Examining the Prevalence and Incidence of Suicidal Thoughts and Behavior in a Smartphone-Delivered Treatment Trial for Body Dysmorphic Disorder

Adam C. Jaroszewski, Natasha Bailen, Simay I. Ipek, Jennifer L. Greenberg, Susanne S. Hoeppner, Hilary Weingarden, Ivar Snorrason, Sabine Wilhelm

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Adam C. Jaroszewski[1] PhD; Natasha Bailen[1] PhD; Simay I. Ipek[1] B.A.; Jennifer L. Greenberg[1] PsyD; Susanne S. Hoeppner[1] PhD; Hilary Weingarden[1] PhD; Ivar Snorrason[1] PhD; Sabine Wilhelm[1] PhD

[1]Department of Psychiarty Harvard Medical School Boston US

Corresponding Author:
Adam C. Jaroszewski PhD
Department of Psychiarty
Harvard Medical School
185 Cambridge Street
Boston
US

Abstract

People with prior suicidal thoughts and behavior (STB) are often excluded from digital mental health intervention (DMHI) treatment trials. This may perpetuate barriers to care and reduce treatment generalizability, especially in populations with elevated rates of STB, like body dysmorphic disorder (BDD). To address this, a recent randomized controlled trial (RCT) of a smartphone-based DMHI for BDD included people with prior STB, excluding only for past-month active suicidal ideation. We reviewed the suicide-risk mitigation procedures and completed secondary data analyses to (1) characterize the sample's lifetime prevalence of STB and (2) estimate and predict STB incidence during the trial. At baseline, 40% of participants reported lifetime active suicidal thoughts and 10% reported lifetime suicide attempts. During the three-month trial, 42.5% reporting thinking about death- and/or suicide via weekly assessment. No participants reported frequent/acute suicidal thoughts, plans, or attempts. Lifetime suicide attempt (OR = 11.0, $p < .01$) and lifetime severity of suicidal thoughts (OR = 1.76, $p < .01$) were significant bivariate predictors of death-/suicide-related thought incidence reported during the trial. Multivariate models including STB risk factor covariates (e.g., age, sexual orientation) modestly improved prediction of death-/suicide-related thoughts (e.g., PPV = .91, NPV = .75, AUC =.83). Although some participants may think about death and/or suicide during a DMHI trial, it may be safe and feasible to include participants with most forms of past STB. Among other procedures, researchers should carefully select eligibility criteria, use frequent, ongoing, low-burden, and valid monitoring procedures, and implement risk mitigation protocols tailored to the presenting problem.

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1) Department of Psychiatry, Massachusetts General Hospital
2) Department of Psychiatry, Harvard Medical School

Correspondence to: Adam C. Jaroszewski, Ph.D. (ajaroszewski@mgh.harvard.edu)

Abstract

People with prior suicidal thoughts and behavior (STB) are often excluded from digital mental health intervention (DMHI) treatment trials. This may perpetuate barriers to care and reduce treatment generalizability, especially in populations with elevated rates of STB, like body dysmorphic disorder (BDD). To address this, a recent randomized controlled trial (RCT) of a smartphone-based DMHI for BDD included people with prior STB, excluding only for past-month active suicidal ideation. We reviewed the suicide-risk mitigation procedures and completed secondary data analyses to (1) characterize the sample's lifetime prevalence of STB and (2) estimate and predict STB incidence during the trial. At baseline, 40% of participants reported lifetime active suicidal thoughts and 10% reported lifetime suicide attempts. During the three-month trial, 42.5% reporting thinking about death- and/or suicide via weekly assessment. No participants reported frequent/acute suicidal thoughts, plans, or attempts. Lifetime suicide attempt (OR = 11.0, $p < .01$) and lifetime severity of suicidal thoughts (OR = 1.76, $p < .01$) were significant bivariate predictors of death-/suicide-related thought incidence reported during the trial. Multivariate models including STB risk factor covariates (e.g., age, sexual orientation) modestly improved prediction of death-/suicide-related thoughts (e.g., PPV = .91, NPV = .75, AUC =.83). Although some participants may think about death and/or suicide during a DMHI trial, it may be safe and feasible to include participants with most forms of past STB. Among other procedures, researchers should carefully select eligibility criteria, use frequent, ongoing, low-burden, and valid monitoring procedures, and implement risk mitigation protocols tailored to the presenting problem.

