This version of the study protocol contains sections relevant to phases 1A and 1B of the study (NCT03221738).

DEVELOPMENT OF A COGNITIVE BEHAVIORAL MOBILE APP FOR BODY DYSMORPHIC DISORDER, AND TESTS OF FEASIBILITY, ACCEPTABILITY, AND PRELIMINARY EFFICACY

I. BACKGROUND AND SIGNIFICANCE

A. Historical Background

BDD is a psychiatric illness that involves a preoccupation with an imagined or greatly exaggerated defect in one's physical appearance (American Psychiatric Association [APA], 2013). This obsessive preoccupation causes clinically significant distress or impairment in functioning (e.g., social, occupational functioning). BDD is also defined by repetitive, compulsive behaviors performed in response to appearance concerns, such as frequent mirror checking (Alliez & Robin, 1969), excessive grooming (Vallat et al., 1971), and skin picking (Phillips & Taub, 1995). BDD is classified as an Obsessive Compulsive Related Disorder in the DSM-5, to reflect its similarities with obsessive compulsive disorder (OCD).

Although the clinical literature has described BDD dating back to the early 1900s (Kraepelin, 1909), research on BDD lags substantially behind that for similar disorders, such as OCD. BDD most commonly onsets in adolescence (Albertini & Phillips, 1999), and untreated BDD has a chronic course which can worsen over time (e.g., Phillips, 1991). BDD occurs relatively equally across men and women, and may occur with a slightly higher prevalence in women (Phillips & Diaz, 1997). Appearance preoccupations in BDD most often include facial features, the skin, or head, but any body part may become the focus of concern (Phillips et al., 1993). Individuals with BDD often have poor insight, such that the individual fixedly believes that their appearance is truly defective. In fact, nearly half of patients are delusional (Phillips et al., 1993). Delusions in BDD focus solely on one's appearance, in contrast to severe psychotic illnesses like Schizophrenia. Individuals with BDD also experience high rates of comorbid major depression (i.e., in 53-81% of cases) and elevated risk for suicide (Frare et al., 2004; Phillips et al., 2005; Phillips et al., 2006). BDD's early onset and chronicity underscore the need to widely disseminate effective treatments.

B. Previous Studies Leading up to the Proposed Research

Cognitive-behavioral therapy (CBT) is the best-studied and most promising form of psychological treatment for BDD (for meta-analysis see Harrison et al., 2016). CBT for BDD is a time-limited psychotherapy focused on targeting maladaptive thinking and self-defeating behaviors. Specifically, CBT aims to teach patients how to identify and challenge maladaptive thoughts ("cognitive therapy," [CT]), while reducing safety behaviors such as rituals and avoidance ("behavior therapy," [BT]). Most studies have included both cognitive and behavioral components, consisting mainly of exposure and response prevention (ERP) to reduce social avoidance and repetitive behaviors (such as mirror checking) and have shown that CBT is effective for BDD in both group (Rosen, Reiter, and Oroson, 1995; Wilhelm et al., 1999) and individual formats (McKay et al., 1997; Neziroglu et al., 1996; Veale et al., 1996).

A meta-analysis of treatment studies for BDD evaluated the effectiveness of CT, BT, and CBT (Williams et al., 2006). When examined together, therapy interventions had a large weighted mean effect size (1.63). CBT had a larger effect (1.78) than BT (1.45) (Xio, 2011), which suggests that combining cognitive and behavioral techniques may be the best psychotherapy approach. However, differences in effect sizes between BT and CBT were not statistically significant (Xio, 2011). Effect sizes did not differ between BT and pharmacotherapy (Williams et al., 2006). The number of sessions

and length of treatment have varied widely across studies and currently there is no data regarding optimal length or frequency of treatment.
After developing and pilot-testing a CBT manual for BDD, we completed a waitlist-control study of cognitive behavioral treatment (CBT) for adults with BDD (see protocol # 2004-P-000478). At the end of our 18-22-session treatment, 72.4% of the patients reported that they were much or very much improved. Moreover, patients were able to maintain their gains, and 6 months after the end of treatment the majority of patients rated themselves as much or very much improved. We are also currently completing a larger randomized controlled trial comparing 120 adults with BDD randomized to receive either CBT or supportive psychotherapy (see protocol #2010P001021). Furthermore, one recent study compared CBT (n = 21) with an anxiety management (n = 25) comparison treatment (Veale et al., 2014). At post-treatment (12 weeks), the CBT group showed significantly greater symptom reduction compared to the anxiety management group, with large effects (Cohen's d = .99) (Veale et al., 2014). Finally, one research group has developed and pilot-tested an Internet-based CBT treatment for BDD (Enander et al., 2016). Participants were randomly assigned to receive either 12 weeks of CBT or supportive psychotherapy for their BDD over the Internet, with a very limited amount of therapist support via the online program. Those in the CBT group showed significantly greater improvement compared to those in the supportive psychotherapy arm, and 56% of those in the CBT group were treatment responders compared to 13% in the supportive psychotherapy arm (Enander et al., 2016). Secondary outcomes such as depression and quality of life also showed significantly greater improvement in the CBT group compared to supportive psychotherapy group, suggesting that technology-based CBT treatments for BDD may be feasible, safe, and effective.

C. Rationale for Proposed Research, and Potential Benefits to Participants and/or Society:

While well-validated treatment for BDD exists, CBT for BDD is highly specialized and, thus, very difficult for patients to access. At our specialty program (the MGH BDD Program), there are consistent waitlists of 3-6 months to obtain access to a CBT therapist for BDD. In rural locations, access to this specialized treatment is likely to be even more challenging. Untreated BDD has a chronic, unremitting course, underscoring the importance of access to treatment. Inadequate treatment access due to limited professionals offering this specialized treatment is compounded by economic barriers and shame preventing many sufferers from seeking in-person care (Fang et al., 2014). Mobile app-based CBT would solve the access gap by addressing each of these barriers. Additionally, given the low rate of doctoral-level clinicians specializing in BDD treatment, it would be advantageous to establish whether mobile app-based CBT can also be administered effectively with assistance from trained bachelors-level coaches who are supervised weekly by licensed, doctoral-level psychologists. This would greatly enhance scalability of the treatment.

Additionally, among those who obtain CBT, practicing skills outside of therapy is a strong predictor of effective treatment, as BDD symptoms occur round-the-clock and can be most impairing at home. However, BDD patients struggle to use skills without therapists' in-the-moment support. App-based CBT that provides on-hand skills coaching at high risk times may address this treatment generalization challenge.

To this end, development of a high-quality CBT mobile app based on our program's empirically supported intervention is likely to benefit individuals with body image concerns, ranging from the severe end (i.e., BDD), which occurs in 1.7-2.4% of the population (Fang et al., 2014) to milder subclinical body image disturbances, which occur in nearly half the population (Cash & Henry, 1995), by providing low-cost, rapid, widely available access to CBT for BDD. The app may also benefit

healthcare providers (e.g., psychologists, psychiatrists, dermatologists) as it could be used as either a stand-alone treatment or in conjunction with treatments with a provider.

II. SPECIFIC AIMS

The overarching purpose of this project is to develop, test feasibility and acceptability, and test effectiveness of a mobile-app version of CBT treatment for BDD. We accomplish this through Phases 1A, 1B, and 2, and Specific Aims 1-2.

Specific Aim 1: To design and develop a new digital (app) CBT intervention for BDD, through utilizing feedback and involvement from stakeholders. **(Phase 1A)**

Specific Aim 2: In a sample of patients with clinical BDD severity, we will pilot test the acceptability and feasibility and iteratively improve the app. **(Phase 1B)**

Primary Hypothesis A: We hypothesize that app-delivered CBT for body image concerns will be feasible and acceptable to individuals with BDD.

Primary Hypothesis B: We hypothesize that app-delivered CBT for body image concerns will be associated with a significant reduction in BDD severity on the BDD-YBOCS, our primary outcome measure, at treatment endpoint, using intent-to-treat analyses.

III. SUBJECT SELECTION

Overview:

Massachusetts General Hospital will be responsible for all participant recruitment and enrollment. We will collaborate with Telefónica Alpha (sponsor), a major, international telecommunication company, in the development, iteration, testing, and launch of the app.

In Phase 1A (development), we will screen and enroll 5 "BDD Consultant" participants. In Phase 1B (open pilot trial), we will enroll 10 individuals with primary BDD. Detailed eligibility criteria for each aim follow. Additionally, a detailed plan for safety and risk management is described below.

