ONLINE THERAPIST-GUIDED MINDFULNESS-BASED COGNITIVE BEHAVIOURAL THERAPY FOR BODY DYSMORPHIC DISORDER: PILOT RANDOMIZED CONTROLLED TRIAL

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Abstract

Objective: While internet-based cognitive behavioural therapy (CBT) is garnering increased empirical support, and standalone mindfulness meditation interventions provide promise, the efficacy of online therapist-guided mindfulness-based CBT (CBT-M) for Body Dysmorphic Disorder (BDD) remains unknown. This study demonstrates the first effort to determine whether CBT-M for BDD delivered online is feasible and acceptable, and whether mindfulness meditation adds to CBT treatment effects for BDD. **Methodology:** In this two-arm, 8-week parallel pilot randomized controlled trial, n= 28 adults (18-55 years) were randomly allocated to an experimental (online therapist-guided CBT-M) or control group (online therapist-guided CBT). Study retention, accrual and adherence was collected, along with self-report measures for BDD, depression, anxiety and pain taken at baseline and post-intervention. **Results:** This study was feasible to implement and deemed acceptable by participants. After the 8-week intervention, significant improvements were found on all outcome measures for both treatment groups, and large between-group effect sizes were found for BDD symptom severity (d= -0.96), depression (d= -1.06), pain severity (d= -1.12), and pain interference (d= -1.28). Between-group differences were not found for anxiety symptoms. **Conclusion:** The results suggest that mindfulness meditation may add to beneficial online CBT treatment effects for BDD. An adequately powered randomized control trial of online CBT-M is warranted.

Dedication

I dedicate this thesis to those affected by Body Dysmorphic Disorder.

Most of all, I dedicate this thesis to those who chose to participate in this study, as your vulnerability and involvement to the advancement of Body Dysmorphic Disorder research have made a lasting impact.

To those I had the privilege of working with, my words cannot fully express how truly inspired I am by your self-expression and resilience. Our conversations have forever left a mark on my life.

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1. Introduction

Body Dysmorphic Disorder (BDD) is a psychiatric disorder hallmarked by an excessive preoccupation with perceived defects in physical appearance that are slight or imperceptible to others (American Psychiatric Association, 2013). Individuals with BDD engage in repetitive behaviours such as analyzing perceived defects in reflective surfaces, seeking reassurance from others, and camouflaging 'defects' with oversized clothing or makeup (Phillips, 2005). Appearance preoccupation and associated behaviours lead to significant distress and high levels of functional impairment, including social interference and difficulties attending school or work (Phillips et al., 2005), which may render many (~30%) housebound (Phillips, 2004; Bjornsson et al., 2010). Suicidal ideation and suicide attempts are common in BDD populations (Buhlmann et al., 2010), and completed suicide rates are ~45 times higher than in the general population (Phillips et al., 2006), reflecting the debilitating course and morbidity of BDD. Traumatic events, including those involving childhood abuse may be associated with the onset and severity of BDD (Buhlmann et al., 2012).

BDD symptoms typically arise during adolescence, and impact ~1.7% to ~2.4% of the general population (Phillips et al., 2006; Buhlmann et al., 2010; Koran et al., 2008; Rief et al., 2006). Population-based studies suggest that a higher proportion of individuals with BDD are women (~60%), but generally, BDD clinical features, demographics, body areas of concern, symptom severity, behaviours, and impairment appear similar between genders (Koran et al., 2008; Rief et al., 2006; Phillips, 2005). However, BDD is frequently underdiagnosed, misdiagnosed and understudied (Buhlmann et al., 2010). Current findings reveal that individuals are reluctant to disclose symptoms associated with the disorder due to feelings of shame (Conroy et al., 2008). In addition, those with BDD are often observed in plastic surgery

or dermatology settings seeking cosmetic enhancement at a reported prevalence of 6% to 15% (Phillips et al., 2000; Sarwer et al., 2002; Carroll et al., 2002).

Individuals affected by BDD typically do not benefit from surgical treatment while Cognitive Behavioural Therapy (CBT) appears to be efficacious (Harrison et al., 2016). Moreover, mindfulness meditation has demonstrated some promise in the treatment of body image distress by introducing strategies that support appearance acceptance and engagement in present-moment awareness (Hartmann et al., 2015). Despite the potential of various treatment options, financial and geographical barriers may impede access to treatment (Cavanagh, 2014). These factors underscore the importance of expanding BDD research to identify appropriate and accessible clinical interventions for BDD. The present study aims to ascertain whether an online therapist-guided mindfulness-based cognitive behavioural therapy (CBT-M) intervention is feasible, acceptable and can demonstrate preliminary effectiveness in the reduction of BDD symptom severity.

2. Literature Review

2.1 Historical Perspectives

In 1891, Italian psychiatrist, Enrico Morselli coined the term 'dysmorphophobia', marking the first clinical conceptualization of a preoccupation with perceived defects in one's own appearance (Berrios et al., 1996). Morselli's descriptions of the disorder align with the current clinical perspective of BDD, indicating that symptoms can range in severity and differ from psychotic disorders. In addition, Morselli observed ruminations and compulsive behaviours in patients (Jerome, 2017), reflected in BDD's current inclusion in the obsessive compulsive and related disorders section of the DSM-5 (American Psychiatric Association, 2013).

In the 1930's, Japanese psychiatrist and philosopher, Shoma Morita, observed concerns that resembled what has since become BDD, and identified them as 'Taijin kyofusho'; loosely translated as an interpersonal fear that others are disapproving of specific aspects of one's physical appearance (Essau et al., 2012). As a result, 'Morita therapy' was developed to treat body image distress. Morita therapy was influenced by Zen Buddhist philosophy, emphasizing discipline, rest, and mindful present-focus awareness (Jerome, 2017). Psychoanalytic theorists at the time believed dissatisfaction with physical appearance reflected unconscious psychodynamic conflict (Jerome, 2017).

In the 1960's, body image perspectives shifted to emphasize sociocultural factors as a powerful influence (Jerome, 2017). In the 1970's and 1980's, interest in 'dysmorphophobia' and BDD classification was renewed where prioritization of symptoms over clinical content was highlighted. English psychiatrist George Hay believed that a range of psychiatric disorders may underlie BDD, including psychotic illness such as schizophrenia (Jerome, 2017).

These differing cross-cultural perspectives provoked a need for distinct diagnostic criteria for BDD in North America. BDD was first recognized in the DSM-III in 1980, where 'dysmorphophobia' was acknowledged as an atypical somatoform disorder (American Psychiatric Association, 1980). In 1987, a revised version of the DSM-III (DSM-III-R) introduced the term "Body Dysmorphic Disorder", postulating it as a discrete disorder (American Psychiatric Association, 1987). The DSM-III-R reflected Morselli's interpretation by defining BDD as "a preoccupation with one or more perceived defects or flaws in physical appearance" (American Psychiatric Association, 1987). Delusional presentations of BDD were

identified as a separate psychotic disorder (delusional disorder, somatic subtype). In 1994, BDD was classified in the somatoform disorders section in the DSM-IV whereby clinically significant distress or impairment in functioning was added as a requirement for diagnosis (American Psychiatric Association, 1994). Ultimately, BDD was moved into the obsessive-compulsive and related disorders section of the DSM-5 upon publication in 2013.

2.2 Diagnostic Criteria and Clinical Features

The Diagnostic and Statistical Manual of Mental Disorders Version 5 (DSM-5) criteria for BDD should be followed to aid in identifying psychopathology in North America. As aforementioned, BDD is categorized within the obsessive-compulsive and related disorders section of the DSM-5 which lists 4 criteria that must be met. Two specifiers for BDD are also included (see Table 1).

Table 1

DSM-5 Clinical Diagnostic Criteria for BDD

DSM-5
Disorder Class: Obsessive-Compulsive and Related Disorders
A. Preoccupation with one or more perceived defects or flaws in physical appearance that are not observable or appear slight to others.
B. At some point during the course of the disorder, the individual has performed repetitive behaviors (e.g., mirror checking, excessive grooming, skin picking, reassurance seeking) or mental acts (e.g., comparing his or her appearance with that of others) in response to the appearance concerns.
C. The preoccupation causes clinically significant distress or impairment in social, occupational, or other areas of functioning.
D. The appearance preoccupation is not better explained by concerns with body fat or weight in an individual whose symptoms meet diagnostic criteria for an eating disorder. Specify if: With muscle dysmorphia: The individual is preoccupied with the idea that his or her body build is too small or insufficiently muscular. This specifier is used even if the individual is preoccupied with other body areas, which is often the case. Specify if:

Indicate degree of insight regarding body dysmorphic disorder beliefs (e.g., "I look ugly" or "I look deformed").

With good or fair insight: The individual recognizes that the body dysmorphic disorder beliefs are definitely or probably not true or that that they may or may not be true.

With poor insight: The individual thinks that the body dysmorphic beliefs are probably true.

With absent insight/delusional beliefs: The individual is completely convinced that the body dysmorphic beliefs are true.

Criterion A

Individuals can become fixated on many different body parts which may change over time (Phillips, 2005). Preoccupations of the skin (73%), hair (56%) and nose (37%) appear to be the most common; however, any area of the body can be of concern (Phillips, 2005). Fixations with symmetry, and unevenness are also present in 25% of individuals with BDD (Hart et al., 2013).

Criterion B

A range of repetitive behaviours may be performed, including skin picking, reassurance seeking, mirror-gazing, excessive grooming, and camouflaging 'defects' by tanning, wearing makeup, hats, accessories, or oversized clothing (American Psychiatric Association, 2013; Phillips, 2005). Moreover, mental acts such as comparing appearance with others or images in the media are often present (Simmons et al., 2017). On average, individuals with BDD spend 3-8 hours each day engaging in compulsive behaviours and mental acts (Phillips, 2005).

Criterion C

Individuals with BDD often avoid situations in which their perceived defect may be exposed (Simmons et al., 2017). Furthermore, emotions associated with BDD preoccupations,

including disgust, grief, anger, social anxiety, and depression are often debilitating (Simmons et al., 2017). Impairments in functioning were observed in a sample of 141 adults with current BDD, finding that 37.6% were unemployed and 22.7% were receiving disability payments (Didie et al., 2008). Another study investigated social functioning in 131 adults with BDD and found that 55.7% did not have a current primary relationship which was correlated with poorer overall social functioning on global social adjustment measures (SAS-SR and LIFE) (Didie et al., 2006).

Criterion D

Eating disorders may present similarly to BDD as body image disturbance and distortion is emphasized. While it is possible to have comorbid diagnoses where both BDD and eating disorder criteria are met, diagnostic overlap may explain elevated rates of co-occurrence (Grant et al., 2017). These disorders differ when assessing body areas of concern, and associated behaviours. Appearance fixation in individuals with an eating disorder primarily focuses on body weight and size. Although some repetitive behaviours may overlap, eating disorders are characterized by disordered eating patterns aimed at trying to lose or control weight (Grant et al., 2017; American Psychiatric Association, 2013).

Specifier: Muscle Dysmorphia

While prevalence of muscle dysmorphia in the general population is unknown due to limited research; 9.3% in a sample of 1150 military personnel has been reported (Campagna et al., 2016), and approximately 87% of those with muscle dysmorphia are male (Tod et al., 2016). Individuals with muscle dysmorphia engage in common BDD behaviours, with emphasis on diet and weightlifting or exercise routines (Sreshta et al., 2017). Several findings have identified associations between muscle dysmorphia and anabolic-androgenic steroid use

which may pose several health risks (Kanayana et al. 2013; Pope et al., 2014).

