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### Development and Pilot Testing of a Cognitive-Behavioral Therapy Digital Service for Body Dysmorphic Disorder

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Body dysmorphic disorder (BDD) has a severe presentation and chronic course when untreated. Although effective BDD treatments exist, most individuals do not have access to them. We therefore developed and pilot tested the first smartphone-delivered individual cognitive-behavioral therapy (CBT) treatment for adults with BDD. The digital service was developed via user-centered design, integrating input from engineering, design, and psychology experts, plus BDD patient consultants. We conducted a 12-week open pilot trial (N = 10) to describe preliminary results for feasibility, acceptability, and treatment outcome. Attrition rates (0%) and feedback on usability and satisfaction

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indicated that smartphone-based CBT for BDD may be feasible, acceptable, and satisfactory. Initial results suggest that smartphone-based CBT for BDD may hold promise for improving BDD symptom severity, BDD-related insight, functional impairment, and quality of life, as scores from baseline to posttreatment improved with large-to-very large effects; depression improved with a medium effect. Ninety percent of participants were responders at posttreatment and 3-month follow-up. Smartphone-based CBT for BDD may have strong potential as a standardized, low cost, and accessible treatment for this debilitating illness. A test of efficacy is merited as a next step, using a well-powered, randomized control trial design.

*Keywords:* body dysmorphic disorder; cognitive-behavioral therapy; smartphone; app; digital health

BODY DYSMORPHIC DISORDER (BDD) is a relatively common psychiatric illness that occurs in 1.7–2.9% of the general population (Buhlmann et al., 2010; Koran, Abujaoude, Large, & Serpe, 2008; Rief, Buhlmann, Wilhelm, Borkenhagen, & Brahler, 2006; Schieber, Kollei, de Zwaan, & Martin, 2015). It involves a preoccupation with a perceived or minor defect in one's physical appearance,

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accompanied by time-consuming rituals intended to hide, check, or fix the perceived flaws (American Psychiatric Association, 2013). BDD is a highly debilitating disorder that typically follows a chronic course when untreated (American Psychiatric Association, 2013; Phillips, Menard, Quinn, Didie, & Stout, 2013). It is associated with substantial functional impairment and low quality of life (Phillips, Quinn, & Stout, 2008), housebound rates of 30% (Phillips & Menard, 2006), suicidal ideation in 79.5% (Phillips & Menard, 2006), and suicide attempts in 27.6% (Phillips & Menard, 2006). Given the economic and individual burden of BDD, it is critical for sufferers to have timely access to effective treatment.

Cognitive-behavioral therapy (CBT) is the psychotherapy with greatest empirical support for BDD (Harrison, Fernández de la Cruz, Enander, Radua, & Mataix-Cols, 2016; Veale et al., 2014; Wilhelm et al., 2014). A recent meta-analysis shows that CBT for BDD has a large effect compared to a wait-list or control condition (d = 1.22; Harrison et al., 2016). However, despite strong evidence that supports the efficacy of CBT for BDD, very few individuals with BDD obtain empirically supported treatment. In fact, one study of barriers to treatment reported that only 23.3% of BDD sufferers had been diagnosed by a professional (Buhlmann, 2011), and a second study documented that only 17.4% had received CBT (Margues, Weingarden, LeBlanc, & Wilhelm, 2011).

There are many barriers to accessing psychotherapy. One key barrier is that the number of patients who need treatment far outweighs the capacity of available clinicians (Lin, Stamm, & Christidis, 2016)-particularly qualified clinicians trained to deliver empirically-based treatments. This access issue may be especially dramatic in BDD, due to the specialty nature of the disorder and its treatment (Margues et al., 2011). Additionally, receiving psychiatric care is often associated with stigma and shame. This barrier may be particularly salient for individuals with BDD as well, as shame around appearance may prevent sufferers from disclosing their concerns to medical or psychological professionals (Weingarden & Renshaw, 2015). Further, psychotherapy can be costly, time-consuming, and difficult to access. Altogether, patients may face psychological, economic, and logistical barriers that prevent them from attending weekly inperson appointments (Marques et al., 2011). Moreover, even among the minority of patients who obtain CBT for BDD, patients can have difficulty generalizing CBT skills outside of the therapy office to the real world, where symptoms are most often triggered. The challenge of generalizing skills may hinder treatment response and increase risk for relapse.

To address some of these treatment barriers, one research group developed and tested an Internetbased CBT for BDD (BDD-NET; Enander et al., 2014, 2016). BDD-NET is a 12-week treatment that resulted in response among 54% of those in the Internet CBT condition, compared to only 6% randomized to Internet-delivered supportive therapy (Enander et al., 2016). Internet-delivered CBT offers promise for low-cost, accessible, standardized, and empirically based treatment, reducing several of the primary barriers to access. However, Internet-based treatments may not adequately address the challenge of generalizing skills to realworld settings where symptoms are triggered. More recently, there have been promising results on the use of smartphones as a delivery channel for CBT. For example, reSET by Pear Therapeutics obtained U.S. Food and Drug Administration (FDA, 2017) clearance as a mobile medical application to treat substance use disorders, in September 2017. As smartphones become ubiquitous—now owned by 77% of the U.S. population (Pew Research Center, 2016)-it is possible that further flexibility and enhanced outcomes may be achieved by developing smartphone-delivered CBT for BDD.