Keywords: Suicide, Body dysmorphic disorder (BDD), Smartphone-delivered, Digital mental health intervention (DMHI)

Mental illness directly affects nearly half of all adults in the US (Kessler et al., 2005). Although effective treatments have been developed for a wide range of disorders, demand far outstrips availability (Kazdin & Blase, 2011). Indeed, care gaps are estimated at above 50% (Patel et al., 2010). Some barriers to accessing mental health care include the limited number of clinicians, high cost of services, limited insurance coverage, and entrenched stigma. Digital mental health interventions (DMHIs) promise to address many of these concerns. DMHIs can be relatively inexpensive, reduce clinician time, and may reduce stigma through increased privacy (Wilhelm et al., 2020; Rief et al., 2024). However, the light-touch nature of many DMHIs presents issues for researchers designing treatment trials, who might wonder if DMHIs are a safe option for people with higher clinical acuity, such as those with past or current suicidal thoughts and behavior (STB).

People with STB are often excluded from treatment studies (e.g., Ronconi, Shiner, & Watts, 2014; Wong et al., 2018). In DMHI trials, where participants are completing study procedures remotely, researchers' concerns regarding STB risk may be heightened still (Wilks et al., 2016; Bisby et al., 2022). Although restrictive STB exclusion practices may mitigate risks associated with adverse events liability and reduce time and effort associated with managing the incidence of STB during a treatment trial, there are important downsides to such procedures. STBs are prevalent among clinical populations (Bachmann, 2018), thus studies with overly-restrictive eligibility criteria may lack real-world generalizability and reproducibility. Also, overly restrictive DMHI in/exclusion criteria may perpetuate endemic barriers to care that people with STB experience in face-to-face clinical research studies and real-world treatment settings (McCall et al., 2021). Indeed, recent meta-analytic reviews of DMHI trials found that about 60% to 90% of studies excluded participants based on 'suicide risk' (Bisby et al., 2022; McCall et al., 2021), with nearly 30% of CBT for depression trials excluding those with a past suicide attempt (Wilks et al., 2016). Moreover, only a small percentage of studies

report on STB incidence during a trial and/or provide details on the relatedness, seriousness, and the content of adverse events (Schatten et al., 2020). This lack of transparency hinders researchers' ability to accurately evaluate the risks and tradeoffs associated with including participants with STB in their treatment trials.

The purpose of the present study was to describe the suicide risk mitigation procedures used in a recent randomized control trial (RCT) of smartphone-delivered CBT for BDD, and to describe and predict the actual occurrence of STBs during the 12-week trial. This study provides a strong test of the risk mitigation procedures followed because (i) in general, people with BDD have high rates of suicidal thoughts (e.g., Perugi et al., 1997; Phillips & Menard, 2006; Snorrason et al., 2019, 2020), suicide attempts (e.g., Phillips & Menard, 2006; Phillips, Didie, & Menard, 2007; Phillips et al., 2005), and completed suicides (Phillips & Menard, 2006), (ii) participants in the current RCT were not excluded based on *past* (i.e., > 30 days before screening) STB, including prior suicide attempt, active suicidal ideation, plans, and intent, and (iii) participants with some forms of *recent* (i.e., ≤ 30 days before screening) death-/suicide-related thoughts were still eligible to participate (e.g., wish to be dead).

Method

A randomized waitlist-controlled trial was conducted with 80 adults with a primary BDD diagnosis. The treatment group had access to the Perspectives BDD, a coach-guided smartphone app that provided CBT for BDD for 12 weeks (Wilhelm et al., 2022). Perspectives BDD included modules on psychoeducation, restructuring maladaptive thoughts, exposure with response prevention, mindfulness and attentional retraining, values and enhancing self-esteem and self-compassion, and relapse prevention. Participants also had access to bachelor's-level coaches who aimed to enhance motivation and engagement via two telephone calls (onboarding and mid-treatment) along with asynchronous in-app text-based messaging throughout the treatment period. Participants answered brief (four-item) weekly in-app surveys related to their current symptom levels

and suicidal thoughts. They were also assessed by a trained doctoral level clinician at screening and baseline, mid- (week 6) and end-of-treatment (week 12). Participants initially allocated to the waitlist received access to the app-based treatment after three months. Weekly data collected from participants while on the waitlist is included and analyzed along with all data collected during active treatment period.

