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PII: S0005-7894(21)00117-9
DOI: https://doi.org/10.1016/j.beth.2021.09.002
Reference: BETH 1117

To appear in: *Behavior Therapy*

Received Date: 1 March 2021
Accepted Date: 16 September 2021

Please cite this article as: M.J. Falkenstein, K.N. Kelley, D. Dattolico, J.M. Kuckertz, A. Bezahler, J. Krompinger, C.A. Webb, C. Beard, Feasibility and acceptability of cognitive bias modification for interpretation as an adjunctive treatment for OCD and related disorders: A pilot randomized controlled trial, *Behavior Therapy* (2021), doi: https://doi.org/10.1016/j.beth.2021.09.002

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Feasibility and acceptability of cognitive bias modification for interpretation as an adjunctive treatment for OCD and related disorders: A pilot randomized controlled trial

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Role of the funding source: This study was supported by the Harvard Medical School Department of Psychiatry Kaplen Fellowship and Livingston Fellowship Awards. Author CB's time was supported by NIMH (MH113600).

Acknowledgements: We thank Sriramya Potluri for assistance in study preparation and running participants, Alexandra Hernandez-Vallant for assistance with study preparation, Rebecca Feenstra for data entry, and Diane Davey for her contributions to the development and ongoing support of the OCD Institute's research program.

Declarations of interest: None.

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Abstract

Cognitive models implicate interpretation bias in the development and maintenance of obsessive compulsive and related disorders (OCRDs), and research supports Cognitive Bias Modification for Interpretation (CBM-I) in targeting this mechanism. However, prior studies in OCRDs have been limited to nonclinical populations, adolescents, and adults in a laboratory setting. This study evaluated the feasibility and acceptability of CBM-I as an adjunctive intervention during intensive/residential treatment (IRT) for adults with OCRDs. We modified a lab-based CBM-I training for adults seeking IRT for OCRDs, and conducted a feasibility trial ($N = 4$) and subsequent pilot RCT; participants ($N = 31$) were randomized to receive CBM-I or psychoeducation. Benchmarks were met for feasibility, acceptability, and target engagement. From pre- to post-intervention, the CBM-I group showed a large effect for change in interpretation bias ($d = .90$), whereas this effect was trivial ($d = .06$) for psychoeducation. This was the first study to evaluate CBM-I in naturalistic treatment for adults seeking IRT for OCRDs. Findings support the feasibility and acceptability of CBM-I in this novel sample and setting. A larger scale RCT is needed to determine whether CBM-I can enhance OCRD treatment response.

Keywords: obsessive compulsive disorder; obsessive compulsive related disorders; cognitive bias modification; interpretation bias; intensive/residential treatment

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Feasibility and Acceptability of Cognitive Bias Modification for Interpretation as an Adjunctive Treatment for OCD and Related Disorders: A pilot randomized controlled trial

Obsessive compulsive related disorders (OCRDs) are associated with substantial functional impairment in occupational, social, and family domains (Fontenelle et al., 2010), greater co-occurring medical and psychiatric conditions (Markarian et al., 2010), and increased risk for suicide attempts and death (Kamath et al. 2007; Angelakis et al. 2015). Exposure and response prevention (ERP; Foa et al., 2005) is considered the gold-standard intervention for OCRDs, yet 40-50% of patients who receive it do not recover (Fisher & Wells, 2005). Despite the substantial proportion of patients with OCRDs who do not respond to first-line treatment, it is not well understood how best to treat people following an unsuccessful course of therapy. Even at residential programs for OCD offering intensive behavioral and pharmacological treatment, patients may only experience a 30% reduction in symptoms (Stewart et al., 2005). Thus, there is a pressing need to improve clinical care for patients with severe OCRDs.

One potential route to improving outcomes for individuals with OCRDs is to more directly target mechanisms underlying the etiology and maintenance of OCRDs via novel intervention strategies. Cognitive-behavioral models posit that learning experiences can lead to the development of dysfunctional beliefs and cognitive biases, such as interpretation biases (Tolin, et al., 2003; Reuther et al., 2013; Wilhelm & Steketee, 2006). Specifically, people with OC-relevant beliefs show a bias when encountering ambiguous information, misinterpreting ambiguity as dangerous or predictive of harm (Rachman, 1997; Frost & Steketee, 2002). Shifting interpretation bias is critical in disrupting the development and maintenance of OCRDs, as these cognitive-behavioral models propose that maladaptive interpretations give rise to obsessions, subsequent attempts to control or suppress the obsessions through compulsions, and resulting

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distress and impairment. Because intrusive, unwanted thoughts are common in the general population (Radomsky et al., 2014), the threatening misinterpretation of such thoughts, rather than the content, is an essential target. However, gold-standard treatments for OCD (i.e., ERP) generally target this mechanism only indirectly.