In particular, while Internet-based CBT requires patients to log in from a computer (i.e., patients generally must be at home to use the program), smartphone-delivered CBT can be accessed whenever or wherever symptoms arise. In this way, smartphone-based treatments have great potential to address challenges in generalizing skills to the real world. Moreover, while Internet-based treatments have traditionally been designed to mimic the structure of in-person therapy (i.e., patients sit down for a length of time at regular intervals to read substantial content, complete worksheets, and practice skills, much like a formal therapy appointment; Mohr et al., 2017), people are more accustomed to interacting with their phones in brief, frequent intervals. Thus, smartphonedelivered treatments that are designed to package skills and education into short segments available at any time may be utilized with greater frequency than Internet-based CBT. More frequent engagement with skills may generate enhanced practice and learning. Finally, like Internet-based treatments, smartphone-delivered CBT maintains the advantages over in-person treatment of being widely disseminable, immediately accessible, low cost, and standardized.

The primary aims of this study were to describe the development of the first smartphone-delivered individual CBT for BDD digital service ("Perspectives"),

and to conduct a pilot test of Perspectives, to obtain very preliminary data on its feasibility, acceptability, and treatment outcome. A digital service is a technology-enabled intervention that is primarily automated but includes minimal supplemental intervention by a person. We elected to develop a digital service as opposed to an entirely standalone app because extant literature suggests that even circumscribed accountability to another person may substantially increase engagement with technologybased interventions (Newman, Szkodny, Llera, & Przeworski, 2011).

We approached our aims through two phases. Development was accomplished via a collaborative user-centered design phase that involved engineering and design experts, clinician-researchers with expertise in CBT for BDD, and BDD patient consultants. Subsequently, preliminary data on feasibility, acceptability, and outcomes were obtained via an open pilot trial in 10 adults with primary fifth edition Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013) BDD. We hypothesized that smartphone-delivered CBT for BDD would show initial evidence of (a) feasibility, demonstrated through low attrition rates, high rates of engagement with the digital service, and positive feedback about the usability of the app; (b) acceptability, demonstrated through high ratings on a satisfaction questionnaire and qualitative feedback; and (c) improvement, demonstrated by clinically significant improvements on primary (i.e., BDD severity) and secondary (i.e., BDD-related insight, depression severity, functional impairment, and quality of life) outcomes from baseline to posttreatment. Additionally, we hypothesized that (d) clinical improvements would show initial evidence of maintenance at 3-month follow-up, demonstrated by a lack of clinically significant changes in outcomes from posttreatment to follow-up.

#### Method

#### PHASE I: USER-CENTERED DESIGN

#### **Participants**

Development of the digital service involved close collaboration between engineering and design experts (i.e., technology experts) from a large telecommunications company with experience in app development and user-experience design (n = 2), clinician-researchers specialized in CBT for BDD (n = 3), and BDD patient consultants (n = 5) who were asked to inform the design process with stakeholder insights.

BDD consultants were adults with current or lifetime diagnoses of primary DSM-5 BDD, recruited through our academic medical center's specialty BDD program. BDD consultants had each completed (or were actively engaged in) CBT for BDD with a clinician from the Massachusetts General Hospital (MGH) Obsessive-Compulsive Disorder (OCD) and Related Disorders Program. Individuals were not eligible to serve as BDD consultants if (a) they had comorbid psychopathology that could interfere with their ability to provide substantial consultation (i.e., current substance dependence, mania or hypomania, active suicidal ideation, borderline personality disorder, or lifetime psychosis, as determined by the Structured Clinical Interview for DSM-IV-Patient Version [SCID-P and SCID-II; First, Gibbon, Spitzer, Williams, & Benjamin, 1997; First, Spitzer, Gibbon, & Williams, 2002]; or severe major depression, as indicated by a total score  $\geq 20$  on the Patient Health Questionnaire-9 [PHQ-9; Kroenke, Spitzer, & Williams, 2001]); (b) lacked sufficient BDDrelated insight, defined by a Brown Assessment of Beliefs Scale (BABS; Eisen et al., 1998) score in the delusional range; or (c) did not own a supported smartphone. BDD consultants ranged in age from 22 to 44 and had a mean age of 30 (SD = 8.28) years at the time of enrollment. Consultants were White, single, a mix of males (40%) and females (60%), and had each obtained a college education or higher. On average, they had subclinical BDD severity as measured by the Yale-Brown Obsessive Compulsive Scale, Modified for BDD (BDD-YBOCS; Phillips et al., 1997; *M* = 14.8, *SD* = 2.68).

#### PROCEDURES

Perspectives' initial structure, features, and planned content were established over the course of two development "sprints," during which the technology experts met with the clinical researchers for several consecutive days, to teach one another about their respective areas of expertise. During sprints, the technology and research experts also collaborated to develop the general program outline and flow. Following development sprints, the two teams worked closely together to create a prototype of the digital service, with the clinical researchers leading in writing content (e.g., psychoeducation, CBT skills exercises) and the technology experts leading in design and user interface.

