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Pilot Study of Single-Dose Psilocybin for Serotonin Reuptake Inhibitor-Resistant Body Dysmorphic Disorder

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Abstract

Objective: Body dysmorphic disorder (BDD) is an often-severe condition in which individuals are preoccupied by misperceptions of their appearance as defective or ugly. Only serotonin reuptake inhibitors and cognitive-behavioral therapy have been demonstrated efficacious in randomized controlled trials. Psilocybin is a psychedelic drug with growing evidence for safety and efficacy in treatment of depression. This study aimed to pilot test the feasibility, tolerability, safety, and efficacy of psilocybin treatment of adults with BDD.

Methods: In this open-label trial, 12 adults (8 women, 4 men) with moderate-to-severe non-delusional BDD that had been unresponsive to at least one serotonin reuptake inhibitor trial received a single oral dose of psilocybin 25mg. There was no control group. Psychological support was provided before, during, and after the dosing session. The primary outcome measure for efficacy was the Yale-Brown Obsessive Compulsive Disorder Scale Modified for BDD (BDD-YBOCS) score during 12 weeks of assessments after dosing.

Results: All participants completed dosing and all follow-up assessments. BDD-YBOCS scores decreased significantly over 12 weeks of follow-up ($p<0.001$) with a large effect size (partial eta squared =.54), and significant changes from baseline were present at week 1 and persisted through week 12. Secondary efficacy measures of BDD symptoms, conviction of belief, negative affect, and disability also improved significantly, and no serious adverse events occurred. At week 12, seven participants (58%) were rated responders, based on ≥30% decrease in BDD-YBOCS.

Conclusion: This study provides promising preliminary support for psilocybin as a treatment of BDD, warranting future controlled studies.

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Keywords

Body dysmorphic disorder; psilocybin; hallucinogen; clinical trial

Introduction

Individuals with body dysmorphic disorder (BDD) are preoccupied by aspects of their appearance that they misperceive as defective or ugly. Prevalence in the general population is 1.7–2.9% (Koran et al. 2008; Rief et al. 2006). Persons with BDD often experience obsessive thoughts and compulsive behaviors, anxiety, social withdrawal, and depression, with a high rate of suicide attempts (Angelakis et al. 2016). Only selective serotonin reuptake inhibitors or clomipramine, and disorder-specific cognitive-behavioral therapy have shown efficacy in randomized controlled trials (RCTs) (reviewed in Castle et al. 2021). There is a great need for novel treatments.

Psilocybin is a psychedelic drug acting as a partial agonist at 5-HT_{2A} and 5-HT_{1A} receptors, with growing evidence for efficacy in depression from several RCTs (Carhart-Harris et al. 2021, Davis et al. 2021, Goodwin et al. 2022), and preliminary evidence for efficacy in obsessive compulsive disorder (Moreno et al. 2006) and substance dependence (Johnson et al. 2014; Bogenschutz et al. 2022). Additionally, a single case report described a patient with BDD, who after taking unsupervised psilocybin perceived his appearance to have improved and then doubted whether he in fact had a “deformity” (Hanes, 1996). The tendency of psilocybin to relax rigid thinking patterns and alter bodily self-awareness and has led to suggestions that it may be particularly helpful for disorders involving rigid and distorted bodily perceptions, such as BDD (Ho, Preller, and Lenggenhager 2019; Ledwos et al. 2022).

This study aimed to pilot test the feasibility, efficacy, safety, and tolerability of psilocybin in the treatment of patients with BDD with previous nonresponse to serotonin reuptake inhibitor (SRI) treatment.

Material and Methods

This was an open-label study in 12 adults with BDD. Participants, investigators, raters, and statisticians were not masked to treatment assignment.

Participants:

Participants were recruited between 3/2021 and 4/2022 through notices on social media and research study websites. After telephone screening, a study psychiatrist determined eligibility based on a comprehensive psychiatric assessment interview and structured diagnostic interviews with the BDD module of the Structured Clinical Interview for DSM-5 (First et al. 2015) and the Mini-International Neuropsychiatric Interview (MINI) 7.0.2 (Sheehan et al. 1998), rating scales described below, and physical examination including blood tests, urinalysis, urine toxicology screen, urine pregnancy test for females, and electrocardiogram.

Inclusion criteria were age 18–55; principal diagnosis of non-delusional DSM-5 BDD for >6 months with at least moderate severity (total score ≥24 on the Yale Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS, Phillips et al. 1997) and score ≥4 on the Clinical Global Impression Severity Scale (Guy 1976)), and history of nonresponse to (or intolerance of) a prior trial of an SRI, serotonin-norepinephrine reuptake inhibitor, or clomipramine, at dose equivalent to ≥ 20 mg/day fluoxetine for ≥2 months. Absence of delusionality was operationalized by a 6-item total score of ≤18 on the Brown Assessment of Beliefs Scale (BABS) (Eisen et al. 1998).