In contrast, Cognitive Bias Modification for Interpretation (CBM-I; Menne-Lothman et al., 2014) directly targets interpretation bias. CBM-I reinforces a more adaptive cognitive style by requiring repeated practice responding to ambiguous stimuli in a benign manner. A common variant of CBM-I is the scenario-based task (Mathews & Macintosh, 2000) whereby participants read a series of brief ambiguous scenarios, in which the situation could be resolved with either a threat or benign interpretation. Participants are asked to complete a word fragment that resolves the scenario with a benign interpretation, thus reinforcing this interpretation style.

While a number of studies have examined CBM-I for obsessive compulsive symptoms, such studies have typically focused on nonclinical populations (e.g., Clerkin & Teachman, 2011; Conley & Wu, 2018; Grisham et al., 2014). To date, one small pilot study ($N = 16$) suggested that CBM-I augmented response to treatment as usual for adolescents with OCD in a naturalistic treatment setting (Salemink et al., 2015). In another related pilot study ($N = 22$), brief CBM-I was effective in augmenting response to ERP for adults with OCD in a laboratory setting (Amir et al., 2015). In addition to OCD, several studies of CBM-I have also been conducted with participants with another OCRD, body dysmorphic disorder (BDD). Premo and colleagues (2016) and Wilver and Cougle (2019) both found CBM-I improved interpretation in BDD more than comparison conditions. Additionally, Summers and Cougle (2016) found four sessions of CBM-I led to greater improvements in BDD symptoms than a control condition for participants with high levels of BDD, and improvements were maintained through one-month follow-up.

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To date, no studies have adapted CBM-I for adults in naturalistic OCRD treatment settings (only adolescents with OCD) or those receiving intensive OCRD treatment – exactly the population who may be in most need of novel augmentation strategies. Thus, in the current study, we aimed to adapt a lab-based CBM-I protocol as an adjunctive intervention to intensive residential OCRD treatment. In approaching this aim, we considered two important lessons learned from the broader CBM field. First, given enthusiasm for the potential of CBM to yield clinical effects (Holmes et al., 2009), some early CBM research did not adequately prioritize demonstration that any given CBM procedure effectively changed the intended mechanism prior to evaluating clinical effects (Clarke et al., 2014; Grafton et al., 2017). As expected based on the underlying theory of CBM, studies with procedures that failed to produce the intended bias change have also not found effects on clinical outcomes (Price et al., 2016). In order to test the target mechanism in this new population, we needed to adapt the typical interpretation bias training and scenario recognition tasks to OCRD scenarios and pilot test these versions in the sample as an important first step.

Second, only limited CBM-I research has examined patient attitudes towards this type of intervention (e.g., Beard et al., 2012; Beard et al., 2020), and no studies have examined this in people with OCRDs. Consistent with the National Institutes of Health (NIH) Stage Model, it is critical to first demonstrate feasibility and acceptability of any new treatment in the target population. We view this step as especially important for the current aim of adapting CBM-I for OCRDs because of the different nature of interpretation bias in OCRDs compared to anxiety disorders, the heterogeneous symptom presentation in OCRDs, and the high severity of symptoms observed in intensive OCRD treatment settings. Thus, we focused on patient ratings of satisfaction and helpfulness, as well as their feedback about this new CBM-I.

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Current Study

Our primary aims were: 1) to adapt a lab-based CBM-I training to be an adjunctive intervention for adults seeking treatment for OCRDs, along with a corresponding interpretation bias assessment task, and 2) to evaluate the feasibility and acceptability of this intervention in a sample of adults seeking treatment in an intensive/residential hospital-based program for OCRDs, with the purpose of obtaining real-world, generalizable feasibility and acceptability data. In line with Stage 1 of the National Institutes of Health (NIH) Stage Model, this study involved developing the CBM-I intervention and pilot testing to obtain feasibility and acceptability data, with the ultimate goal of enabling more rigorous testing of its efficacy in subsequent studies (Onken et al., 2014). Participants were first recruited for a feasibility trial, and then for a subsequent pilot RCT in which they were randomly assigned to eight sessions of CBM-I or psychoeducation. We hypothesized the CBM-I and control conditions would meet a priori benchmarks for feasibility and acceptability, and the benchmark set for change in interpretation bias would be met by participants in the CBM-I condition, though not the control.

Material and Methods

Overview

We first modified a lab-based CBM-I training and assessment task designed for an undergraduate sample with OCD symptoms (Clerkin & Teachman, 2011) to be an adjunctive intervention and assessment for patients with OCRDs in a treatment setting. Participants were recruited from an IRT program for OCRDs, which has an average length of stay of 30 to 90 days. The program is based on a CBT model, with a focus on ERP (Foa et al., 2005). The intensive/residential treatment program day is approximately eight hours long, with four hours spent on ERP, and the remaining four hours per day spent on meetings with behavioral