Once an initial prototype was developed, BDD consultants were recruited to provide in-depth feedback. User-centered design procedures were approved by the MGH IRB, and BDD consultants

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provided informed consent at an in-person screening visit. An independent evaluator (IE) who was trained and reliable on diagnostic measures conducted a screening assessment to evaluate eligibility criteria. Enrolled BDD consultants met individually with the technology experts in the consultants' homes, for approximately 2.5 hours. The aim of this interview was for the technology experts to learn about the consultants, their personal experience with BDD and receiving CBT for BDD, what they would hope for in a CBT for BDD digital service, and their concerns about potential roadblocks with the digital treatment.

After the initial in-home interviews, BDD consultants completed prototype testing over 1 week. During this time, consultants gave brief daily feedback on separate modules of the prototype. Based on this feedback, adjustments were made to the program's design, flow, interface, and content. Once the digital service was developed, incorporating input from each party, the BDD consultants tested and provided feedback on a functional beta version of the app over 12 days. At the end of the prototype testing period, the BDD consultants completed exit interviews with the technology experts via video call, to further explain their feedback. BDD consultants were compensated for their role in app development. Once user-centered design was complete, we preliminarily tested the digital service in an open trial.

PHASE 2: OPEN PILOT TRIAL

#### **Participants**

Participants were recruited nationally to enhance generalizability, through advertisements on our BDD specialty program's website, Facebook, and public transportation, e-mails to professional colleagues, and e-mail broadcasts to our affiliated health care system. Participants were recruited between July 2017 and April 2018 and concluded the 3-month follow-up phase by October 2018.

Our aim was to treat 10 adult participants with primary BDD in the pilot trial. Inclusion criteria required that participants were 18 years or older; had a current diagnosis of primary BDD based on the Structured Clinical Interview for DSM-5 (SCID-5; First, Williams, Karg, & Spitzer, 2015) criteria, had at least moderately severe BDD symptoms, as indicated by a BDD-YBOCS score  $\geq 20$ ; were appropriate for an outpatient level of care; and were living in the United States. Participants were excluded if they had participated in prior CBT for BDD; met diagnostic criteria for current severe substance use disorder, severe major depressive disorder based on a score  $\geq 20$  on the PHQ-9, or borderline personality disorder, met diagnostic criteria for lifetime bipolar disorder or psychosis; had an intellectual disability or cognitive impairment that would interfere with their ability to engage in CBT; presented with active, acute suicidal ideation; or did not own a supported smartphone (i.e., iPhone 5S or later, running iOS 9 or newer). Additionally, participants were not permitted to be engaged in concurrent psychological treatments. Participants on psychotropic medications were required to have been on a stable dose for at least 2 months prior to enrollment and were asked not to make medication changes while enrolled in the study.

Twenty-three participants initiated a combined screening and baseline interview with an IE via Health Insurance Portability and Accountability Act (HIPAA)-compliant video calls. Of these, eight participants did not complete their screening visits, and five participants who completed screens did not meet eligibility criteria (difficulties with technology [n = 1], prior CBT for BDD [n = 1], symptom severity that warranted a higher level of care [n = 2],

Table 1 Demographic Characteristics at Baseline (N = 10)

	M (SD) / n (%)						
Age	27.6 (5.66)						
Sex—female	8 (80%)						
Race							
White	8 (80)						
African American	1 (10%)						
More than one race	1 (10%)						
Ethnicity—Hispanic	1 (10%)						
Marital status							
Single	5 (50%)						
Married	3 (30%)						
Living with partner	2 (20%)						
Highest level of education							
Some college	1 (10%)						
College graduate	5 (50%)						
Some postgraduate	2 (20%)						
Postgraduate	2 (20%)						
Current comorbid psychiatric diagnoses <sup>a</sup>							
Agoraphobia	3 (30%)						
Social anxiety disorder	2 (20%)						
Obsessive-compulsive disorder	2 (20%)						
Posttraumatic stress disorder	2 (20%)						
Generalized anxiety disorder	2 (20%)						
Panic disorder	1 (10%)						
Bulimia nervosa	1 (10%)						
Binge-eating disorder	1 (10%)						

*Note.* M = mean; SD = standard deviation.

<sup>a</sup> Percentages do not add up to 100 because some participants met criteria for more than one comorbid psychiatric diagnosis.

and severe substance use disorder [n = 1]). Ten participants were deemed eligible to participate and enrolled in the trial. See Table 1 for sample characteristics at baseline. All 10 participants completed a 3-month follow-up assessment and were included in analyses.

#### Procedures

The MGH IRB approved study procedures. Prior to initiating the screening and baseline assessment, the IE explained procedures and obtained electronic informed consent. At the conclusion of the screening and baseline assessment, a research assistant instructed eligible participants on how to download Perspectives onto their personal smartphone via the iOS app store. An initial welcome call was arranged with the digital service therapist (see below for additional details).

Clinical Assessments. IEs conducted all baseline assessments via video calls. Use of video calls allowed the IEs to evaluate whether participants' appearance concerns were better accounted for by a true physical defect, which would preclude a diagnosis of BDD. IEs were trained by a gold-standard rater on the primary diagnostic and outcome measures and were required to demonstrate reliability on the BDD-YBOCS and BABS (minimum intraclass correlation coefficient [ICC] of 0.80) and SCID-5 (100% agreement) with the gold-standard rater, prior to conducting assessments. Clinical assessments were audiotaped so that a random selection of 15% could be used for interrater reliability. Interrater reliability for each diagnostic and outcome measure was strong in the present study (SCID-5 BDD module: 100% agreement; BDD-YBOCS: single-score ICC = 0.97; BABS: singlescore ICC = 0.98; Shrout & Fleiss, 1979).

