PEER REVIEW HISTORY

This paper was submitted to the JECH but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Therapist-guided Internet-based Cognitive Behavioral Therapy for Body Dysmorphic Disorder (BDD-NET): A Feasibility Study
AUTHORS	Enander, Jesper; Ivanov, Volen; Andersson, Erik; Mataix-Cols, David; Ljótsson, Brjánn; Rück, Christian

VERSION 1 - REVIEW

REVIEWER	Jamie Feusner UCLA Semel Institute for Neuroscience and Human Behavior, USA
REVIEW RETURNED	23-Jun-2014

REVIEWER	Sabine Wilhelm and Jennifer Greenberg MGH/Harvard Medical School, USA
REVIEW RETURNED	10-Jul-2014

GENERAL COMMENTS	Thank you for the opportunity to review this paper. This empirical research paper represents an innovative and methodologically sound study that tests the feasibility of an internet-based CBT for BDD (BDD-NET). The authors developed and tested the feasibility of a 12-session, therapist-supported, internet-based CBT for BDD. This paper identified that BDD-NET was highly acceptable to patients and was associated with significant treatment gains. At post-treatment, 82% of participants were considered treatment responders. Gains were maintained at 3-month follow-up. Therapists spent an average of 10 minutes per patient per week providing support. Taken together, these findings provide preliminary support for an internet-based CBT that has the potential to vastly improve access to CBT for individuals with moderately severe symptoms and reasonably good insight. The authors did a nice job of providing background on the need to enhance access as well as on previous studies examining internet-based treatments in related disorders. Although the paper is well written and clearly presented, the following recommendations are offered: 1. In the abstract, please correct this typo "BBD-YBOCS."

	2. The authors excluded individuals suffering from problems that are highly comorbid with BDD (e.g., acute suicidal ideation, substance dependence disorder). Although this is defendable from an internal validity and safety perspective, the impact of this design choice on external validity should be addressed. The authors also note exclusion of participants with "a personality disorder that could jeopardize treatment participation. The MINI assesses only antisocial personality disorder. Were other personality disorders assessed, and if so, which measure was used? 3. The authors noted that 19 individuals were excluded for "living in another part of the country." Geographic proximity was not mentioned in the description of eligibility criteria. Seemingly, an advantage of ICBT would be to enhance access to treatment regardless of geographic locale. Please elaborate on the rationale for excluding based on geographic reason (e.g,, providing the study team with the opportunity to conduct in-person assessment, the opportunity to intervene in case of safety concerns etc). 4. To be included, participants needed to meet DSM diagnostic criteria for BDD and have a total score > 16 on the BDD-YBOCS. A BDD-YBOCS score of > 20 generally indicates a current DSM diagnosis of BDD (Phillips, 2005). Those individuals with a score < 20 might represent a sub-threshold sample. Presumably, a benefit of BDD-NET is its wide applicability and ability to function as part of a stepped care approach, thus making it suitable for individuals with a wide range of symptom severity, including those with minimal or sub-threshold symptoms. It would be helpful to know the range of scores and also whether results (treatment completion, outcome, and feasibility) are similar for individuals with BDD-YBOCS in the mild vs. severe range. 5. Did participants provide informed consent? 6. The authors reference manuals by Veale & Neziroglu (2010) and Wilhelm et al (2013) in the background and description of treatment development. However, in the Method section, they only mention Wilhelm et al (2013). Please clarify/reconcile. Given that this treatment was based on these manuals which suggest a longer duration of treatment, it would prove useful if the authors provided additional detail regarding the decision to provide a 12-session treatment. 7. Please elaborate on quality assurance measures. What was the training of the therapists? Were therapists subject to any quality assurance measures, including weekly supervision and measures of adherence/competence? Similarly, please elaborate on measures taken to establish and monitor inter-rater reliability. 8. The module selection process needs to be clarified. The authors report that each module contained specific information and homework assignments that needed to be complete in order to move to the next module. Was there a specific cut-point (e.g., percentage of assignments to be completed) that needed to be met to allow movement to the next module? This should be clarified. Also, it is unclear whether individuals needed to complete all prior modules before being able to access Module 7 "Difficulties during treatment." Presumably, individuals with difficulties during treatment may drop out prior to module 7. It would seem beneficial to offer this module flexibly at any point during treatment to enhance motivation and