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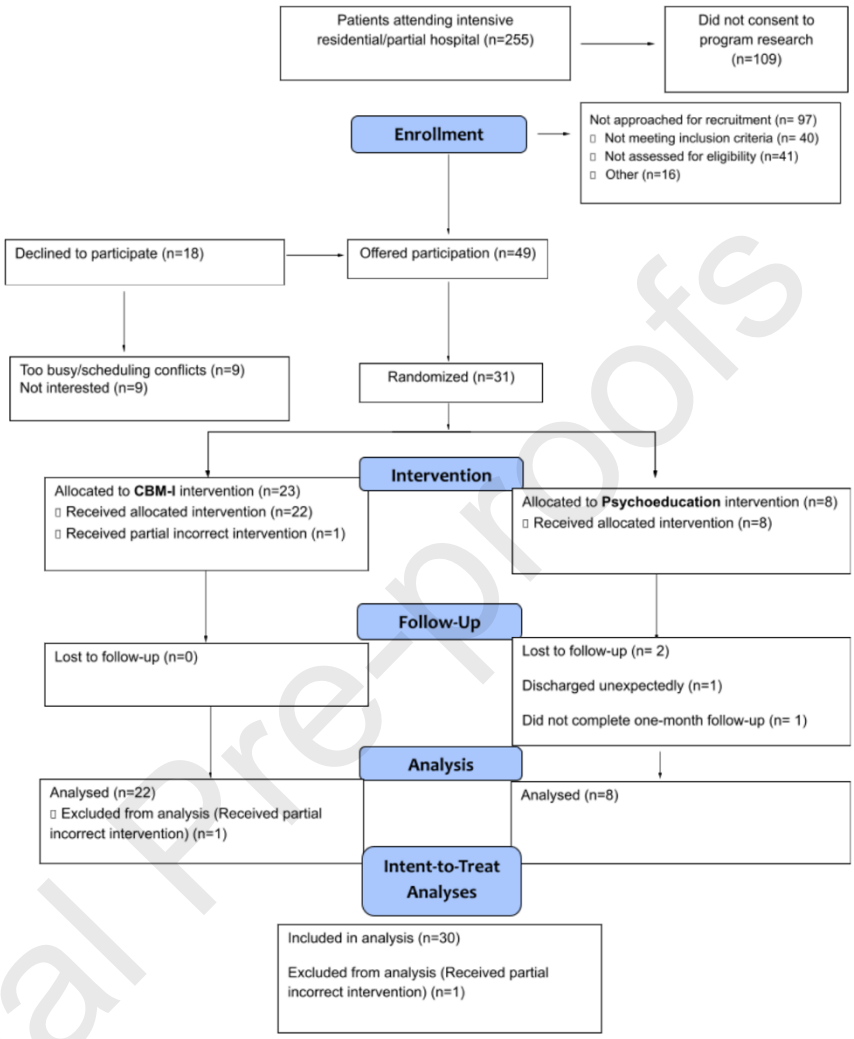
therapists, psychiatrists, and social workers and therapy groups (e.g., family issues group, cognitive therapy group); meetings with behavioral therapists included elements of all "waves" of CBT, including traditional cognitive structuring, behavioral intervention, and acceptance-based approaches.

Figure 1. *CONSORT Flow Diagram for RCT*



First, we conducted a feasibility trial with four participants, collected data on feasibility and acceptability, and made modifications as needed. Second, we conducted a pilot RCT in which patients were randomized to receive eight sessions of CBM-I or psychoeducation, and we collected further data on feasibility, acceptability, interpretation bias, and preliminary, descriptive clinical outcomes through one-month follow-up.

Participants

See Table 1 for demographic and clinical characteristics across both studies.

Feasibility Trial. Participants ($N = 4$) were recruited to study feasibility of the protocol and were enrolled from July to August 2018. Inclusion criteria were: ≥ 18 years old and able to

Journal Pre-proofs

complete a computer task for 20 minutes. All participants identified as non-Hispanic/Latino White females, three had a primary diagnosis of OCD, and one with primary BDD.

Pilot RCT. Enrollment occurred from March 2019 to March 2020. Inclusion criteria were the same as in the feasibility trial, with the addition of ≥ 131 on the Obsessive Beliefs Questionnaire-44 [1 SD above the mean score of the non-clinical sample reported in the original validation paper by the Obsessive Compulsive Cognitions Working Group (OCCWG, 2005)]. Our inclusion criteria were based on level of the intervention target - obsessive beliefs. Because obsessive beliefs are a transdiagnostic mechanism, DSM-5 diagnosis was not an inclusion criterion. DSM-5 diagnosis was also not a relevant inclusion criterion due to our aim of examining the feasibility and acceptability of providing this intervention to patients seeking treatment in a real world clinic for OCRDs. The exclusion criteria were: acute symptoms of mania and/or psychosis, autism spectrum or psychotic disorder, concurrent electroconvulsive therapy, or a history of traumatic brain injury.

