

BDD-NET for adults with body dysmorphic disorder

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Summary

- The **technology** described in this briefing is BDD-NET. It is designed to treat moderate to severe body dysmorphic disorder (BDD).
- The **scope** for this briefing is to consider the use of BDD-NET in a therapist-guided model of care, in adult IAPT services.
- The **intended place in therapy** would be in a stepped care model for people with moderate to severe body dysmorphic disorder.
- The **main points from the evidence** summarised in this briefing are from 3 studies: 1 randomised controlled trial set in Sweden, a 2-year follow up of that trial, and 1 non-comparative international study, including a total of 115 adults. The randomised controlled trial reports that BDD-NET is more effective than supportive online therapy in adults with body dysmorphic disorder; at 2 years' follow up, the treatment was effective in 69% of people. The non-comparative study reports that people using the English language version of BDD-NET have similar levels of symptom improvements to those reported in people using the Swedish language version.
- **Key uncertainties** around the evidence or technology are that there is currently no evidence comparing BDD-NET with UK standard care, and the English language version has not been trialled in a comparative study.
- The **cost** of BDD-NET is expected to be around £160 per course of treatment (including a therapist's time and VAT). The **resource impact** would be less than a course of 1:1 cognitive behavioural therapy (CBT) with exposure and response prevention (ERP), but more expensive than group CBT with ERP.

- The IAPT expert panel **recommended** BDD-NET for the evaluation in practice phase of the NICE and NHS England IAPT assessment programme.

The technology

BDD-NET (Karolinska Institutet) is an online program designed to treat body dysmorphic disorder (BDD) using CBT with ERP techniques. Throughout treatment the user has contact with a named therapist, who reviews their progress and answers any questions through an inbuilt secure messaging service.

The treatment focuses on how body dysmorphic disorder is maintained by negatively reinforced avoidance (such as avoiding looking in the mirror) and safety-seeking behaviours (such as mirror checking and hiding certain features that the person thinks of as 'defects'). People using BDD-NET are encouraged to expose themselves to situations that cause them to be anxious or fearful, and are taught response prevention techniques that help them to reduce their anxiety rituals.

BDD-NET comprises 8 modules, which are designed to be completed over 12 weeks:

- 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.
- Prevention relapse.

In order to progress to the next module users must complete homework assignments and report back to their therapist. Homework can include reading some text, answering a questionnaire at the end of the previous module, filling

out worksheets or doing ERP. The therapist grants access to the next module after reviewing the homework. BDD-NET is intended to teach users the techniques they need to manage their body dysmorphic disorder in the future. When users have finished the course of treatment they are re-assessed by the therapist, to decide whether any further treatment is needed.

Regulatory status

The technology owner has stated that the platform that runs BDD-NET is CE marked as a class I medical device, but the BDD-NET program itself does not have a CE mark.

Current usage and reach

BDD-NET is not currently available in the UK. It has been used by around 150 people in research studies, mainly in Sweden, and has been offered in routine care in Sweden since autumn 2018.

Current care pathway

BDD-NET is aligned to the NHS England [Adult Improving Access to Psychological Therapies \(IAPT\)](#) programme. IAPT services provide evidence-based treatments for common psychological conditions such as depression and anxiety, including body dysmorphic disorder. IAPT services offer evidence-based psychological therapies given by accredited practitioners, with routine monitoring and regular outcomes-focused supervision.

The care pathway for body dysmorphic disorder is described in the NICE guideline on [obsessive compulsive disorder and body dysmorphic disorder](#). NICE recommends a [stepped-care model](#) for body dysmorphic disorder in which the least intrusive, most effective intervention is provided first; if a person does not benefit from the intervention initially offered, or declines an intervention, they should be offered an appropriate intervention from the next step.

BDD-NET could be used in a therapist-guided care model in primary care, secondary care, or in IAPT services as a step 3 therapy. It could potentially

also be used alongside higher-intensity treatment options in step 4 or 5 treatment. BDD-NET would be offered as an alternative to other therapies and it is not anticipated that any changes would be needed to the current care pathway.