Assessments were conducted at screening/baseline to evaluate eligibility criteria and establish baseline severity. Additional assessments were conducted at midpoint (6 weeks), posttreatment (12 weeks), and 3-month follow-up. Self-report questionnaires were collected at each assessment via Research Electronic Data Capture (REDCap; Harris et al., 2009), an HIPAA-compliant electronic survey program operated by the academic medical center. Participants were compensated for each clinical assessment following the screening/ baseline assessment.

Design Interviews. Within approximately 1 week of the initial screening and baseline assessment, enrolled participants completed a phone or video call with a technology expert. The aim of this interview was to obtain information about participants' initial hopes, expectations, and concerns

about using the CBT for BDD digital service. Subsequently, participants completed midpoint and posttreatment interviews with the technology expert, to provide input on usability, feasibility, likes, dislikes, and recommendations for improving the digital service. Participants were compensated for each interview with the technology expert.

Perspectives' Core Features. Perspectives covered each of the core components of CBT for BDD (see Wilhelm, 2006; Wilhelm et al., 2014; Wilhelm, Phillips, Fama, Greenberg, & Steketee, 2011, for a detailed description). Each treatment module included brief psychoeducation that combined pictures and text, followed by short interactive exercises to engage the user and teach the specific CBT skill(s) from that module. Exercises were designed to be completed relatively quickly and could be repeated as often as desired. Participants could progress through the modules at any pace and could engage with the digital service in any setting where they had their phone. Certain exercise content (e.g., thought records, exposure records) was saved so that users could refer back to it at later dates. During the 12-week treatment, participants had access to the full digital service, including clinician support (see below for additional details). During posttreatment follow-up, participants continued to have access to Perspectives as a self-help program without clinician support.

CBT Modules. Modules included (a) Introduction, Psychoeducation, and Goal Setting, during which participants were oriented to the CBT model and selected treatment goals; (b) Working With Thoughts, which taught cognitive restructuring skills; (c) Living Your Life, which guided the user through completion of exposure with ritual prevention (ERP) hierarchies that were matched to the users' goals, selected in the introduction module. Certain exposure exercises were preceded by a 360° video user experience (i.e., simplified virtual reality delivered via Perspectives, such as a virtual experience of dining with friends in a restaurant), to provide a lower-level practice step before the in vivo exposure; (d) Freeing Yourself From Rituals, which taught strategies for reducing time-consuming rituals common to BDD (e.g., extended morning makeup routines, skin picking or hair plucking) in greater depth; (e) Seeing the Big Picture, which guided the user through BDD-specific audio exercises to learn mindfulness and attentional retraining skills, focused on mirror retraining, reducing comparing rituals, and refocusing attention away from oneself and on to other details in the environment; (f) Enhancing Value-Based Living

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and Self-Esteem, which taught users to set activity goals that align with user-identified values, in order to fill time previously spent ritualizing; users also learned to identify and modify core beliefs (e.g., "I am worthless") and enhance self-esteem through exercises (e.g., self-esteem pie); and (g) Staying Well, which focused on relapse prevention and maintenance of gains.

Therapist and Therapist Portal. Participants were provided with remote access to a Perspectives therapist during their 12-week treatment. The Perspectives therapist was a doctoral-level licensed psychologist from the MGH OCD and Related Disorders Program with experience treating BDD. Participants could interact with the Perspectives therapist in two ways: via brief phone calls, and via a secure, asynchronous messaging system built into the digital service. No expectation of the quantity of participant contact with the Perspectives therapist was provided to participants.

Upon enrollment in the trial, a brief welcome call was arranged between the therapist and participant. The therapist explained how she could be reached through the messaging system, oriented the participant to the program, gave suggestions about how to get the most out of the program (e.g., practice skills at least 30 minutes a day for the next 12 weeks), provided information on what to do in an emergency, and answered questions. A brief midtreatment call was also arranged, during which the therapist checked in on the participant's progress, helped identify symptoms that persisted, and assisted the participant in updating goals for the remainder of treatment. Participants could arrange additional brief check-in calls as needed. On average, the therapist held a total of 2.4 calls per participant. Mean total call time per participant across the 12week treatment was 32 (SD = 4.76) minutes.

Participants were also encouraged to reach out via the secure messaging system with any questions and to update the therapist on successes or challenges they were facing. The therapist replied to these messages through a secure Web-based portal once per business day. The therapist could also initiate chats with the participant (e.g., if a participant had not logged into Perspectives for a number of days). On average, the therapist spent 26.6 minutes per participant responding to chat messages across the 12-week treatment (or 2.22 minutes per participant per week). The secure therapist portal also allowed the therapist to see the content of participants' exercises (e.g., exposure worksheets, thought records, core belief exercises) and view certain basic statistics on the participants' use of the digital service (e.g., most recent login date).