A. Inclusion/Exclusion Criteria:

Phase 1A (app development and stakeholder feedback) – BDD Consultants:

1. Inclusion criteria
    a. at least 18 years of age
    b. Current or former CBT outpatients at MGH or a MGH clinicians' private practice, with current or lifetime diagnosis of primary DSM-5 BDD OR family member (e.g., spouse, parent) of a current or former CBT outpatient at MGH or a MGH clinicians' private practice, where family member has current or lifetime diagnosis of primary DSM-5 BDD
    c. currently living within driving distance of Boston
2. Exclusion criteria
    a. Current substance dependence
    b. Lifetime psychosis
    c. Current bipolar disorder in acute manic or hypomanic episode
    d. Acute, active suicidal ideation
    e. Current severe comorbid major depression, defined by a PHQ-9 total score ≥ 20

f. Personality disorder that could jeopardize study participation (e.g., borderline personality disorder with self-harm)
g. Current lack of BDD-related insight that could jeopardize input in app development
h. Do not own a supported mobile Smartphone with a data plan (currently iPhone 5S or more recent, running iOS 9 or newer)

Phase 1B (Open pilot trial):

1. Inclusion criteria
    i. at least 18 years of age
    a. outpatients
    b. current diagnosis of primary DSM-5 BDD
    c. Score on BDD-YBOCS of ≥ 20
    d. currently living in the United States
2. Exclusion criteria
    a. Psychotropic medication changes within 2 months prior to enrollment
        i. Participants taking psychotropic medication have to have been on a stable dose for at least 2 months prior to enrollment and not change medication during study period
    b. Participated in CBT for BDD ever during lifetime
    c. Current substance dependence
    d. Lifetime bipolar disorder or psychosis
    e. Acute, active suicidal ideation
    f. Current severe comorbid major depression, defined by a PHQ-9 total score ≥ 20
    g. Personality disorder that could jeopardize treatment participation (e.g., borderline personality disorder with self-harm)
    h. Concurrent psychological treatment
    i. Do not own a supported mobile Smartphone with a data plan (currently iPhone 5S or more recent, running iOS 9 or newer)
    j. Intellectual disability or other cognitive impairment that would interfere with ability to engage in CBT

B. Source of Subjects and Recruitment Methods:

Overview:
We never identify potential participants through medical records, and we never contact potential participants without their permission to be contacted. If a medical colleague identifies one of his or her patients to be potentially appropriate for this study, we request that the colleague encourage the patient to contact the PI or the research assistant directly. Alternatively, the colleague may ask the patient to give permission to be contacted over the phone by either the PI or the research assistant.

We will not exclude participants based upon gender or minority status. We expect that a majority of participants (> 50%) will be female, drawing from previous prevalence rates of BDD as well as the composition of patients at the OCD/BDD Clinic at MGH. We expect the percentage of minority participants to reflect that of the general population (at least 10-12%), given that BDD presents across ethnicities. We will work to increase enrollment of minority participants by posting advertisements in minority communities (including medical centers), community mental health centers, colleges and universities, and other settings (e.g., barber shops, beauty salons, dermatology, dental, primary care, and/or cosmetic surgery settings).

Phase 1A - BDD Consultant Recruitment:

In Phase 1A (development), we will screen and enroll approximately 5 "BDD Consultant" participants (who are current or former BDD patients). Patients or family members of patients who have completed our CBT treatment through the MGH BDD Clinic, MGH Outpatient Psychiatry Department, or a MGH clinician's private practice, and who have given permission to be contacted by our program, will be informed about the opportunity to participate as "BDD Consultants" in Phase 1A and invited to complete an eligibility screen. Current patients and family members of patients being seen by clinicians in the BDD Clinic at MGH, Outpatient Psychiatry Department at MGH, or private practice, will also be informed about potential participation in Phase 1A by their clinicians and invited to complete an eligibility screening for Phase 1A. Once interested participants are referred to this study, Dr. Hilary Weingarden, Dr. Jennifer Greenberg, or the research assistant (RA) will contact them and provide them more detailed information about the study and complete an initial phone screen to assess likely eligibility.

Phase 1B:
Please see above for our recruitment targets across phases. For both phases, potential participants will be informed about the study through MBTA advertisements, radio advertisements, OCD and BDD-focused organizations nationally (e.g., International Obsessive Compulsive Disorder Foundation, Association for Behavioral and Cognitive Therapies), by OCD and BDD clinician and research colleagues nationally (see attached recruitment e-mail), fliers posted in specialty clinics and hospitals, coffee shops, restaurants, laundromats, barber shops, churches, daycares, libraries, newspapers, universities, other public locations, through our program's website and the bddapp.org recruitment website created for this study, Partners Clinical Trials and on the Internet. Individuals will also be recruited as part of the BDD clinic's general recruitment protocol #2009P-002227. Interested individuals will be referred to the study RA, who will provide more information about the research study and assess preliminary eligibility over the telephone.

IV. SUBJECT ENROLLMENT

A. Method of enrollment, including procedures for patient registration and/or randomization

Overview
Potential participants in all phases, will be preliminarily screened by the RA, Dr. Weingarden, or Dr. Greenberg over the phone to establish their likely eligibility. We only ask for the potential participant's name and contact information at the end of the phone screen if the individual is eligible and interested in participating (see "RA BDD phone screen," attached). Additionally, during the phone screen the RA may ask permission to send eligible and interested participants a Partners/MGH Authorization for Release of Protected or Privileged Health Information form, which participants may complete with their psychiatrist's contact information and then send directly to the study RA. If permission is obtained, the study clinician may then contact the participant's psychiatrist to verify issues surrounding potential eligibility (e.g., if there is any question/concern about the anticipated stability of the participant's medications), based on information collected by the RA during the phone screen. Screening information of individuals who do not meet study criteria will be destroyed. Across all phases, subjects will be enrolled by MGH. Potential participants will be given as much time as they need to consider participation, prior to providing informed consent. No participant will be involved in more than one phase of the study.

Phase 1A – BDD Consultants
Interested and likely eligible participants will be invited for an in-person evaluation. At this initial appointment, BDD Consultant participants will be fully informed about the study's purpose and

procedures. If the individual wishes to participate in the study, the IE, or Drs. Wilhelm, Weingarden, or Greenberg, will obtain electronic informed consent and eligibility will be assessed. The informed consent document will be provided to the potential participant electronically through REDCap, a secure data capture system, and they will be asked to select an "I agree" button in REDCap to indicate their consent (see more REDCap information below: "Monitoring and Quality Assurance")
Of note, no treatment will be administered in Phase 1A. This phase focuses on treatment development only. The objectives are to understand stakeholder participants' unmet needs (e.g., from existing available treatments such as in-person CBT) and hopes for BDD treatment, define the value that a CBT app could provide to patients and other stakeholders, and obtain input on prototypes, for further iteration and development. There is no randomization in Phase 1A.

Phase 1B
Interested and eligible participants will be invited to complete the baseline assessment with the IE by Skype for Business, phone, or Virtual Visit, a Partners IS-approved, secure, HIPAA-compliant video calling program (see more Virtual Visit information below: "Monitoring and Quality Assurance"), as recruitment for these phases is nation-wide. At that time, patients will be informed about the study's purpose and procedures and advised regarding alternative treatment options. Before eligibility is assessed, the IE, Dr. Weingarden, Dr. Greenberg, or Dr. Wilhelm will obtain electronic informed consent. The informed consent document will be provided to the potential participant electronically through REDCap, a secure data capture system, and they will be asked to select an "I agree" button in REDCap to indicate their consent (see more REDCap information below: "Monitoring and Quality Assurance"). Self-report measures for the baseline assessment will be completed through a secure REDCap link emailed to participants if participants consent and are deemed eligible. As Phase 1B is an open pilot trial to assess feasibility and acceptability, there is no randomization.

C. Procedures for obtaining informed consent (including timing of consent process)

Phase 1A:
Before coming for their first visit, participants will be given information about the study via phone and initial eligibility will be assessed. After this initial phone call, the RA will email interested potential participants a pdf copy of the online informed consent document, prior to the screening/baseline assessment. The potential participants will be asked to abstain from signing the consent form until study procedures are discussed with the IE, or Drs. Wilhelm, Weingarden, or Greenberg, during the in-person baseline screening visit. At the initial screening visit, potential participants will be fully informed about the study's purpose and procedures. Patient participants from Phase 1A and 1B will also be advised regarding alternative treatment options in our clinic or elsewhere. If the potential participant wishes to participate in the study, the IE, or Drs. Wilhelm, Weingarden, or Greenberg, will obtain informed consent electronically by asking participants to click an "I agree" button at the end of the electronic informed consent document on REDCap, a secure data capture system. Online consent will be used to maintain a consistent consent process across all study phases, as Phase 1B is nation-wide, prohibiting in-person written consent. Subjects will be given as much time as they need to consider participation. Participants will have the ability to download and print the electronic informed consent document, or save the pdf copy to their computer for their records.

Phase 1B:
Before participating in the screening and baseline assessment, patients will be given information about the study via phone and initial eligibility will be assessed. After this initial phone call, the RA will email interested potential participants a pdf copy of the online informed consent document, prior to the screening/baseline assessment. The potential participants will be asked to abstain from signing

the consent form until study procedures are discussed with the IE, or Drs. Wilhelm, Weingarden, or Greenberg, during the baseline screening video call. Before the baseline assessment appointments, the RA will send participants an appointment confirmation e-mail with detailed instructions for installing and logging onto the HIPAA-compliant Skype for Business or Virtual Visit software on their devices, which is used for video call assessments (see index). In advance of the appointments, the RA may conduct a brief test call with the subject to ensure that the subject installed the software, and can access it from their devices. At the start of the screening/baseline assessment, before beginning study procedures, the IE, or Drs. Wilhelm, Weingarden, or Greenberg will inform potential participants about the study's purpose and procedures and advised regarding alternative treatment options. If the potential participant wishes to participate in the study, the IE or Drs. Wilhelm, Greenberg, Weingarden will obtain informed consent electronically by asking participants to click an "I agree" button at the end of the electronic informed consent document sent through REDCap, a secure data capture system. Subjects will be given as much time as they need to consider participation. Participants will have the ability to download and print the electronic informed consent document, or save the pdf copy to their computer for their records.