Population, setting and intended user

BDD-NET could be used in any setting in which the user has access to the internet, including in the home or in outpatient clinics. It would be used by adults with body dysmorphic disorder, guided by an appropriately trained therapist. In IAPT services this would likely be an appropriately trained psychological wellness practitioner.

The technology owner states that no special training is needed for patients using BDD-NET. Therapists would need some training to use BDD-NET. This would be provided by the technology owner and would probably take the form of a workshop.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Digital technologies such as BDD-NET may be unsuitable for people with visual impairment or learning disabilities. Disability is a protected characteristic under the Equality Act.

The content

The care model

The therapist assesses each person's suitability for BDD-NET. This assessment can be done in person or through videoconferencing. The therapist guides the user through the program, and can be contacted freely by the user through the secure, 2-way messaging platform built into the program, as well as reviewing homework and granting access to the next module. Therapists are expected to answer any messages received from users during the working week within 24 hours.

BDD-NET uses several alert triggers, which flag to the therapist potential risks to the user. These triggers include a user recording a score of 2 or 3 on the suicidality item of the PHQ-9 measure (indicating a risk of self-harm) and user inactivity in the program. The developer has noted that these alert triggers can be altered to fit IAPT service needs, if necessary.

Outcome measures

BDD-NET uses the PHQ-9 and the appearance anxiety inventory (AAI) outcome measures. These measures are recorded weekly and are visible to the therapist but not the user, presented as summary total scores and as graphs plotting scores over time.

The standard outcome measure for body dysmorphic disorder for use in IAPT is a modified version of the Cosmetic Procedures Screening Scale (COPS), with an introduction modified for all cases of body dysmorphic disorder. The developer has added COPS as a weekly outcome measure on the platform.

Content assessment

The therapeutic content of BDD-NET was assessed using a framework designed to measure how closely its content maps to the standard principles of CBT with ERP for body dysmorphic disorder.

The assessors noted that therapist training in IAPT teaches the Veale model of CBT for body dysmorphic disorder, but BDD-NET uses the Wilhelm model, which is less cognitive and more behavioural than the Veale model. This difference is not expected to be a barrier for IAPT therapists to deliver treatment with BDD-NET, but therapists may be unfamiliar with some aspects of the Wilhelm model.

The developer has produced a therapists' manual, which the assessors concluded to be appropriate and comprehensive.

The assessors noted the following points about BDD-NET:

- The Wilhelm model of CBT is more suitable for mild to moderate body dysmorphic disorder and this could be more explicitly stated in the introduction to the program.
- Treating body dysmorphic disorder can be difficult and there is no single treatment that works in all cases. BDD-NET would benefit from more explanation to help users manage their expectations of treatment. Some people will not recover using BDD-NET but they may be left with feelings of failure if their expectations are set unrealistically high.
- The text can be somewhat dense overall with some complex language which some people may find hard to follow.
- BDD-Net is like a textbook in its structure. It lacks any interactive user elements to show changes in symptom scores, such as quizzes or charts.

Scalability

The technology owner has considered the challenges of scalability if the demand for BDD-NET increases substantially. It has stated that the current platform is designed to manage over 10,000 concurrent users.

Technical standards

Technical assessment

BDD-NET has undergone a technical evaluation using sections of the [Digital Assessment Questions \(DAQ\)](#), a pilot tool currently available to developers in beta form. The evaluation included 6 domains of the DAQ: clinical safety, privacy and confidentiality, security, usability and accessibility, interoperability and technical stability.

BDD-NET met the digital standards set out in the DAQ.

Clinical evidence

A literature search was carried out for this briefing in accordance with the [process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology.

This briefing summarises 1 randomised controlled trial (94 patients), a 2-year follow-up report from this study and 1 non-comparative study (21 patients).

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The randomised controlled trial (Enander et al. 2016) used the Swedish language version of BDD-NET, whereas the non-comparative study reported in the La Lima (2018) PhD thesis used the English language version. The studies showed similar improvements in body dysmorphic disorder and depression symptoms using both versions of the program.