Given that our primary aim was to examine feasibility and acceptability of CBM-I rather than statistically compare clinical outcomes, similar to other pilot feasibility trials (e.g., Beard et al., 2019), we randomized 66% of participants to CBM-I ($N = 23$) and 33% to a psychoeducation comparison condition ($N = 8$), using a random number generator. Independent assessors were masked to condition; staff masking was broken for 10% of participants due to participants inadvertently revealing condition during clinical interviews involving the Y-BOCS ($n = 3$). One participant in the CBM-I condition was excluded after erroneously receiving one session of psychoeducation (See Fig. 1: CONSORT flow diagram).

The mean score on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) at pre-intervention among the CBM-I group was 26.18 ($SD = 5.31$) and among the psychoeducation

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group was 25.25 (*SD* = 5.65); both in the "severe" range. The mean age of participants was 29.26 (*SD* = 7.58), with 50% of participants identifying as female, 47% as male and 3% as Not listed - participant's write-in response was "none." Regarding race and ethnicity, 87% of participants identified as White, 7% multiracial, 3% Hispanic/Latino, and 3% Middle Eastern/North African. Primary diagnoses were OCD (90%, *n* = 27), generalized anxiety disorder (3%, *n* = 1), post-traumatic stress disorder (3%, *n* = 1), and panic disorder (3%, *n* = 1). Of the three participants who did not have primary OCD, each had a secondary diagnosis of an OCRD; OCD (*n*=2) and BDD (*n*=1). Upon entering the study, 93% (*n* = 28) of participants reported having previously received therapy for OCD, and 77% (*n* = 23) reported previously receiving ERP specifically. Psychiatric medication data was obtained for 87% *(n* = 26) of participants at the time of program admission. Of these participants, 12% (*n* = 3) were not taking any medications, 96% (*n* = 25) were taking an antidepressant, 33% (*n* = 7) were taking a mood stabilizer, 31% (*n* = 8) were taking an antipsychotic, 23% (*n* = 6) were taking an anxiolytic, and 19% (*n* = 5) were taking a stimulant. During the study, 53% of participants (*n* = 16) reported a change in their medications; this did not differ between CBM-I (55%) and Psychoeducation (50%) conditions (*p* = .823).

Treatment arms

CBM-I. The CBM-I task was previously developed (Clerkin & Teachman, 2011) and further modified (Beadel, Smyth, & Teachman, 2014) for OC-relevant interpretations. It is based on the widely-used ambiguous scenario training (Mathews & MacKintosh, 2000). Due to the heterogeneity of presentations within OCRDs, stimuli were broad in that they targeted interpretations related to six belief domains proposed by the OCCWG (1997) as central to OCD: Inflated responsibility, overestimation of threat beliefs, perfectionism, intolerance of uncertainty, importance of thoughts and the control of thoughts (Salkovskis, 1985; OCCWG, 1997; 2001).

Journal Pre-proofs

All participants viewed the same stimuli in a different randomized order; six scenarios from each belief domain, with scenarios being ambiguously consistent with OC beliefs until the final word, which contained a single missing letter that participants were prompted to complete. Filling in the word with the correct letter resolved the sentence with a non-OC interpretation. A comprehension question was then displayed to reinforce the healthy, non-OC interpretation. One example from the perfectionism domain is, *"Your friend let you borrow his expensive car while yours is in the shop. While driving, you sometimes have unwanted thoughts of crashing your friend's car. Occasionally having thoughts like these is n_rmal."* Filling in the word as "*normal*" resolves the sentence with a non-OC interpretation. The comprehension question is then, *"Do these thoughts indicate that you want to crash the car? Press Y for 'Yes' and N for 'No.'"*

Overall, there were 288 trials across the eight sessions; 144 training scenarios were administered across four CBM-I sessions of 36 scenarios in random order, each containing six scenarios from each of the six belief domains (36 trials per session). Participants completed the four sets of scenarios twice, totaling eight sessions. The order of the training blocks was counterbalanced. After each session, participants were shown feedback regarding their accuracy and response time.

Adapting CBM-I training and assessment for a psychiatric setting. We modified this lab-based task and its corresponding assessment (Clerkin & Teachman, 2011; Beadel et al., 2014), originally designed for a single session administration to undergraduates, to be appropriate for our clinical objectives, time frame, and patient population. First, given the clinical objectives, we decided not to administer the Neutral training condition (half of the scenarios were OC-consistent, half were OC-inconsistent) from the original paradigm, and only administered the Positive training condition (only OC-inconsistent).

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Second, to adapt the CBM-I and assessment scenarios from a single-session administration to be an eight-session intervention with three separate study assessment visits, we developed additional CBM-I training and assessment (Scenario Recognition Task) scenarios. To develop additional scenarios for each of the six OC belief domains, the PI and two research assistants wrote scenarios in consultation with an OCD treatment expert who serves as Director of Psychological Services at the study site (the sixth author), and all scenarios were then reviewed by a CBM-I expert (the last author). After administration, we examined the reliability of the revised Scenario Recognition Task, presented in *Measures.*

Third, we modified the instructions where they sounded more appropriate for a lab-based experimental paradigm rather than an intervention that took place over the course of intensive/residential treatment (IRT; i.e., removed text which thanked subjects for participating). Finally, given that we were developing this training for adults from different socioeconomic backgrounds in a psychiatric hospital program, we adapted many of the scenarios from being relevant to college students' daily lives to being more relevant for employed or unemployed adults (i.e., replaced the word "class" with "meeting," or "academic advisor" with "friend").