STUDY PROCEDURES

Of note, per advisement from Maria Sundquist (Partners IRB) on 2/7/17, technologists from Telefónica Alpha who will conduct in-person feedback interviews in Phase 1A and over-the-phone feedback interviews in Phase 1B and 2 are hired and paid by the sponsor, Telefónica Alpha. These interviews are not considered part of the human subjects research and is development work for the app. Therefore, they are not included as study staff in this application, but the informed consent process will fully inform participants about the interactions with technologists and as such, these procedures are described in full in this protocol. Across all phases, MGH study staff will introduce participants to the technology experts via phone call, email, or in person introduction after the participant is fully consented. This will serve to protect participants' identifying information (e.g., we will not share access to participants' email addresses or phone numbers, but rather MGH study staff will initiate conference calls and schedule appointments between participants and technologists).

Email Correspondence

All email communications with participants will be sent in accordance with Partners' Send Secure email encryption policy.

A. Study visits and parameters to be measured

Phase 1A:

Based on Dr. Wilhelm's self-help CBT book for BDD (*Feeling Good About the Way You Look*), Telefónica Alpha (corporate sponsor) team members' expertise in app development and human interaction with technology, and input from stakeholder participants, we will iteratively develop and improve our initial CBT app until we create a beta version.

BDD Consultant Participants: Study Visits and Parameters to be Measured

Screening Visit: At the Phase 1A screening visit, subjects will first provide informed consent. They will then be assessed for eligibility, using the assessment instruments below (Table 1), including a structured diagnostic interview and clinician-rated measures. Eligibility screening will take approximately 1-1.5 hours. The SCID-I and II assessments will be administered to participants only when questions exist about whether the participant meets inclusion/exclusion criteria for the study.

Downloading the app: Prior to concluding the screening visit, the IE will assist the BDD consultant in downloading the app on their iPhone. The IE will generate an enrollment code for each study participant linked to their unique study identifier on the study server. Participants will download the study app from Apple Testflight (for "beta") version or the Apple iOS App store (for later versions). Of note, Apple Testflight is Apple's secure platform for Beta versions of apps is similar to the Apple iOS App store. Apps on TestFlight are not available for public download. Rather, the study staff will directly invite participants to download the app via e-mail. When subjects launch the study app for the first time they will be prompted for the enrollment code. This enrollment code screen will be the only screen available to anyone downloading the app from the app store/Testflight but not participating in the study. Study content will only be available to participants after entering their enrollment code.

In-Person Feedback Visit with technologists: Eligible and consented participants will then meet with Telefónica Alpha team members, to provide consultation and input on a range of topics related to the BDD Consultant's experience with BDD and with obtaining CBT for BDD (see "Phase 1A Technologist Interview Guide for BDD Consultants and Clinicians," attached), such as treatment needs, the individual experience with BDD, barriers to treatment, and factors that influenced motivation and success. The objectives will be to understand stakeholders' unmet needs (e.g., from existing available treatments such as in-person CBT) and hopes for the CBT app, define the value that a CBT app could provide to different stakeholders, and obtain input on the interface and usability for further iteration and development. Prior to the interview, patients will be asked to collect examples of homework they used during their CBT treatment. Each individual will be asked to bring to the interview and talk about their three most helpful/useful pieces of homework, and their three least helpful/useful pieces of homework. The in-person feedback visit will last approximately 2.5 hours and will take place either in the BDD Consultant's home or at the MGH OCD and Related Disorders Clinic, depending on the BDD Consultant's preference. In-home interviews allow for greater understanding of how the BDD Consultant applied CBT treatment for BDD in their naturalistic settings (i.e., outside of the office) which will inform how an in-app CBT treatment for BDD may best be translated to out-of-office settings. If participants choose to meet technologists at the participant's home, the participant would provide his or her address to the technologist. The participant's address will not be stored in any study data bases, will not be analyzed, and will be destroyed immediately after use. Alternatively, the participant can choose to complete this interview at MGH. These feedback meetings will be audiorecorded. Names will not be included on digital recordings, in computerized data files, or in any published reports, and digital recordings will be stored securely (see Monitoring and Quality Assurance, below). Phase 1A consultants will also have the option to allow technologists to photograph and/or video tape the feedback materials they provide, for the purposes of app development. Records of these materials will only be to guide improvements in the app design, and no photographs or video tapes will include the participant.

At-home daily diary: After the initial in-person meeting between BDD Consultant participants and our technology experts, BDD Consultants will be asked to keep a brief (~5 minutes per day) electronic daily diary for approximately 2 weeks, capturing their thoughts, emotions, and behaviors. The daily diary entries will consist of daily semi-structured questions and an open-ended reflection (see "Phase 1A Daily Diary questions," attached). The purpose of the daily diary is to better understand the daily habits, thoughts, feelings, and behaviors of the BDD Consultants. Daily diary data will be collected through the mobile app, which will "push" the daily questions to participants and provide participants with the ability to complete questions via the app.

Prototype Testing: After completing the daily diary, BDD Consultant participants will test the prototype version of the CBT app at home over the course of up to 12 days. After testing each module within the app, they will be prompted through the app to give feedback via 3 open-text questions:

(e.g., "What did you LIKE about the treatment module you just completed?"; see "Prototype testing feedback questions," attached). After testing all modules, BDD consultants will also provide input and feedback on their experience using the app, via an exit interview. The exit interview will be either face-to-face (audiorecorded), over the phone (audiorecorded), or via Skype for Business or Virtual Visit, a HIPAA-compliant, Partners IS-approved video conference calling system. Before the exit interview, the RA will send consultants an e-mail with detailed instructions for installing and logging onto Skype for Business or the Virtual Visit software on their devices (see index). In advance of the exit interviews, the RA may conduct a brief test call with the subject to ensure that the subject installed the software, and can easily access it from their own devices.

Brief Ongoing Consultation: BDD Consultant participants may be contacted by email or phone every 6 months, or more often as needed, for 18 months, in order to continue to serve as consultants across Phase 1B. Ongoing consultation may take place via email, audio recorded phone calls, face-to-face in-person meetings, Skype for Business, or Virtual Visit video conference calls.

Altogether, BDD Consultant participation in Phase 1A will consist of two in-person visits (for eligibility screening and initial feedback interview with technologists), lasting approximately 2 hours each, brief daily diary completion from home for approximately 2 weeks, prototype testing of the app for up to 12 days, and the option of providing brief ongoing consultation throughout Phase 1B. Participants will be compensated $75 for the each of the two in-person visits, $200 for daily diary completion, $150 for prototype testing and feedback, and $15/hour for ongoing consultation as needed. Consultants who elect to provide ongoing feedback may be asked to complete a brief questionnaire about the feasibility of a related technology project in our lab (see *Feasibility Questionnaire*, in Appendix).

Table 1: Phase 1A BDD Consultant Assessment Measures to be Collected

Measures	*Rater*	*Self*		*Eligibility Screen*	*Feedback Visit*	*Daily Diary Phase*	*Prototype Testing Phase*	*Brief Ongoing Consultation*
SCID	X			X**				
SCID-II	X			X**				
BDD-YBOCS	X			X				
BABS	X			X				
BDD PSR	X			X				
PHQ-9		X		X				
Consulting Interview with technologists	X				X			
Semi-structured daily diary questions						X*		
Open-text response following each							X*	

module, "Can you describe what you liked and didn't like about this activity?"								
Exit interview with technologists for feedback on prototype							X	
Feasibility questionnaire								X

*Note: Collected via the app.
**Note: Only administered when questions exist about whether the participant meets inclusion/exclusion criteria

Phase 1B:

By the time we will enroll our first subject for Phase 1B, we will have developed a beta version of the CBT mobile treatment app. Treatment techniques incorporated into the app will be based on Dr. Wilhelm's self-help book, *Feeling Good About the Way You Look* (Wilhelm, 2006) and results from Phase 1A feedback from stakeholders.

After initial beta development of the CBT app for BDD concludes, we will launch Phase 1B of the project. The primary purpose of Phase 1B is to establish the feasibility and acceptability of the CBT mobile app for BDD. Secondary outcome of therapeutic progress will be broadly assessed with measures of BDD severity, beliefs, behaviors, mood, functioning, and quality of life before, during, and after treatment.

Study Visits and Procedures:

Phone screen: Potential participants will be preliminarily screened over the phone by an RA, the IE, or Drs. Weingarden or Greenberg, to establish their likely eligibility. See above, "IV. Subject Enrollment: Overview" for additional details about initial phone screen. Those who appear eligible during the phone screen and who are interested will be invited to an in-person screening and baseline visit.

Screening/Baseline Visit: The screening and baseline visit will take place over the phone (or HIPAA-compliant video conference call) and will last approximately 1-2 hours. Subjects will first provide electronic informed consent with the IE, or Drs. Wilhelm, Weingarden, or Greenberg (See Section C, "Procedures for obtaining informed consent" for further details). They will then be assessed by the IE for eligibility, using the below assessment instruments (see Table 2), including a structured diagnostic interview, clinician-rated measures, and self-report measures. Baseline severity and symptom data will also be obtained, using the below assessment instruments. If an enrolled participant has already completed the same clinician-administered and self-report questionnaires within the past six months as part of a different study within the OCD and Related Disorder program, they will be able to consent to give us permission to access data from their previous screening assessment. After the Screening/Baseline visit, participants will be notified by study staff via e-mail (see appendix) regarding their eligibility status, and they will be given the opportunity to discuss this further with our study staff by phone. Ineligible participants will be provided with treatment referrals and resources.

Eligible participants will receive instructions for downloading the app (see above, Phase 1A, "downloading the app"). If more than ten days elapse between a patient's initial baseline screening assessment and the start of treatment, the study IE would re-administer the Y-BOCS and BABS measures to that participant, as those measures measure symptom severity in the past seven days. Additionally, participants will complete an additional self-report PHQ-9 form if more than ten days elapsed between a patient's initial baseline screening assessment and the start of treatment.