Both studies recruited people through online and media advertising, accepting self-referred people. These people had good IT skills and were engaged in managing their conditions and so they may not be representative of the whole body dysmorphic disorder population.

Enander et al. (2016) compared BDD-NET with supportive online therapy. Although this is an interesting comparator, because it allows the effects of the content of BDD-NET to be compared with general online therapist contact, it is not a therapy used in IAPT services. There are currently no studies comparing BDD-NET with any of the standard care options for body dysmorphic disorder in IAPT services. The follow-up study from Enander et al. (2018) provides data for people in the trial at 2 years after completing the treatment. Although the data are useful and show different patterns of recovery, they are non-comparative and so their value is somewhat limited.

Tables 1-3 show the summary of evidence from 3 studies.

Table 1 [Enander et al. \(2016\)](#)

Study size, design and location	Randomised controlled trial (n=94), Sweden.
Intervention and comparator(s)	Swedish language version of BDD-NET (n=47); online supportive therapy (n=47). After 3 months, the online supportive therapy group were offered BDD-NET. In total 88 people had BDD-NET. Of these 81 completed the post-treatment assessment, 75 completed follow up at 3 months and 54 completed follow up at 12 months.
Population	Adults aged 18 and over who responded to advertisements in Sweden. Principle diagnosis of BDD with a score of at least 20 on the BDD-YBOCS. Exclusion criteria included changes to psychotropic drug treatment in last 2 months, completed CBT for BDD in last 12 months, bipolar disorder, psychosis or suicidal ideation, severe personality disorder or concurrent psychological treatment.
Key outcomes	Primary outcome: People having BDD-NET had statistically significantly improved BDD-YBOCS scores at 3 months and 6 months after treatment compared with supportive therapy. Supportive therapy group mean BDD-YBOCS (SD): <ul style="list-style-type: none"> • Baseline 29.13 (5.02), post-treatment 26.64 (5.75), 6 months 25.56 (5.95). BDD-NET group mean BDD-YBOCS (SD): <ul style="list-style-type: none"> • Baseline 28.51 (4.55), post-treatment 20.04 (7.93), 6 months 19.10 (8.82).

	<p>The between group effect size was 0.95 (95% CI 0.52 to 1.38) at post-treatment and 0.87 (95% CI 0.42 to 1.31) at 6 months.</p> <p>Secondary outcomes:</p> <p>People having BDD-NET showed a decrease in depression symptoms measured with the MADRS-S, but people having supportive therapy did not.</p> <p>Supportive therapy group mean MADRS-S (SD):</p> <ul style="list-style-type: none"> • Baseline 18.83 (7.91), post-treatment 18.3 (10.08), 6 months 18.18 (9.89). <p>BDD-NET group mean MADRS-S (SD):</p> <ul style="list-style-type: none"> • Baseline 18.92 (8.43), post-treatment 13.72 (11.07), 6 months 12.75 (8.68). <p>Post-hoc analysis showed that people having BDD-NET had an increase in global functioning (GAF), whereas people having supportive therapy did not. There was a statistically significantly larger increase in quality of life (EQ-5D) in the BDD-NET group compared with the control group at 6 months.</p> <p>Remission was defined as not fulfilling diagnostic criteria of BDD according to the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders.</p>
Strengths and limitations	<p>This study was adequately powered to detect the changes measured, and reported validated outcome measures. However, the comparator was not relevant to standard care in IAPT services. The people in the study self-referred and had reasonably good insight, and so this group may not be representative of the whole BDD population. Six of 47 people (13%) in the BDD-NET group withdrew or were lost to follow up after the 3-month treatment; all 47 people in the control group completed 3 months of supportive therapy.</p>
Declarations of interest	None.