Exclusion criteria included current major depressive disorder of greater than moderate severity (17-item Hamilton Rating Scale for Depression score >20, HRSD) (Hamilton 1960); current significant suicidality or attempt in the past year; current or past bipolar disorder, psychotic disorder, borderline personality disorder, or dissociative disorder; alcohol or drug use disorder in the past 3 months, or positive urine drug screen for illicit substances of abuse; significant cognitive impairment; use of investigational medication within 3 months, depot antipsychotic within 6 months, or serotonergic medication within 2 weeks (6 weeks for fluoxetine); presence of significant medical illness; history of seizure disorder; and females who were pregnant, breastfeeding, or sexually active and not using adequate contraception. Current cognitive-behavioral therapy (CBT) was exclusionary, but participants were required to be seeing a psychotherapist with whom they could continue non-CBT psychotherapy after dosing, to further support integration of their psilocybin experience (beyond the psychological support provided within the study).

The investigation was conducted in accordance with the latest version of the Declaration of Helsinki, the study design was reviewed and approved by the NY State Psychiatric Institute Institutional Review Board, and participants' informed consent was obtained after study procedures had been fully explained. Participants received monetary compensation for time completing study assessments.

Treatment Procedures:

Participants met with two psychotherapists trained in manualized supportive procedures developed for psilocybin depression studies (Tai et al. 2021), for 4 weekly preparatory sessions. These sessions included psychoeducation about psilocybin effects and training in relaxation techniques.

Study drug was administered orally at 9AM as five 5 mg capsules of COMP360 psilocybin, COMPASS Pathways' proprietary synthetic formulation. The 25mg dose was selected based upon prior findings of efficacy and tolerability for depression (Carhart-Harris et al. 2016).

Dosing sessions lasted 7–8 hours in a room designed for psychedelic drug administration, with psychological support from the same two psychedelic therapists. Participants were given eyeshades and listened to music designed to help direct attention internally and engage with the psychedelic experience. After at least 7 hours, a psychiatrist assessed participants for safety and discharge accompanied by a companion or staff member. The psychotherapists also met with the participant at one day and one-week post-dosing for debriefing and to support processing of the experience.

Assessments:

Participants were assessed at baseline (1 day before dosing), the end of the dosing day (day 0), day 1, and 1, 2, 3, 6, 9, and 12 weeks post-dosing. Secondary assessments were conducted at a subset of these visits (see Table 2). Clinician assessments were conducted by a single study psychiatrist (FS) in person at baseline, day 0, day 1, and week 3, and by phone at other assessment points. Vital signs were taken just prior to dosing and 8 hours later. Screening laboratory tests and EKG were repeated at week 3.

The primary efficacy measure was BDD symptom severity, as measured by the BDD-YBOCS, a clinician-rated scale (total score range: 0–48, with higher scores indicating greater severity). Response to treatment has been defined and validated as ≥ 30% decrease in total score, and partial-to-full remission as total score ≤16 (Fernandez de la Cruz et al. 2019).

Secondary clinician-rated efficacy measures included the Clinical Global Impression (CGI) Change scale (Guy 1976), rated on a 7-point scale from 1 (very much improved) to 7 (very much worse), the 17-item HRSD (Hamilton 1960) for depression (total score range 0–52, higher scores indicating greater depression), and the BABS for strength of conviction in appearance beliefs (total score range: 0–24, higher scores indicating poorer insight).

Secondary self-report outcome measures included the Dysmorphic Concerns Questionnaire (DCQ)(Oosthuizen et al. 1998) (total score range: 0–21, higher scores indicating greater severity of BDD symptoms); the Positive and Negative Affect Scale (PANAS) (Watson et al. 1998) (total score range: 10–50 for positive and negative affect subscales, higher scores indicating greater intensity); the Sheehan Disability Scale (range: 0–10 for each item – Work/School, Social, Home/Family, higher scores indicating greater impairment); and the Psychological Insight Scale (Peill et al. 2022) (6-item total PIS-6 score range 0–100, higher scores indicating greater increase in insight since the psychedelic experience, and an additional single item PIS-7 item score range 0–100, higher scores indicating greater behavioral change associated with insight).

Safety was assessed with the clinician-administered Columbia Suicide Severity Rating Scale (C-SSRS, Posner et al. 2011), vital signs, clinical laboratory tests, and adverse events reported at each visit in response to open-ended query. Transient non-serious psychological experiences during the dosing session were not recorded as adverse events unless they remained present at the assessment done 8 hours after dosing.

Additional measures of the psychedelic experience and exploratory outcome measures are described in the Supplemental Files. Resting state fMRI was conducted 1 day prior to administration and 1 day after, and these results will be reported separately.