Participants in CBM-I were told that the computer program ("I-Change") was designed to help them develop healthier mental habits and may lead to decreased symptoms and improved quality of life. Participants were encouraged to apply what they learned to their daily life.

Psychoeducation. Psychoeducation has been utilized as a control condition for prior intervention studies, including CBM (e.g., Stanley et al., 2018). It is a validated low-intensity intervention which augments therapy, yet does not contain the mechanism of change (i.e., interpretation bias) that is the focus of CBM-I. This condition involved eight computerized lessons describing symptoms of OCRDs, biased thinking in OCRDs and anxiety, and common

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psychosocial as well as pharmacological treatments for OCRDs, with material assembled by the study authors from resources in the public domain (e.g., International OCD Foundation; DSM-5, APA, 2013). The sessions provided relevant information but did not provide practice in changing thinking styles. We determined this would be an appropriate control condition because it contains core elements of the CBM-I training without the active ingredient of repeatedly practicing responding to stimuli in an adaptive, non-OC consistent manner. The core elements common to both conditions were: receiving a credible treatment rationale, reading OC-relevant material including about obsessive beliefs and biased thinking on clinic computers in the same room, engaging in an additional intervention during the program, and receiving corrective feedback in response to quizzes on material participants read.

Participants assigned to the psychoeducation condition were told that the computer program was designed to enhance their understanding of OCD, which may lead to a better sense of control over one's condition and healthier responses to one's symptoms, and that learning more about OCD-related thoughts and behaviors is important because these are often hard to control and can become automatic. Participants were encouraged to apply what they learned in the program in their daily life, and were told that repeated practice may lead to more benefits.

Measures

All interviewer-rated, self-report measures, and the Scenario Recognition Task were administered at pre-intervention and post-intervention. In addition, self-report measures and the Scenario Recognition Task were administered at mid-intervention, and interview and self-report measures were administered 1-month following the post-intervention assessment. Self-report measures were completed using REDCap (Harris et al., 2009).

Journal Pre-proofs

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Primary outcomes: feasibility and acceptability benchmarks. A priori benchmarks (see *Statistical Analyses* and Table 2) were created for the RCT to assess feasibility and acceptability of the intervention and control condition. The benchmarks were adapted from prior studies examining CBM-I in acute clinical settings (Beard et al., 2019; Beard et al., 2020).

Scenario Recognition Task/Bias Index (adapted from Mathews and Mackintosh, 2000 and version of task targeting OC-relevant beliefs by Clerkin & Teachman, 2011; Beadel et al., 2014). The Scenario Recognition Task is a measure of interpretation bias and was the primary measure of target engagement. In Phase 1 of the task, 12 scenarios describing ambiguous OC-related situations are presented, two for each of the six obsessional belief domains. Scenarios are titled with a description, and have a missing word in the final sentence, leaving the ambiguity of the scenarios unresolved (unlike CBM-I trainings which resolved the ambiguity in a benign manner). Example: *"You are standing on a rooftop with some friends who are enjoying the view. You begin to have thoughts about what it would be like to fall from this height. You try to think about something other than falling."*). Between Phases 1 and 2, participants completed a filler task in which they rated the pleasantness of 60 neutral images from the International Affective Picture System (IAPS; Lang et al., 1997), as done by Grisham and colleagues (2014). Neutral images were selected from a prior study which obtained ratings with participants in the same study site (Krompinger et al., unpublished).

In Phase 2 titles of the prior scenarios are presented with four potential interpretations of the scenarios (in randomized order): 1) Positive, healthy OC-irrelevant interpretation (example: *"As you are on the rooftop, you can't keep the falling thoughts under control, but you are still safe on the rooftop, enjoying the view"*); 2) Negative, OC-relevant interpretation (*"As you are on the rooftop, you can't keep the falling thoughts under control, and this ruins your evening with*

Journal Pre-proofs

friends"); 3) Positive distracter (Foil), which was not related to any of the obsessive belief domains (*"As you are on the rooftop, you are thinking about what a great time you are having"*), and 4) Negative distracter (Foil), (*"As you are on the rooftop, you are thinking about how cold you are"*). Participants are prompted to rate each interpretation for its similarity to the original scenario from *1 (very different in meaning)* to *4 (very similar in meaning)*.