Specifier: Degree of Insight

Research evidence demonstrates that BDD symptom severity is associated with level of insight (Phillips et al., 2012). Findings from a study comparing insight in BDD, relative to OCD and psychotic disorders suggest that appearance related fixations in BDD can somewhat resemble delusions observed in psychosis (Toh et al., 2017). However, pharmacotherapy treatment studies have found that individuals with absent insight significantly improved with serotonin reuptake inhibitor (SRI) monotherapy, and no studies have shown antipsychotic treatment to be effective (Phillips et al., 2002; Hollander et al., 1999; Phillips, 2017). Ultimately, the BDD-related insight specifier in the DSM-5 marks delusional BDD beliefs on a continuum as opposed to a separate diagnostic disorder as previously observed in earlier iterations (American Psychiatric Association, 2013).

2.3 Etiology

Research findings pertaining to etiology and pathophysiology are limited as research investigating genetics, neurochemistry, neurocircuitry and visual processing for BDD is still in its infancy. However, there is detailed evidence to suggest that these factors may contribute to the developmental risk of BDD.

Genetic Factors

Family studies have concluded that ~8% of individuals with BDD had a family member with BDD (Bienvenu et al., 2000), and ~7% had a first degree relative with OCD (Phillips et al., 1998). Twin studies have also identified genetic contributions to BDD indicating that 64% of the covariation between dysmorphic concerns and obsessive-compulsive traits could be accounted for by common genetic factors (Monzani et al., 2012). A

preliminary study investigating the genetic relationship between BDD and OCD demonstrated an association between the GABA (A)-gamma-2 1(A) allele and BDD (Richter et at., 2004). These findings suggest that BDD is, to some extent, heritable.

Brain Circuitry

Brain imaging studies investigating neurocircuitry in those with BDD have focused on observing white matter integrity, connectivity, and organization. Feusner et al. (2013) examined white matter using diffusion tensor imaging (DTI). Although no significant difference in white matter between unmedicated individuals with BDD and healthy controls were identified, correlations were found between fiber disorganization and poorer BDD-related insight in the forceps major and inferior longitudinal fasciculus (Feusner et al., 2013). These findings suggest that difficulties in interhemispheric communications between visual and emotional/memory systems may lead to difficulties in accurately perceiving appearance.

Findings from a study by Arienzo et al., examining patterns in brain activity identified that individuals with BDD displayed higher 'edge betweenness centrality' for connections between bilateral occipital poles, and between anterior temporal and occipital regions of the brain (2013). This indicates that these connections are more influential on the entire brain network such that a large proportion of mental functioning in individuals with BDD involve structures connected to visual stimuli processing (Arienzo et al., 2013).

Visual Processing

Neuroimaging studies examining visual processing have showcased reliable evidence that individuals with BDD have disturbances in visual perception (Feusner et al., 2007; Feusner et al., 2010, Feusner et al., 2011). In one study, left hemisphere activation in the brain was found for both healthy controls and BDD participants when observing detailed

photos of faces; however, the BDD participants maintained left hemisphere activation for low detail faces (Feusner et al., 2007). These findings suggest that individuals with BDD had greater detail processing relative to holistic processing when observing low detail photos which may contribute to a greater likelihood of 'flaw' detection (Feusner et al., 2007). Feusner and colleagues (2011) also examined visual processing in individuals with BDD when observing non-appearance-related stimuli. Findings from this study show that individuals with BDD may have general global processing difficulties as abnormal activity in higher-order visual processing systems were found (Feusner et al., 2011).

Socio-Cultural Factors

Unrealistic standards of beauty in mainstream media, and perfectionistic attitudes appear to contribute to body image concerns (Neziroglu et al., 2017). Additional factors, including childhood experiences of being bullied and teased may lead to the onset and maintenance of BDD. A study exploring perceived teasing experiences found that those with BDD reported experiencing more appearance-related teasing than healthy controls (40% vs. 17%) (Buhlmann et al., 2007). A general population study noted similar results (40% vs. 15.6%), and additionally observed that the BDD group remembered teasing experiences as more traumatic and vivid than healthy controls (Buhlmann et al., 2011).

A study by Didie et al. (2006) highlighted that 78.7% of individuals with BDD reported a history of childhood maltreatment and experiences of abuse including emotional abuse (56.0%), physical abuse (34.7%), and sexual abuse (28.0%). Findings from a study comparing traumatic experiences in individuals with BDD versus healthy controls detailed a significantly higher number of past traumatic events and higher frequencies of abuse in BDD, including physical abuse (39% vs 0%) and sexual abuse by a family member who was at least 5 years

older (28% vs. 5%). In all cases, the onset of BDD occurred after the traumatic event (Buhlmann et al., 2012). This data suggests that exposure to traumatic events may be associated with the onset and severity of BDD symptoms (Buhlmann et al., 2012; Didie et al., 2006; Malcolm et al., 2021).

2.4 Comorbidities

Co-occurring psychiatric disorders are common in BDD populations. Major Depressive Disorder (MDD) is the most frequent lifetime comorbid disorder presenting in ~75% of individuals with BDD (Gunstad et al., 2003; Phillips et al., 2005). An important finding identified that MDD and BDD may have significant longitudinal associations wherein improvements in MDD predicted BDD remission, and improvements in BDD predicted MDD remission (Phillips et al., 2006). Moreover, findings support that there are high frequencies of comorbid lifetime substance use disorder (~48%), social anxiety disorder (~39%), and obsessive-compulsive disorder (~33%) (Gunstad et al., 2003; Phillips et al., 2005). Overall, comorbid concerns may influence the presentation and course of BDD. Concurrent treatment of comorbid disorders may improve outcomes (Hart et al., 2017).

2.5 Treatment Considerations

Many factors impede access to efficacious BDD treatment including poor insight, socio-economic status, shame, and geographical barriers (Eisen et al., 2004; Marques et al., 2011; Cavanagh, 2014). Oftentimes, mental health professionals lack knowledge pertaining to BDD which can lead to misdiagnosis and misdirected treatment (Phillips, 2005). Individuals affected by BDD may be ambivalent about therapy and treatment outcomes, even seeking nonpsychiatric treatment (Veale et al, 2014; Marques et al., 2010). Marques et al. (2010) found that those with BDD pursued dermatologists (24.6%), dentists (19.9%), and plastic surgeons

(13.8%) to treat their appearance concerns. Retrospective outcome studies suggest people affected by BDD typically do not benefit from cosmetic treatment (Crerand et al., 2006).

Pharmacological Treatment

The use of serotonin reuptake inhibitors (SRIs) has been empirically supported for the treatment of BDD (Phillips et al., 2003; Phillips et al., 2016); however, a study utilizing a self-report survey identified that only 18.6% of BDD sufferers were currently taking psychotropic medication for appearance concerns (Buhlmann, 2011). Five open-label SRI trials (two with fluvoxamine, one with citalopram, and two with escitalopram) found that BDD and associated symptoms were reduced in 63%-83% of participants (Phillips et al., 2016; Perugi et al, 1996; Phillips et al, 1998; Phillips et al. 2003; Phillips et al., 2006). Although more randomized, placebo-controlled pharmacotherapy studies are warranted, SRIs are recommended as a first-line treatment (Phillips, 2017).

Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) is the most empirically supported psychotherapy treatment for BDD whereby individuals develop skills to identify and challenge distorted cognitions surrounding appearance and adjust compensatory behaviours through exposure and ritual prevention (Harrison et al., 2016; Wilhelm et al., 2014). As indicated in a relatively recent systematic review and meta-analysis of CBT for BDD, in the seven RCTs (N=299) that met inclusion criteria, CBT was superior to waitlist control or credible psychological placebo in reducing BDD symptoms (7 studies; $d = -1.22$, 95% CI: −1.66, −0.79) and depression symptoms (5 studies; $d = -0.49$, 95% CI: −0.76, −0.22) (Harrison et al., 2016). The comparative reductions in BDD symptoms versus depression symptoms suggest that BDD symptoms may be more amenable to CBT for BDD treatment

than associated depression symptoms. This demonstrates that CBT is an efficacious treatment for BDD with room for improvement given the high comorbidity rate with MDD (Gunstad et al., 2003).

Internet-based CBT

A survey identified that only 17.4% of individuals seeking psychotherapy services for BDD received CBT despite the empirical support (Marques et al., 2011; Bjornsson et al., 2010). Internet-based CBT for BDD has great promise to increase mental healthcare equity and access to specialized treatment. Albeit limited, research investigating the efficacy of internet-based CBT for BDD is encouraging. In Sweden, Enander et al. (2016) conducted a 12-week RCT comparing a developed internet-based CBT for BDD (BDD-NET, 2014) with online supportive therapy. The results of this study reveal a between group effect size of d= 0.95 (95%CI: 0.52, 1.38) after treatment, indicating significantly reduced BDD severity outcome scores for BDD-NET compared to supportive therapy. In 2020, Wilhelm and colleagues developed, and pilot tested a CBT digital service marking the first smartphone-delivered individual CBT treatment for BDD. BDD symptom reduction was reported after the 12-week open trial (d= 2.60); however, efficacy must be interpreted with caution as this study was underpowered with a small sample size (n= 10) and did not utilize a randomized design. Moreover, depression did not meaningfully reduce. In 2021, McCausland et al. highlighted the importance of developing and evaluating internet-based CBT for BDD in other contexts which further signifies the necessity of the current study.

Mindfulness Meditation

Mindfulness meditation, originating from Buddhist tradition, emphasizes the importance of a non-judgmental awareness of thoughts and emotions, and introduces strategies for

acceptance (Keng et al., 2011), demonstrating great promise for reducing body image distress and appearance-related thoughts (Hartmann et al., 2015). Findings from an exploratory study looking at the short-term effectiveness of targeting intrusive appearance-related thoughts through mindfulness identified that positive affect increased in individuals with BDD compared to healthy controls (Hartmann et al., 2015). Furthermore, a form of loving-kindness meditation (self-compassion meditation) was used in a 3-week RCT to treat body image dissatisfaction in women (Albertson et al., 2015). After completion of the program, the intervention group compared to the control group had significant reductions in body dissatisfaction (d= 0.73), body shame (d= 0.68), and achieved significant gains in body appreciation (d= 0.62). These results were maintained at 3-months post-intervention indicating that long-term outcomes can be achieved with short-term mindfulness interventions; however, more exploration is warranted to address BDD symptoms beyond intrusive appearance-related thoughts.

Purpose of Current Study

While internet-based CBT interventions address many BDD treatment barriers and garner increased empirical support, there is still important room for improvement. Firstly, CBT interventions for BDD appear to minimally reduce comorbid depression. Given that individuals with BDD have high rates of suicidal ideation, functional impairment, and major depressive disorder, this appears a priority to address. There is evidence from existing online therapist-guided clinical trials that CBT-M interventions reduce depression symptoms (Ritvo et al., 2021; Segal et al., 2020). Although these trials did not include BDD participants, they demonstrate promise as an accessible and effective treatment for psychological subpopulations. Moreover, mindfulness meditation introduces techniques to engage in self-compassion (Boellinghaus et al., 2014), acceptance, and non-judgement (Keng et al., 2011). This is essential to consider for BDD

treatment given the extreme negative perceptions of self-appearance that characterize sufferers. In addition, mindfulness techniques emphasize relaxation and non-reactivity (Kabat-Zinn, 2003) which may strengthen participants propensity to engage in CBT practices including analyzing maladaptive beliefs that fuel BDD, and subsequent behaviour change. While the efficacy of online CBT-M for BDD is unknown; reductions in BDD symptoms in separate online CBT and mindfulness meditation interventions demonstrate that a combined treatment approach appears an important priority to investigate.