Baseline Feedback to Technologists: At or within 1 week after the initial baseline visit, eligible and enrolled participants will also meet with technologists from Telefónica Alpha (sponsor)via audiorecorded telephone call, Skype for Business, or via Virtual Visit video conference call. For participants' feedback calls with the technologists, MGH study staff will initiate the video call via our Skype for Business account and conference call the participant and the technologist on their Skype accounts. We will then leave the conference call after connecting the participant and technologist.

The purpose of this meeting is for the technology experts to gain an understanding of the participants' initial hopes, expectations, concerns, etc. about the app-based CBT for BDD (see "Phase 1B baseline, midpoint, endpoint technologist interview," attached). The meeting will take approximately 1- 1.5 hours, and participants will be reimbursed $25 for completion of the baseline feedback visit.

Treatment (at-home): Participants will then complete treatment through their mobile CBT app on their own, over the course of approximately 12 weeks. As described above, if patients encounter questions about skills being learned through the app, they can communicate with an assigned therapist through an in-app portal.

Assessment Visits: Therapeutic progress and relevant symptoms (e.g., mood, beliefs) will be assessed using the measures described below. Participants will be re-assessed remotely by phone (audiorecorded) Skype for Business, or Virtual Visit video call, at mid-treatment (6 weeks), end-of-treatment (12 weeks), 3-month follow up and 6-month follow up. Participants will be reimbursed $25 for mid-treatment, end-of-treatment, 3-month follow up, and 6-month follow up visits.

Mid-Treatment and End-of-Treatment Feedback to Technologists: Participants will again meet with technologists from Telefónica Alpha (sponsor) via audiorecorded telephone call, Skype for Business, or via Virtual Visit video conference call. The procedures for MGH study staff initiating Skype video calls via Skype for Business will be identical to the procedure outlined above (see "Baseline Feedback to Technologists.") The purpose of these assessments is for the technology experts to obtain input and feedback on the usability and feasibility of the CBT app (see "Phase 1B baseline, midpoint, endpoint technologist interview," attached). These meetings will take approximately 1 – 1.5 hours each, and participants will be reimbursed $25 for the completion of each feedback visit with technologists.

The complete pretest battery will require approximately 4 hours; mid-treatment, post-treatment and follow-up assessments will require approximately 2-3 hours each. These assessment times are comparable to assessments in the PI's other ongoing studies and have been well tolerated by participants. If participants prefer, they may complete the initial assessment battery over two sessions. To avoid dropout, participants will be paid $25 for each assessment visit, excluding the screening/baseline visit.

The masters or doctoral-level study IE will conduct clinician-rated assessments, and participants will complete self-report questionnaires (see above) on the computer via REDCap, a secure data capture system. The rater will be supervised closely by the PI. Training and reliability procedures are detailed below. When interviewed patients do not qualify for or choose not to participate in the study, reasons will be documented.

Table 2: Phase 1B Assessment Measures by Occasions

Measures	*Rater*	*Self*	*Baseline*	*Weekly*	*After Completion of a CBT Module*	*Mid-Treatment (6 weeks)*	*Post-Treatment (12 weeks)*	*3-Month Follow-Up*	*6-Month Follow-Up*
MINI	X		X						
SCID-I BDD Module	X		X						
SCID-II BPD Module	X		X						
BDD-YBOCS	X		X			X	X	X	X
BABS	X		X			X	X	X	X
Body Parts of Concern List	X		X						
CGI Severity & Improvement - Clinician	X		X (severity only)			X	X	X	X
BDD PSR	X		X			X	X	X	X
Medications/ Psychosocial treatment form	X		X						
CGI Improvement - Patient		X		X*		X	X	X	X
Expectancy Rating Scale		X	X			X			
Client Satisfaction Questionnaire		X				X	X		
BDD-SS		X	X			X	X	X	X
PHQ-9		X	X			X	X	X	X
PHQ-2 & QIDS-SR item #12 (suicide item)		X		X*					
ASI-R		X	X				X		
QLESQ		X	X			X	X	X	X
SDS		X	X			X	X	X	X
Demographics Form		X	X						

Concomitant medication and therapy form	X			X			X	X	X	X
Open-ended feedback question		X				X*		X		
Consulting Interview with technologists	X			X			X	X		
App Feedback Questionnaire		X						X		
Treatment Utilization Questionnaire		X					X			

Note: All measures collected via paper or RedCAP unless indicated with an *. Those measures indicated with an * will be collected via the app.

Measures Descriptions

Diagnostic Measures

Structured Clinical Interview for DSM-IV Patient Version (SCID-P and SCID-II): The SCID is a reliable, gold-standard semi-structured instrument for diagnosing current and lifetime major mental illnesses (First et al., 1995; Spitzer et al., 1992). It will be used to diagnose BDD and other disorders in Phases 1A and 1B, to assess eligibility. The SCID-II (First et al., 1997; First et al., 1995a; First et al., 1995b) will also be used to assess for presence of personality disorders, to assess eligibility.

Mini International Neuropsychiatric Interview (M.I.N.I.) (Phase 1B)*:* The M.I.N.I. (Sheehan et al., 2006) is a semi-structured diagnostic assessment of DSM-5 psychiatric illnesses. The M.I.N.I. is efficient, reliable, and well-validated. In Phase 1B, it will be supplemented with the SCID-I BDD module.

Assessment of Body Image and Related Symptoms

Yale Brown Obsessive Compulsive Scale Modified for BDD (*BDD-YBOCS)* (Appendix): This gold-standard 12-item semi-structured clinician-administered scale rates past-week BDD symptom severity (Phillips et al., 1997). It will be the study's primary outcome measure. The BDD-YBOCS has excellent internal consistency (α=.80), interrater and test-retest reliability (ICC for total score=.99 and .88, respectively), convergent validity (r=.55 with the CGI), and sensitivity to change (Phillips et al., 1997).

BDD-Symptom Scale (BDD-SS) (Appendix): The PI developed the BDD-SS to rate the severity of specific BDD symptoms (Wilhelm et al., 2016). It will be used in the present study to obtain a broader assessment of participants' BDD symptoms and associated thoughts, feelings, and behaviors.

Clinical Global Impression – Improvement Scale (CGI-I) and severity scale (CGI-S) (Appendix): This rating scale, which ranges from 1 (very much improved) to 7 (very much worse), is commonly used in clinical trials (Guy, 1976). Participants and the rater will each complete a CGI for BDD symptoms (CGI-BDD) and for overall symptoms (CGI-global). The CGI will be a secondary outcome measure and will also be used to determine clinical deterioration of BDD (see Minimizing Risks, below).The CGI also has a severity scale (CGI-S) which is rated by the clinician at baseline. The CGI-S determines the patient's level of severity, in comparison to others the clinician has treated or assessed with the same diagnosis.

Psychiatric Status Rating Scale for Body Dysmorphic Disorder (BDD PSR) (Appendix): The BDD PSR (Phillips et al., 2006; Phillips et al., 2013) is a 7-item, clinician-completed rating scale of the patient's BDD diagnostic status. It ranges from 1 (Full Remission) to 7 (Meets full diagnostic criteria with extreme/severe BDD).

Brown Assessment of Beliefs Scale (BABS) (Appendix): This 7-item semi-structured clinician-administered interview assesses delusional thinking related to one's appearance concerns (Eisen et al., 1998). It has very strong psychometric properties, including internal consistency, interrater and test-retest reliability, convergent validity, divergent validity, and sensitivity to change (Eisen et al., 1998).

Patient Health Questionnaire-9 (PHQ-9) (Appendix): The PHQ-9 (Kroenke & Spitzer, 2002) self-report measure of depression severity includes 9 Likert scale items ranging from 0 (*not at all*) to 3 (*every day*). Higher scores correspond with greater depression severity, and the measure includes well-validated descriptive ranges for minimal symptoms, mild depression, moderate depression, and severe depression. Scores ≥ 10 have a sensitivity and specificity of 88% to detect major depression. In phases 1A and 1B, scores on the PHQ-9 will be used to evaluate eligibility at the screening visit. Specifically, those with total scores ≥ 20, indicating severe comorbid depression, will be excluded from participating in any study phase. Additionally, item 9 assesses suicidality and will be used in conjunction with the clinical interview to exclude those with current active suicidal ideation in phases 1A and 1B.

Patient Health Questionnaire-2 (PHQ-2) (Appendix): The PHQ-2 (Kroenke & Spitzer, 2002) self-report measure of depression severity includes 2 Likert scale items ranging from 0 (*not at all*) to 3 (*every day*). The 2 items are taken from the longer PHQ-9 measure and are selected because they assess the core diagnostic symptoms of depression. The PHQ-2 will be administered weekly via the app to monitor changes in depression symptom severity.

Quick Inventory of Depressive Symptomatology- Self Report (QIDS-SR) (Appendix): The QIDS-SR (Rush et al., 2003) is a self-report measure of depressive symptoms consisting of 16 scale items with responses ranging from 0 to 3, including one suicide item (item #12). Higher scores correspond with greater depression severity, and the measure is well-validated, sensitive measure of symptom severity in depression. The response choices on the suicide item include 0: "I do not think of suicide or death"; 1: "I feel that life is empty or wonder if it's worth living"; 2: I think of suicide or death several times a week for several minutes"; and 3: "I think of suicide or death several times a day in some detail, or I have made specific plans for suicide or have actually tried to take my life". The QIDS-SR i12 will be delivered weekly to participants via the app to monitor for risk concerns during the trial. Scores >0 will trigger a popup message to the participant about calling 911/going to the ER, and will provide information about contacting a suicide hotline. Scores >1 will also trigger a text message alert to the coach with the specific item response given by the participant (i.e., 2 vs. 3). A

study clinician will follow up with the participant within 24 hours by phone to assess for risk, and to refer to a higher level of care if clinically indicated (see Minimizing Risks, below).

