NET than for supportive therapy, both at the end of treatment (three months) and at six months (table 3 and fig 2). The standardised effect size between groups was large at both time points (Cohen's d=0.95 at three months and 0.87 at six months). The effect size within groups at six months was 1.42 (95% confidence interval 0.95 to 1.89) for BDD-NET and 0.55 (0.13 to 0.96) for supportive therapy.

Secondary outcomes

Depressive symptoms, measured with the MADRS-S, decreased over the course of the trial with BDD-NET but not with supportive therapy, and there was a significant difference between groups at both follow-up times (table 3). At three months, the effect size between groups was small (Cohen's d=0.43), whereas at six months it was medium (d=0.58) There was also a significant correlation between the change in symptoms of body dysmorphic disorder and change in depressive symptoms at both follow-up times ($r_s(92)$=0.46, P<0.001) and $r_s(80)$=0.41, P<0.001, respectively). Of the 51 participants with a diagnosis of major depressive disorder at baseline, 32/57 (56%) no longer met diagnostic criteria for depression at three months and 27/57 (47%) were still in recovery at the six month follow-up.

Post hoc analysis of global functioning and quality of life showed that there was an increase in global functioning with BDD-NET but not with supportive therapy, with a significant group difference on the global assessment of functioning scale at both three and six months (table 3). At three months, there were no significant differences between groups on health related quality of life (EQ5D). At six months, however, the health related quality of life (EQ-5D) had further improved in BDD-NET, and there was a significant difference between groups, favouring BDD-NET (table 3). Appendix 2 shows the observed means and standard deviations at the different time points for primary and secondary outcomes.

Treatment response and remission

The proportion of participants classified as responders was significantly higher in the BDD-NET group at three months (25/46 (54%) *v* 3/47 (6%), χ^2=25.42, df=1, P<0.001) and at six months (23/41 (56%) *v* 6/45 (3%), χ^2=17.55, df=1, P<0.001). At the six month follow-up, 23/41 (56%) of the participants in the BDD-NET group were classified as improved or much improved on the clinical global improvement scale, compared with 7/45 (16%) in the supportive therapy group (χ^2=15.52, df=1, P<0.001). The number needed to treat was 2.34 (95% confidence interval 1.71 to 4.35).

The number of participants no longer meeting criteria for body dysmorphic disorder was 15/46 (32%) versus 1/47 (2%; χ^2=15.16, df=1, P<0.001) at three months, and 16/41 (39%) versus 4/45 (9%; χ^2=10.92, df=1, P<0.001) at six months, always favouring BDD-NET.

Table 2 | Clinical characteristics of participants with body dysmorphic disorder according to allocation to internet based cognitive behavioural therapy (BDD-NET) or supportive therapy. Figures are number (percentage) of participants unless stated otherwise

Variable	BDD-NET (n=47)	Supportive therapy (n=47)
Mean (SD) scores; min-max:		
BDD-YBOCS	29.13 (5.02); 20-40	28.51 (4.56); 20-42
MADRS-S	18.92 (8.43); 4-35	18.83 (7.91); 3-38
GAF	55.32 (6.01); 41-65	57.32 (6.51); 40-65
EQ5D	0.71 (0.22); 0.20-1	0.75 (0.18); 0.29-1
Insight:		
Good	19 (40)	18 (38)
Poor	22 (47)	21 (45)
Delusional	6 (13)	8 (17)
Median duration (years) of BDD	16	16
Most common body areas of concern*:		
Skin	35 (75)	27 (58)
Face in general	30 (64)	29 (62)
Nose	27 (58)	26 (55)
Body weight (too much or too little)	24 (51)	19 (40)
Teeth	22 (47)	20 (43)
Body hair	14 (30)	15 (32)
Genitals	8 (17)	12 (26)
Comorbidity		
Current depressive episode	28 (60)	23 (49)
Panic disorder	2 (4)	0 (0)
Social anxiety disorder	15 (32)	14 (30)
Generalised anxiety disorder	9 (19)	9 (19)
Bulimia nervosa	2 (4)	2 (4)
Attention deficit hyperactivity disorder	1 (2)	1 (2)
Obsessive compulsive disorder	8 (17)	3 (6)
Current drug treatment		
SSRI	5 (11)	8 (17)
SNRI	1 (2)	1 (2)
Other antidepressants	4 (9)	4 (9)
Mood stabilisers	3 (6)	1 (2)
Benzodiazepines	3 (6)	0 (0)
Neuroleptics	2 (4)	0 (0)
Methylphenidate	1 (2)	1 (2)
Previous psychosocial treatment		
CBT for BDD	5 (11)	6 (13)
Psychosocial treatment for anxiety or depression	30 (64)	27 (58)
Plastic surgery		
Previous plastic surgery	13 (28)	8 (17)
Mean No of surgeries (SD)	2.61 (1.89)	1.88 (1.36)
Min-max No of surgeries	1-6	1-5