To be eligible for the study, individuals were required to have a primary BDD diagnosis, be at least 18 years old, and reside in the United States. Individuals were excluded if they were currently in therapy, had previously completed four or more sessions of CBT for BDD, had undergone psychotropic medication changes less than two months prior to starting the study, reported acute and active suicidal ideation (see below), or were unable to engage with the smartphone treatment. Other exclusion criteria included a current severe substance use disorder, current severe comorbid major depressive disorder, or a lifetime bipolar or psychotic disorder. The sample was predominantly female (84%), non-Hispanic (88%), and white (71%) with a mean age of 27 (SD = 9.6; see ClinicalTrials.gov NCT04034693 trial registration and Wilhelm et al., 2022 for additional information regarding the treatment, participants, and study design and procedures). To reduce burden, demographic information was not collected from people excluded from participating in the trial. All procedures were approved by the Mass General Brigham IRB.

Measures

Clinician-administered. Relevant clinician-administered measures included the Yale-Brown Obsessive Compulsive Scale Modified for BDD (BDD-YBOCS; Phillips et al., 1997), Mini International Neuropsychiatric Interview (MINI 7.02; Sheehan et al., 1998), and the Columbia-Suicide Severity Rating Scale (C-SSRS; Posner et al., 2008; see Wilhelm et al., 2022 for additional measures administered). The BDD-YBOCS is the gold-standard measure of BDD symptom severity and was used to characterize the sample and track symptom severity. The MINI, a standardized diagnostic interview, was used to determine DSM-5 psychiatric diagnoses and to evaluate whether

BDD was primary. The C-SSRS was used to assess lifetime and past 30-day suicidal ideation, intent, and behavior. Measures were administered at baseline by blinded, doctoral-level independent evaluators.

Self-report. Relevant self-report measures include the Quick Inventory of Depressive Symptomatology – Self Report (QIDS-SR; Rush et al., 2003) and the Clinical Global Impressions scale (Guy, 1974) adapted for assessing BDD symptoms (CGI-BDD), and the Patient Health Questionnaire-2 (PHQ-2; Kroenke & Spitzer, 2002).

The QIDS-SR and CGI-BDD were administered at baseline, mid- and end-of-treatment assessments. To assess past-week death- and suicide-related thought severity, item #12 of the QIDS-SR was administered to participants via weekly in-app surveys and via web-based surveys to those on the waitlist. The item's label was: "Thoughts of Death and Suicide." Answer choices included: 0 ("I do not think of suicide or death"); 1 ("I feel that life is empty or wonder if it's worth living"); 2 ("I think of suicide or death several times a week for several minutes"); and 3 ("I think of suicide or death several times a day in some detail, or I have made specific plans for suicide or have actually tried to take my life").

An item from the CGI-BDD was used to determine whether participants perceived their past-week BDD symptoms improving or worsening. Participants rated their current symptoms "compared to how [they] felt when first entering the study." Answer choices ranged from 1 (very much improved) to 7 (very much worse). The PHQ-2 was used to assess core diagnostic symptoms of depression severity (low mood, anhedonia), answer choices ranged from 0 (*not at all*) to 3 (*every day*). The QIDS-item #12, CGI-BDD, and PHQ-2 were used as indicators of suicide and/or psychiatric risk, which triggered the risk-mitigation procedures detailed below.

Procedures used for mitigating clinical deterioration and suicide risk

During screening. Exclusion criteria sought to limit participants with 'very severe depression' (≥ 21 on the QIDS-SR; Rush et al., 2003) and active, acute suicidal ideation (≥ 2 on the C-SSRS suicide

ideation severity subscale for past-month suicidal thoughts). Prospective participants endorsing these symptoms were contacted by a doctoral-level independent evaluator, who followed up with the participant via phone within 24 hours to evaluate safety and make a referral to a higher level of care if clinically indicated.