Appearance Schemas Inventory-Revised (ASI-R) (Appendix): The Appearance Schemas Inventory-Revised (ASI-R) is a self-report assessment of individuals' psychological investment in their physical appearance. This 20-item measure examines the extent to which individuals define or measure themselves and their self-worth by their physical appearance, as well as the extent to which people attend to their appearance and engage in appearance-management behaviors (Cash, Melnyk, & Hrabosky, 2003).

Body Parts of Concern List (Appendix): This list names a wide range of body parts that are the most common areas of appearance concerns for BDD patients. The measure asks participants to indicate which body parts they are preoccupied with.

Assessment of Functioning and Quality of Life

Sheehan Disability Scale (Appendix): The SDS uses a Likert scale from 0 (not at all) to 10 (extremely) to assess impairment in occupational, social, and family domains. It has strong internal consistency and validity (Sheehan et al., 1996).

Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF) (Appendix). The Q-LES-Q-SF (Endicott, Nee, Harrison, & Blumenthal, 1993) is a self-report measure of subjective quality of life. Higher scores correspond with greater ratings of quality of life. The Q-LES-Q-SF has strong psychometric properties (Endicott et al., 1993).

Assessment of Expectancy, Motivation and Satisfaction

Expectancy Rating (Appendix): This 4-item self-report questionnaire assesses patients' judgments about the credibility of the treatment rationale, expectancy of change, and treatment acceptability (Borkovec & Nau, 1972). It has good reliability (α=.81-.86), and validity is evident in its ability to differentiate between treatment rationales (Devilly & Borkovec, 2000).

The Client Satisfaction Questionnaire (CSQ) (Appendix) is a 25 item self-report questionnaire which assesses the satisfaction with clinical services received. It has excellent internal consistency and good discriminant validity (McMurtry & Hudson, 2000).

Open-Ended Feedback Question (Appendix) is a 1-item open-ended question to obtain feedback from the participant after completion of each treatment module. The question asks, "Can you describe what you liked and didn't like about this activity?" Participants provide a free-text response.

Other Assessments

Medications and Psychosocial Treatment Form (Appendix): This form will be used to assess any current and former medications taken as well as any current or lifetime psychosocial treatment. It will be administered by the IE at the baseline screening visit.

Concomitant medication and therapy form: (Appendix): This log tracks any changes in medication and therapy that the participant has made since the prior assessment.

Demographics Form (Appendix): This self-report form collects basic demographic data, and will be administered at baseline.

App Feedback Questionnaire (Appendix): This self-report form collects participant feedback pertaining to the content and aesthetics of the app (e.g., "How clear was the layout of the app?") It will be included in the self-report questionnaire at the end of treatment visit in Phase 1B.

Treatment Utilization Questionnaire (Appendix): This self-report form measures how much time participants are practicing treatment skills both on and off the app. In Phase 1B, it will be completed as a self-report measure at the mid-treatment assessment and end of treatment visits.

Baseline Technologist Questions (Appendix): This self-report questionnaire asks about participant's expectations of using the app (e.g., "How frequently do you intend to use Perspectives?"

Midpoint Technologist Question (Appendix): This open-ended question asks participants to describe their initial perceptions of the app at midpoint (e.g., "Please describe your first impressions of Perspectives?")

Treatment Condition Questionnaire (Appendix): This brief measure will be used to assess whether the independent evaluator believes each subject was assigned to either immediate CBT or waitlist, as well as their confidence in this belief. This questionnaire will be completed at either the end-of-treatment timepoint (for those in the immediate treatment condition), or at the end-of-waitlist timepoint (for those randomized to the waitlist).

Life Events Questionnaire (Appendix): This question will be used to assess whether any major life events occurred that might have had a psychological impact on the subject.

Feasibility Questionnaire (Appendix): This questionnaire will be administered to consultants who elect to provide ongoing feedback on a related technology project in our lab.

Passively Collected Sensor Data and App-Based Data

During Phase 1B, data from sensors in participants' mobile phones will also be collected, to optimize the program through personalization and improve of the app. This will include the following. (For a detailed description of storage and protection of de-identified mobile data, see Monitoring and Quality Assurance, below.) We will use sensors in phone to collect data on participant's mobility and sleep patterns.

Inferring sleep patterns: Obtaining data on participants' sleep/wake patterns offers a useful way to detect clinically relevant changes to a person's mental health status. For example, increased depression or body image distress may lead individuals to withdraw and remain in bed for more hours of the day than usual. Alternatively, when BDD patients encounter periods of high stress, this can trigger hours of getting "stuck" doing BDD rituals at all hours of the day or night, disrupting regular sleep patterns. Therefore, by identifying changes in participants' normal sleep patterns, our app may be able to detect times when additional intervention delivered via the app would benefit the participant. Although wearable devices would allow for a reliable detection of sleeping time, we opted for a less intrusive solution that relies on the device that is already habitually carried by individuals – his or her Smartphone. As an indication that a person went to sleep, using Smartphone sensing capabilities, we will monitor a) noise level (sampled from the microphone every 10 minutes and storing only the ambient noise level expressed in decibels [dB]), b) light level (sampled every 10

minutes from the light sensor and storing one value expressed in Lux) and, c) phone-unlock events. Once a low noise, low light and no phone unlock events are detected for a specific amount of time (to be defined) it will be assumed that a person is sleeping. Once the noise level reaches a threshold that we will define as above silence and/or the phone is unlocked, such an event will be marked as "waking-up."

Quantifying mobility: Obtaining data on participants' mobility also offers a useful way to detect clinically relevant changes to a person's mental health status. Specifically, up to 30% of individuals with BDD become housebound due to their symptoms (Phillips et al., 2006). In addition to becoming housebound, individuals with BDD may avoid out of the home tasks such as running errands or going to work on days when symptoms are especially severe. Therefore, mobility patterns (e.g. the time spent at home) provide highly relevant information to monitor in our app-based treatment. However, sampling raw GPS location coordinates may intrude on one's privacy. To protect privacy of the study participants, we will apply the following procedure. The location coordinates will be first collected at the secured server located at the hospital or locally on the phone. We will subsequently remove the raw location coordinates by replacing them with randomly generated strings as location labels (such as "ghhu45", "235oh4", "8n8hj3", …), where each unique location in the dataset will correspond to a unique de-identified label. This will allow us to quantify mobility of the participants without requiring us to store actual geographical locations in the long-term. In addition to location, other sensor data collected by the participant's Smartphone will be used to quantify mobility, including accelerometer, steps, calories burnt, and sedentary time.

Application Usage Metrics: In order to improve the usability of the application, usage metrics will be collected (for example operating system version and device model, time and date when the application is opened or closed, time spent on each page visited, notification timing, etc.). Additionally, we may collect user's battery status and charging patterns, and network traffic (e.g., number of bytes sent/received, and the hashed Wi-Fi-antenna indicator). These metrics will be stored in the same fashion as passive sensor data and user survey responses collected via the app.

Phone Usage Patterns: Dynamics of the phone usage provides an additional insight into clinically relevant changes to a person's mental health status. For that reason, we will collect phone-unlock events (used also to detect sleep patterns, as described above), screen-on events, and data traffic to characterize patterns and quantify daily phone and internet usage. Note that the data traffic refers only to the periodically sampled number of bytes sent and received, and it does not include any sensitive information such as internet history or the names of the installed applications.

The Treatment:

Pending stakeholder input during Phase 1A, the CBT app will include the following components of CBT for BDD: 1) education about a CBT model of BDD; 2) use of self-monitoring to record trigger situations and symptoms; 3) cognitive techniques to identify and challenge distorted thoughts related to one's BDD; 4) exposure to avoided situations; 5) response prevention to decrease repetitive behaviors; 6) mindfulness/ perceptual retraining (to help patients to learn to balance distressing emotional states with rational thinking and to control their attentional processes); 7) increasing valued activities, and 8) relapse prevention (to teach patients to expect and react effectively to setbacks that may occur during times of stress). Additionally, passively collected sensor data (described above) will provide information on changes in participants' mobility and sleep patterns. The treatment will be adapted to address changes in sleep and mobility patterns (e.g., prompting the participant via a

message through the app encouraging him or her to engage in the treatment when mobility is notably low).

Assessment and Psychoeducation: The first component of the treatment app will focus on assessing BDD and related symptoms and educating the patient in the CBT model (Wilhelm & Neziroglu, 2002). The app will guide the patient in deriving a cognitive behavioral model for BDD. This assessment process and hypothesized model will be used to guide the patient through the treatment techniques and will form the basis for educating the patient about BDD and related symptoms.