	treatment compliance. 9. The authors note: “all participants kept their dose stable during treatment.” However, during treatment, one participant started an SSRI for increased depression. Please clarify. 10. Table 4. It should be Wilhelm et al 2014 (not 2013). 11. Page 28. It looks like 36 were excluded after the phone screen but the numbers only add up to 34. Also, it looks like 2 were lost to follow-up, and if so, the number who completed 3-month follow-up assessment should be 20 (not 21).

REVIEWER	Ulrike Buhlmann WWU Münster
REVIEW RETURNED	16-Jul-2014

GENERAL COMMENTS	The authors report an internet-based CBT study for individuals with body dysmorphic disorder (BDD). The current study is clearly novel and innovative, and effective treatment concepts are still much needed in BDD. Thus, this study is likely to fill an important gap in the literature of BDD treatment research. I have several concerns the authors may wish to consider: In general, the manuscript is very well written and clearly structured. A few minor typos should be corrected though (e.g., patients were classed as... ; critera). The authors state that the new DSM-5 specifiers were used to determine degree of insight in BDD. Please add the information how many patients were in each “insight” group. Also, the BDD-YBOCS insight question was used to assess changes in delusionality as a function of treatment. It is unclear why the widely used BABS was not used to assess delusionality. This limitation should be added to the limitation section. Further, participants had to have a primary BDD diagnosis. Was this based on symptom severity? If so, please add this information. In addition, please provide a short example for how personality disorders could jeopardize treatment participation. It is unclear whether or not the participants had at least one therapist contact at pre-treatment assessment. The BDD sample should be described in more detail. For example, no information about the specific body areas of concern is reported and how these areas of concerns might have changed over the course of treatment. Effect sizes should be reported whenever appropriate (that is, for both significant as well as not significant results). The authors report an ITT analysis. Do the results look different when conducting a completers-only analysis? The authors state in the discussion that the study aimed at dramatically increasing access to CBT for BDD. I suggest softening

	the language a bit and remove the word “dramatically”given that it is unclear how this would be exactly defined.

VERSION 1 – AUTHOR RESPONSE

REVIEWER 1

COMMENT:
No written comments returned. Checklist indicated study limitations are not adequately discussed. [Managing Editor]

RESPONSE:
We hope that the revised manuscript adequately addresses the limitations observed by reviewer 1.

REVIEWER 2

COMMENT:
In the abstract, please correct this typo “BBD-YBOCS.”

RESPONSE:
Thank you for noticing the typo, it has been corrected.

COMMENT:
The authors excluded individuals suffering from problems that are highly comorbid with BDD (e.g., acute suicidal ideation, substance dependence disorder). Although this is defendable from an internal validity and safety perspective, the impact of this design choice on external validity should be addressed. The authors also note exclusion of participants with “a personality disorder that could jeopardize treatment participation. The MINI assesses only antisocial personality disorder. Were other personality disorders assessed, and if so, which measure was used?

RESPONSE:
The reviewer makes an important point, as both acute suicidal ideation, and substance dependence are common in BDD. This has been addressed under the limitations section of the manuscript (page 18). It should also be noted that suicidal ideation up until 4 out of 6 in the MADRS suicidality item was permitted. No other personality disorders were assessed. Information about previous psychiatric diagnoses was gathered at the assessment through patient interviews and digital patient records. No patients were excluded due to a personality disorder.

COMMENT:
The authors noted that 19 individuals were excluded for “living in another part of the country.” Geographic proximity was not mentioned in the description of eligibility criteria. Seemingly, an advantage of ICBT would be to enhance access to treatment regardless of geographic locale. Please elaborate on the rationale for excluding based on geographic reason (e.g., providing the study team with the opportunity to conduct in-person assessment, the opportunity to intervene in case of safety concerns etc).