Statistical Analyses:

For outcome measures, repeated measures ANOVAs with Greenhouse-Geiser corrections were conducted across time points from baseline to week 12 using SPSS Version 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp), with post

hoc pairwise Bonferroni-corrected comparisons. For the HRSD a paired samples *t*-test was performed to compare baseline to week 12 scores.

Results

Sample:

198 inquiries led to 37 psychiatric assessments, yielding 12 eligible participants (Figure 1). Clinical and demographic features are displayed in Table 1. Comorbid psychiatric disorders included major depressive disorder (n=4), attention deficit hyperactivity disorder (n=2), posttraumatic stress disorder (n=1), and generalized anxiety disorder (n=1). Two participants entered the study taking concomitant psychiatric medications (lisdexamfetamine n=1, amphetamine/dextroamphetamine, n=1). Participants' primary area of concern involved face/nose/ears (n=6), hair/head (n=3), abdomen (n=2), or legs (n=1).

During the 12 weeks of follow-up, two participants discontinued their non-study psychotherapy rather than following through with the plan to continue it. At 4 weeks post-dosing, one participant reported starting SRI treatment due to distress from increased social stressors. For categorical outcome analyses this participant was designated a non-responder at timepoints after week 4.

Efficacy:

All participants completed visits for all assessment points of the study, yielding complete data for all outcome efficacy measures.

Severity of BDD, as assessed by the BDD-YBOCS, changed significantly across 12 weeks ($F(1.92, 21.13) = 13.08$, $p < 0.001$) with a large effect size (partial eta squared = .54). Post hoc pairwise testing revealed that BDD-YBOCS scores were significantly lower ($p < .05$) than baseline at each timepoint, except for trend-level at week 9 ($p = .059$). There was no significant difference in BDD-YBOCS total scores between any two timepoints from week 1 to week 12 (Table 2 and Figure 2). At week 12 mean difference from baseline was −13.33 (95% CI −3.43 to −23.23). A sensitivity analysis carrying forward week 3 YBOCS scores for the participant who started SRI treatment at week 4 did not change significance of the above findings.

At week 12, the response rate was 7 (58.33%) of 12, whether based on ≥30% decrease in BDD-YBOCS or on CGI-change score of 1 (very much improved) or 2 (much improved) (Figure 3). Seven participants had ≥ 30% decrease in BDD-YBOCS sustained at every follow-up assessment, 4 of whom had a sustained remission with BDD-YBOCS total ≤ 16 at every follow-up assessment. Secondary measures of BDD symptoms, conviction of belief, negative affect (but not positive affect), and disability also improved significantly over 12 weeks of assessments (Table 2).

No serious adverse events or suicidal ideation occurred, and there were no significant changes in laboratory values or vital signs (See Supplemental Files). Eleven participants reported the following mild adverse events that began and resolved within two days after dosing: fatigue (n=5), headache (n=3), nausea (n=2), somnolence (n=1), lightheadedness

(n=1), insomnia (n=1), and spaciness (n=1). Other adverse events reported during the 12 weeks of follow-up were mild episodes of COVID-19 (n=1) and pneumonia (n=1).

Additionally, one participant reported several adverse events that were possibly drug-related and occurred or persisted beyond the first week after dosing: Low libido that began in the first week and persisted for 2 weeks, brief episodes of emotion and mood disturbance (e.g., tearfulness, sadness) that occurred in the 2nd and 3rd weeks after dosing, and four episodes of visual hallucinations (two each occurred in the 3rd and 7th weeks after dosing. The visual hallucinations consisted of 5- to 45-minute episodes of seeing smoke or seeing a sidewalk crack appear to be moving. The participant was aware that these perceptions were not real and reported being only mildly disturbed by them.

Discussion

Findings of this small open trial support the feasibility, tolerability, safety, and efficacy of a single dose of psilocybin administered with psychological support for the treatment of BDD that had previously been unresponsive to an SRI trial.

Feasibility was shown by successful recruitment and conduct of this trial despite restrictive entry criteria limiting enrollment to participants with non-delusional BDD, a prior ineffective SRI trial but no current SRI treatment, and willingness to continue naturalistic psychotherapy after the dosing. Tolerability and safety were evidenced by completion of all study visits by all participants, and absence of persistent or serious adverse events.

Efficacy was robust across 12 weeks of follow-up, as evidenced by significant improvement in the primary efficacy measure, the BDD-YBOCS, that persisted throughout the study, with symptom severity at all time points except week 9 remaining significantly improved from baseline. Secondary measures of BDD symptom severity, conviction of beliefs, depression, positive and negative affect, psychological insight, and disability all similarly showed significant improvement. While the significant reduction in BABS scores suggests that increased insight contributed to overall improvement, some of the participants who improved reported anecdotally that their appearance-related beliefs changed little but that they were less distressed by these beliefs.