BDD-YBOCS=Yale-Brown obsessive compulsive scale modified for BDD; MADRS-S=Montgomery-Åsberg depression rating scale-self report; GAF=global assessment of functioning; EQ5D=EuroQol EQ5D; SSRI=selective serotonin reuptake inhibitors; SNRI=serotonin-noradrenaline reuptake inhibitors.
*Participants could report more than one body area of concern.
CGI-I, GAF, and EQ5D were not registered at clinicaltrials.gov because of administrative error but were included in original trial protocol approved by regional ethics committee.

Treatment credibility, expectancy, and acceptability

After two weeks, participants randomised to BDD-NET rated the treatment as more credible than participants randomised to supportive therapy ($t(85)=-2.42$, P=0.02), but this did not translate in greater expectancy of improvement ($t(85)=-0.58$, P=0.57).

Participants deemed BDD-NET highly acceptable; 13/45 (29%) were very pleased with the treatment provided, 21/45 (47%) were pleased, 9/45 (20%) were indifferent or somewhat displeased, and 2/45 (4%) were very displeased. In total, 37/45 (82%) reported that if they were in need of additional CBT in the future they would use BDD-NET, and 40/45 (89%) would recommend BDD-NET to a friend with similar problems.

Crossover patients

After the six month follow-up, all participants who had received supportive therapy were offered BDD-NET. Two participants were lost to follow-up, and four declined. Participants who crossed over to BDD-NET (n=41) showed a significant decrease on the BDD-YBOCS after receiving BDD-NET, with a mean reduction of −7.14 (95% confidence interval −9.06 to −5.23, P<0.001; fig 3). Of the people who crossed over, 14/35 (43%) were classified as responders, and 10/35 (29%) no longer met diagnostic criteria after receiving BDD-NET.

Similar improvements were observed on the MADRS-S with a mean reduction of −2.18 (95% confidence interval −4.29 to −0.07; P=0.043) and the global assessment of functioning, with mean improvement of 4.69 (2.93 to 6.45; P<0.001). On the EQ5D, there was a non-significant increase of 0.04 points (−0.05 to 0.14; P=0.378). The four participants in the supportive therapy group who declined to cross over to BDD-NET had made significant improvements after receiving supportive therapy, and three of them were classified as responders.

Adverse events and protocol deviations

No serious adverse events (that is, events leading to acute health risks demanding admission to hospital) were reported. Fifteen (32%) participants in the BDD-NET group and six (13%) in the supportive therapy group reported mild adverse events (that is, increased levels of anxiety and general negative wellbeing) at the beginning of the trial, which had subsided for everyone at three months, except for four participants in the BDD-NET group. Of these, two participants reported increased sleep disturbances because of heightened anxiety levels attributed to the exposure exercises, one reported depressive mood, and one reported that the insight gained throughout the treatment regarding time spent on concerns about appearance was emotionally painful but also enhanced motivation to make changes. Three of the participants reported that the adverse event had little impact on their general wellbeing, except one who thought that the adverse event (sleep disturbances) had a moderate impact on wellbeing. The occurrence of adverse events during treatment was not related to responder status at follow-up ($\chi^2=0.91$, df=1, P=0.34).

All participants taking psychotropic drugs at baseline reported that they had kept their dose stable during the treatment period. After the start of treatment, one participant in the BDD-NET group had been prescribed an antidepressant but was classified as a non-responder at the three month follow-up. None of the other participants reported that they had received any other type of healthcare during the duration of the trial. From the three to the six month follow-up, three participants in the BDD-NET group and two participants in the supportive therapy group had received additional healthcare in the form of CBT, pharmacological treatment, or both.