Safety Features. The introductory program content included a notice about suicide risk, and information on what to do in case of suicidal thoughts was available at all times via a "safety" tab in the digital service. The safety tab included links to 911 and a national suicide hotline, plus links to professional organization Web pages. During the welcome call, the therapist instructed participants not to use the chat feature to communicate safety concerns, since messages were checked only once per business day. Suicide risk and signs of clinical deterioration were monitored at each clinical assessment.

Data Security Features. Participants downloaded the app via the iOS app store but required an enrollment code to launch it. The enrollment code was provided by the research team only once informed consent was obtained and the participant was determined to be eligible via the screening assessment. To download the digital service, participants' iPhones were required to be password protected. Data from the digital service were encrypted at rest and in transit. Data were stored deidentified on the medical center's hosting structure using study IDs and were not shared with third parties. The digital service was subjected to automated vulnerability screening and the builds of the mobile app were validated using a securityfocused static analysis platform. Security features of the app were explained to study participants during the informed consent process.

#### MEASURES

#### Diagnostic Assessment

The SCID-5 (First et al., 2015) BDD module was administered by the IE at the screening visit to evaluate diagnostic criteria for BDD. The SCID-5 is the gold-standard, semistructured, clinician-administered diagnostic assessment. The Mini International Neuropsychiatric Interview (MINI 7.02; Sheehan et al., 1997) was also administered by the IE to assess comorbid psychiatric illnesses and further evaluate diagnostic eligibility criteria. The MINI 7.02 is a semistructured, clinician-administered diagnostic assessment based on DSM-5 criteria. The MINI is well-validated against the SCID, reliable (interrater reliability: kappas > .75), demonstrates sensitivity and specificity, and is efficient to administer (Sheehan et al., 1997, 1998).

#### Safety

Adverse events were monitored by the IE at each clinical assessment.

Measures of Feasibility, Acceptability, and Satisfaction An eight-item self-report feedback questionnaire was designed for the present study and administered at posttreatment, to assess initial feasibility and usability of the app. Likert-style questions evaluated the extent to which exercises were easy to understand and helpful, digital service layout was clear, design and look of the digital service was likable, educational content was easy to understand, and amount of educational content, therapist communication, and prompts and alerts were appropriate. Participants could provide free text responses to further explain any items, in addition to giving a Likert rating.

The Client Satisfaction Questionnaire–8 (CSQ-8; Attkisson & Zwick, 1982) was our primary measure of satisfaction with treatment. It was administered at midpoint and posttreatment assessments. The CSQ-8 is an eight-item self-report measure with a total score ranging from 8 to 32. Higher scores correspond with greater satisfaction. The CSQ-8 evaluates a range of aspects of treatment satisfaction, including overall satisfaction, the extent to which needs were met, quality of services, and likelihood of recommending services to a friend. The CSQ-8 has strong internal consistency (Cronbach's alpha = .93) and demonstrates construct validity (Attkisson & Zwick, 1982).

#### Primary Treatment Outcome

The BDD-YBOCS (Phillips et al., 1997) is a 12-item gold-standard, semistructured clinician assessment of past-week BDD severity, which served as the primary outcome measure. Total scores range from 0 to 48, with higher scores indicating more severe BDD symptoms. The BDD-YBOCS has strong internal consistency (Cronbach's alpha = .80), test-retest reliability (ICC over 1 week = 0.88), interrater reliability (ICC = 0.99), and construct validity (Phillips et al., 1997). The BDD-YBOCS was administered at screening/baseline to establish eligibility criteria, and it was administered at each subsequent assessment.

#### Secondary Treatment Outcomes

The BABS (Eisen et al., 1998) is a gold-standard, clinician assessment of BDD-related insight (e.g., questions ascertain participants' conviction in an overarching maladaptive belief about their appearance, the fixedness of this belief, and the extent to which they believe appearance concerns reflect a true flaw vs. having a psychological cause). Scores range from 0 to 24, and higher scores indicate worse insight (with scores greater than or equal to 18, in addition to a score of 4 on an item measuring conviction, suggesting delusional beliefs). The BABS has strong internal consistency (Cronbach's alpha = .87), test-retest reliability, interrater reliability (ICC = 0.96), and construct validity (Eisen et al., 1998). The BABS was administered at screening/baseline, and it was readministered at each subsequent assessment to examine changes in insight.

The PHQ-9 (Kroenke et al., 2001) is a nine-item Likert-style self-report screening and severity measure for depression. It has strong psychometric properties, including internal consistency (Cronbach's alpha = .86–.89), test–retest reliability, and construct validity (Kroenke et al., 2001). The PHQ-9 was completed by participants at baseline to evaluate eligibility criteria, and participants completed the PHQ-9 at each subsequent assessment to evaluate changes in depression and suicide risk.

The Sheehan Disability Scale (SDS; Sheehan, Harnett-Sheehan, & Raj, 1996) is a three-item Likert-style self-report measure of impairment due to one's illness. Responses range from 0 (*not at all*) to 10 (*extremely*), and a total score can be calculated by summing the items. It has strong psychometric properties, including sensitivity and specificity for detecting disability in psychiatric samples, and validity (Sheehan et al., 1996). The SDS was administered at each clinical assessment.