The week 12 response rate of 58.33%, whether based upon the previously validated cut-off of 30% improvement in BDD-YBOCS or by a rating of at least much improved on the CGI, was slightly below the 70–80% response rates reported in uncontrolled trials of SRIs for BDD (Castle et al. 2021). There are no comparable figures in the literature for a sample with prior nonresponse to an SRI trial.

Findings of a robust and persistent response to a single dose of psilocybin is consistent with some studies in other disorders finding persistent benefits after one or two doses of psilocybin, including abstinence from tobacco (Johnson et al. 2014), reduction in drinking among alcohol-dependent participants (Bogenschutz et al. 2022), and reduced anxiety and depression in participants with cancer-related anxiety and depression. (Carhart-Harris et al. 2018)

Notably, the strong therapeutic effects seen here occurred in a sample of patients whose BDD had not responded to at least one prior trial of an SRI medication and who had remained symptomatic despite prior psychotherapy as well, suggesting a potential role for psilocybin in treatment-refractory BDD. However, while all participants had some level of documented treatment resistance, most had not experienced a full course of >12 weeks of SRI treatment at maximum approved dose, as currently recommended in some BDD treatment guidelines (Castle et al. 2021), nor a full course of BDD-specific cognitive behavioral therapy.

Several major limitations apply to this study. First, given the uncontrolled design, clinical improvement may have been driven by nonspecific effects, including high expectancy for this novel treatment that has received much positive attention in the popular press. The sample was small and of limited socioeconomic diversity. The concomitant naturalistic psychotherapy may also have contributed to efficacy. In regard to safety, we did not systematically assess non-serious adverse experiences during the dosing itself, unless the experience remained present at the end of the dosing day. Additionally, the occurrence of sporadic brief visual hallucinations until week 7 in one participant, though only mildly distressing in this case, suggests potential for hallucinogen persisting perception disorder to emerge in vulnerable individuals, as has been reported in recreational users of hallucinogens. Furthermore, it suggests that careful screening of participants and provision of psychological support in addition to psilocybin, as was included here along with ongoing psychotherapy, may be important for minimizing risk of developing such complications.

In conclusion, this preliminary study suggests that psilocybin 25mg with psychological support may be well-tolerated, safe, and efficacious in persons with BDD. Given that the sample had not responded to a prior trial of SRI medication, psilocybin might have a particular role in the management of treatment-resistant BDD. The robust clinical improvement observed in this study suggests the value of further examination under controlled conditions and with longer follow-up assessments to determine whether psilocybin has efficacy in the treatment of BDD.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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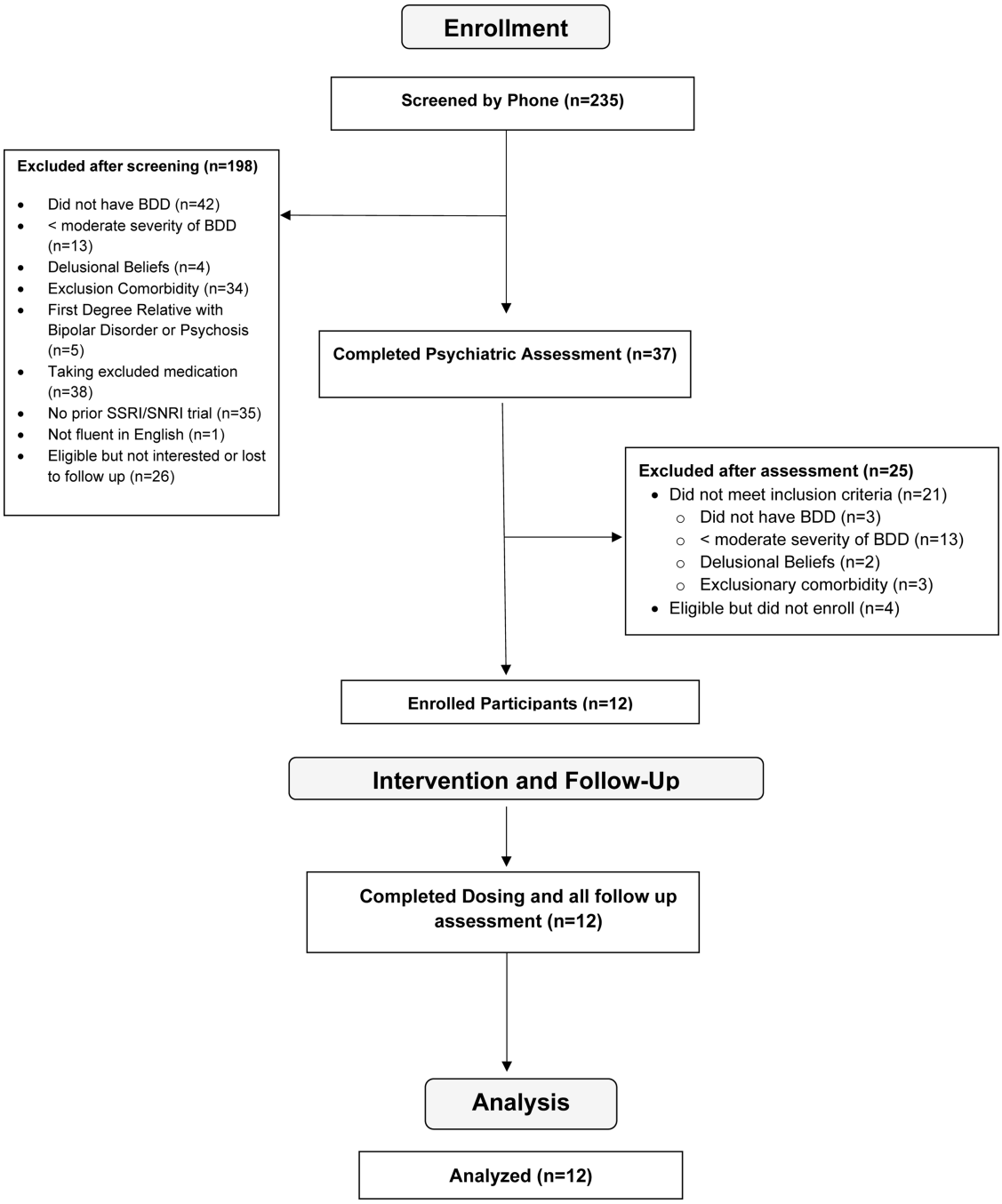