Basic Interventions: After assessment and psychoeducation, the app will focus on teaching basic cognitive and behavioral methods. For example, cognitive techniques may include skills to help patients identify and evaluate maladaptive BDD-related beliefs. Patients will also learn behavioral techniques, which may include learning skills to identify avoidance behaviors (e.g., social situations, work or school, physical activities) and develop an exposure hierarchy of situations, activities, people, and body parts that provoke fear or discomfort. For example, exposure hierarchies may be used to increase social activities (e.g., attend family gatherings), increase work attendance, and expose appearance concerns to others (e.g., leave the house without sunglasses or a hat). To reduce ritualistic behaviors (e.g., mirror checking), participants may be asked to monitor the frequency and context of behaviors and identify strategies to resist or delay them. Patients may also learn mindfulness and perceptual retraining skills (e.g., observing with a nonjudgmental stance). This approach aims to help patients develop a more accurate view of themselves by attending to environmental and social cues other than BDD-relevant ones. Motivational enhancement will be incorporated into the treatment, to help patients increase and maintain motivation for change through treatment. Additionally, patients' values will be assessed and as patients' BDD symptoms reduce across treatment, patients will be coached to introduce new, healthy activities into their lives that are in line with their values.

Relapse Prevention: The final module will focus on relapse prevention, which aims to help patients maintain their gains after treatment. For example, patients may learn to anticipate possible symptom recurrence and its relationship to stress, mood, and other factors; differentiate between lapses and relapses; counter negative thoughts about setbacks; and handle lapses and setbacks.

Treatment Length: We initially expect treatment to consist of 12 sessions, although length of treatment may be shortened or lengthened during the course of the pilot trial, depending on stakeholder feedback from the initial development phase (Phase 1A) and feasibility data from the pilot trial (Phase 1B) (e.g., early drop-out may indicate that 12 weeks is too lengthy). While our manualized CBT intervention for BDD is 22 sessions in length, we do not think this will be a feasible length of time to keep individuals engaged in an app-based treatment. Therefore, we will begin by testing a 12-session version. Twelve week CBT treatments for BDD have been tested previously and shown to be acceptable and effective (e.g., Veale et al., 2014), including in a computer-delivered format (Enander et al., 2016).

Module Frequency and Duration: An advantage of app-based CBT for BDD is that participants can self-direct the frequency and duration of modules, and they can re-visit sessions as many times as is useful to them. Duration of modules will be largely determined during the development phase (Phase 1A), pending stakeholder feedback, and self-directed by the user based on how long they choose to spend on a given skill.

Treatment Format: Each treatment component will be presented through modules on the mobile app, and exercises will be logged and practiced through the app on one's Smartphone. Upon initiating the app-based CBT treatment, each participant will be assigned a Masters or doctoral-level therapist with

prior experience and training in CBT and some familiarity with BDD (see "Therapist Training and Qualifications," below). Participants can communicate with their therapist through a secure messaging system incorporated into the app. The therapist will have a separate portal inside the Partners firewall to receive and respond to these in-app communications from patients. The therapist communication aims to provide support and additional motivational enhancement to patients, and to provide feedback about the skills and homework that the patient is learning through the app. Patients will be notified that the therapist will respond to all in-app communications within 36 hours on weekdays. Moreover, brief phone check-ins may be arranged between the participants and therapists on an as-needed basis to supplement the chat system (e.g., to more thoroughly answer a participant question about a skill, help set goals for 2nd half of treatment at treatment mid-point, evaluate and enhance motivation). Based on a similar, online CBT treatment for BDD, we expect average therapist contact per week will be minimal (e.g., less than 15 minutes per week, per patient) (Enander et al., 2016).

Rater Training and Qualifications, and Procedures to Ensure Assessment Integrity and Interrater Reliability

Assessments will be conducted by an independent evaluator (IE) who have a Masters or Doctoral-level degree in clinical psychology or related mental health field and will be employed at MGH. The IE will be otherwise uninvolved in study procedures. Training and reliability checks will be done to ensure that IEs conduct ratings in a uniform way. Raters will first receive instruction in the SCID-I/P, MINI, SCID-II, BDD-YBOCS, BABS, and CGI from Dr. Wilhelm or another gold-standard expert rater, prior to beginning as an IE. The IE will be supervised twice monthly by the PI. The IE will be required to demonstrate reliability on the BDD-YBOCS and BABS at a criterion of .80 ICC, compared to measures rated by Dr. Wilhelm or another gold-standard rater. All assessments will be audiotaped for reliability ratings. Names will not be included on digital recordings. To reduce rater drift, a trained reliability rater meeting the same qualifications as the IE will review 15% of randomly selected audiotaped interviews at regular intervals during the second half of Phase 1B. If reliability falls below .75, we will institute retraining procedures.

Therapist Training and Qualifications

Therapists in Phase 1B will have a Masters or Doctoral degree in clinical psychology or related mental health field and will have prior experience and training in CBT and some familiarity with BDD. Therapists receive specific training before treating study patients, including reading materials, such as Dr. Wilhelm's self-help CBT book for BDD, on which the app will be based. To ensure ongoing high-quality treatment, Dr. Wilhelm will provide weekly supervision in CBT to therapists.

Privacy and Confidentiality

Privacy and confidentiality procedures in Phase 1B will be identical to those described above, in Phase 1A.

CBT App Revision

Throughout Phase 1B, the study team will have regular discussions of patient progress and positive and negative experiences in using the CBT app. We will also obtain feedback from patients regarding the treatment at the assessment sessions, which we will incorporate into our revisions. When revising the app throughout this phase, we will consider reasons for dropout, patient satisfaction and acceptability of the treatment as measured with the Expectancy Rating and the Client Satisfaction

Inventory, and patient feedback. Agreed-upon app alterations will be incorporated and applied to new participants. After all participants have completed treatment in Phase 1B, we will finalize revisions to version 1.0 of the CBT app.

To make edits to the app, we will use a Content Management System (CMS). The CMS allows MGH study staff without developer skills to edit and write app content and make structural changes to the app flow. The CMS will only manage the program content (i.e., exercise content, information cards, questions) but will not contain or manage any patient data or protected health information (PHI). No patient data or PHI can be accessed by using the CMS or from within the CMS. Users of the CMS can only edit and add content within tightly defined templates and according to designated roles. Changes need to be approved and can be reversed by the team at any time. The CMS enables relative independence of the MGH research team to undertake writing and editing app content via the CMS interface, based on our clinical expertise and feedback on the app from participants in our pilot trial, with limited reliance on Telefonica Alpha developers. Telefonica will be responsible for configuring the CMS to work with the app, leading the incorporation of content from the CMS into the app, and making timely fixes to any residual bugs or adaptations to the design and/or functionality of the product, and to keep the app and its functions running smoothly. In the role of working with the CMS, Telefonica Alpha will not have any access to patient data or protected health information.

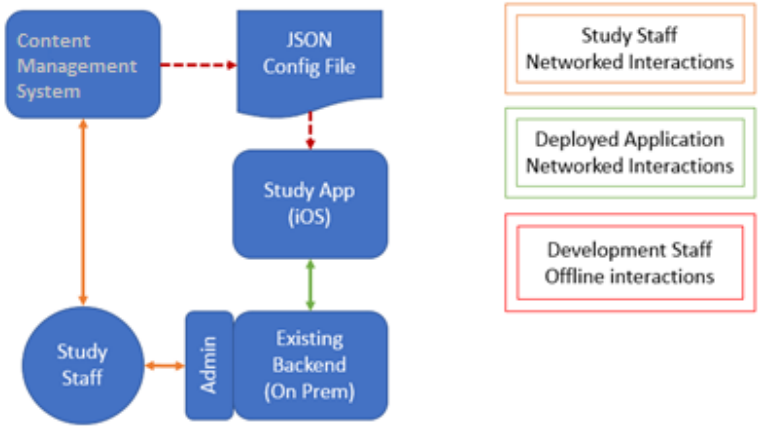


Figure 1. Information flow to/from content management system to app.

Privacy and Confidentiality

All information gathered will be kept strictly confidential. We will adhere to the following procedures to protect privacy and confidentiality:

1) Participants will be assigned a code number. A link between ID number and participant's names will be kept in a separate secure password-protected file, saved on our secure MGH lab server and/or Partners Dropbox Business. Participants' names or other identifying information will not appear on any questionnaires, study documents, digital recordings, computerized data files, or published reports. Case records will be reviewed only by study personnel or, if necessary, by institutional, state, or federal regulatory personnel. Research assistants and others working on this study (e.g., technologists) will be educated about the importance of strictly protecting participants' rights to confidentiality.

2) All personnel will be trained in research confidentiality procedures and HIPAA, including completion of CITI training and Healthstream training. Only the study personnel will have access to the identifiable data (see Figure 1, below). 4) For clinical data collected during MGH assessments: Computerized data and digital audiofiles will be stored de-identified, in password protected files saved on the protected lab server. Hard Data within Partners is stored automatically and securely on an MS SQL Server, accessed over industry standard SSL 128 bit RSA encryption during data transfers. Data is routinely backed up locally onto a redundancy server and stored in a separate database that is locked with 256 AES encryption. Long term storage on Partners servers occurs nightly and allows for incremental backup over multiple systems. Therefore, should one drive be physically damaged, there will be multiples within the chain to replace it. Both data servers are stored within PHS IS corporate firewall, in a secure, key access facility with password protected computers. Only trained PHS security officials will have access to physical machines storing study data. Since data are stored on a protected server, a compromise of any individual computer at a research facility will not lead to a breach of the secure database.
copy data (paper forms) will be stored securely in locked file cabinets, within locked offices in the MGH OCD and Related Disorders Program.

5) Technologist data: Computerized data and digital audiofiles collected from feedback interviews with technologists will be stored de-identified, in password protected files in the Partners Healthcare Dropbox Business folder. The PHS Dropbox Business folder will be set up by a listed owner with a Partners email address. Per Partners Research Information Services and Computing, "The enterprise rollout of Dropbox Business at Partners HealthCare is an approved storage and collaboration solution. This version of Dropbox Business provides unlimited storage, fully encrypted data (AES-256 encrypted) and is compliant with Partners' policies and procedures. Dropbox Business allows you to sync, share, and manage your files online" (https://rc.partners.org/kb/article/2285).