In addition, research exploring physical pain in those with BDD appears vacant. Speculatively, symptoms such as skin-picking and excessive exercise, along with suicide attempts (Phillips et al., 2005) and high prevalence rates of cosmetic surgeries (Crerand et al., 2006) may involve pain. In extreme cases, self-mutilation (Phillips, 2005), and request for amputation of healthy limbs (Chan et al., 2011) have been reported. Given the notable gap in the literature, pain exploration could provide novel insight into BDD.

3. Methodology

3.1 Study Aims

The current pilot study aims to expand treatment accessibility, and to evaluate the feasibility, acceptability, and preliminary effectiveness of an 8-week online multimodal intervention for individuals with self-reported symptoms of BDD. Specifically, the current study compares two online treatment approaches: (1) therapist-guided mindfulness-based cognitive behavioural therapy (CBT-M), and (2) therapist-guided CBT without reference to mindfulness meditation. The purpose of this comparison is to ascertain whether the inclusion of mindfulness adds to positive outcome effects in self-report symptoms of Body Dysmorphic Disorder to expand the existing literature.

3.2 Research Questions

(1) Can this intervention be feasibly implemented as planned and proposed?

(2) Will the participants involved evaluate the intervention as acceptable?

(3) Does this online RCT provide promise for novel BDD treatment (online CBT-M) by reducing BDD symptom severity, along with depression, anxiety, and pain?

(4) Will the online CBT-M intervention provide greater reductions in BDD symptom severity, depression, anxiety, and pain than the control intervention (online CBT)?

Exploratory Research Question

(1) Is there a relationship between BDD and pain?

3.3 Hypotheses

(1) The online intervention will be feasible to implement as demonstrated by rates of accrual, retention, and attendance at therapist-guided coaching calls.

(2) The intervention will be acceptable as demonstrated by participant satisfaction responses on the NexJ - My Program Experience survey.

(3) (a) Preliminary effectiveness of the online intervention will be demonstrated by symptom reduction in the online CBT-M treatment group as indicated by quantitative outcomes assessed at baseline and post-intervention.

(3) (b) Participants in the CBT-M treatment group will reveal greater reductions in BDD, depression, anxiety and pain as demonstrated by between-group and within-group effect sizes.

3.4 Design

This 8-week pilot study employed a two-arm parallel design to evaluate the feasibility, acceptability, and preliminary effectiveness of a novel online intervention for BDD. The online

software platform used, NexJ Connected Wellness, is developed by NexJ Health, Inc. NexJ Health, Inc provides use of the NexJ Connected Wellness platform free of charge (as a research partner) but contributes no other funding or support for the study. The RCT was reviewed and approved by York University Research and Ethics (Human Participants Review Committee protocol number 2022-290) and is registered with ClinicalTrials.gov (NCT05402475).

3.5 Participants

Intervention participants were recruited through advertisements posted to online platforms including, Facebook, Instagram, Reddit, and CloudResearch (http://cloudresearch.com). In addition, individuals with BDD from the OCD and Anxiety Specialty Clinic at the Centre for Addiction and Mental Health (Toronto, Ontario) were referred to the study by psychiatrist, Dr. Jamie Feusner (MD).

Participants of any gender identity, race, or ethnicity between 18 and 55 years of age that reside in the United States or Canada were eligible to participate if they passed screening for BDD by disclosing self-reported symptoms on the Body Dysmorphic Disorder Questionnaire (BDDQ). Fluency in English and smartphone access were additionally required.

Exclusion criteria included self-reported diagnosis of: eating disorder, bipolar disorder, borderline personality disorder, schizophrenia (or other primary psychotic disorder) or severe substance abuse disorder/addiction. Those who disclosed imminent intent or attempted suicide in the past six months, were receiving current psychological treatment, or had no smart phone access were additionally excluded. Participants had no prior relationship with researchers.

3.6 Sample Size Justification

Given the pilot nature of the current study, a sample size calculation was not required. However, according to Julious (2005) recommendation of 12 participants per group, considering

15% attrition, 28 participants were enrolled with a final recruitment target of 24. This was a justifiable target given the study resources and time, sample population, and research aims.

3.7 Procedures

Screening

Potentially eligible participants were provided with an online (SurveyMonkey) pre-screen which included the Body Dysmorphic Disorder Questionnaire (BDDQ) (Appendix A). SurveyMonkey is a HIPAA compliant platform that maintains and safeguards the security of data collection. The BDDQ is a valid self-report questionnaire utilized to screen participants for BDD. The BDDQ has high sensitivity (100%) and specificity (89-93%) for BDD (Phillips, 2017).

Participants who passed the BDDQ screening were invited to a virtual interview where they were provided with study details and asked about their psychological history along with additional inclusion criteria questions. This allowed the co-investigator (master's student undertaking this project) to assess English fluency and eligibility. Participants who were in therapy outside of the study were asked to suspend treatment for the duration of the trial. Upon interview completion, the co-investigator informed the participant of their eligibility. Eligible participants who wished to join the study completed an online consent form that was signed and dated to indicate consent.

Data Collection

A virtual meeting was organized between the enrolled participant and co-investigator for measurement completion. A SurveyMonkey link was provided to participants where they entered a unique study ID number to further safeguard data (created using a random ID generator: http://shortunique.id) before completing a demographic questionnaire and 4 self-report baseline questionnaires: Body Dysmorphic Disorder – Symptom Scale; Patient Health Questionnaire-9;

Generalized Anxiety Disorder -7; Brief Pain Inventory. ID number and corresponding participant names were recorded on a password-protected Excel document to maintain confidentiality.

Upon questionnaire completion, participants provided their phone number to the co-investigator which was documented on a spreadsheet and later provided to their designated therapist. The therapists in this trial were graduate students trained and supervised by study clinical psychologist, Dr. Paul Ritvo. Self-report psychometric data was collected from participants at two-time points: baseline (T1) and post-treatment (T2). Post-treatment data collection was facilitated by researchers not involved with participants. Participants were compensated up to $30 for intervention and final measurement completion.

Randomization Plan

A 1:1 ratio randomization schedule (7 blocks) with randomly selected block sizes of 4 with two treatment arm allocations (CBT-M and CBT) was created using a randomization sequence generator (http://randomization.com) by the co-investigator prior to enrollment. The randomization schedule was concealed (highlighted black) on a spreadsheet (Excel) up until treatment allocation. The co-investigator allocated participants to their treatment group consecutively, based on the order of their inclusion by individually unhighlighting the randomization schedule for each participant. Allocation for each enrolled participant was completed after obtained consent, prior to self-report baseline measurement collection to reduce bias.

The Principal Investigator (Dr. Paul Ritvo) assigned participants to a designated therapist for the duration of the trial. Participants were additionally connected to the NexJ Connected Wellness app where they could access designated group BDD content, and secure text message exchange with their therapist.

3.8 Interventions

Online CBT-Mindfulness with Therapist-guided Support

Experimental participants received CBT and mindfulness meditation content (modules and video) with 24/7 online access through NexJ Connected Wellness.

The intervention content builds on two prior successful internet-based CBT-M RCTs with students (Ritvo et al., 2021; El Morr et al., 2020). BDD researchers suggest specifically tailoring CBT treatment to BDD concerns given the distinct preoccupations and behaviours of the disorder (Rasmussen et al., 2017). As such, the online content was further developed and tailored for BDD.

The content includes 8 chapters reflecting the following: perfectionism, sociocultural norms, unchangeable features, acceptance, restructuring body-based assumptions, self-esteem, internal versus external body image, self-compassion, loving-kindness meditation, befriending our bodies, overcoming avoidance, bringing health from most preferred body parts to least preferred body parts, mindfulness, and media. Content themes provide psychoeducation, mindfulness techniques (relaxation, deep breathing, awareness, non-reactivity, and non-judgement), cognitive restructuring, and behavioural activation strategies to address negative automatic thoughts, appearance fixations, camouflaging, avoidance, mirror-checking rituals, social comparison, social functioning, relationships, and core beliefs with the intention of decreasing symptoms and elevating mood. Mindfulness meditation videos (~135 minutes) were available on the platform on a 24/7 basis as needed. Participants were encouraged to complete one module and 1 hour of mindfulness meditation per week; however, treatment goals were identified between participant and designated therapist as interactions with the online content

were combined with client-centered therapist-guided calls (total 60 minutes/week over 8 weeks) and text message exchange as needed.

Control: Online CBT with Therapist-guided Support

CBT group module content was provided online through NexJ Connected Wellness and covered the same topics as the experimental group including perfectionism, sociocultural norms, unchangeable features, acceptance, restructuring body-based assumptions, internal versus external body image, befriending our bodies, overcoming avoidance, bringing health from most preferred body parts to least preferred body parts, and media; however, mindfulness meditation components were excluded.

Psychoeducation, cognitive restructuring, and behavioural activation techniques provided through modules addressed negative automatic thoughts and appearance fixations, camouflaging and avoidance behaviours, mirror-checking rituals, comparison, societal pressure, social functioning, relationships, and core beliefs.

Participants were encouraged to complete one module per week; however, treatment goals were discussed during therapist-guided calls that were provided (1 hour/week) over 8 weeks. Mindfulness meditation was additionally excluded during calls in the control group. Key intervention features could be accessed on a 24/7 basis, including text message exchange with the therapist and CBT content that addresses BDD symptoms.

All therapists in the study attended weekly training and 1-on-1 supervision sessions with the clinical psychologist involved in this study.

3.9 Outcome Measures

Primary Outcome Measures

(1) Rates of accrual reported as the total number of enrolled participants divided by the

number of months recruitment occurred.

(2) Rates of retention reported as the percentage of participants who completed the 8-week intervention from randomization to completion of post-intervention measures by dividing the numbers of participants who were present at these time points.

(3) Adherence as identified by percentage of participants attending weekly therapist-guided calls.

(4) The NexJ – My Program Experience survey: A 7-item questionnaire (1-5 rating scale) developed by Nex J Health Inc. used to obtain information about the acceptability of the intervention. Questions ask participants about their overall satisfaction with the study including intervention content, therapist, hours spent using the app, ease of use, and likelihood of using the app in the next 6 months. Higher scores represent greater participant satisfaction.

(5) Body Dysmorphic Disorder Symptom Scale (BDD-SS): The BDD-SS is a recently developed (Wilhelm et al., 2016) reliable and valid self-report questionnaire used to examine the severity of a broad range of body dysmorphic disorder symptoms. Given the self-report approach, it can be easily administered and interpreted. The BDD-SS provides symptom and severity ratings wherein both total scores correlated strongly with the gold standard clinician-administered Body Dysmorphic Disorder Yale-Brown Obsessive-Compulsive Scale (BDD-YBOCS) (Wilhelm et al., 2016). The questionnaire was modified for the current study to include 7-items (0-10 rating scale) with higher scores representing greater severity (of symptoms), up to a sum score of 70.

Secondary Outcome Measures

(1) Patient Health Questionnaire-9 (PHQ-9): A reliable and valid 9-item self-report questionnaire for depression screening and severity, with a sensitivity of 88% and specificity of 88% for Major Depressive Disorder (Kroenke et al., 2001). Scores for each item range from "0" (not at all) to "3" (nearly every day). To obtain the total PHQ-9 score (0-27), all 9 item scores are added. Interpretation of total scores are as follows: minimal depression: 1-4, mild depression: 5-9, moderate depression: 10-14, moderately severe depression: 15-19, and severe depression: 20-27.

(2) Generalized Anxiety Disorder-7 (GAD-7): The GAD-7 is a valid measure for screening and assessing severity of Generalized Anxiety Disorder. The GAD-7 has a sensitivity of 89% and specificity of 82% indicating good reliability (Spitzer et al., 2006). The scale has 7 items with scores ranging from "0" (not at all) to "3" (nearly every day) for each item. The total score ranges from 0-21, with cut-points for mild (5), moderate (10), and severe (15) anxiety.