During the trial. The app homepage presented a reminder to participants that if they were experiencing suicidal thoughts, they should go to the emergency room right away. Links to 911 and the national suicide hotline were also presented. Participants designated an emergency contact (e.g. friend or relative) in the instance that the participant was unreachable, and the study team was concerned about their well-being. Also, participants could be withdrawn if, in the judgment of the principal investigator, remaining in the study posed a substantial risk to the participant or a higher level of psychiatric care was needed due to significant clinical deterioration or active, acute suicidal thoughts.

Participants' clinical deterioration and suicide thoughts/behaviors were assessed weekly via a brief in-app/web-based survey and at study mid- and endpoints via self-report. Clinical deterioration was defined by a combination of: (1) a rating of 6 (much worse) or 7 (very much worse) on the weekly, participant-rated CGI-BDD across 2 subsequent weeks, and (2) PI judgment that remaining in the study was not clinically indicated. Of note, a single rating of 6 or 7 on the weekly, participant-rated CGI-BDD triggered an alert to the clinician/coach via text message or email, which was followed up by a study clinician within 24 hours of the alert (see below).

Active, acute suicidal ideation was assessed via QIDS-SR item 12. A score > 0 triggered a pop-up message presented to the patient within the mobile app reminding participants that if they were experiencing suicidal thoughts, they should seek professional help or go to the emergency room right away. Links to 911, as well as a national suicide hotline, were provided within this popup notification. A score >1 triggered an alert to the clinician and coach. A study clinician followed up with a phone evaluation within 24 hours of an alert. Risk was assessed via clinical assessment,

referencing the participant's recently reported scores and appropriate follow-up questions related to severity, impairment, and distress. Participants were referred to a higher level of care if clinically indicated.

Data analyses

To examine the differences between participants included versus excluded from the trial, we computed a *t*-test with unequal variance to compare mean depression severity and a chi-square test to compare prevalence of death- and suicide-related thoughts collected at screening. To characterize participants' lifetime STB, we computed descriptive statistics (e.g., mean, percentage) on C-SSRS variables collected at baseline. To calculate the incidence of STB during the trial, we took several steps. First, we aggregated all weekly, mid- and endpoint QIDS-SR item #12 responses. There were 1440 possible observations, of which 397 were missing (27.5%). Second, we created three dichotomous variables: (a) to capture any 'life not worth living, death- or suicide-related thought,' we recoded item responses as 0 vs. ≥ 1; (b) to capture 'several death- or suicide-related thoughts in any week,' we recoded responses as ≤ 1 vs. ≥ 2; and (c) to capture increased severity of death- or suicide-related thoughts, we evaluated whether any subsequent QIDS-SR item #12 response was > baseline response (increased severity) vs. whether any subsequent response was $\leq$ baseline response (no increase in severity). Third, we calculated descriptive statistics (e.g., count, percentage) for each variable. To predict STB incidence, we ran a series of bi- and multivariate logistic regressions to predict dichotomous outcomes. Bivariate models predicted STB with either (1) lifetime suicidal ideation intensity or (2) lifetime suicide attempt, both of which were collected via C-SSRS at baseline. Multivariate models included the following baseline variables: Birth sex (female n = 67 [83.8%]), age (M(SD) = 27(9.64) , C-SSRS lifetime SI severity (M(SD) = 1.83(1.86); median = 1) and lifetime suicide attempt (n = 8 [10.0%], QIDS-SR depression severity total score, excluding the death/suicide related thoughts item #12 (M(SD) = 10.94(3.90)), BDD symptom severity (BDD Y-BOCS, M(SD) = 30.35(4.4)), and sexual orientation. Sexual orientation was categorical variable with

three levels: ‘straight/heterosexual,’ (n = 49, 61.3%) ‘Lesbian, Gay/Homosexual, or Bisexual,’ (LBG; n=20, 25%), and ‘Other,’ (*n* = 11, 13.8%), which includes participants endorsing sexual orientation options, “Something else”, “don’t know”, or “choose not to disclose.” We included these covariates because they are known risk factors of STB (Franklin et al., 2017). We included both bi- and multivariate models to evaluate whether single variables (e.g., suicide attempt) or a collection of variables would be helpful in predicting which trial participants would report STB during the treatment phase. All analyses were carried out using R (R Core Team, 2021).