Figure 1.
Consort Diagram

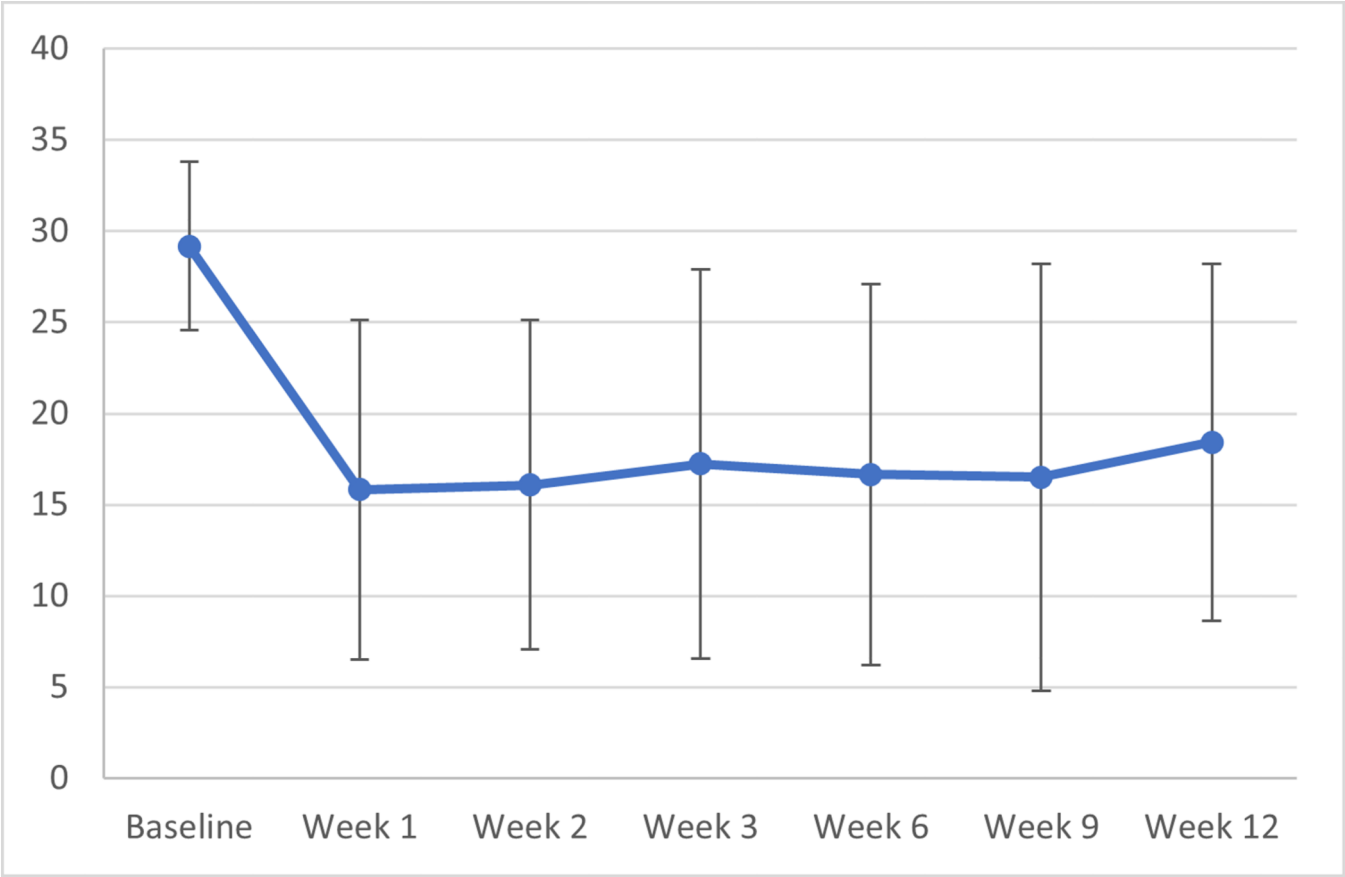

Figure 2.
BDD-YBOCS mean (SD) total scores by week

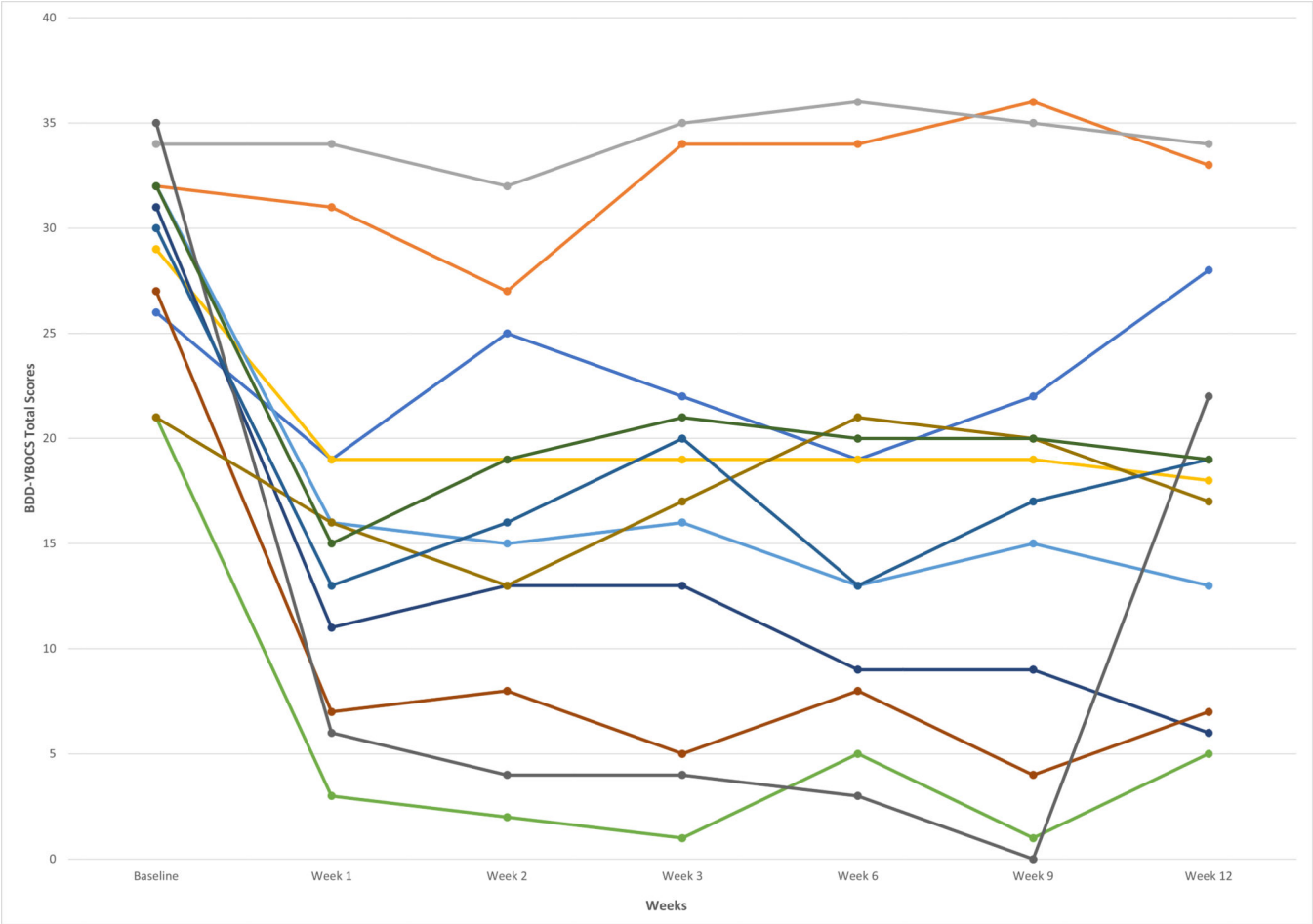

Figure 3.
BDD-YBOCS Total Score of each participant by week

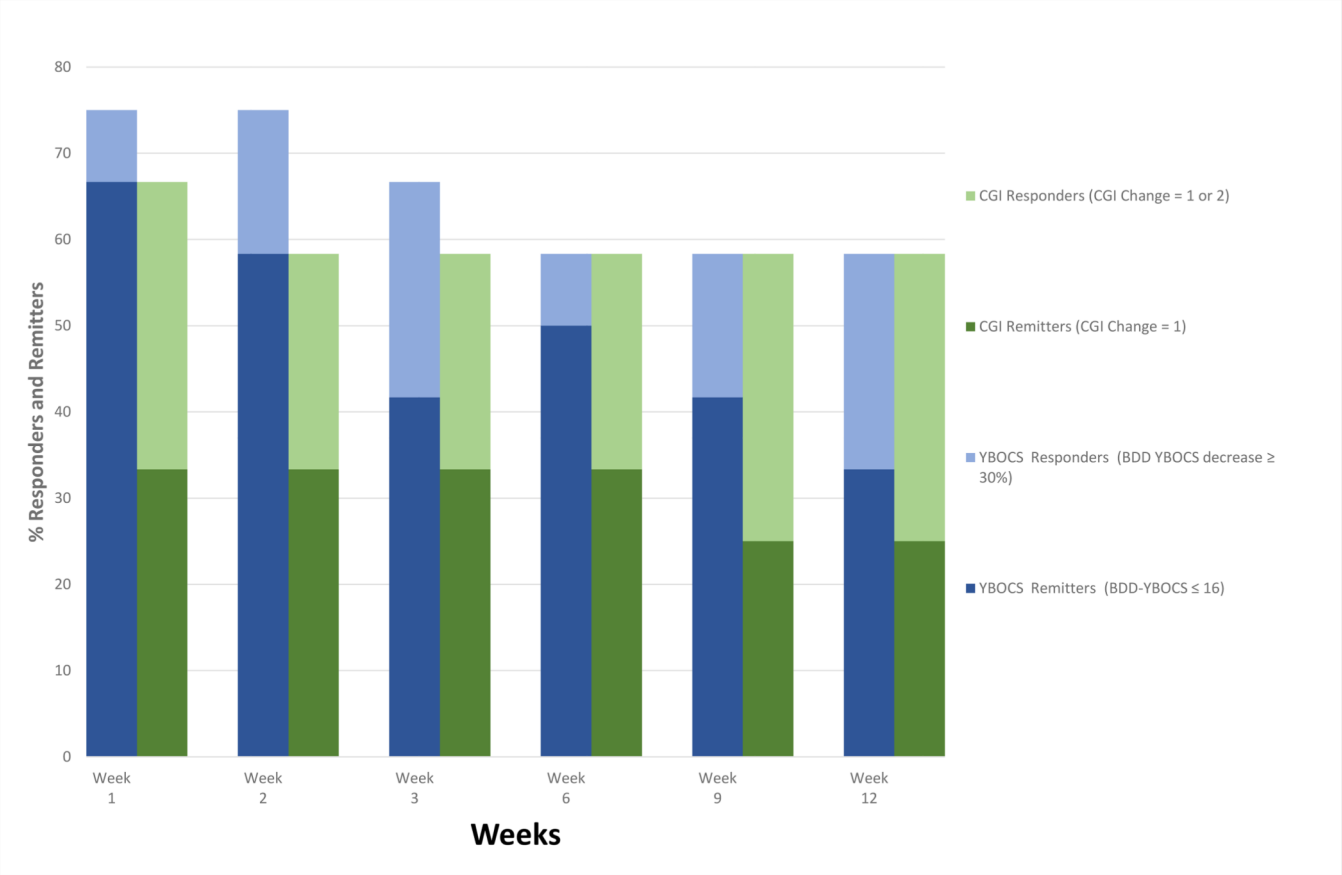

Figure 4.
Response and remission rates based on YBOCS and CGI change score by week

Table 1:

Demographic and Clinical Features

Gender, n (%)	
Male	4 (33)
Female	8 (66)
Marital status, n (%)	
Married	4 (33)
Separated or divorced	1 (8)
Living with partner	3 (25)
Never Married	4 (33)
Race/Ethnicity, n (%)	
White, non-Hispanic	9
White, Hispanic	0
Black, non-Hispanic	0
Black, Hispanic	0
Asian/Pacific Islander	3
Other	0
Employment, n (%)	
Employed	6 (50)
Unemployed	2 (17)
Student	4 (33)
Education, n (%)	
College graduate	6 (50)
Graduate or professional school	6 (50)
Age, mean (SD) years	34.31 (8.86)
Duration of BDD, mean (SD) years	21.06 (10.73)
Comorbidity, n (%)	
Major Depressive Disorder	4