Table 2 [Enander et al. 2018](#)

Study size, design and location	Naturalistic 2-year follow-up study of people who had BDD-NET (n=88) in the Enander et al. (2016) study.
Intervention and comparator(s)	As for Enander et al. (2016). Of the 88 people who had BDD-NET, 56 completed follow up at 2 years; no comparator.
Population	As for Enander et al. (2016).
Key outcomes	Overall the mean change in BDD symptoms measured using BDD-YBOCS score was a 13.42-point improvement in symptoms. Remission was defined as having a BDD-YBOCS score of less than 20.

	<p>Responder status was defined as showing at least a 30% reduction in BDD symptoms using the BDD-YBOCS symptom score.</p> <p>At 24 months, 69% of people were classified as responders and 56% were in remission.</p> <p>40% of people responded to therapy at post-treatment and maintained improvements at 24 months.</p> <p>29% had not responded at post-treatment but subsequently showed a delayed response at 24 months.</p> <p>10% had responded at post-treatment but relapsed to non-responder status at 24 months.</p> <p>21% had not responded at post-treatment and this was maintained at 24 months.</p>
Strengths and limitations	There was no control group with which to compare the follow-up data. Only 63% of people who had treatment were available for follow up at 24 months.
Declarations of interest	None.

Table 3 [La Lima \(2018\)](#) (PhD thesis)

Study size, design and location	Uncontrolled study (n=21), international (Sweden, US, UK and others).
Intervention and comparator(s)	English language version of BDD-NET (n=21); no comparator.
Population	<p>Mix of clinician-referred and self-referred people, fluent in English, aged 18 or over with a positive screen for BDD using the BDDQ, DCQ, DSM-5 and BDD-YBOCS measures.</p> <p>Exclusion criteria included people with changes to psychotropic medication in prior 12 weeks, completed CBT for BDD in last 12 months, substance dependency or diagnosis of bipolar disorder or psychosis.</p>
Key outcomes	<p>Primary outcome:</p> <p>There was a statistically significant improvement in BDD-YBOCS score with BDD-NET.</p> <p>BDD-NET group mean BDD-YBOCS (SD):</p> <ul style="list-style-type: none"> • Baseline 27.71 (5.03), mid-treatment 20.25 (8.59), post-treatment 15.71 (8.54). <p>Secondary outcomes:</p> <ul style="list-style-type: none"> • Responder status: 6 of the 16 people who completed the mid-treatment assessment were considered to be responders (at least 30% decrease on severity score). 8 of the 14 people who completed post-treatment

	<p>assessment were considered to be responders and 5 were considered to be in remission from BDD.</p> <ul style="list-style-type: none"> • Depression: there was a statistically significant improvement in MADRS-S scores from baseline to mid-treatment, and from baseline post-treatment.
Strengths and limitations	<p>There was no control group with which to compare the data. The study was small and some data points could not be reported due to data not being returned. 19% (4 of 21) people completed all 8 modules of BDD-NET, whereas 29% (6 of 21) completed the 'core modules' (modules 1 to 5).</p>
Declarations of interest	<p>Not stated.</p>

Abbreviations: BDD, body dysmorphic disorder; BDDQ, BDD questionnaire; BDD-YBOCS, Yale-Brown obsessive compulsive scale modified for BDD; DCQ, dysmorphic concern questionnaire; DSM-5, the Diagnostic and Statistical Manual of Mental Disorders; EQ5D, EuroQol-5D instrument for measuring quality of life; GAF, global assessment of functioning; MADRS-S, Montgomery-Åsberg depression rating scale.

Recently completed and ongoing studies

One recently completed trial on the use of BDD-NET for body dysmorphic disorder was identified in the preparation of this briefing, which is listed on ClinicalTrials.gov:

- [NCT03517384](#): Feasibility Pilot Study of Internet-based Cognitive Behavioral Therapy (CBT) for Body Dysmorphic Disorder with Global Recruitment (BDD-G). Study start date: April 2016. Completion date: July 2018. Actual enrollment: 32 patients.

Cost and resource impact

Technology costs

It is expected that each course of treatment using BDD-NET would cost around £120, including VAT. The technology owner has stated that the median therapist time needed is 10 minutes per week over the 12 weeks of the course, bringing the total cost to £160 including a therapist's time.