The Quality of Life, Enjoyment, and Satisfaction Questionnaire—Short Form (Q-LES-Q-SF; Endicott, Nee, Harrison, & Blumenthal, 1993) was used to measure quality of life at each clinical assessment. It is a self-report measure that evaluates quality of life across broad domains, using Likert items ranging from 1 (*very poor*) to 5 (*very good*). Total scores are presented as a percent of the maximum value (i.e., ranging from 0 to 100, with higher scores indicating greater quality of life). The Q-LES-Q-SF demonstrates strong internal consistency (subscale Cronbach's alphas = .90–.96) and validity (Endicott et al., 1993).

#### Results

Data were analyzed using SPSS Version 24 (IBM Corp., 2016). Primary and secondary outcome variables appeared relatively normally distributed from visual inspection, and Shapiro-Wilk tests of normality were nonsignificant for baseline primary and secondary outcome measures (BDD-YBOCS, BABS, PHQ-9, Q-LES-Q-SF, and SDS).

PRELIMINARY FEASIBILITY, ACCEPTABILITY, AND SATISFACTION

No serious adverse events were reported. Attrition rates (0%) indicate that the treatment was highly acceptable in our open-pilot trial sample. Moreover, usage data indicate that participants spent a mean of 398 (*SD* = 310.25) minutes using the

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digital service across the 12 weeks of treatment, indicating that participants found the digital service to be both feasible and acceptable. A question was added toward the end of the pilot trial (n = 3)documenting that, in addition to time spent *actively using* the digital service, on average about two thirds of participants' total time spent practicing CBT skills occurred *offline* (e.g., completing exposure exercises or evaluating the accuracy and helpfulness of cognitions on their own).

Total CSQ-8 scores at posttreatment suggest that participants were highly satisfied with treatment, M = 27.90, SD = 3.51. Median scores on individual CSQ-8 items indicate that participants were overall "very" satisfied with the service, found the quality of service "excellent," "definitely" received the kind of service they wanted, and found that "most" of their needs were met by the program. Qualitative feedback from participants likewise suggests that participants were highly satisfied with the treatment. For example, one participant noted that "I am increasingly happy and would highly recommend the app. I've experienced real progress, as it forces you out of your comfort zone, provides structure to be able to do so, and gives me tools to be able to handle the situation." Another participant noted that "I thought there was no help for me. It's been way more helpful than I expected."

#### PRELIMINARY TREATMENT OUTCOME

Given the small size of our pilot sample, greater focus was placed on initial examination of clinical significance and effect sizes than on tests of statistical significance. To this end, we first examined Cohen's d for paired t tests, calculated as the mean change score divided by the standard deviation of the change score (see Table 2). Paired t tests were used to preliminarily examine changes in primary and secondary outcomes from baseline to posttreatment, and to initially examine maintenance of gains from posttreatment to follow-up. We also calculated the reliable change index (RCI) based on BDD-YBOCS total scores for the whole sample and for each participant at both posttreatment and follow-up, using methods recommended by Jacobson and Truax (1991): RCI =  $(X_1 - X_2)$  /  $(s_{ref pooled} * sqrt(1 - r_{xx}))$ , where  $X_1$  and  $X_2$  were the pretreatment and posttreatment group means (or individual scores), respectively, s<sub>ref pooled</sub> was the pooled standard deviation from the BDD patient samples used in the two psychometric evaluation papers of the BDD-YBOCS (Phillips, Hart, & Menard, 2014; Phillips et al., 1997), and  $r_{xx}$  was the average of the two test-retest correlations reported in the same psychometric papers.

#### **BDD** Severity

On average, participants had severe BDD symptoms at baseline and mild symptoms at posttreatment (see Table 2). BDD-YBOCS scores decreased across treatment (M = 45.27%, SD = 14.66%) with a large effect (d = 2.60). Moreover, 90% of participants were treatment responders at posttreatment, as defined by the frequently used criterion of  $\geq 30\%$  reduction on the BDD-YBOCS (Phillips et al., 2014). At 3-month follow-up, participants appeared to maintain their gains (see Table 2). Treatment response rate remained at 90% at follow-up. For the whole sample, the RCI was 5.08 at posttreatment and 5.69 at follow-up,

Table 2

Baseline, Midtreatment, Posttreatment, and 3-Month Follow-Up Scores on Outcome Measures

Outcome	Baseline Mean ( <i>SD</i> )	Mid-tx Mean ( <i>SD</i> )	Post-tx Mean ( <i>SD</i> )	3-month FUP Mean ( <i>SD</i> )	Baseline to post-tx			Post-tx to 3-month FUP		
					t ( <i>df</i> ) 95% Cl <sup>a</sup>	p	d	<i>t (df</i> ) 95% Cl <sup>a</sup>	p	d
BDD-YBOCS	30.60 (2.88)	20.50 (6.64)	16.50 (3.63)	14.80 (6.14)	8.22 (9) [10.22, 17.98]	<.001	2.60	0.82 (9) [-2.97, 6.37]	.43	.26
BABS	16.30 (3.06)	10.00 (3.94)	5.10 (1.45)	5.80 (3.12)	8.93 (9) [8.36, 14.04]	<.001	2.82	-0.65 (9) [-3.13, 1.73]	.53	20
PHQ-9	5.50 (5.74)	4.90 (5.78)	3.50 (3.47)	3.20 (3.29)	1.75 (9) [59, 4.59]	.12	.55	0.38 (9) [-1.49, 2.09]	.71	.12
SDS	15.00 (7.51)	8.40 (7.44)	5.60 (6.04)	3.70 (3.77)	3.52 (9) [3.36, 15.44]	<.01	1.11	1.91 (9) [35, 4.15]	.09	.60
Q-LES-Q-SF	59.46 (11.57)	63.39 (13.07)	67.86 (10.48)	75.18 (11.37)	-2.67 (9) [-15.49, -1.29]	<.05	84	-1.57 (9) [-17.90, 3.25]	.15	50