Results

Reasons for exclusion. 107 people were screened for the trial. 27 (25.2%) were not included for the following reason, some did not meet multiple inclusion criteria: 14 (51.9%) for a non-primary BDD diagnosis, four (14.8%) for endorsing acute SI in the past month (i.e., active suicidal ideation as indicated by clinical judgement and/or score of 2 or greater on the suicidal ideation subscale of the C-SSRS), four (14.8%) for not meeting criteria for BDD, four (14.8%) for having received > 3 sessions of CBT, three (11.1%) for bipolar symptoms, three (11.1%) for declining to participate (e.g., due to life stress, learning more about the treatment offered), and one (3.7%) for acute depression, as indicated by clinical judgement and/or QIDS-SR total score of >= 21.

Differences between participants excluded vs. included. Participants included in the study did not significantly differ from those excluded on past-week depression severity (QIDS-SR total *M*[*SD*] = 11.28[4.14] vs. 12.44[3.90], $t = 1.33$, $d = -.29$ [-0.73-0.16], $p = .19$), nor on prevalence of past week death and/or suicide related thoughts (i.e., >0 on QIDS-SR item 12, 32.5% [$n = 26$] vs 44.4% [$n = 12$]; chisq = 1.25, $p = .26$). Demographic and other data were not collected for people deemed ineligible during screening to reduce burden.

Suicide risk alerts and outcomes. During the treatment phase—that is, the first three months for those randomized to receive the app immediately and the first 6 months for those randomized to waitlist—12 risk alerts were triggered by 11 different participants. All risk alerts were generated by

responses to weekly in-app/web-based surveys. Ten alerts related to elevated death- or suicide-related thoughts, and two related to increased clinical severity (one for depressive symptoms, one for BDD symptoms). Per protocol, study clinicians followed up with participants via telephone. In all but one instance, participants were reached within hours of triggering the alert. With those reached, a study clinician completed an in-depth risk assessment and created or reviewed a safety plan; all participants were deemed to be at low risk for attempting suicide in the near future, and as such did not require a higher level of care or withdrawal from the study. The participant who was not reached after multiple attempts via telephone and email was monitored for responsiveness to in-app notifications and engagement (e.g., completion of CBT exercises). The participant continued to engage with the treatment and did not meet criteria for the study team to call their emergency contact; however, due to non-responsiveness and increased clinical severity, this participant was withdrawn from the study and provided symptom-specific resources and clinical referrals via email.

Trial participants' lifetime and past-month prevalence of STB as assessed by C-SSRS.

Lifetime. At baseline, most trial participants (65.0%; *n* = 52) reported experiencing a wish to die at some point in their lifetime (C-SSRS Q1), with just under half of participants (41.3%, *n* = 33) reporting nonspecific active suicidal thoughts (Q2), 37.5% (*n* = 30) experiencing active thoughts without plan or intent (Q3), 20% (*n* = 16) experiencing active suicidal thoughts with some intent but without specific plan (Q4), and 13.5% (*n* = 11) experiencing active suicidal thoughts with some intent and a specific plan (Q5). 10% (*n* = 8) of participants reported having attempted suicide, and 16% (*n* = 13) reporting engaging in some form of suicidal behavior (i.e., suicide preparation or aborted, interrupted, or actual suicide attempt). 30% (*n* = 24) reported past non-suicidal self-injury (NSSI). These results are in line with prior literature indicating that STB are relatively common among people with BDD (Phillips & Menard, 2006).

Past month. Twenty-five percent (*n*= 20) of participants reported a wish to die (Q1) in the month prior to starting the trial. No participants reported experiencing more severe suicidal thoughts

because this was an exclusion criterion.