(3) Brief Pain Inventory (BPI) Short Form: A reliable self-report questionnaire for physical pain experiences, employing 4 pain severity items (worst pain in the past 24 hours, least pain in the past 24 hours, average pain, and present pain), and 7 pain interference items (general activity, mood, walking ability, work, relations with other people, sleep, and life enjoyment). The BPI pain severity items use an 11-point numeric scale of 0-10 where 0= no pain and 10= pain as bad as you can imagine (Cleeland et al., 1991). The 7 BPI pain interference items use an 11-point numerical scale of 0-10 where 0= does not interfere and 10= completely interferences. The BPI has demonstrated good to excellent validity and reliability (Furler, 2013).

3.10 Statistical Analysis Plan

IBM Statistical Package for the Social Sciences (SPSS) version 28.0 for Windows was used to conduct quantitative statistical analysis of the survey data. Data was cross-checked and cleaned prior to statistical analysis. Numeric variables (ie. age) were presented as means and standard deviations, and categorical data (ie. gender) was presented as frequencies and percentages. Initial analyses were conducted to assess baseline characteristics between groups. Statistical analysis procedures for study hypotheses are discussed below.

Feasibility and Acceptability

> ***H1****: The online intervention will be feasible to implement as demonstrated by rates of accrual, retention, and attendance at therapist-guided coaching calls.*
>
> ***H2:*** *The intervention will be acceptable as demonstrated by participant satisfaction responses on the Nex J - My Program Experience survey.*

Descriptive statistics for feasibility regarding retention and phone call adherence are reported as percentages. Responses on the NexJ My Program Experience survey are reported as means and standard deviations to identify acceptability of the intervention.

Pre-Post Changes in Psychometric Outcomes

> ***H3a:*** *Preliminary effectiveness of the online intervention will be demonstrated by symptom reduction in the online CBT-M treatment group as indicated by quantitative outcomes assessed at baseline and post-intervention.*
>
> ***H3b:*** *Participants in the CBT-M treatment group will reveal greater reductions in BDD, depression, anxiety and pain as demonstrated by between-group and within-group effect sizes.*

Independent samples t-tests and Fisher-Freeman-Halton Exact tests for all outcomes and categorical variables were employed to detect differences between study groups at baseline, and

between study completers and dropouts to determine whether missing post-intervention measurements were considered missing at random (MAR). Linear mixed model (LMM) analyses for repeated measures were used as this ensured an intention-to-treat (ITT) approach could be utilized, which accounts for all enrolled participants who completed baseline measures. An unstructured restricted maximum likelihood (REML) approach was used for the main analysis (Table 4a), although a multiple imputation (MI) approach was additionally analyzed (Table 4b) for robustness and validity of findings. The analysis was employed for measures: BDD-SS, PHQ-9, GAD-7, BPI (severity) and BPI (interference). Fixed effects including group and time, and their interaction (group x time) were evaluated. Further analysis was conducted to adjust for BDD-SS scores at baseline to ensure statistical precision. Cohen's d within-group and between-group effect sizes were evaluated with means, standard deviations and correlations calculated for all participants with completed data (N=18) for REML analysis (see Table 4a), and (N=28) for MI analysis (see Table 4b).

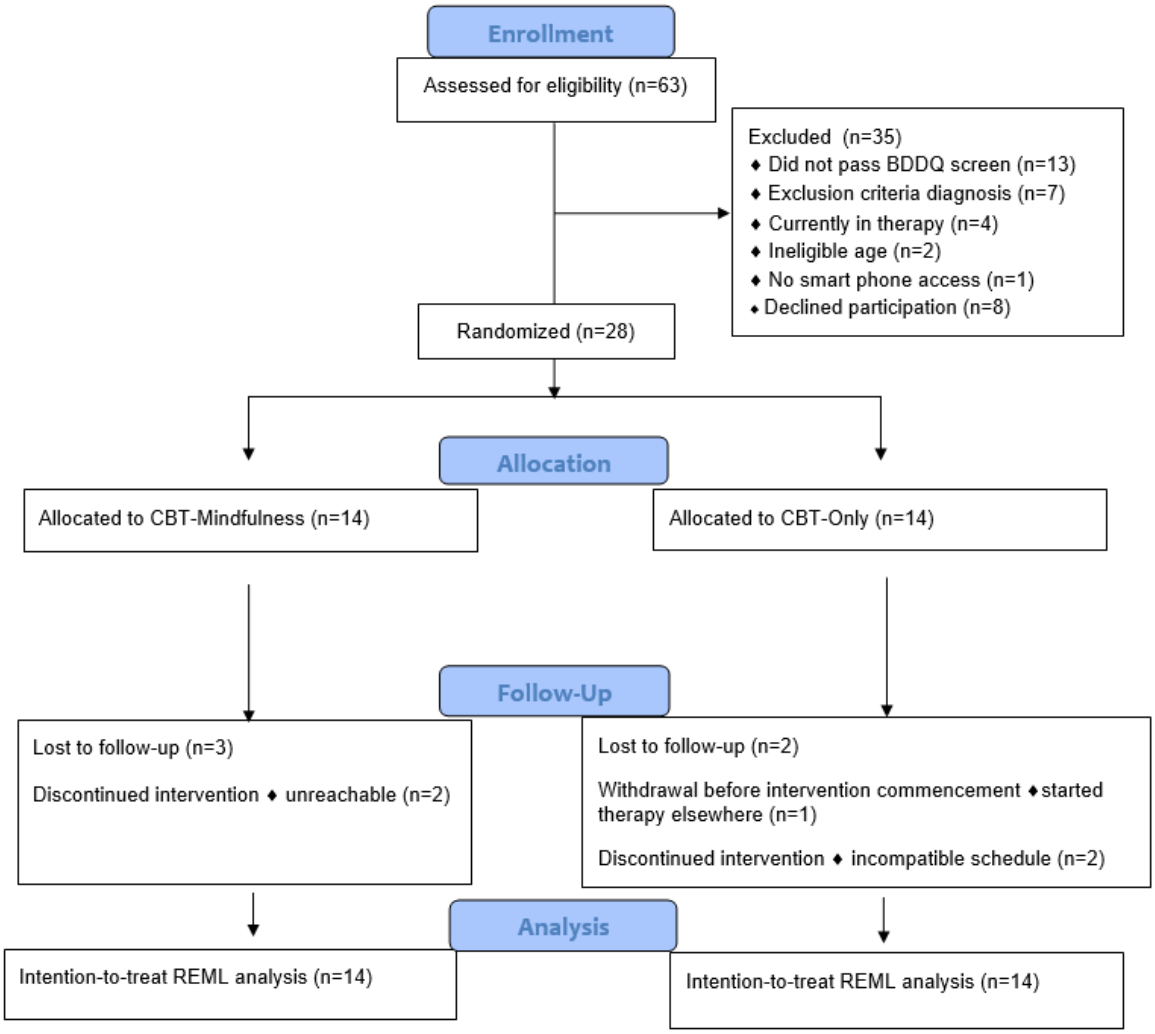
EQ1: *Is there a relationship between BDD and pain?*

Pearson's *r* bivariate correlation was computed to assess the relationship between BDD-SS and BPI scores.

4. Results

Figure 1

CONSORT Participant Flow Diagram



4.1 Participant Flow

The CONSORT flow diagram (Figure 1) illustrates this study's participant recruitment and flow. Overall, 63 adults, ages 18-55 years, were screened and interviewed to determine eligibility from September 2022 to February 2023. Of those interviewed, 35 adults were deemed ineligible due to the following: did not pass BDDQ screening (n=13), exclusion psychiatric diagnosis (n=7), currently in therapy (n=4), ineligible age (n=2), no access to a smart phone

(n=1) or chose not to participate (n=8). As a result, 28 adults met the inclusion criteria and provided informed consent to participate. Demographic and psychological characteristics for both CBT-M and CBT groups are presented in Table 2.

Table 2
Demographic and Psychological Characteristics for Both Groups at Baseline (N=28)

Variable	CBT-M	CBT-only	*P*
Age (years) (*M* ± *SD*)	31.14 (7.81)	34.43 (11.33)	0.380
Gender (*n, %*)			0.379
Female	7, 50.0%	10, 71.4%	
Male	5, 35.7%	4, 28.6%	
Other	2, 14.3%	0, 0.0%	
Ethnicity (*n, %*)			0.529
White	8, 57.1%	7, 50.0%	
Black	2, 14.3%	3, 21.4%	
South Asian	2, 14.3%	1, 7.1%	
East Asian	0, 0.0%	2, 14.3%	
Latin American	0, 0.0%	1, 7.1%	
Multi-ethnic	2, 14.3%	0, 0.0%	
Education (Highest level) (*n, %*)			0.577
High school	3, 21.4%	1, 7.1%	
College	1, 7.1%	3, 21.4%	
Bachelor's Degree	8, 57.1%	6, 42.9%	
Master's Degree	2, 14.3%	3, 21.4%	
Other	0, 0.0%	1, 7.1%	
Marital Status (*n, %*)			0.352
Married/Common-law	7, 50.0%	5, 35.7%	
Single	7, 50.0%	9, 64.3%	
Psychological Variables (*M* ± *SD*)			
BDD-SS (Severity)	35.50 (10.47)	41.64 (11.24)	0.147
PHQ-9	10.07 (3.69)	11.36 (5.44)	0.470
GAD-7	8.36 (4.34)	8.57 (4.13)	0.895
BPI (Severity)	10.29 (8.79)	10.64 (9.18)	0.917
BPI (Interference)	15.79 (16.22)	23.86 (22.88)	0.291

Note. Categorical variables reported as frequencies and percentages; numeric variables reported as means and standard deviations. BDD-SS = Body Dysmorphic Disorder Symptom Scale; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7; BPI = Brief Pain Inventory.

4.2 Intervention Feasibility

H1*: The online intervention will be feasible to implement as demonstrated by rates of accrual, retention, and attendance at therapist-guided coaching calls.*

Twenty-eight eligible participants enrolled during a 5-month recruitment period (September 2022 to February 2023) to partake in the current study. As a result, the accrual rate for this study was 5.6 participants per month. After randomization and prior to the first call, 5 participants were lost to follow-up, and one participant chose to withdraw (reason: started therapy elsewhere). Of the 22 participants that commenced active participation in the intervention, 2 participants withdrew from the study (week 2 *n*= 1; week 3 *n*= 1) indicating scheduling difficulties, and 2 were unreachable part way through (week 3 *n*= 1, week 4 *n*= 1) representing 81.8% retention. Overall, 18 participants completed the intervention, resulting in 10 total dropouts from randomization to 8-weeks, representing a 64.3% retention rate for this study.

Adherence to scheduled phone-based counselling calls was recorded for each participant, as evaluated by attendance to scheduled weekly calls. All 18 (100%) participants completed 8 calls; however, 5 participants had to reschedule 1 call and another 5 participants had to reschedule 2 calls. Reasons for rescheduling included family and holiday obligations, work and school schedule changes, phone service outage, COVID-19 illness, dental procedure, and loss of a family member. As a result, eight (44.4%) participants maintained perfect attendance for scheduled weekly calls throughout the study.

4.3 Intervention Acceptability

H2: *The intervention will be acceptable as demonstrated by participant satisfaction responses on the Nex J - My Program Experience survey.*

All 18 participants who completed the intervention provided program satisfaction ratings at post-intervention. Participants were asked to rate their experience from 1-5 for all questions on the NexJ - My Program Experience survey (see Table 3). The mean score for the question "How would you rate your overall program experience?" was 4.67 (*SD*= 0.59), whereby 1 indicated "poor" and 5 indicated "excellent". 13 participants (72.2%) identified that their overall experience in the study was "excellent", 4 participants (22.2%) answered that their experience was "very good", and the final participant (0.06%) said their experience was "good".