6) Mobile data: All mobile data will be transmitted from the participant's mobile device to the clinical study server via an encrypted Internet connection. The clinical study server will be located in the PHS/MGH Secure Data Center. The collected data will be linked to the study identifier only. The administrative interface to the clinical study server (channels 1 and 5 below) will be password protected with access limited to study staff. To further minimize risk the administrative interface of the clinical study server will only be available over the PHS network. Prior to deployment of the digital application, the application will be scanned with Veracode.

7) Virtual Visit is the system that we will use for video calls throughout the study phases. Virtual Visit is a Partners IS-approved, secure, and HIPAA compliant system for video calls. Virtual Visit uses a combination of the 'Vidyo' videoconference platform and Skills Based Routing (SBR) patient management software. This solution addresses clinical privacy and security in a variety of different ways.

Vidyo ensures that the video and audio transmissions are protected by encrypting the data with a key starting at 128 AES up to 256 AES. Vidyo allows users access to these transmissions through secure virtual video rooms, which are managed by SBR.

8) Only de-identified data will be shared with the sponsor (Telefonica Alpha), under the terms of the Data Use Agreement (i.e., Statement of Work).

See Figure 2 in "Independent Monitoring of Source Data" for a detailed diagram and description of the secure data flow and storage. The administrative interface to this system will only be accessible to work stations on the PHS/MGH network.

B. Drugs to be used

Not applicable

C. Devices to be used

Not applicable

D. Procedures, surgical interventions, etc.

Not applicable

E. Data to be collected and when the data will be collected

See above for the assessment schedules and assessment batteries for each phase.

VI. BIOSTATISTICAL ANALYSES

Drs. Weingarden, Greenberg, the IE and the RA will be primarily responsible for data entry. Data will be entered in REDCap, a HIPAA-compliant, Partners-approved platform for electronic data capture that streamlines data collection and management, and ensures data integrity, resulting in improved data quality and reduced costs. The REDCap software allows users to design and implement study surveys for collecting, storing, retrieving, and manipulating data electronically. Participants and/or research staff enter survey responses into electronic assessment forms, and the responses are then transmitted and stored into a secured database. This electronic data capture obviates the need for subsequent data entry by staff, thus minimizing human error. These surveys are completed securely via the internet by using any device with standard web access and browsers.

Suraj Sarvode, M.A. and Dr. Susanne Hoeppner will be responsible for data management and analysis. All project staff will receive training in data management and data confidentiality procedures. Analyses of missing data will be done periodically to assure that all forms are entered and available for analysis. Questions or problems will be resolved promptly by communication between study staff. Data and analysis files will be backed up on the lab server and stored in separate locked cabinets.

To characterize our sample, data will be displayed graphically, and summary statistics (e.g., means and frequencies) will be calculated for all variables, including demographic and clinical descriptors (e.g., from the SCID-I/P, SCID-II). Prior to data analysis, all major variables will be screened for inconsistent or abnormal values, and continuous measures will be assessed for skewness and outliers. Variable distributions will be examined and transformations made when distributions are skewed or otherwise violate analytic assumptions.

A. Specific data variables being collected for the study (e.g., data collection sheets)

Specific variables being collected and their timeline are presented above, and described in the Study Procedures section.

B. Study endpoints

Note: There are no study endpoints, hypotheses, or planned analyses for Phase 1A, as it is an information-gathering stage, to inform the development of the CBT app.

Phase 1B:

Primary endpoint: feasibility and acceptability

Hypothesis 1: We hypothesize that app-delivered CBT for body image concerns will be feasible and acceptable to individuals with BDD.

Secondary endpoint: preliminary effectiveness for reducing severity of BDD symptoms

Hypothesis 2: App-delivered CBT for body image concerns will be associated with a significant reduction in BDD severity on the BDD-YBOCS, our primary outcome measure, at treatment endpoint, using intent-to-treat analyses.

C. Statistical methods

Phase 1B:

Primary endpoint: feasibility and acceptability

Analysis:

We will test feasibility and acceptability by examining:

1. Refusal and dropout rates and reasons
2. Patient satisfaction on Client Satisfaction Questionnaire
3. Patient feedback (open-ended)
4. Patient's expectancy for treatment to help on Expectancy Ratings measure (4-item self-report questionnaire to assess pt judgments about credibility of treatment rationale, expectancy of change, and treatment acceptability)

Secondary endpoint: preliminary effectiveness for reducing severity of body image concerns

Analysis:

Intention-to-treat repeated measures ANOVAs will examine differences between pre- and post-treatment BDD-YBOCS scores, using α=.05 (two-tailed test), and the effect size will be calculated. In addition, we will calculate the prevalence of treatment responder, defined as those with BDD-YBOCS reductions of 30% or greater.

D. Power analysis

Given the pilot nature of the study and the lack of data on effect size of app-based CBT for BDD, sample size was based on standard sizes for open pilot-trial (e.g., Protocol # # 2004-P-000478) and initial waitlist control RCT (e.g., Protocol # 2005-P-001251/27) from our prior work. Data from these proposed pilot and waitlist-controlled trials will help to establish an effect size for app-based CBT for BDD, so that more formal power analysis may be completed for a future, larger, RCT. Given small sample sizes in pilot trials, effect sizes will be examined in addition to statistical significance in our analyses.

VII. RISKS AND DISCOMFORTS

A. Complications of surgical and non-surgical procedures

Not applicable

B. Drug side effects and toxicities
Not applicable

C. Device complications/malfunctions
Not applicable

D. Psychosocial (non-medical) risks
Participants may feel uncomfortable due to the sensitive nature of the questions they may be asked. Likewise, some participants may feel uncomfortable about having assessment sessions digitally recorded and reviewed by project staff (which is necessary for rater supervision as well as assessment of the reliability of ratings adherence and competence). Participants could experience an increase in symptoms related to the natural waxing and waning of BDD symptoms. Breach of confidentiality, which great care will be taken to prevent, represents a potential risk. Finally, in Phase 1B, the treatment procedures, particularly the exposure exercises, will potentially provoke some anxiety. As discussed below, we will take precautions to ensure that these potential risks are minimized (see Adequacy of Protection Against Risks below).

Minimizing of Risks and Safety Reporting.

The following procedures will be implemented to protect participants against risks. The information provided in this section pertains to all study phases, unless otherwise indicated.

1. Participants with active suicidal ideation at the screening assessment will be excluded from participating (see Inclusion/Exclusion criteria).

2. Participants with severe major depressive disorder will be excluded from participating (see Inclusion/Exclusion criteria).

3. A disclaimer will be presented on the home page of the digital CBT program. The disclaimer will alert participants that "If you are having thoughts of suicide or death, please note that this program is not the right treatment for you. You should seek professional help without delay. If you feel unsafe, call 911 or go to your nearest emergency room." Links to 911 and suicide hotline numbers will be provided along with this disclaimer.

4. A general resources page will be available on the app at all times to participants, which will include a suicide hotline number.

5. In Phase 1B, participants' clinical improvement or deterioration will be assessed weekly via a participant-rated CGI-BDD collected via the app. Participants will be withdrawn from the study if their clinical condition deteriorates substantially. Deterioration will be defined by a rating of 6 (much worse) or 7 (very much worse) on the weekly, participant-rated BDD-CGI, across 2 subsequent weeks. Of note, a single rating of 6 or 7 on the weekly, participant-rated BDD-CGI will also trigger a notification to the clinician/coach via text message. In the case that a BA-level coach is notified that a participant's CGI indicates deterioration, they will notify a doctoral-level clinician as soon as possible (and within 24 hours). A study clinician will follow up with a phone evaluation within 24 hours of the alert and refer the participant to a higher level of care if clinically indicated.

6. In Phase 1B, ratings on the QIDS-SR item 12 (suicide item) will be carefully monitored weekly via the app; a score >0 at any assessment will trigger a pop up message to be presented to the patient within the mobile app, stating, "Seek emergency help if you are having recurring thoughts of death, suicide, or wanting to die" (language borrowed with permission from DF/HCC Protocol #14-055). Links to 911, as well as a national suicide hotline, will be provided within this popup notification. A score >1 will also trigger notification to the clinician/coach via text message. In the case that a BA-level coach is notified that a participant reported a score>1, they will notify a doctoral-level study clinician as soon as possible (and within 24 hours). A study clinician, PI, or independent evaluator will follow up with a phone evaluation within 24 hours of the alert and refer the participant to a higher level of care if clinically indicated. To be able to determine which participant triggered the alert (i.e., to link the de-identified trigger with the actual participants' name) and to be able to contact the person (i.e., to be able to look up that person's telephone number), the clinicians on call will require remote access to the key that links the de-identified study ID with the patient identifier. We will use Partners Dropbox Business to store this password-protected Excel spreadsheet that links the participants' de-identified and identified data. Partners Dropbox Business is a secure and appropriate platform for storing participant de-identified and identified data (see attached RISO approval). Access to this secure spreadsheet will only be provided to those who are directly responsible for risk assessment, and will be provisioned/deprovisioned accordingly as clinicians join or depart the study.

7. Participants may also be withdrawn if, in the judgment of the PI, remaining in the study poses a substantial risk to the participant or a higher level of care is needed.