Table 1. Incidence, New Onset, and Increased Severity of Participants' Death and Suicide-related Thoughts/behaviors during the Three-month Treatment Phase of a Smartphone-delivered Treatment Trial for BDD (*N* = 80)

	n (%)
Incidence	34 (42.5%)
Life feels empty or I wonder if worth living	24 (30.0%)
Several suicide- or death-related thoughts this week	10 (12.5%)
New onset	3 (3.8%)
Life feels empty or I wonder if worth living	2 (2.5%)
Several suicide- or death-related thoughts this week	1 (1.3%)
Increased severity	
Relative to the week before baseline[1]	20 (25.0%)
Relative to lifetime[2]	1 (1.3%)
Suicide attempt	0 (0.0%)
Withdrawn for worsening symptoms/suicidal thoughts	1 (1.3%)

Note. QIDS-SR, the Quick Inventory of Depressive Symptomatology-Self-Report. Incidence was assessed weekly via QIDS-SR item 12. Worsening is defined as an increase in severity of suicide/death-related thoughts relative to:
[1] Greatest severity in the week before baseline as assessed by QIDS-SR.
[2]Greatest lifetime severity as assessed by C-SSRS at baseline.

Incidence of STB during the trial. Table 1 displays the incidence of STB during the trial. We note here that no participants reported experiencing daily suicide- or death-related thoughts or making a specific suicide plan. Notably, 20 participants (25%) reported that their death- or suicide-related thoughts were worse during the trial relative to the week before baseline, but only one participant reported that these thoughts were worse/more severe during the trial relative to their lifetime.

Table 2. Incidence of Death- and Suicide-related Thought Outcomes during the Three-month Treatment Phase of a Smartphone-delivered Treatment Trial for BDD (*N* = 80)

	Dichotomous outcomes occurring during the 12-week trial assessed by weekly QIDS-SR16 item 12[1]								
	Any life feels empty, death- or suicide-related thoughts[2] (*n* = 34)			Several death- or suicide-related thoughts in any week[3] (*n* = 10)			Increased severity of death- or suicide-related thoughts[4] (*n* = 20)		
Model & Predictors	OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Lifetime suicide-thought severity[5]	1.61	1.24 – 2.14	**.001**	1.76	1.21 – 2.77	**.006**	1.31	1.00 – 1.74	**.050**
	PPV = .70, NPV = .63, AUC = .67			NA, model did not predict any positive cases			NA, model did not predict any positive cases		

	R^2 = .160			R^2 = .117			R^2 = .047		
Lifetime suicide attempt (Yes)	11.67	1.93 – 22 4.35	**.025**	11.00	2.14 – 59 .14	**.004**	3.50	0.75 – 16 .37	.100
	PPV = .63, NPV = .88, AUC = .75			PPV = .92, NPV = .50, AUC = .71			PPV = .78, NPV = .50, AUC = .64		
	R^2 = .092			R^2 = .143			R^2 = .037		
Birth sex (M)	1.74	0.37 – 7. 97	.470	0.00	0.00 – 100+	.994	1.17	0.21 – 5. 24	.845
Age	0.97	0.91 – 1. 02	.279	0.97	0.84 – 1. 08	.660	0.98	0.91 – 1. 05	.605
Sexual orientation: LGB[6]	1.25	0.35 – 4. 48	.724	0.82	0.11 – 5. 22	.834	1.01	0.27 – 3. 60	.986
Sexual orientation: Other[7]	0.48	0.09 – 2. 22	.366	0.44	0.02 – 4. 40	.531	0.57	0.07 – 2. 89	.528
Lifetime suicide-thought severity	1.45	1.04 – 2. 07	**.034**	1.55	0.90 – 2. 93	.132	1.34	0.92 – 1. 99	.135
Lifetime suicide attempt (Yes)	3.40	0.35 – 80 .14	.339	3.19	0.30 – 37 .54	.335	1.23	0.17 – 8. 98	.837
Baseline depression severity[8]	1.12	0.97 – 1. 32	.148	1.11	0.86 – 1. 47	.450	0.99	0.85 – 1. 16	.934
Baseline BDD severity	1.06	0.93 – 1. 21	.408	0.86	0.68 – 1. 09	.221	0.95	0.81 – 1. 09	.444
	PPV = .70, NPV = .69, AUC = .69			PPV = .91, NPV = .75, AUC = .83			PPV = .76, NPV = .50, AUC = .63		
	R^2 = .236			R^2 = .244			R^2 = .073		

Note. Bold indicates p ≤ .05. PPV, positive predictive value. NPV, negative predictive value. AUC, area under the receiver operator characteristic (ROC) curve. NA, not available.