Resource consequences compared with standard care

Table 2 Costs per treatment course per person of BDD-NET compared with current treatments for body dysmorphic disorder

Treatment	Existing cost	Cost using BDD-NET (including VAT)	Cost/saving
10 hours of 1:1 CBT with ERP	£401	£160	£241 saved
10 hours of group CBT with ERP	£98	£160	£62 cost
More intensive 1:1 CBT with ERP	£601	£160	£441 saved
A course of SSRI treatment	£75	£160	£85 cost
Combination of SSRIs and group CBT	£173	£160	£13 saved
Combination of SSRIs and 1:1 CBT	£476	£160	£316 saved

Abbreviations: CBT, cognitive behavioural therapy; ERP, exposure and response prevention; SSRI; selective serotonin reuptake inhibitor.

The following costing assumptions have been made for BDD-NET:

- Each course of treatment using BDD-NET is expected to cost £120 per person.
- BDD-NET may be delivered by a psychological wellness practitioner (AFC band 5); costs include 120 minutes of their time per person, over the 12 weeks of the course.
- There will be no extra cost for training.

Overall impact

Using BDD-NET is unlikely to deliver cash-releasing savings but it may free staff time which could in turn reduce waiting times and increase access to care. For example, a reduction in face-to-face CBT would release therapist time.

Cost and resource impact statement from the developer

The developer has stated that using BDD-NET reduces costs because less therapist time is needed compared with face-to-face therapy.

IAPT expert panel considerations

The expert panel considered the assessments of therapeutic content, digital technological factors, clinical evidence and resource impact in making their decision that BDD-NET should progress to the evaluation in practice phase of this programme.

Technical assessment

A full technical assessment of BDD-NET was not completed, as the developer stated that the technical aspects would be identical to the previously assessed technology from the same developer, OCD-NET. OCD-NET had been referred for development funding to address technical issues with the shared platform that runs these 2 technologies. Completion of this development work would bring BDD-NET in line with technical standards.

The clinical safety section of the DAQ was completed for BDD-NET and the answers given for these questions were deemed to be satisfactory to pass this assessment.

Content assessment

The panel noted that the therapist manual had been assessed as being appropriate and comprehensive.

The panel noted that the developer had added the modified version of the Cosmetic Procedures Screening Scale (COPS), with an introduction modified for all cases of body dysmorphic disorder, to the program.

The panel also noted the content assessors' comments on the structure of BDD-NET and agreed that the program would benefit from more interactive elements and explanation to help users manage their expectations of

treatment. However, the panel did not consider these to be essential for the technology to progress to evaluation in practice in IAPT services.

Clinical evidence

The panel noted that the randomised clinical trial evidence for BDD-NET suggested that people may have long-term benefits after using BDD-NET. This suggests that the format of BDD-NET may not be a barrier to its effectiveness. The panel concluded that the evaluation in practice stage of the programme should be able to detect whether this is an issue in IAPT populations.

Cost and resource impact

The panel noted that the cost of delivering therapy with BDD-NET was expected to be around £160 per user.

Development of this briefing

This briefing was developed by NICE for NHS England's [assessment of digitally enabled psychological therapies for IAPT](#). The briefing was presented to NICE's IAPT expert panel, who considered BDD-NET for this assessment programme. The [process and methods statement](#) sets out the process for selecting topics, and how the briefings are developed, quality-assured and approved for publication.

Panel members

- Professor Tim Kendall (chair), national clinical director for mental health, NHS England and NHS Improvement.
- Ms Lauren Aylott, lay member.
- Professor Peter Bower, professor of health services research, Manchester University.
- Professor Chris Hollis, professor of child and adolescent psychiatry, University of Nottingham.
- Ms Toni Mank, clinical director for planned and scheduled care and head of IAPT, Sheffield Health and Social Care NHS Foundation Trust.

- Dr Ifigeneia Mavranouzouli, senior health economist, University College London.
- Dr Nicholas McNulty, primary care psychologist, South London & Maudsley NHS Trust.
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