RESPONSE:
We thank reviewer 2 for pointing out that geographic proximity was missing as an inclusion criterion. It has now been added to methods section (page 6). As this was a pilot study exploring the feasibility of Internet-based CBT, geographic proximity was used in order to conduct in person assessments, as well as the possibility to intervene in case of safety concerns. Future studies should explore the possibility of doing telephone-based assessments and widen the geographical catchment area in order to increase availability of BDD-NET.

COMMENT:
To be included, participants needed to meet DSM diagnostic criteria for BDD and have a total score > 16 on the BDD-YBOCS. A BDD-YBOCS score of > 20 generally indicates a current DSM diagnosis of BDD (Phillips, 2005). Those individuals with a score < 20 might represent a sub-threshold sample.

Presumably, a benefit of BDD-NET is its wide applicability and ability to function as part of a stepped care approach, thus making it suitable for individuals with a wide range of symptom severity, including those with minimal or sub-threshold symptoms. It would be helpful to know the range of scores and also whether results (treatment completion, outcome, and feasibility) are similar for individuals with BDD-YBOCS in the mild vs. severe range.

RESPONSE:
As the reviewer points out, a cut-off of 16 on the BDD-YBOCS would represent minimal symptoms. However, only one participant had a score on the BDD-YBOCS below 22, and the range and median were 16-42 and 30, respectively, indicating that the sample in general endorsed moderate to severe symptoms. This new information has been added to the discussion section (page 15). The current data does not allow any meaningful analysis of differences in outcome between the mild vs. severe range.

COMMENT:
Did participants provide informed consent?

RESPONSE:
All participants provided written informed consent. This has been added to the methods section (page 6).

COMMENT:
The authors reference manuals by Veale & Neziroglu (2010) and Wilhelm et al (2013) in the background and description of treatment development. However, in the Method section, they only mention Wilhelm et al (2013). Please clarify/reconcile. Given that this treatment was based on these manuals which suggest a longer duration of treatment, it would prove useful if the authors provided additional detail regarding the decision to provide a 12-session treatment.

RESPONSE:
Techniques from both manuals inspired the development of BDD-NET. However, the conceptualization of maintenance of BDD was mainly based on the model described in the treatment manual by Wilhelm et al (2013). A 12-week long treatment was deemed appropriate based on our previous experience and research on ICBT for various disorders. For example, 10 weeks of ICBT for OCD yields the same results as 15 weeks of ICBT for OCD. In ICBT the therapist also has several contacts a week with the patient. A paragraph clarifying the choice of a 12-week long treatment has been added to the manuscript (methods section, page 10).

COMMENT:
Please elaborate on quality assurance measures. What was the training of the therapists? Were therapists subject to any quality assurance measures, including weekly supervision and measures of adherence/competence? Similarly, please elaborate on measures taken to establish and monitor inter-rater reliability.

RESPONSE:
The two therapists providing the treatment were both licensed psychologists with several years of experience in treating obsessive-compulsive and related disorders. To ensure treatment integrity a licensed psychologist monitored messages sent by the therapists for protocol adherence throughout the entire treatment. One advantage of ICBT is that the treatment is protocol based and delivered as a series of modules online. This greatly reduces the risk of therapist drift. For example, all information about how to conduct ERP is presented as pre-written text to the participant. Inter-rater reliability was not established. Information about the training of the therapists and that inter-rater reliability was not established has been added to the manuscript (pages 7 and 11).
COMMENT:
The module selection process needs to be clarified. The authors report that each module contained specific information and homework assignments that needed to be complete in order to move to the next module. Was there a specific cut-point (e.g., percentage of assignments to be completed) that needed to be met to allow movement to the next module? This should be clarified. Also, it is unclear whether individuals needed to complete all prior modules before being able to access Module 7 “Difficulties during treatment.” Presumably, individuals with difficulties during treatment may drop out

prior to module 7. It would seem beneficial to offer this module flexibly at any point during treatment to enhance motivation and treatment compliance.