The average rating for the question "On average, how much time did you spend on the program each week?" was 3.83 (*SD*= 0.79), whereby a score of 1 indicated "less than 15 minutes", and 5 indicated "more than 2 hours". Thirteen participants (72.2%) indicated that they spent "1-2 hours" on the program each week. Two (11.1%) participants reported spending "more than 2 hours" on the program each week. Another 2 (11.1%) participants spent "15-30 minutes" on the program each week, and 1 (0.06%) participant stated that they spent "31 minutes to 1 hour" on the program each week.

The mean score was 4.50 (*SD*= 0.92) for the question "To what extent did the program meet your needs?" wherein "none of my needs were met" was a score of 1, and "almost all of my needs were met" was a score of 5. Thirteen (72.2%) participants in this study indicated that "almost all of my needs were met" and zero participants indicated that "none of my needs were met". Two (11.1%) participants answered with a score of 4 indicating that "most of their needs were met", two (11.1%) participants indicated a score of 3 suggesting that "some of their needs were met", and 1 (0.06%) participant indicated a score of 2.

The mean score for the question "How would you rate the ease of using our platform?" was 4.28 (*SD*= 1.02), whereby "very hard to use" was a score of 1, and "very easy to use" was a score of 5. Ten (55.5%) participants felt as though the platform was "very easy to use", and the remaining participants chose mixed responses, with 5 (27.8%) participants indicating a score of 4, and the remaining 3 (16.7%) participants indicating a score of either 2 or 3.

The average rating was 3.28 (*SD*= 1.18) for the participants agreement with the statement "The information in the modules helped me work towards my mental health goal(s)", wherein "strongly disagree" was rated a 1, and "strongly agree*"* was rated a 5. Eight (44.4%) participants responded with a score of 3, indicating a "neutral" response to the modules. Four (22.2%) participants found the modules "helpful", and 3 (16.6%) participants "strongly agreed" that the modules were helpful. One (0.06%) participant "disagreed" with the statement and two (11.1%) participants "strongly disagreed" with the statement.

The highest mean score of 4.89 (*SD*= 0.47) obtained on the acceptability questionnaire, was for the participants response to the statement "Overall, my experience with my therapist was…" with responses ranging from 1 (poor) to 5 (excellent). Seventeen (94.4%) participants indicated that they had an "excellent" experience with their therapist. The remaining participant had a "good" experience.

Lastly, the average score for the question "How likely are you to continue using the NexJ Connected Wellness platform over the next 6 months?" was 3.33 (*SD*= 1.33), with responses ranging from 1 (not very likely) to 5 (very likely). A wide range of responses were provided from the participants; 4 (22.2%) stated that they are "very likely" to use the platform in the next 6 months, and 2 (11.1%) indicated that they are "not very likely" to. The remaining 12

participants chose responses in the middle, with 5 (27.7%) participants scoring a 4, 4 (22.2%) participants scoring a 3, and 3 (16.6%) participants indicating a score of 2.

Table 3

Results from the NexJ My Program Experience Survey Post-Intervention

Satisfaction Metric	**M (*SD*)**
Overall program experience	4.67 (0.59)
Time spent on the program each week	3.83 (0.79)
Extent program met participant's needs	4.50 (0.92)
Platform ease of use	4.28 (1.02)
Module content	3.28 (1.18)
Therapist experience	4.89 (0.47)
Likelihood of platform use over the next 6 months	3.33 (1.33)

Note. Satisfaction scores ranged from 1-5.

4.4 Preliminary Effectiveness

H3a: *Preliminary effectiveness of the online intervention will be demonstrated by symptom reduction in the online CBT-M treatment group as indicated by quantitative outcomes assessed at baseline and post-intervention.*

H3b: *Participants in the CBT-M treatment group will reveal greater reductions in BDD, depression, anxiety and pain as demonstrated by between-group and within-group effect sizes.*

EQ1: *Is there a relationship between BDD and pain?*

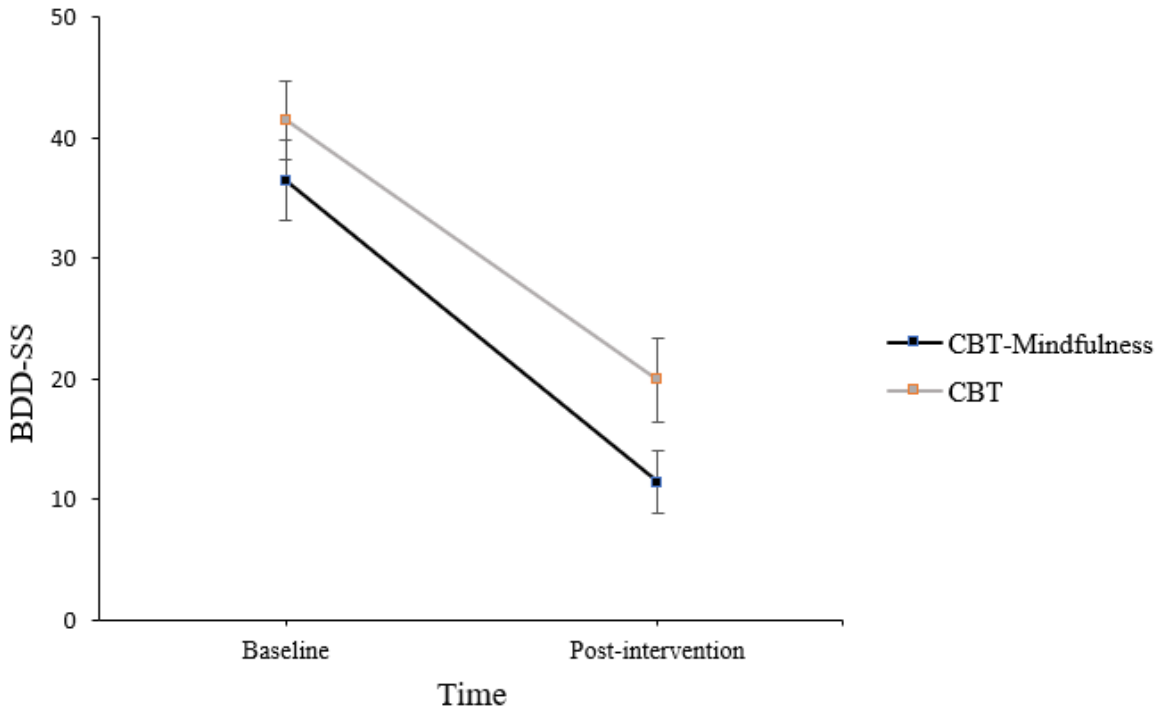
As shown in Table 2, independent samples t-tests and Fisher-Freeman-Halton Exact tests revealed no significant differences between groups on baseline measures for all outcomes and categorical variables. This suggests that randomization allocation resulted in reasonably equivalent treatment groups. In addition, the main analysis did not include covariates within the statistical model. Before testing hypothesis 3a and 3b, independent samples t-tests and Fisher-Freeman-Halton Exacts revealed that there were no significant differences at baseline in dropout patterns (those who stayed in vs dropped out): age (p= 0.84), gender (p= 0.84), education (p= 0.89), ethnicity (p= 0.25), marital status (p= 0.43), BDD-SS score (p= 0.82), PHQ-9 score (p= 0.55), GAD-7 score (p= 0.67), BPI (severity) score (p= 0.95), or BPI (interference) score (p= 0.84). As a result, missing post-intervention measurements (n= 10) were considered missing at random (MAR). Unstructured REML data (Table 4a), baseline BDD-SS adjusted analysis, and Cohen's *d* effect sizes for each psychometric outcome, along with correlation coefficients between BDD and pain are discussed below. Multiple Imputation data results (Table 4b) are comparable to the main REML analysis.

BDD-SS

LMM analysis revealed a statistically significant main effect for group, F(1, 25.63)= 5.12, p = 0.03, a statistically significant main effect for time F(1, 22.24)= 76.93, p= <0.001, but no significant group by time interaction, F(1, 22.24)= 0.24, p= 0.63. This indicates that there was no statistically significant difference in BDD-SS change between CBT-M and CBT-only groups from baseline to post-treatment. However, an overall 22.9 (95%CI: -28.42, -17.56) reduction in BDD-SS scores across both groups was observed. A between and within-groups evaluation of Cohen's d effect sizes indicated a between-group effect size at 8-weeks of d= -0.96, and within-group effect sizes of d= -2.41 for CBT-M, and d= -1.87 for CBT-only.

Figure 2

BDD-SS Change from Baseline to Post-Intervention



Note. The plot depicts the mean BDD-SS ratings at baseline and post-intervention. Error bars represent ±1 standard error.

PHQ-9

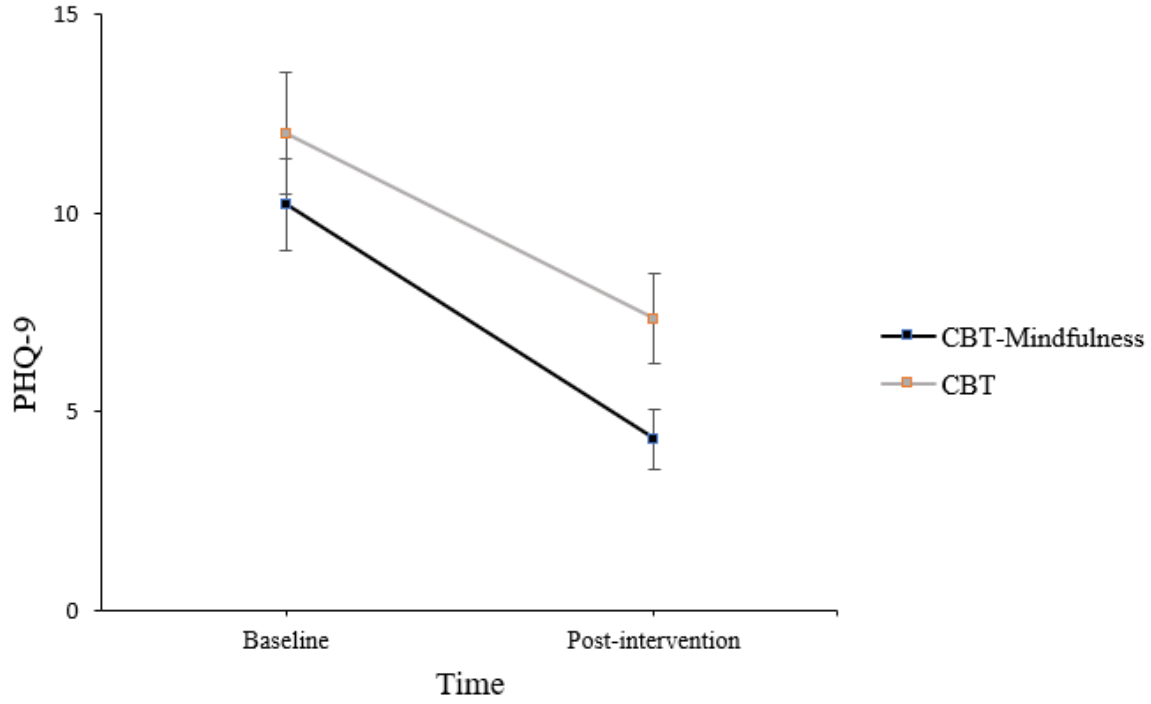
Results from LMM analysis revealed that participants in the CBT-M group did not differ from the CBT group in symptom reduction from baseline to 8-weeks on the PHQ-9 as indicated by a non-statistically significant group by time interaction, $F(1, 24.26)= 0.72$, $p= 0.40$. In addition, no statistically significant main effects were found for group $F(1, 26.42)= 2.52$, $p= 0.13$, however main effects for time did reveal statistical significance, $F(1, 24.26)= 32.79$, $p= <0.001$, indicating an overall 4.94 (95%CI: -6.72, -3.16) reduction across both groups. Considering a baseline mean difference of 6.14 in BDD-SS between groups, we further

conducted LMM adjusted for baseline BDD scores which provided comparable results to the main analysis, indicating a -4.96 PHQ-9 change from baseline to 8-weeks over both groups.