To examine change in interpretation, we calculated Target Bias scores to measure the amount of positive OC-irrelevant vs. negative OC-relevant interpretations, and Foil Bias scores to measure positive vs. negative information more generally. Bias scores were calculated in accordance with prior studies by subtracting mean negative scores from mean positive scores for Targets or Foils (Clerkin & Teachman, 2011; Grisham et al., 2014). Each index demonstrated excellent internal consistency in our sample [Target (Positive: Cronbach's $\alpha = .926$; Negative: Cronbach's $\alpha = .875$) and Foil (Positive: Cronbach's $\alpha = .938$; Negative: Cronbach's $\alpha = .929$)]. Higher Target Bias scores indicated lower levels of interpretation bias (i.e., greater tendency to endorse positive interpretations relative to negative interpretations).

Obsessive Beliefs Questionnaire (OBQ-44; OCCWG, 2005; **OBQ-9;** Gagné et al., 2018). OBQ-44 is a 44-item self-report measure of obsessive beliefs which was given to participants upon admission to the program as part of routine intake procedures, and used to determine study eligibility. OBQ-9 (Gagné et al. 2018) is a 9-item validated short form of the OBQ-44 and administered at all timepoints as a secondary measure of target engagement, due to the similarities in content between the CBM-I training and Scenario Recognition Task. (Cronbach's $\alpha = .77$ in the current sample).

Structured Clinical Interview for DSM-5 Disorders (SCID-5; First et al., 2015). The SCID-5 is a structured clinical interview that assesses for DSM-5 diagnoses, administered by

Journal Pre-proofs

trained staff and graduate students under the supervision of a licensed clinical psychologist. Primary and comorbid diagnoses were assigned from the SCID-5 for 100% of participants in the feasibility study, and 83% of participants in the RCT. Due to program scheduling conflicts, the remaining participants were assigned diagnoses by their program therapists.

Yale-Brown Obsessive Compulsive Scale (Y-BOCS; Goodman et al. 1989). The Y-BOCS is considered the gold-standard interview assessment of OCD symptom severity. Responses are rated on a 5-point Likert scale from 0 (not at all/none) to 4 (extreme). The Y-BOCS was administered by trained research staff and graduate students under the supervision of a licensed clinical psychologist.

Exit Interview (adapted from Beard et al., 2019). The exit interview was conducted by a member of the study staff with participants in both conditions to assess acceptability. It included five items that were rated by level of agreement from 0-7 (Cronbach's $\alpha = .80$), as well as open-ended prompts about the most helpful and least helpful aspects of the intervention and suggestions for improvement. This qualitative data was independently reviewed by the first, third and fifth authors to create an initial coding framework. These three raters then met together to compare codes, resolve inconsistencies, and refine codes until 100% agreement was reached. Broader categories were agreed upon and reviewed with the last author. Interrater reliability was not calculated given that the coding was refined iteratively until consensus was obtained.

Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000). Participants rated credibility (Cronbach's $\alpha = .78$) and expectancy (Cronbach's $\alpha = .85$) after receiving a brief rationale for either CBM-I or psychoeducation. The CEQ consists of 3 items rated 1 through 9 to assess credibility (i.e., "*At this point, how logical does the treatment seem?*''), and 2 items rated from 0 to 100% to assess expectancy (i.e., "*By the end of the computerized treatment sessions,*

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how much improvement in your OCD symptoms do you really feel will occur?"). Higher scores indicate higher expectancy or credibility.

Procedure

Interested participants who consented to the study completed a pre-intervention assessment during their first week of treatment at the residential treatment clinic and were then randomized to CBM-I or psychoeducation. Following the pre-intervention assessment and randomization, participants were scheduled for eight sessions of CBM-I or psychoeducation (ideally administered twice weekly across four weeks; however, due to the varying duration of program admission, we allowed the weekly number of sessions to vary as needed), a post-intervention assessment, and a one-month follow-up assessment which was completed in person (43%) or by phone (57%). Between the fourth and fifth sessions, a mid-point assessment was also administered.

CBM-I and psychoeducation sessions took approximately 10-15 minutes to complete, and were completed during the treatment day between appointments or during the lunch hour. All sessions were administered through a desktop computer in a large office space in the clinic, relatively free from distractions. Participants were compensated $30 overall for completing the pre-, mid-, and post-intervention assessments, and $15 for the follow-up assessment. Because our primary goal was to determine feasibility in a clinic setting, we did not compensate for completing intervention sessions. The study was approved by the Partners Human Research Committee and pre-registered at clinicaltrials.gov (NCT03799419).

Statistical Analyses

Missing Data. In accordance with the intention-to-treat principle, the last collected data of participants who did not complete all assessments (n = 3) was carried forward (Alshurafa et

Journal Pre-proofs

al., 2012). Specifically, at post-intervention, was carried forward for OBQ-44 (n = 1), Scenario Recognition Task (n = 2), and Y-BOCS (n = 1) scores, and at 1-month follow-up, data was carried forward for Y-BOCS scores (n = 2). These participants had discharged suddenly from the IRT program due to the COVID-19 pandemic (n = 1 Psychoeducation, n = 1 CBM-I), or were lost to follow-up (n = 1).