[1] Quick Inventory of Depressive Symptomatology—Self-report (16-item); item 12 concerns "Thoughts of death or suicide."

[2] Negative response to QIDS-SR item 12 option 0: "I [did] not think of suicide or death."

[3] Affirmative response to QIDS-SR item 12 option 2: "I think of suicide or death several times a week for several minutes."

[4] Severity increasing relative to baseline death- and suicide-related thoughts assessed via QIDS-SR item 12.

[5] Lifetime suicide thought severity assessed via the C-SSRS at baseline.

[6] LGB, Lesbian, Gay/Homosexual, Bisexual (*n* = 20).

[7] Other, includes participants (*n* = 11) endorsing sexual orientation options "Something else", "don't know", or "choose not to disclose."

[8] Baseline depression severity assessed via the QIDS-SR16 excluding item 12, as this item was used to create death-/suicide-related thought outcome variables.

Predicting STB

Results of logistic regressions using baseline variables to predict the incidence of death- and suicide-

related thoughts during the 12-week trial are presented in Table 2. In the left most column, bivariate models revealed that higher severity of suicidal thoughts and, separately, reporting a prior suicide attempt at baseline were significant predictors of reporting any death- or suicide related thought during the trial. However, after adjusting for covariates known to be associated with STB (e.g., age, birth sex, sexual orientation), only baseline suicide thought severity remained a significant predictor of death- or suicide thought incidence. Similarly, bivariate models presented in the middle column revealed that higher baseline suicide-thought severity and lifetime suicide attempt, respectively, significantly predicted experiencing several death- or suicide-related thoughts for several minutes in any given week; however, these relationships did not remain significant after adjusting for STB risk factor covariates. Bivariate models presented in the right column revealed that only baseline suicide thought severity predicted which participants would report their death- or suicide-related thoughts had increased in severity during the trial relative to the week prior to baseline. No variables were significant predictors of this outcome after adjustment for covariates.

Discussion

The purpose of this study was to examine the rates of STBs in participants of a recent RCT of smartphone-delivered CBT for BDD. There were three main findings. First, consistent with the results of prior research (e.g., Phillips & Menard, 2006), lifetime history of relatively severe STB was prevalent among this sample of participants with primary BDD, with many reporting prior active suicidal thoughts (40%) and a prior suicide attempt (10%). Second, over the course of the three-month treatment phase, nearly half the participants reported experiencing a death- and/or suicide-related thought, but no participants experienced acute and frequent suicidal thoughts, made a suicide plan, or attempted suicide. Third, prior suicide attempt(s) and severity of suicidal thoughts were significant predictors of who would experience death- and or suicide-related thoughts during the trial; however, only baseline suicide thought severity remained a significant predictor after adjusting

for known STB risk factors (e.g., demographics, sexual orientation). Notably, even the best models had only relatively modest predictive accuracy (e.g., AUCs ranging from .63 - .83), highlighting the difficulty of short-term prediction of STB (Ribeiro et al., 2016).

The main implication of these findings is that with carefully selected in/exclusion criteria and robust yet relatively low-burden and ongoing monitoring procedures, it is possible to conduct a safe, light-touch DMHI even when including participants with moderately elevated risk profiles (i.e., recent thoughts of death, past suicide attempt). Despite excluding for recent 'active' suicidal thoughts and behaviors, a meaningful proportion of participants with a psychiatric disorder such as BDD may still experience death- or suicide-related thoughts during a several months long treatment trial, particularly those with previous acute STB, such as suicide attempt or active suicidal ideation. This highlights the importance of assessing STB in an ongoing (e.g., weekly) fashion that imposes low burden on participants but also provides actionable data to the research team. Questions and answer options that are concise and easily understood are always preferrable, but especially so in DMHIs, because participant adherence/engagement tends to decline precipitously as treatments progress (Linardon et al., 2020). Items with high face and construct validity that researchers can use to quickly inform decisions about when to follow up with participants are essential in DMHIs, given these interventions are remotely administered and historically suffer from low engagement, limiting opportunities for observing/assessing risk relative to more traditional, face-to-face treatments.