Cohen's d effect sizes revealed a between-group effect size of d= -1.06 at 8-weeks. The within-group effect size for CBT-Mindfulness was *d*= -1.61, and *d*= -0.91 for the CBT group.

Figure 3

PHQ-9 Change from Baseline to Post-Intervention



Note. The plot depicts the mean PHQ-9 ratings at baseline and post-intervention. Error bars represent ±1 standard error.

GAD-7

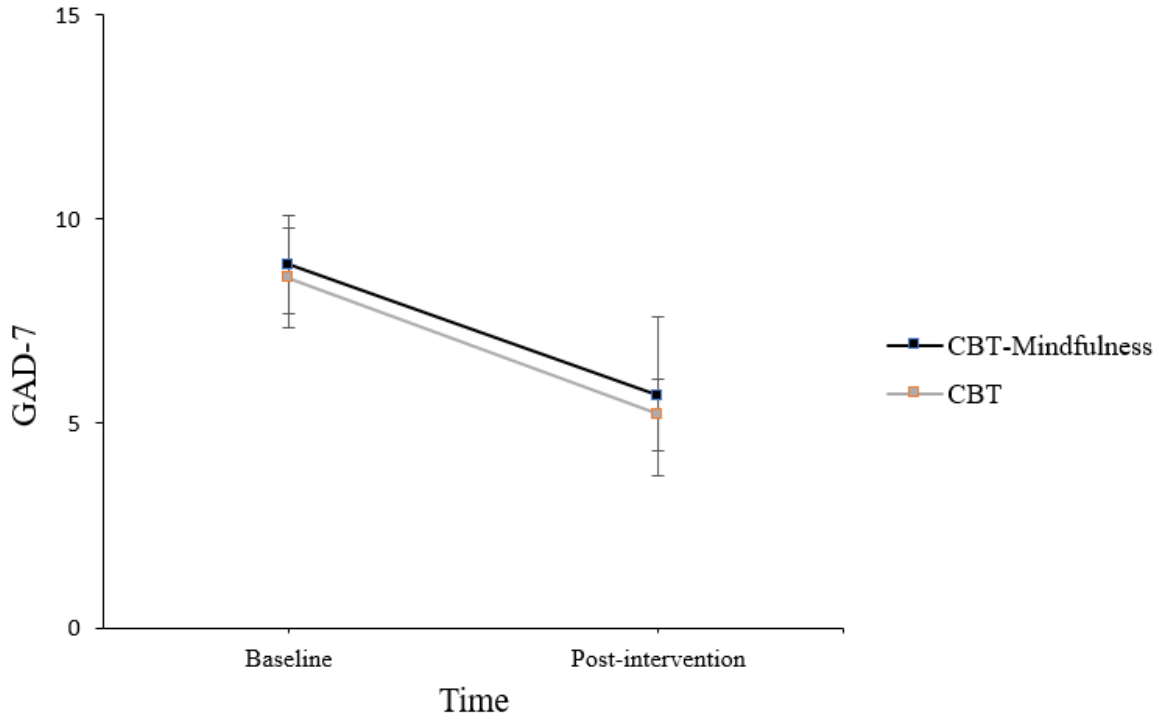
LMM main effects for group F(1, 23.64)= 0.001, *p*= 0.98, and the group by time interaction F(1, 19.53)= 0.05 *p*= 0.83 for GAD-7 scores were not statistically significant. However, a statistically significant main effect for time F(1, 19.53)= 7.11, *p*= 0.02 emerged,

indicating an overall 3.10 (95%CI: -5.52, -0.67) reduction across both groups. Further LMM analysis, adjusted for baseline BDD scores was conducted revealing a 3.11 (95%CI: -5.54, -0.67) change from baseline to 8-weeks over both groups, which is comparable to the main analysis.

The Cohen's d between-group effect size at 8-weeks was *d*= -0.11. The within-group effect size for the CBT-M group was *d*= -0.61, and for the CBT group was *d*= -0.87.

Figure 4

GAD-7 Change from Baseline to Post-Intervention



Note. The plot depicts the mean GAD-7 ratings at baseline and post-intervention. Error bars represent ±1 standard error.

BPI (Severity)

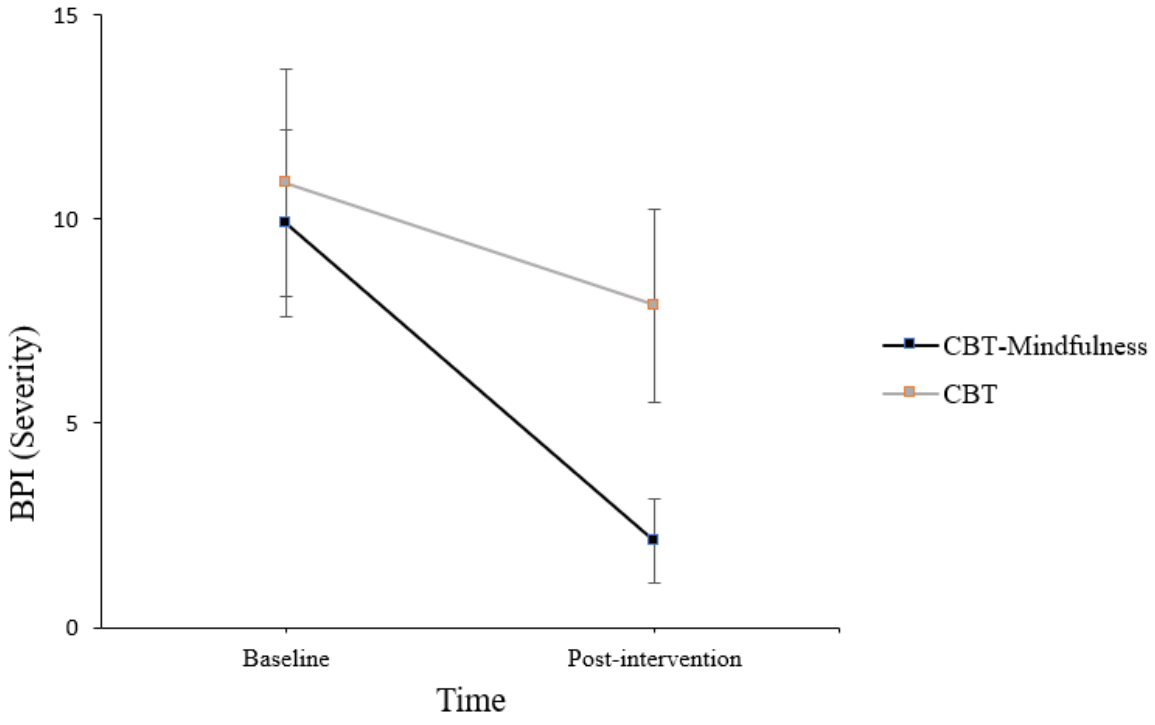
There was a weak, positive correlation between BDD-SS and BPI (severity) at baseline, r= 0.29, n= 28; however, the relationship was not statistically significant (p= 0.14).

LMM analysis revealed a statistically significant main effect for time F(1, 24.18)= 7.80, p= 0.01, revealing an overall 5.46 (95%CI: -9.49, -1.43) reduction in BPI severity scores across both groups. Main effects for group F(1, 25.26)= 1.76, p= 0.20 and the group by time interaction F(1, 24.18)= 1.87, p= 0.18 were not statistically significant. When adjusting for baseline BDD scores, a comparable change of 5.52 (95%CI: -9.52, -1.51) to the main analysis was revealed from baseline to 8-weeks across both groups.

Cohen's d effect sizes were calculated for between-group and within-group changes, revealing a between-group effect size at post-treatment of d= -1.12, and within-group effect sizes of d= -1.20 for CBT-Mindfulness, and d= -0.33 for CBT.

Figure 5

BPI (Severity) Change from Baseline to Post-Intervention



Note. The plot depicts the mean BPI (severity) ratings at baseline and post-intervention. Error bars represent ±1 standard error.

BPI (Interference)

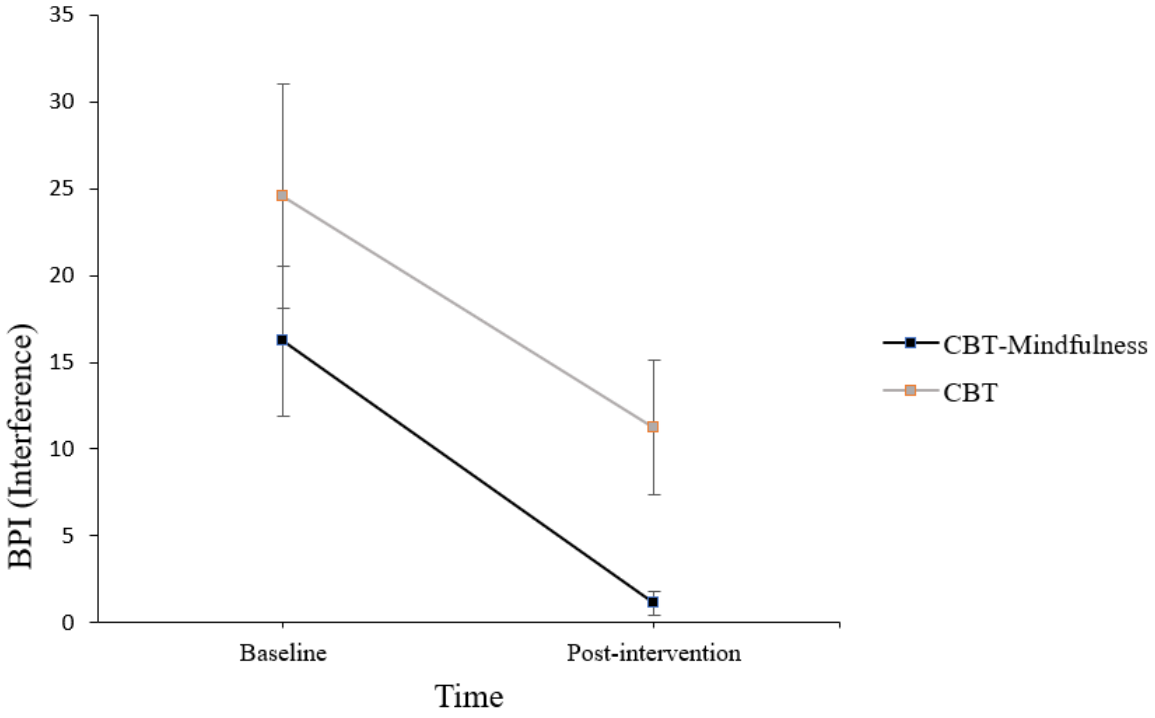
A statistically significant (p= 0.002), positive correlation was found between BDD-SS and BPI (interference) at baseline, r= 0.56, n= 28.