First, to test our hypotheses about feasibility benchmarks that at least 50% of participants approached would consent to the study, dropout rate would be below 25%, and at least 75% of participants would complete at least six out of the training sessions, we examined frequency data. Second, to test our hypothesis that CBM-I would be found at least moderately credible (measured by mean score of ≥5 on item #1 of the CEQ), and meet acceptability benchmarks (mean score on the Exit Interview of ≥4.5 of 7), we examined descriptive data. Third, to test our hypothesis that the benchmark for change in interpretation bias (d = .20, small effect) would be met by participants in the CBM-I condition, though not in the control, we examined effect sizes. All analyses were conducted using SPSS software version 24 (SPSS Inc., Chicago, IL, USA).

Results

Feasibility Study

All four participants completed the eight sessions. Participants provided positive feedback; we did rapid coding of this feedback to be able to make any needed modifications to the protocol immediately. Feedback included, *"[CBM-I] prompted me to think about things in a non-OCD and non-perfectionistic way; modeling a more normal response/behavior"* and *"it made me pause and think about how I should react to certain situations vs. how my OCD wants me to respond."* Our initial findings suggested CBM-I was acceptable and feasible within our

Journal Pre-proofs

naturalistic setting without disrupting treatment as usual. This supported the next step of conducting a pilot RCT with a larger sample and control condition.

CBM-I modifications. After reviewing feedback from the exit interviews, we decided not to change the content of the training, and only made minor formatting changes and protocol adjustments. We had originally intended to administer the trainings during the program's lunch hour due to this facilitating participation in CBM-I in another naturalistic hospital setting (Beard et al., 2019). However, we learned during the feasibility study the clinical importance for some patients with OCRDs to have lunch with a behavioral coach and decided to be more flexible about training times during the treatment day.

Pilot RCT

Sample Characteristics. Groups did not differ on gender ($\chi^2(2) = .39$, $p = .823$), race ($\chi^2(4) = 3.84$, $p = .428$), primary DSM-5 diagnosis ($\chi^2(3) = 1.29$, $p = .733$), age ($t(28) = .999$, $p = .326$, $d = 0.48$), baseline OCD symptoms ($t(28) = .42$, $p = .679$, $d = 0.17$), baseline interpretations ($t(28) = .844$, $p = .406$, $d = 0.32$), or baseline expectancy ($t(28) = -.52$, $p = .604$, $d = 0.22$) or credibility ($t(28) = -.49$, $p = .63$, $d = .21$).

Feasibility and Acceptability. See Table 2 for full data on our primary outcomes of feasibility and acceptability. Of the patients who were offered participation, 63% consented. Most participants in both the CBM-I (87%) and Psychoeducation (88%) conditions completed all eight sessions, supporting our hypothesis that at least 75% of enrolled participants would complete at least six of the eight training sessions. The mean number of sessions completed by participants was 7.77 ($SD = .75$; range = 5-8) in the CBM-I condition and 7.63 ($SD = 1.06$; range = 5-8) in the psychoeducation condition. Ten percent ($n = 3$) of participants did not complete the sessions twice weekly across four weeks due to early discharge and scheduling difficulties.

Journal Pre-proofs

Our benchmarks were met for credibility ratings in both conditions (see Table 2). Credibility and expectancy scores were similar across the CBM-I and psychoeducation groups, supporting psychoeducation as a credible control condition. For CBM-I, the mean CEQ credibility subscale score was 4.68 (*SD* = 1.40; range = 2.33-7.33) and mean expectancy was 3.20 (*SD* = 1.97; range = 1.00-9.50). For psychoeducation, the mean credibility score was 4.96 (*SD* = 1.21; range = 2.67-6.67) and mean expectancy was 3.63 (*SD* = 1.87; range = 1.50-7.00).

On the Exit Interview, benchmarks were met for acceptability for most individual items (see Table 2 for the specific items), with the mean response across all items above the benchmark for both the CBM-I (*M* = 4.82, *SD* = 1.18) and psychoeducation conditions (*M* = 5.1, *SD* = .79). The individual items that were slightly below benchmark were the mean rating for helpfulness of the computer program (*M* = 4.18, *SD* = 1.82) and help in practicing what was learned in the IRT program (*M* = 4.27, *SD* = 1.72) , with the other items (relevance of content, user-friendliness, and enjoyment of the task) well above the benchmarks (see Table 2). Qualitative feedback about CBM-I was largely positive, with overarching themes related to the helpful repeated practice of skills, perceived changes in thinking styles, and perceived mechanisms of action (see Table 3).

Target engagement: OC-relevant interpretation bias. Benchmarks for target engagement were met (see Table 2). Due to the preliminary nature of the study and small sample size, we examined effect sizes of target engagement, as indexed by Target Bias scores. There were large effects between groups at mid-intervention (*d* = 1.09, 95: CI: .23 to 1.94), and post-intervention (*d* = 1.54, 95% CI: .62 to 2.43). The percent change from pre to post-intervention in Target Bias scores for the CBM-I condition was 143% and for psychoeducation it was 35%, reflecting greater change in interpretation bias scores in the CBM-I condition (see Fig. 2).