The findings from this study must be interpreted in the context of several limitations. First, nearly a third of participants' weekly death- and suicide-related thought responses were missing. Although this amount of missing data is on the low end compared to other DMHIs (Linardon et al., 2020), any missing data limits our ability to estimate the true incidence of death- and suicide-related thoughts. Future studies could attempt to address this by making some proportion of weekly surveys mandatory or incentivizing their completion; however, the former runs the risk of increasing participant burden and, therefore, decreasing adherence, whereas the latter may not be financially

feasible in real-world implementations, limiting the generalizability of findings. Second, the item we chose to assess weekly death- and suicide-related thoughts included answer options that vary on the constructs they assess (e.g., three answer options specifically mention death- and suicide-related thoughts, one does not; two options assess frequency, two do not), limiting precision. We chose this item to maximize the tradeoff between high face validity and low participant burden while matching our a priori risk-mitigation decision rules for when to actively check with participants to assess current risk. Future studies could attempt to pilot and validate additional items with more favorable precision.

In conclusion, our findings indicate that it is feasible to conduct an RCT of a DMHI among a sample of clinically acute participants with relatively high rates of lifetime STB. There are inherent risks in conducting treatment trials and tradeoffs when establishing thresholds for in/exclusion, particularly for highly prevalent and stigmatized symptoms such as STB. Trials with very strict eligibility criteria may effectively limit risk of STB, but findings will likely lack generalizability and potentially perpetuate treatment barriers for patients in high need. Trials with overly lenient eligibility criteria may fail to mitigate the risk of serious adverse events, jeopardizing participant safety, trial feasibility, and the implementation of an otherwise promising treatment. Researchers can include participants with moderately elevated risk profiles by carefully selecting eligibility criteria based on rational and empirical grounds, carefully screening participants with trained study staff, using frequent, ongoing, low-burden, and valid monitoring procedures, implementing risk mitigation protocols that are tailored to the presenting problem, ensuring staff are adequately supervised and trained to handle anticipated STB and/or adverse events as well as active risk mitigation efforts, and that patients are aware of these procedures and understand why they are answering such questions. More research should examine the safety procedures implemented in RCTs and report more fully on adverse events and other key outcomes such as STB. Doing so will help ensure that as a field we are following adequate and generalizable risk mitigation practices, while not needlessly excluding

participants who could benefit from treatment.

Declaration of interests:
The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:
Dr. Jaroszewski has received salary support from Koa Health (formerly Telefónica Alpha, Inc). Dr. Greenberg has received salary support from Koa Health (formerly Telefónica Alpha, Inc) and is a presenter for the Massachusetts General Hospital Psychiatry Academy in educational programs supported through independent medical education grants from pharmaceutical companies. Dr. Snorrason has received salary support from Koa Health. Dr. Weingarden receives salary support from Koa Health (formerly Telefónica Alpha, Inc) and is a presenter for the Massachusetts General Hospital Psychiatry Academy in educational programs supported through independent medical education grants from pharmaceutical companies. Additionally, Dr. Weingarden has a consulting agreement with Hello Therapeutics, Inc. Dr. Wilhelm is a presenter for the Massachusetts General Hospital Psychiatry Academy in educational programs supported through independent medical education grants from pharmaceutical companies; she has received royalties from Elsevier Publications, Guilford Publications, New Harbinger Publications, Springer, and Oxford University Press. Dr. Wilhelm has also received speaking honoraria from various academic institutions and foundations, including the International Obsessive Compulsive Disorder Foundation, the Tourette Association of America and the Centers for Disease Control and Prevention. In addition, she received payment from the Association for Behavioral and Cognitive Therapies for her role as Associate Editor for the Behavior Therapy journal, as well as from John Wiley & Sons, Inc. for her role as Associate Editor on the journal Depression & Anxiety. Dr. Wilhelm has also received honoraria from One-Mind for her role in Psy¬berGuide Scientific Advisory Board. Dr. Wilhelm is also on the Scientific Advisory Board for Koa Health, Inc. and for Noom, Inc. Dr. Wilhelm has received research and salary support from Koa Health, Inc. Additionally, Dr. Wilhelm has a consulting agreement with Noom, Inc. The other authors have no disclosures.

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