LMM revealed a non-statistically significant main effect for group F(1, 25.95)= 3.63, p= 0.07, and group by time interaction F(1, 25.42)= 0.08, p= 0.78 for pain interference; however, the main effect for time F(1, 25.42)= 15.04, p= 0.001 was statistically significant, indicating an overall reduction of 13.76 (95%CI: -21.06, -6.46) across both CBT-Mindfulness and CBT groups. After conducting LMM adjusted for baseline BDD scores, an overall reduction of 13.98 (95%CI: -22.41, -5.55) from baseline to 8-weeks across groups was found, which is comparable to the main analysis.

Cohen's d evaluation of effect sizes revealed a between-group effect size of d= -1.28 at post-intervention, and within-group effect sizes of d= -1.34 for CBT-Mindfulness, and d= -0.62 for CBT.

Figure 6

BPI (Interference) Change from Baseline to Post-Intervention



Note. The plot depicts the mean BPI (interference) ratings at baseline and post-intervention. Error bars represent ±1 standard error.

Table 4a.

Results from Linear Mixed Model (LMM) analysis for Changes in Outcomes - Baseline to 8-weeks Post-Intervention Between and Within Intervention Groups (Intention-to-treat using REML)

Outcomes	CBT-M[a]	CBT-only[a]	*d* (between-groups)	Group		Time		Group × Time	
				F	*P*	F	*P*	F	*P*
BDD-SS (Severity)									
Baseline	36.44(12.39)	41.44 (12.20)	-	5.12	0.03	76.93	<0.001	0.24	0.63
8-weeks	11.44 (7.84)	19.89 (10.61)	-0.96						
d (within-groups)	- 2.41	- 1.87							
PHQ-9									
Baseline	10.22 (4.30)	12.00 (5.79)	-	2.52	0.13	32.8	<0.001	0.72	0.40
8-weeks	4.44 (2.30)	7.33 (3.39)	-1.06						
d (within-groups)	-1.61	-0.91							
GAD-7									
Baseline	8.89 (4.54)	8.56 (4.59)	-	0.001	0.98	7.11	0.02	0.05	0.83
8-weeks	5.67 (5.83)	5.22 (2.64)	-0.11						
d (within-groups)	-0.61	-0.87							
BPI (Severity)									
Baseline	9.89 (8.54)	10.89 (10.40)	-	1.76	0.20	7.80	0.01	1.87	0.18
8-weeks	2.11 (3.10)	7.89 (7.08)	-1.12						
d (within-groups)	-1.20	-0.33							
BPI (Interference)									
Baseline	16.22 (16.45)	24.56 (24.21)	-	3.63	0.07	15.04	0.001	0.08	0.78
8-weeks	1.11 (2.03)	11.22 (11.64)	-1.28						
d (within-groups)	-1.34	-0.62							

Note. BDD-SS = Body Dysmorphic Disorder Symptom Scale; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7; BPI = Brief Pain Inventory; REML = Restricted Maximum Likelihood

[a] LMM analysis based on N=28 participants at baseline and N=18 participants at 8-weeks; Outcomes are presented as means and standard deviations

Table 4b.

Results from Linear Mixed Model (LMM) analysis for Changes in Outcomes - Baseline to 8-weeks Post-Intervention Between and Within Intervention Groups (Intention-to-treat using Multiple Imputation)

Outcomes	CBT-M[a]	CBT-only[a]	*d* (between -groups)	Group		Time		Group × Time	
				F	*P*	F	*P*	F	*P*
BDD-SS (severity)									
Baseline	35.50 (10.47)	41.64 (11.24)	-	4.37	0.05	106.62	<0.001	0.03	0.88
8-weeks	12.97 (6.53)	18.41 (8.58)	-0.74						
d (within-groups)	-2.59	-2.29							
PHQ-9									
Baseline	10.07 (3.67)	11.36 (5.44)	-	1.84	0.19	37.65	<0.001	0.19	0.73
8-weeks	4.92 (1.93)	6.75 (2.80)	-0.79						
d (within-groups)	-1.71	-0.97							
GAD-7									
Baseline	8.36 (4.34)	8.57 (4.13)	-	0.005	0.95	10.77	0.003	0.02	0.89
8-weeks	5.52 (4.60)	5.47 (2.12)	-0.01						
d (within-groups)	-0.63	-0.93							
BPI (Severity)									
Baseline	10.29 (8.79)	10.64 (9.18)	-	1.07	0.31	9.48	0.005	0.96	0.34
8-Weeks	3.11 (2.82)	6.94 (5.71)	-0.88						
d (within-groups)	-1.10	-0.48							
BPI (Interference)									
Baseline	15.79 (16.22)	23.88 (22.88)	-	2.76	0.11	15.37	0.001	0.05	0.83
8-weeks	2.80 (2.85)	9.34 (9.51)	-0.97						
d (within-groups)	-1.15	-0.74							

Note. BDD-SS = Body Dysmorphic Disorder Symptom Scale; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7; BPI = Brief Pain Inventory

[a]LMM analysis based on N=28 participants at baseline and N=28 participants at 8-weeks due to Multiple Imputation approach; Outcomes are presented as means and standard deviations

5. Discussion

The purpose of the current RCT was to develop and evaluate the feasibility, acceptability, and preliminary effectiveness of an online therapist-guided CBT-M intervention versus an online therapist-guided CBT alone comparison for BDD. Our main research objectives were as follows: (1) determine the feasibility of this intervention through participant accrual, adherence, and retention rates, (2) identify whether participants were satisfied with the intervention, and (3) ascertain the within and between-group effect sizes in self-reported psychometric outcomes (BDD-SS, PHQ-9, GAD-7, BPI), along with LMM results to determine if mindfulness meditation added to symptom severity improvement.

5.1 Intervention Feasibility

The current study collected data on participant accrual and retention, along with participant attendance to weekly therapist-guided calls to determine whether the CBT-M RCT could be feasibility implemented. Despite findings indicating that individuals with BDD may have low levels of insight (McCausland et al., 2021) and seek nonpsychiatric treatment at a staggering rate of 71% (Crerand et al., 2006), 28 participants were enrolled during a 5-month recruitment period (September 2022 to February 2023) indicating feasible recruitment. This challenges the notion that BDD sufferers may be difficult to recruit for psychological treatment studies, and further strengthens the identified need for accessible interventions (Harrison et al., 2016). In further support of our feasibility hypothesis, adherence to scheduled phone-based counselling calls were positive as all 18 (100%) study completers attended 8 calls. Although 10 participants had to reschedule either 1 or 2 calls for various reasons, eight (44.4%) participants maintained perfect attendance.

A retention rate of 64.3% was achieved as 18 participants completed the intervention suggesting that the RCT can be successfully implemented online. However, Gu et al. (2023) indicates that a 75% retention rate is consistent with feasibility for past BDD therapy treatment studies. When considering those who engaged in active participation (n= 22), 81.8% retention was achieved. As a result, the retention rates partially supported our hypothesis.

5.2 Intervention Acceptability

Participants appeared to be satisfied with participation given responses on the NexJ - My Program Experience survey. Most participants (72.2%) indicated that their overall program experience was excellent, and at minimum a good experience was achieved by all study completers. Moreover, quantitative findings indicate that most participants (72.2%) felt as though almost all of their needs were met, and participants found the NexJ Connected Wellness platform mostly easy to use with a mean score of 4.28 (*SD*= 1.02).

However, satisfaction ratings regarding module content were mixed, with 44.4% indicating a neutral response. Although 38.6% found the modules helpful, 16.6% did not. Despite high overall satisfaction ratings, mixed module ratings may be due to participant distress or perceived inconvenience surrounding an emphasis on homework in the CBT framework (Tang & Kreindler, 2017). Findings also indicate that individuals may be ambivalent about engaging in treatment tasks (Westra, 2004). This may lead to homework non-compliance, which remains an issue in CBT (Hupper & Baker-Morrissette, 2003).

Considerable attention must be placed on the participants' experience with their designated therapist. 94.4% of participants indicated that they had an excellent experience with their therapist, with one remaining participant indicating that they had a good experience.

Overall, responses on the NexJ – My Program Experience survey substantiate intervention acceptability with room for module content improvement.

5.3 Preliminary Effectiveness

Body Dysmorphic Disorder

Although no significant between-group differences from baseline to post-intervention were observed on the BDD-SS, a statistically significant reduction in symptom severity (-22.9) from baseline to post-intervention across groups was found. This supports our hypothesis that CBT-M treatment for BDD will demonstrate preliminary effectiveness.

Given the pilot sample size, emphasis was placed on the between-group effect sizes for the proposed hypothesis that CBT-M will be more effective than CBT. A between-group effect size of d= -0.96 at post-intervention revealed that mindfulness meditation may add to beneficial treatment outcomes for BDD. Mindfulness meditation introduces strategies to cultivate non-judgement (Keng et al., 2011) and self-compassion (Boellinghaus et al., 2014), which may allow for deeper examination of self-critical thoughts and engagement in behavioral activation, emphasizing the potential of CBT-M.

Very large within-group effect sizes were found for CBT-Mindfulness (d= -2.41), and CBT (d= -1.87). These findings parallel results from a smartphone-based CBT for BDD RCT, indicating a within-group effect size of d= -2.26 (95%CI: -2.93, -1.58) at 12-weeks (Wilhelm et al., 2022). The current study achieved comparable reductions in BDD after 8 weeks versus Wilhelm and colleague's (2022) 12-week intervention. In combination with an online approach, a shorter intervention may be more cost effective, cut wait lists, and reduce clinician or therapist time (Kavanagh et al., 2021) which is an important consideration as trained BDD clinicians and access to treatment are limited (Buhlmann, 2011).

Depression

While the BDD-SS results reflect BDD symptom severity reductions directly, additional scales indicated important co-morbid symptom reductions. Large within-group effect sizes for CBT (*d*= - 0.91) and CBT-Mindfulness (*d*= -1.61), along with a statistically significant time effect support our hypothesis that online CBT-M will reduce depression symptoms. Despite observing large effect sizes in both groups, CBT-M had a notably larger effect size. In addition, a large between-group effect size (*d*= -1.06) was found in the current study suggesting that mindfulness meditation in combination with CBT may add to reductions in BDD related depression. The effect size observed exceeds findings from 5 previous CBT for BDD RCTs in a previous meta-analysis (Harrison et al., 2016), which revealed a moderate overall effect size (*d*= -0.49, 95% CI: −0.76, −0.22) for depression symptoms. Given that BDD and MDD are highly comorbid and have longitudinal associations (Phillips et al., 2006), CBT-M's preliminary effectiveness for BDD related depression is encouraging.

Anxiety

LMM analysis and Cohen's *d* between-group effect size (*d*= -0.11) for anxiety revealed that treatment effects did not statistically differ between groups, rejecting our hypothesis that mindfulness meditation combined with CBT will be more effective than CBT alone. Although significant symptom severity improvement was observed after 8-weeks on GAD-7 scores in both groups, only a moderate CBT-M within-group effect size was found (*d*= -0.61). These findings are comparable to GAD-7 within-group effect sizes observed in a 16-week CBT for BDD RCT, *d*= 0.65 (Veale et al., 2014). Researchers conclude that comorbid anxiety may be more amenable to combined SSRI and CBT treatment (Hollander et al.,1999).

Pain

With limited insight into whether pain and BDD are associated, the BPI was employed as a measure to explore the presence of pain interference and pain severity. As increased risk of self-injurious behaviors including excessive exercise, restrictive eating, skin-picking, cosmetic surgery, self-surgery, suicide attempts, alcohol/drug dependency and steroid abuse (Phillips, 2005; Pope et al., 2005) are prevalent, Pearson's correlation coefficient was computed to assess the relationship between BDD and pain. Interestingly, a statistically significant, positive correlation was found between BDD and pain interference; however, only a weak positive correlation was found between BDD and pain severity. Although pain exploration appears to be a notable gap in BDD research, there is some evidence that there may be associations between body image dissatisfaction and pain in eating disorder populations. Specifically, Yamamotova et al. (2022) found that body dissatisfaction may induce a greater sensitivity to bodily pain. As body dissatisfaction is a cornerstone for BDD diagnosis, this research supports our preliminary insights. Moreover, in another study, when healthy individuals were confronted with distorted images of their own body, pain perception increased (Osumi et al., 2014).