*Note.* Tx = treatment; FUP = follow-up; *SD* = standard deviation; BDD-YBOCS = Yale–Brown Obsessive Compulsive Scale Modified for BDD; BABS = Brown Assessment of Beliefs Scale; PHQ-9 = Patient Health Questionnaire–9; SDS = Sheehan Disability Scale; Q-LES-Q-SF = Quality of Life, Enjoyment, and Satisfaction Questionnaire–Short Form.

<sup>a</sup> 95% confidence interval for the mean difference.

indicating that improvements were reliable. Individually, nine participants (90%) demonstrated reliable improvements in symptom severity from baseline to posttreatment, as well as from baseline to follow-up. At each time point, the remaining 1/10 participants had improved, but the change did not meet the criterion for reliable change.

#### **BDD-Related** Insight

Participants presented with poor insight on average prior to starting treatment, and they demonstrated good insight at posttreatment (see Table 2). BABS scores decreased across treatment (M = 67.08%, SD = 12.57%), with a large effect (d = 2.82). At 3-month follow-up, participants appeared to maintain their gains in insight (see Table 2).

#### Depression

Participants were mildly depressed on average at baseline (see Table 2) and depression did not reduce meaningfully across treatment, likely due to a floor effect (d = 0.55). Depression severity did not change meaningfully between posttreatment and 3-month follow-up (see Table 2).

#### Functional Impairment

Participants had moderate functional impairment due to BDD on average at baseline (see Table 2). Impairment improved across treatment with a large effect (d = 1.11), such that posttreatment impairment was mild overall. At 3-month follow-up, participants appeared to maintain their gains (see Table 2).

#### *Quality of Life*

Quality of life improved across treatment, with a large effect (d = -0.84), and participants appeared to maintain gains at 3-month follow-up (see Table 2).

#### Qualitative Feedback

Participants qualitatively described ways in which symptoms had reduced meaningfully. For example, one participant noted, "I'm saving a couple of hours a day by not doing rituals." Likewise, one participant noted, "I would not have thought an app can get me out of the house!" Similarly, another user expressed, "I feel so much more in the moment. I walk and notice how pretty things are. I have more free energy, more free mental space for other things."

#### Discussion

When untreated, BDD is a chronic, severe, and disabling psychiatric illness (Phillips et al., 2013). Despite the existence of effective, empirically sup-

ported treatments for BDD, the vast majority of individuals with BDD are unable to obtain appropriate care because of a shortage of clinicians trained to provide effective treatment. Smartphone-based CBT offers solutions to treatment barriers by enabling lowcost, standardized treatment that is widely and quickly accessible. Moreover, smartphone-delivered treatments can be used flexibly, whenever and wherever a patient's symptoms arise. Given the need for increased access to CBT for BDD, the primary aims of this study were to describe the development of the first smartphone-based CBT treatment for BDD (Perspectives), and to obtain preliminary data on feasibility, acceptability, and outcome via an initial pilot test of Perspectives. Preliminary findings from this small open-pilot trial suggest that smartphonedelivered CBT may hold strong potential as a mode of disseminating standardized, acceptable, and feasible treatment for BDD. Results suggest that a wellpowered, randomized control trial (RCT) is merited as a next step, to test Perspectives' efficacy.

To develop Perspectives, we established a team that synthesized diverse experiences and backgrounds. Namely, the project was a collaboration between a large telecommunications company that offered expertise in engineering, design, and usercentered design, and clinical researchers who offered expertise in CBT and BDD. Moreover, patient consultants who had completed courses of CBT for BDD were closely involved in development of the digital service. We expect that synthesizing diverse input enabled the creation of a service that met our study benchmarks for success.

Most health apps are characterized by low engagement (Torous, Nicholas, Larsen, Firth, & Christensen, 2018), in some cases documenting large drop-off rates just days after download (Owen et al., 2015). To enhance engagement with Perspectives, we aimed to not only develop visually appealing and relevant content via user-centered design but also to provide patients with accountability to a therapist who was available to guide the user by phone and chat messaging. It appears that our efforts to bolster engagement were effective. In particular, the 100% retention rate, coupled with the amount of time users spent engaging with the program, point to Perspectives as a potentially engaging, convenient, and satisfactory means of delivering CBT for BDD. Although the therapistsupport feature added modest professional burden and cost to the digital service, on average the therapist spent only ~1 hour per participant communicating via chat and phone combined, across the 12-week treatment (i.e., about 6 minutes per participant weekly). This represents a substantially lower professional burden compared to a

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typical course of face-to-face CBT for BDD, which requires time from a specialty-trained clinician over 12–22 fifty-minute sessions (Veale et al., 2014; Wilhelm et al., 2014). Participants' mean feedback scores indicated that the amount of therapist communication was "just right" (range = "a bit too little" to "just right"). While in this pilot test a licensed clinician served as the therapist, future research should evaluate whether paraprofessionals with some standardized training can serve as effective "coaches" for the Perspectives digital service (e.g., Mohr et al., 2017). Establishing similar results facilitated by less highly trained coaches would translate into greater scalability and lower cost for smartphone-based CBT.