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Attention Deficit Hyperactivity Disorder	4
Generalized Anxiety Disorder	1
Posttraumatic Stress Disorder	1
Number of SSRI/SNRI trials, mean (SD, range)	1.5 (1.17,0–3)
Time from last dose of SSRI/SNRI to study treatment, mean (SD, range), weeks	311.33 (205.58, 6–572)
Total number of psychotherapy trials, mean (SD, range)	3.08 (2.68, 0–10)
Exposure based therapy trials, mean (SD, range)	0.5 (1.17, 0–4)
Prior psilocybin use n (%)	1 (8)
Concomitant psychiatric medications were continued during study n (%)	1 (8)

Table 2

Mean values (SD) for primary and secondary outcome ratings

	n	Baseline (Day-1)	End of Day 0	Week 1	Week 2	Week 3	Week 6	Week 9	Week 12	F/t	df	P*	Partial Eta Squared
BDD-YBOCS	12	29.17 (4.60)[a]		15.83 (9.30)[b]	16.08 (9.04)[b]	17.25 (10.67)[b]	16.67 (10.44)[b]	16.50 (11.72)[ab]	18.42 (9.8)[b]	13.08	1.92	<.001 *	0.54
BABS	12	14.42 (2.07)[a]		9.58 (5.47)[a]	9.50 (5.33)[a]	10.75 (5.82)[a]	9.92 (5.63)[a]	10.92 (6.52) [a]	11 (4.82)[a]	5.94	2.35	.005 *	0.35
HRSD	12	7.92 (5.25)							8.76 (6.84)	0.45	11	.66	--
SDS-work/ school **	9	3.88 (3.0)[a]				1.63 (2.07)[b]			2.13 (2.03) [ab]	5.94	2	.014 *	0.46
SDS – social	12	6.00 (2.83)[a]				3.08 (3.58)[b]			3.92 (3.32)[b]	12.81	2	<.001 *	0.54
SDS – family life/ home	12	4.92 (2.91)[a]				2.17 (2.72)[b]			3.42 (3.42)[ab]	9.30	2	.001 *	0.46
SDS-3-item total **	9	12.63 (7.80)[a]				4.63 (5.45)[b]			7.13 (6.49)[b]	10.31	2	.02 *	0.60
DCQ	12	14.67 (3.17)[a]				9.33 (5.31)[b]	9.25 (4.05)[b]		10.17 (5.18)[ab]	9.65	3	<.001 *	0.47
PANAS-positive	12	22.17 (8.11)[a]	26.17 (8.36)			25.17 (10.49)	23.50 (9.34)			2.50	3	.076	0.19
PANAS-negative	12	22.42 (6.53)[a]	13.25 (4.05)[b]			16.5 (4.87)[b]	19.0 (6.94)[ab]			13.22	3	<.001 *	0.55
PIS-total (Items 1–6)	12		64.49 (25.70)[a]			63.68 (29.45)[a]	55.63 (28.73)[a]		48.90 (30.73)[a]	3.86	3	.018 *	0.26
PIS-item 7	12		45.92 (24.13)			62.42 (29.95)	54.42 (32.0)		51.50 (32.47)	1.60	1.65	.232	0.13

* On post hoc pairwise analyses, values with different superscript letters in a row differed significantly (p<.05).

** Excludes participants who reported at any point in study that they were not working or in school

Abbreviations: BDD-YBOCS, Yale-Brown Obsessive Compulsive Scale Modified for BDD (score range: 0–48, with higher scores indicating higher symptom severity); BABS, Brown Assessment of Beliefs Scale (range: 0–24, with higher scores indicating poorer insight about symptoms; mean scores are in the poor insight range); SDS, Sheehan Disability Scale (range: 0–10 for each item and 0–30 for total, with higher scores indicating greater functional impairment); DCQ, Dysmorphic Concerns Questionnaire (range: 0–21, with higher scores indicate greater levels of concerns about appearance); PIS, Psychological Insight Scale (PIS-total (items 1–6) measures psychological insight, and PIS-item 7 assesses positive behavioral change resulting from gained insight. (range: 0–100 for total and for item 7, with higher scores indicating greater insight and behavioral change); PANAS, Positive and Negative Affect Schedule (range: 10–50 for Positive and Negative scores, with higher scores indicating greater affect); HRSD, Hamilton Rating Scale for Depression (range: 0–52 with higher score indicating greater severity of depressive symptoms.)