This prompts us to our supported hypothesis that online delivered CBT-M for BDD can reduce pain interference and pain severity scores as demonstrated by statistically significant time effects. Although LMM did not reveal between group significance, large between-group effect sizes for pain interference (d= -1.28), and pain severity (d= -1.12) were found. The within-group effect sizes for pain severity greatly differed between treatment groups, noting a large effect (d= -1.20) for CBT-M and small effect (d= -0.33) for CBT. Moreover, within-group effect sizes notably differed for pain interference (CBT-M: d= -1.34, CBT: d= -0.62). Large effect sizes observed in the CBT-M group for both pain severity and interference may be due to better chronic pain management (Hilton et al., 2017) obtained through mindfulness meditation practice.

5.4 Limitations

Several limitations must be considered when interpreting the current study's findings. Given the pilot nature of this RCT, the sample size was small limiting our capacity to test for significance between treatment groups. In addition, the BDDQ screening tool was used for BDD inclusion diagnosis rather than the Structured Clinical Interview for DSM-5 (SCID) administered by a clinical psychologist. This may have resulted in an unrepresentative sample.

Due to resource limitations, the student undertaking this thesis was responsible for study procedures including randomization, enrollment, and allocation, and contributed as one of three intervenors. Although frequent consultation and review with the study clinical psychologist was undertaken at each step, this eliminated the possibility of blinding and introduced potential experimenter biases.

Although CBT-M module content and therapist-guided calls emphasized mindfulness meditation, data pertaining to participants historical meditation practice (Bowles et al., 2022) and active practice time throughout the 8-week intervention were not gathered. This limits our understanding of the dose-response relationship. Moreover, future CBT-M studies must consider including a mindfulness measure such as the Five Facet Mindfulness Questionnaire (FFMQ) to establish potential mechanisms of change for BDD.

Despite the novelty of pain exploration in BDD research, qualitative information was not obtained to determine whether the pain identified was specific to BDD symptoms (i.e., skin-picking, excessive exercise) or body areas of concern. Further research should include a thorough pain assessment along with a qualitative interview examining pain experiences.

5.5 Conclusion

In this pilot RCT, two 8-week online interventions were compared in the treatment of Body Dysmorphic Disorder. Both interventions employed therapist-guided CBT; however, one intervention combined CBT with mindfulness meditation approaches. Given the high accrual rate and adherence rate, moderate retention rate and overall participant program satisfaction, this RCT was acceptable and feasible to implement online. Preliminary effectiveness was demonstrated for both active treatment groups, with suggestions that mindfulness meditation could add to CBT treatment effects for BDD and comorbid symptoms. In addition, a relationship between BDD and pain may be present which requires further exploration. Given that individuals with BDD may be housebound, and have high rates of suicidal ideation and depression, prompt access to effective treatment is imperative. This pilot trial provides promising insight into BDD, and short-term online accessible treatment for sufferers.

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Appendices

Appendix A

Body Dysmorphic Disorder Questionnaire (BDDQ)

This questionnaire asks about concerns with physical appearance. Please read each question carefully and answer what is true for you.

Are you worried about how you look?	Yes	No
If yes, do you think about your appearance problems a lot and wish you could think about them less?	Yes	No
NOTE: If you answered "No" to either of the above questions, you are finished with the questionnaire. Otherwise please continue.		
Is your main concern with how you look that you aren't thin enough or that you might get too fat?	Yes	No
How has this problem affected your life?		
Has it often upset you a lot?	Yes	No
Has it often gotten in the way of doing things with friends, dating, your relationships with people, or your social activities?	Yes	No
Has it caused you any problems with school, work, or other activities?	Yes	No
Are there things you avoid because of how you look?	Yes	No

Appendix B

Body Dysmorphic Disorder Symptom Scale (BDD-SS)

Each box below contains several thoughts or behaviors you may have experienced recently. Please check for each symptom in each box whether you have had it in the past week. Then rate the combined severity of all symptoms in one box on the scale on the right of each box. Severity refers to the average amount of frequency and distress that have occurred during the past week.

EXAMPLE:

Yes No	If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale:
☐ ☑ Visiting plastic surgeons, dermatologists or dentists to improve appearance. ☐ ☑ Obtaining cosmetic surgery. ☑ ☐ Using medications or topical treatments to correct defects (e.g., skin, baldness). ☑ ☐ Applying self-surgery.	0 1 2 3 4 5 6 7 8 9 10 no problem — moderately severe (frequency & distress) — very severe (frequency & distress)

Please look at the example above. This person indicated using medications or topical treatments to correct defects and applying self-surgery by checking 'yes' for those symptoms. Then the severity of the two symptoms was rated combined as “very severe” (referring to frequency and distress) by marking 10 on the rating scale.

Yes	No		
☐	☐	Checking or inspecting certain parts of my body.	If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale: 0 1 2 3 4 5 6 7 8 9 10 no problem — moderately severe (frequency & distress) — very severe (frequency & distress)
☐	☐	Measuring or counting body part.	
☐	☐	Touching or feeling body part.	
☐	☐	Asking questions about my appearance over and over again, even though I understood the answer the first time.	
☐	☐	Mentally reviewing past events, conversations, and actions to find out how people reacted to my appearance.	
☐	☐	Checking mirrors repeatedly.	
☐	☐	Comparing my appearance to others' appearance (in person, in pictures or in the media).	
☐	☐	Scrutinizing others.	

Yes	No		
☐	☐	Grooming myself longer than necessary.	If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale: 0 1 2 3 4 5 6 7 8 9 10 no problem — moderately severe (frequency & distress) — very severe (frequency & distress)
☐	☐	Spending a lot of money to improve my appearance.	
☐	☐	Tanning.	
☐	☐	Combing hair.	
☐	☐	Applying makeup.	
☐	☐	Shaving.	
☐	☐	Changing clothes.	

Yes	No		
☐	☐	Lifting weights.	If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale: 0 1 2 3 4 5 6 7 8 9 10 no problem — moderately severe (frequency & distress) — very severe (frequency & distress)
☐	☐	Using steroids.	
☐	☐	Exercising excessively.	
☐	☐	Eating in special ways.	

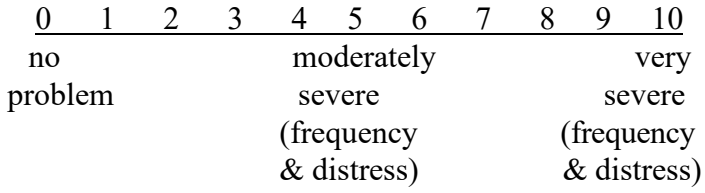
Yes	No		
☐	☐	Skin picking.	If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale: 0 1 2 3 4 5 6 7 8 9 10 no problem — moderately severe (frequency & distress) — very severe (frequency & distress)
☐	☐	Pulling or plucking hair.	

Yes	No		
☐	☐	Avoiding mirrors or reflective surfaces.	If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale: 0 1 2 3 4 5 6 7 8 9 10 no problem — moderately severe (frequency & distress) — very severe (frequency & distress)
☐	☐	Avoiding social situations where family, friends, acquaintances, co-workers are present (work, parties, family gatherings, meetings, talking in small groups, having a conversation, dating, speaking to boss or supervisor).	
☐	☐	Avoiding public areas (shopping, stores, busy streets, restaurants, movies, buses, trains, parks, waiting in lines, public restrooms).	
☐	☐	Avoiding intimate or close physical contact with others (sexual activity, hugging, kissing, dancing, talking closely).	
☐	☐	Avoiding physical activities like exercise or recreation because of concern about appearance.	
☐	☐	Avoiding being seen nude or with few clothes.	
☐	☐	Hiding appearance (with make-up, clothing, hairstyle, jewelry, hats, hands, or body position).	
☐	☐	Changing appearance (getting a haircut).	
☐	☐	Discounting compliments	
☐	☐	Becoming upset by compliments.	

Yes	No		
☐	☐	Visiting plastic surgeons, dermatologists or dentists to improve appearance.	If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale: 0 1 2 3 4 5 6 7 8 9 10 no problem — moderately severe (frequency & distress) — very severe (frequency & distress)
☐	☐	Obtaining cosmetic surgery.	
☐	☐	Using medications or topical treatments to correct defects (e.g., skin, baldness).	
☐	☐	Applying self-surgery.	

Yes	No	
☐	☐	I believe others are thinking of my appearance.
☐	☐	The first thing people notice about me is what's wrong with my appearance.
☐	☐	I think that others are staring at or talking about me.
☐	☐	I believe others treat me differently because of my physical defects.
☐	☐	If my appearance is defective, I am worthless.
☐	☐	If my appearance is defective, I will end up alone and isolated.
☐	☐	If my appearance is defective, I am helpless.
☐	☐	No one can like me as long as I look the way I do.
☐	☐	If my appearance is defective, I am unlovable.
☐	☐	I must look perfect.
☐	☐	I look defective or abnormal.
☐	☐	I am an unattractive person.
☐	☐	What I look like is an important part of who I am.
☐	☐	Outward appearance is a sign of the inner person.
☐	☐	No one else my age looks as bad as I do.
☐	☐	If I could look just the way I wish, I would be much happier.
☐	☐	People would like me less if they knew what I really looked like.
☐	☐	My appearance is more important than my personality, intelligence, values, skills, how I relate to others, and my performance at work or in other settings.
☐	☐	If I learn to accept myself, I'll lose my motivation to look better.

If you checked 'yes' for any symptoms in the box on the left, please mark the overall severity of these symptoms during the past week on the following scale:



Appendix C

Patient Health Questionnaire (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite orovereating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

Appendix D

Generalized Anxiety Disorder (GAD-7)

Over the last two weeks how often have you been bothered by any of the following problems?	**Not at all** (0)	**Several days** (1)	**More than half the days** (2)	**Nearly every day** (3)
a. Feeling nervous, anxious or on edge	☐	☐	☐	☐
b. Not being able to stop or control worrying	☐	☐	☐	☐
c. Worrying too much about different things	☐	☐	☐	☐
d. Trouble relaxing	☐	☐	☐	☐
e. Being so restless that is hard to sit still.	☐	☐	☐	☐
f. Becoming easily annoyed or irritable	☐	☐	☐	☐
g. Feeling afraid as if something awful might happen	☐	☐	☐	☐

Appendix E

Brief Pain Inventory (BPI)

1. Please rate your pain by indicating the number that best describes your pain at its worst in the last 24 hours. (0 = no pain, 10 = pain as bad as you can imagine).

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

2. Please rate your pain by indicating the number that best describes your pain at its least in the last 24 hours. (0 = no pain, 10 = pain as bad as you can imagine).

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

3. Please rate your pain by indicating the number that best describes your pain on average in the last 24 hours. (0 = no pain, 10 = pain as bad as you can imagine).

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

4. Please rate your pain by indicating the number that tells how much pain you have right now. (0 = no pain, 10 = pain as bad as you can imagine).

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Please indicate the number that describes how, during the past 24 hour, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10

B. Mood

0	1	2	3	4	5	6	7	8	9	10

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10

D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10

F. Sleep

0	1	2	3	4	5	6	7	8	9	10

G. Enjoyment in life

0	1	2	3	4	5	6	7	8	9	10