Table 3 | Estimated means, group differences (BDD-NET *v* supportive therapy), and effect sizes for primary and secondary outcomes at follow-up

Outcome	Estimated mean (SE)		Group difference (95% CI); P value	Effect size* 95% CI
	BDD-NET	Supportive therapy		
BDD-YBOCS				
3 month	19.8 (0.98)	26.9 (0.96)	−7.13 (−9.82 to −4.44); P≤0.001	0.95 (0.52 to 1.38)
6 month	19.7 (1.00)	25.3 (0.97)	−5.58 (−8.31 to −2.85); P≤0.001	0.87 (0.42 to 1.31)
MADRS-S				
3 month	13.7 (1.10)	18.2 (1.09)	−4.49 (−7.53 to −1.44); P=0.004	0.43 (0.02 to 0.84)
6 month	12.8 (1.21)	18.0 (1.12)	−5.20 (−8.43 to −1.96); P=0.002	0.58 (0.13 to 1.03)
GAF				
3 month	63.7 (0.85)	57.1 (0.84)	6.60 (4.24 to 8.97); P≤0.001)	0.68 (0.26 to 1.10)
6 month	63.6 (0.87)	57.4 (0.85)	6.27 (3.88 to 8.66); P≤0.001	0.71 (0.27 to 1.14)
EQ5D				
3 month	0.73 (0.04)	0.67 (0.03)	0.06 (−0.03 to 0.16); P=0.198	0.21 (−0.21 to 0.61)
6 month	0.80 (0.04)	0.67 (0.04)	0.13 (0.03 to 0.23); P=0.012	0.53 (−0.08 to 0.98)

BDD-NET=internet based cognitive behavioural therapy for body dysmorphic disorder (BDD); BDD-YBOCS=Yale-Brown obsessive compulsive scale modified for BDD; MADRS-S=Montgomery-Åsberg depression rating scale-self report; GAF=global assessment of functioning; EQ5D=EuroQol EQ5D.
*Cohen's d effect sizes between groups calculated from observed data.
Six month follow-up time and all outcomes other than BDD-YBOCS and MADRS-S at three months were not pre-specified in registration at clinicaltrials.gov becasue of administrative error but were included in original trial protocol approved by regional ethics committee before start of trial.

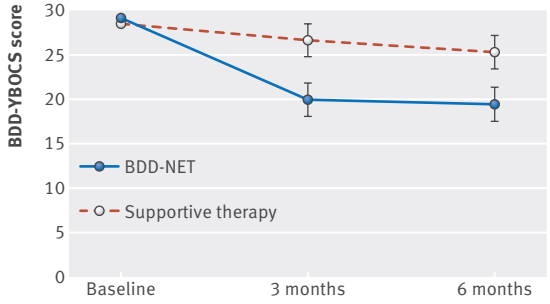

Fig 2 | Effect of treatment over time on Yale-Brown obsessive compulsive scale modified for body dysmorphic disorder (BDD-YBOCS) with 95% confidence intervals. Scores are shown at baseline, after treatment (3 months), and follow-up (6 months) according to treatment group. Six month follow-up point was not registered at clinicaltrials.gov because of administrative error

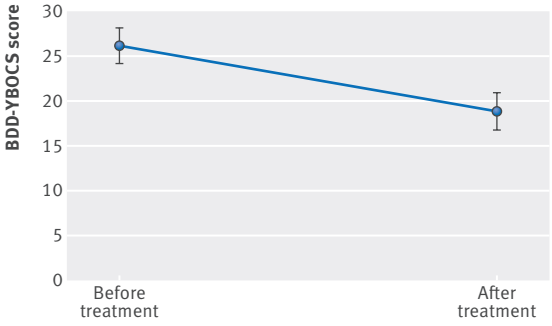

Fig 3 | Mean scores of participants initially randomised to supportive therapy who crossed over to BDD-NET (n=41) and received 12 weeks of additional treatment after 6 month follow-up

Discussion

Principal findings

In this trial, we compared the efficacy of BDD-NET, a novel therapist guided internet based CBT programme for body dysmorphic disorder, with online supportive therapy, a kind of non-specific talking therapy that mimics the psychosocial support that most patients with body dysmorphic disorder report receiving in the real world.[19 20] Overall, BDD-NET was superior to supportive therapy and was associated with significant improvements in symptom severity, depression, global functioning, and quality of life. These gains were maintained for at least three months after the end of treatment. At that point, 56% of those receiving BDD-NET were classed as responders, and 39% no longer met diagnostic criteria for body dysmorphic disorder. The number needed to treat to achieve one responder was 2.34. Participants in the supportive therapy group who crossed over to BDD-NET after six months also improved robustly on primary and secondary outcome measures. No serious adverse events were reported. Some participants reported mild adverse events (such as heightened anxiety levels associated with exposure tasks) during the trial, but these were generally short lived and were not associated with responder status at the end of treatment. Most participants were satisfied with BDD-NET, despite no face to face contact with a therapist, and deemed the treatment as highly acceptable. The results indicate that BDD-NET has potential to greatly increase access to evidence based psychiatric treatment for patients with body dysmorphic disorder, in line with the NICE priority recommendations.[17]