While this small pilot trail does not allow for firm conclusions related to efficacy, descriptive examination of preliminary outcome data suggest that Perspectives may hold promise for reducing primary and secondary psychiatric outcomes at posttreatment, and for maintenance of gains at 3-month follow-up. BDD severity and insight improved with very large effects across treatment in this sample. Moreover, 90% of participants were treatment responders at posttreatment and 3-month followup, and the sample demonstrated reliable improvements in BDD symptoms at both posttreatment and 3-month follow-up. Participants' functional impairment and quality of life likewise improved across treatment with large effects, suggesting that smartphone-based CBT for BDD may have potential to improve quality-of-life domains that are broader than BDD symptoms. On the other hand, depression symptoms did not reduce meaningfully across treatment. This may be due to the mild baseline PHQ-9 scores (i.e., floor effect) and relatively large variability in PHQ-9 scores across participants.

It is notable that clinically significant and reliable change may be achieved in a relatively short time frame with Perspectives, as many in-person CBT for BDD protocols are delivered over 24 weeks (Wilhelm et al., 2014). It is possible that the fast response to treatment may be attributable to participants' ability to self-pace in using the digital service, and to access treatment at all times. In other words, participants did not have to wait a week or more to attend their next therapy session to continue learning skills, and they had direct support via the digital service to practice skills in all settings where symptoms arose. Maintenance of gains at follow-up preliminarily suggests that participants' fast responses to treatment may also be stable over time. Future research should examine how patterns of engagement with the digital service correspond with response to treatment.

It is often assumed that more severely ill patients require face-to-face therapy, whereas lighter-touch Internet or smartphone-based treatments should be reserved for mildly or moderately ill patients. However, the present sample had severe BDD symptoms and poor BDD-related insight on average at baseline, raising the question of whether smartphone-delivered CBT for BDD may be appropriate for severely ill patients, as well. It is important to note, however, that our sample was less depressed than the typical BDD population presenting for treatment, which may have influenced their response to treatment. Relatedly, participants with active suicidal ideation were excluded from participating in this pilot study. Future research is needed to determine the extent to which the digital service may be appropriate for samples at risk for suicide. Given the early, pilot nature of this trial, our sample size was small and we used an open-trial design. As with all such first trials of a new treatment, we were underpowered and effect sizes may not be reliable. Our sample was also predominantly female and only mildly depressed, and thus might have not been fully representative. Taken together, the present results should not be interpreted as lending evidence for the efficacy of Perspectives. Rather, results strongly suggest that further testing of promising initial results is merited as a next step, in a larger RCT.

This study is the first to test smartphone-based CBT for BDD. We utilized a multidisciplinary team, including patient consultants and technology and design experts, to develop the program. Additionally, whereas many app-based treatment trials rely on self-reported symptoms and diagnoses to establish eligibility criteria and outcomes, we used goldstandard, clinician-administered diagnostic evaluations delivered by trained and reliable IEs. Altogether, results from this pilot trial suggest that the multidisciplinary development process we used may be highly promising for development of CBT digital services. Additionally, very preliminary results suggest that Perspectives may have strong potential as a safe, feasible, and acceptable digital CBT service to improve BDD severity and related outcomes. As a next step, Perspectives must be further tested in a larger sample, utilizing an RCT design. Moreover, treatments such as Perspectives may be enhanced in subsequent trials by harnessing passively collected smartphone data, such as one's location and mobility patterns, to personalize services and enable just-in-time interventions (e.g., using global positioning system [GPS] and accelerometer sensors to detect housebound avoidance and trigger delivery of targeted, timely CBT interventions). If replicated in a larger RCT,

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Perspectives holds substantial promise for addressing critical barriers to treatment access in BDD.

#### Conflict of Interest Statement

SW, HW, JLG, THM, and IL have received salary support from Telefónica Innovación Alpha, S.L. SW and JLG are presenters for the Massachusetts General Hospital Psychiatry Academy in educational programs supported through independent medical education grants from pharmaceutical companies. SW has received royalties from Elsevier Publications, Guilford Publications, New Harbinger Publications, and Oxford University Press. SW has also received speaking honorarium from various academic institutions and foundations, including the International Obsessive Compulsive Disorder Foundation and the Tourette Association of America. In addition, she received payment from the Association for Behavioral and Cognitive Therapies for her role as associate editor for Behavior Therapy journal, as well as from John Wiley and Sons, Inc. for her role as associate editor on the journal Depression and Anxiety. THM has received unrelated research funding from the Stanley Center, Brain and Behavior Foundation, and National Institute of Aging. AM and OH are employees of Telefónica Innovación Alpha, S.L.

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