8. In Phase 1B, treatment through app-based CBT will be supplemented with electronic communication with a study therapist/coach, who can answer questions and guide participants through the treatment as needed.
9. The independent evaluator(s) will be highly experienced, highly trained, and closely supervised.

10. Dr. Wilhelm will be available, if necessary, to discuss the study, alternative treatments, or any concerns about the study with participants if requested by the participant, therapist, or rater.

11. Drs. Wilhelm, Weingarden, Greenberg, and the participants' study clinician/coach will be available to answer study questions via the app or phone. This will be clearly communicated orally and in writing to study participants.

12. All participants who fail to respond to treatment or withdraw prematurely will be provided with referral resources.

13. The study clinicians, coaches and raters will make every attempt to help participants feel comfortable when discussing sensitive material. Participants may skip questions on assessments that they are uncomfortable answering.

14. If exposure exercises suggested through the treatment app are too anxiety provoking, participants will be able to do alternative exercises that cause less anxiety.

15. The CBT treatment will initially emphasize cognitive restructuring, which we anticipate will be less anxiety provoking than exposure treatment alone and will make exposure more tolerable.

16. Technologists from Telefonica Alpha who conduct the technology feedback interviews are highly trained professional staff with experience conducting patient interviews. They have

received additional training (including a multi-day workshop) from the MGH PI, Dr. Weingarden, and Dr. Greenberg, on CBT for BDD, the protocol, and issues of confidentiality. They have completed CITI training.

17. Three clinical psychologists or researchers familiar with BDD will be selected to serve as a Data Safety Monitoring Board, to review the study once a year.

18. Significant effort will be invested in minimizing the risk of unauthorized access to study data and to mitigating the consequences of an unauthorized access were it to occur. To mitigate harm of unauthorized access and to increase confidentiality in the setting of authorized access, participants will be assigned a code number. Participants' names or other identifying information will not appear on any questionnaires, study documents, digital recordings, computerized data files, or published reports. A link between ID number and participant's names will be kept in a separate secure password-protected file, saved on our secure MGH lab server and/or Partners Dropbox Business. Case records will be reviewed only by study personnel or, if necessary, by institutional, state, or federal regulatory personnel. Research assistants and others working on this study (e.g., technologists) will be educated about the importance of strictly protecting participants' rights to confidentiality. *Clinical data:* All data will be stored securely in locked file cabinets, within locked offices in the MGH OCD and Related Disorders Program. Computerized data will be stored de-identified, in REDCap. *Technologist data:* Data from technologist interviews will be stored de-identified, in password protected files in the Professional Partners Healthcare Dropbox Business folder. *Mobile data:* All mobile data will be sent from the participant's mobile device to the clinical study server via an encrypted Internet connection. The clinical study's server will be located within the secure PHS/MGH data center. See Figure 1 in "Independent Monitoring of Source Data" for a detailed diagram and description of the secure data flow and storage. The administrative interface to this system will only be accessible to work stations on the PHS/MGH network.
19. The subject will designate a relative or friend who could be contacted should the subject be unavailable and the investigator has concerns about the subject's well-being.

We anticipate that the above procedures will be effective in protecting study participants against potential risks.

Adverse event reporting:
See below: "Adverse event reporting guidelines"

E. Radiation risks
Not applicable

VIII. POTENTIAL BENEFITS

A. Potential benefits to participating individuals
Participants may benefit from the comprehensive diagnostic assessment with a BDD expert. Participants in Phase 1B may benefit from careful clinical monitoring, and they may benefit by experiencing some relief from their BDD symptoms through the CBT app.

B. Potential benefits to society
If app-based CBT for BDD is effective, it may offer increased, cost-effective access to CBT for BDD, a treatment which is otherwise difficult to access.

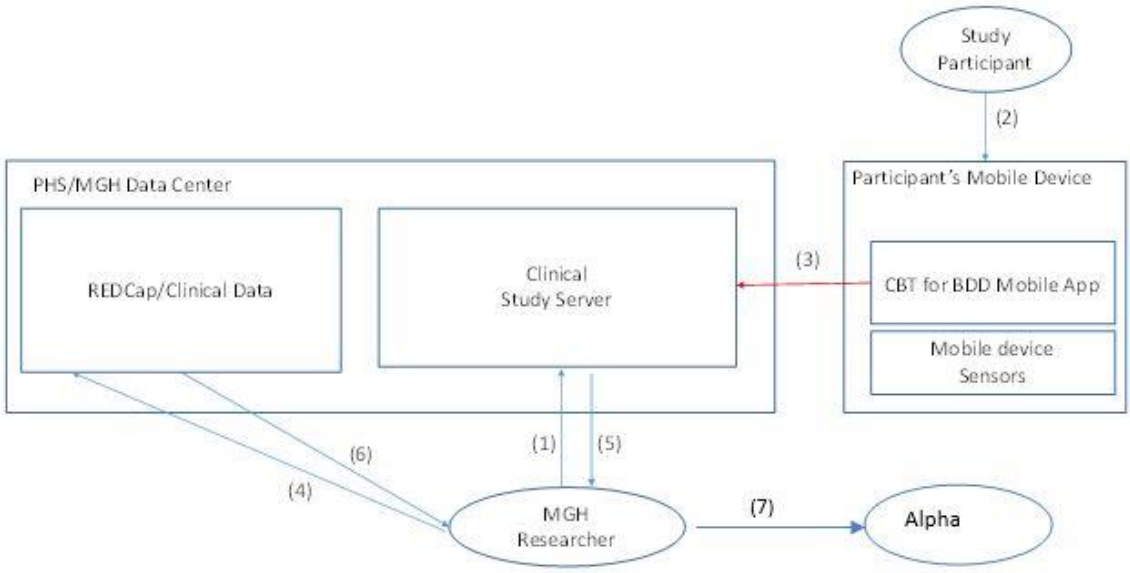
IX. MONITORING AND QUALITY ASSURANCE

A. Independent monitoring of source data

The PI will have overall responsibility for study data and participant safety. Please see "Privacy and Confidentiality" above for more information about the data collected for the present study including (1) Clinical data (formal assessments with the MGH IE, which includes self-report and audio recorded clinician-administered assessments completed on paper and via REDCap) (2) Technologist data (feedback interviews with Telefonica Alpha technology experts will include audiofiles and digital files [e.g., Microsoft Office files]); (3) Mobile data (self-report questions collected electronically within the mobile app, and passively collected data through sensors in participants' mobile phones). All aspects of the study will be conducted in accordance with the hospital's policy on confidentiality.

Paper research records will be kept de-identified, in a locked file in a locked office at MGH. Self-report measures and some clinician administered measures will be collected using REDCap. REDCap (Research Electronic Data Capture) is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. Data collection projects rely on a study-specific data dictionary defined by members of the research team with planning assistance from Harvard Catalyst | The Harvard Clinical and Translational Science Center EDC Support Staff. The REDCap software allows researchers to design and implement study surveys for collecting, storing, retrieving, and manipulating data electronically. The iterative development and testing process results in a well-planned data collection strategy for individual studies. Web-based self-report measures rely on a study-specific data dictionary built by members of the research team. Once built, participants and study staff can enter data directly into REDCap surveys via any computer or tablet with standard web access and browsers. To ensure confidentiality, data will be identified in the database solely by subject number, mapped patient initials (whereby each initial is replaced with the next letter in the alphabet), week number, and visit date (i.e., subjects' names will not be entered into the database). By identifying study records in this manner, the information can be considered 'de-identified' and therefore compliant with the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") of the Health Insurance Portability Act of 1996 (HIPAA). Any data that is transmitted electronically will be encrypted and password protected. This electronic data capture system precludes the need for subsequent data entry by staff, thus minimizing human error, and resulting in improved data integrity and quality. Patients will enter survey responses into an electronic assessment form on subject-facing REDCap, and the responses will then be transmitted and stored in a secured and confidential database. Each participant will only have access to his or her own survey, but not the survey data. All users will have defined roles and privileges pre-determined by the system administrator. Thus, the PI can determine the level of access for each study staff such that only a limited number or people have access to sensitive study data. To protect patient privacy, when completing REDCap questionnaires, participants will be asked to enter their random codes in place of any identifying information (e.g., name, birth date). All identifying information will be stored separately from data in a password-protected file.

Figure 1. Data flow and storage chart.



(1) MGH Researchers have accounts on the Clinical Study Server that allow them to create participant accounts (random IDs) that they then give to study participants.
(2) Study Participants install mobile app on their mobile devices, then enter the activation code provided by MGH and grants access to collect data passively using their device.
(3) The application collects sensor data passively and actively prompts the user to ansewr questionnaires at certain times.
(4) MGH Researchers collect additional information on subjects using REDCap
(5) MGH Researchers access the data collected via the mobile app, check user progress, etc.
(6) MGH Researchers pull data from REDCap
(7) MGH Researchers share de-identified data with Telefonica Alpha, as outlined in the data use agreement (SOW).

We anticipate that the above procedures will ensure the confidentiality and integrity of study data.

B. Safety monitoring

Three clinical psychologists or researchers knowledgeable about BDD will be selected to serve as a Data Safety Monitoring Board, to review the study once a year. The PI will have overall responsibility for monitoring the integrity of study data and participant safety. Procedures for managing participant safety, including the monitoring of participants throughout the trial and response to clinical deterioration (as defined above) should it occur, are detailed above in "**Minimizing of Risks and Safety Reporting."**

C. Outcomes monitoring

The project is an outcomes monitoring project, and these data will be examined on at least a yearly basis.

D. Adverse event reporting guidelines

Adverse event reporting:

Adverse events will be reported per PHRC guidelines.

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