Strengths and limitations of study

Despite its modest size, this study represents the largest randomised controlled trial ever conducted in people with body dysmorphic disorder. The inclusion of a control intervention with high ecological validity, the use of masked assessors, and minimal data loss are other strengths of the study. One potential limitation of the trial is that the results might not be generalisable to everyone with body dysmorphic disorder as the participants were self referred and most had reasonably good insight. We also took the precaution, on safety grounds, of excluding participants with substance dependence and severe suicidal ideation. Thus, despite the fact that most participants had been ill for many years, had had previous contact with mental health services, and a fifth had undergone plastic surgery, participants in this trial might have been particularly motivated to engage in psychotherapy compared with more severely affected and delusional patients seen in specialist clinics. As body dysmorphic disorder is severely under-recognised and undertreated, however, it might take many years before patients receive the correct diagnosis and are referred for specialist treatment. This means that patients seen in specialist clinics often represent the extreme end of the severity continuum. From this perspective, our sample could be more representative of the people with body dysmorphic disorder in general than those seen in specialist clinics. Another potential limitation is that participants were informed that if they were randomised to supportive therapy, they would be offered BDD-NET after the six month follow-up

assessment, although they were not explicitly told that we expected BDD-NET to be superior to supportive therapy. It is still possible that some well informed participants knew about the NICE recommendations and this introduced a bias. Participants randomised to BDD-NET found the treatment more credible than participants in the supportive therapy group, but perceived credibility did not translate to greater expectancy of improvement as there were no differences between groups on how much participants thought they would improve at end of treatment. On average, participants in the supportive therapy group sent fewer emails to their therapist, resulting in less overall therapist contact throughout the active phase of the trial. The estimated differences in treatment effects, however, remained unchanged when we adjusted for the amount of therapist contact.

Comparison with other studies

Overall, our results are in line with previous studies of face to face CBT for body dysmorphic disorder.[14 15] The proportion of comorbidities were the same in our sample as in previous clinical trials, though symptoms of depression were on average of mild severity compared with moderate to severe depression as seen in the two recent randomised controlled trials of CBT for body dysmorphic disorder.[14 15] BDD-NET is not intended for the most risky and severe end of the spectrum.

Conclusions and policy implications

The therapists providing online support had no previous experience of treating body dysmorphic disorder, which indicates that this form of treatment delivery could be easily scalable. BDD-NET is delivered online as a series of interactive modules, and the role of the therapist is mainly to encourage the participant to engage in the treatment, making it reasonable to assume that BDD-NET can be used in non-specialist settings. BDD-NET could be particularly useful in a stepped care approach, where mild to moderately affected patients can be offered BDD-NET by their general practitioner, or other health professionals, thus freeing resources for patients in more severe and complex cases to be treated in specialised settings. Logistic barriers are also eliminated, as patients receiving BDD-NET do not have to travel to the clinic once a week to receive the treatment. This makes BDD-NET particularly promising in more rural areas, where the access to trained CBT therapists is limited.[18] Future stepped care trials of BDD-NET in non-specialist settings are warranted.

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Contributors: JE and CR had the original idea for the study and, with DM-C and BJ, designed the trial variables and obtained the funding. JE and CR were responsible for study supervision. All authors were responsible for the acquisition of the data. JE, EA, and CR carried out the statistical analysis. JE drafted the manuscript, which was revised by all authors. All researchers were independent of the funders. The funders had no part in the study design, in the collection, analysis, and interpretation of data, in the writing of the report or in the decision to submit the article for publication. JE and CR are guarantors.

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Ethical approval: The regional ethical review board in Stockholm approved the protocol (registration ID: 2013/1773-31/4). All participants gave written informed consent.

Transparency: The lead author affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that and discrepancies from the study as planned (and if relevant, registered) have been explained.

Data sharing: No additional data available.

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Appendix 1: Screen-shot of BDD-NET
Appendix 2: Supplemental table: Observed score for primary and secondary outcomes at assessment points