RESPONSE:
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. This has been clarified in the manuscript (methods section, page 10). The reviewer makes a good point of being flexible with module 7. It mainly deals with problems encountered during ERP and should probably be offered after modules 4-5 which contains the main material on how to do ERP, instead of after the values-based behavior change module.

COMMENT:
The authors note: “all participants kept their dose stable during treatment.” However, during treatment, one participant started an SSRI for increased depression. Please clarify.

RESPONSE:
The line reads “All participants on psychotropic medication had kept their dose stable during treatment…”. We have changed it to “All participants on psychotropic medication prior to treatment had kept their dose stable during treatment…” for clarity.

COMMENT:
Table 4. It should be Wilhelm et al 2014 (not 2013).

RESPONSE:
We have modified the table.

COMMENT:
Page 28. It looks like 36 were excluded after the phone screen but the numbers only add up to 34. Also, it looks like 2 were lost to follow-up, and if so, the number who completed 3-month follow-up assessment should be 20 (not 21).

RESPONSE:
The reviewer is right. Two persons were excluded due to concurrent psychological treatment. This has been added to the flowchart. One participant was lost to follow-up. Figure 2 has been modified and is now correct.

REVIEWER 3

COMMENT:
A few minor typos should be corrected though (e.g., patients were classed as... ; critera).

RESPONSE:
The manuscript has been proofread and minor typos have been corrected.

COMMENT:
The authors state that the new DSM-5 specifiers were used to determine degree of insight in BDD. Please add the information how many patients were in each “insight” group. Also, the BDD-YBOCS insight question was used to assess changes in delusionality as a function of treatment. It is unclear why the widely used BABS was not used to assess delusionality. This limitation should be added to the limitation section.

RESPONSE:
Information about how many patients were in each insight group has been added to patient characteristics in Table 1. The reviewer is probably right in saying that the BABS would have provided additional information about delusionality. This has been added to the limitations section of the manuscript (page 18).

COMMENT:

Further, participants had to have a primary BDD diagnosis. Was this based on symptom severity? If so, please add this information. In addition, please provide a short example for how personality disorders could jeopardize treatment participation.

RESPONSE:
If the participant had any other comorbid diagnoses the assessing clinician determined primary diagnosis based on symptom severity and impairment. We have added the following example to the exclusion criterion: “e.g., borderline personality disorder with self-harm” (methods, page 6). It should also be noted that no one was excluded because of a personality disorder.

COMMENT:
It is unclear whether or not the participants had at least one therapist contact at pre-treatment assessment.

RESPONSE:
Participants had no therapist contact at pre-treatment assessment. This has been clarified in the manuscript (methods, page 11).

COMMENT:
The BDD sample should be described in more detail. For example, no information about the specific body areas of concern is reported and how these areas of concerns might have changed over the course of treatment.

RESPONSE:
The most frequent areas of concern have been added to the manuscript (methods, page 6). Mean number of body areas of concern has also been added to participant characteristics in Table 1. Data on body areas of concern was unfortunately not systematically collected at post-treatment.

COMMENT:
Effect sizes should be reported whenever appropriate (that is, for both significant as well as not significant results).

RESPONSE:
Effect sizes with 95% CI have been added to the manuscript where appropriate (results, page 14).

COMMENT:
The authors report an ITT analysis. Do the results look different when conducting a completers-only analysis?

RESPONSE:
We had very little data loss in the trial (1 participant at post-treatment, and 2 at follow-up). Results do not look different when conducting a completer-only analysis.

COMMENT:
The authors state in the discussion that the study aimed at dramatically increasing access to CBT for BDD. I suggest softening the language a bit and remove the word “dramatically” given that it is unclear how this would be exactly defined.

RESPONSE:
We have removed the word as suggested (discussion, page 15).

VERSION 2 – REVIEW

REVIEWER	Jennifer Greenberg, PsyD and Sabine Wilhelm, PhD Massachusetts General Hospital and Harvard Medical School, USA
REVIEW RETURNED	18-Aug-2014

GENERAL COMMENTS	Were the therapy and assessments conducted in English? If not, please note the limited generalizability of results in the Discussion. (Also, provide a description of the translation of measures.)