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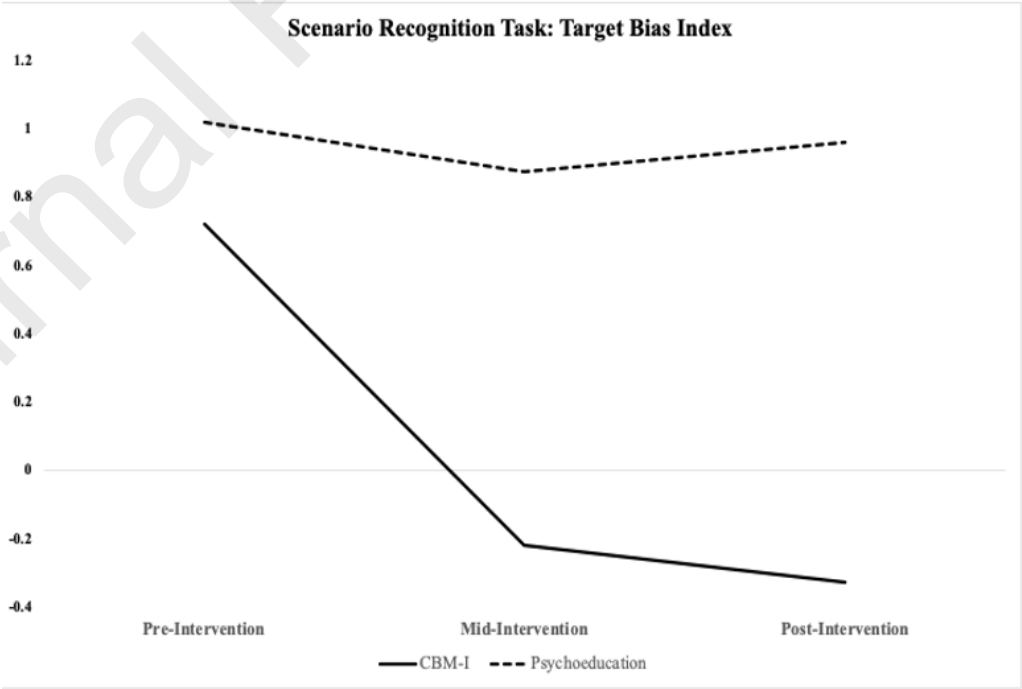
From pre- to post-intervention, the effect of the change in Target Bias was large (d = .90, 95% CI: 1.39 to .40) for CBM-I and trivial (d = .06, 95% CI: .75 to .64) for psychoeducation. As expected, the change in Target Bias in the CBM-I group was greater than the pre- to post-intervention effect for Foil Bias (d = .41, 95% CI: .84 to .03). We examined change between each time point and found there was significant change in the expected direction from pre- to mid-intervention for the CBM-I group (d = .85, 95% CI: 1.3 to .35) but no change from mid- to post-intervention (d = .10, 95% CI: .52 to .32).

Target engagement: obsessive beliefs. We also examined obsessive beliefs as a secondary measure of target engagement, and found the percent change from pre to post-intervention in obsessive beliefs scores were comparable across conditions; 29% in CBM-I and for psychoeducation it was 26% (see Table 2). Overall from pre- to post-intervention, the effect of the change in obsessive beliefs was large in both CBM-I (d = 1.09, 95% CI: .55 to 1.62) and psychoeducation (d = 1.04, 95% CI: .14 to .1.89).

Figure 2. *Interpretation Bias by Condition*



Preliminary clinical outcomes. Given that the primary aim of this pilot RCT was to establish feasibility and acceptability, the

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design does not allow for tests of between-group differences in clinical outcomes, and therefore we have only presented changes in OCD symptoms as descriptive data (see Table 2). Y-BOCS scores consistently decreased from pre- to post-intervention in CBM-I (d = 1.25, 95% CI: .68 to 1.80) and psychoeducation (d = .85, 95% CI: .01 to 1.65]. Of note, these results remained the same when the scores from the 3 participants where staff masking was broken were removed from the analyses.

Discussion

Summary of Results

This study was the first investigation of CBM-I in a naturalistic treatment setting for adults seeking IRT for OCRDs. Our primary aim was to evaluate the feasibility and acceptability of our adapted CBM-I protocol. Our benchmarks for feasibility and acceptability were met; consent rate, retention, and adherence were all strong. CBM-I showed strong feasibility in this setting - nearly two-thirds of patients offered to participate consented to participate, with no dropout. The vast majority (87%) of participants completed all eight sessions; reasons for not completing them were early discharge from the IRT program for reasons unrelated to this study. The high retention rate is likely due to the ease in which these brief trainings fit into patients' schedules, even during a full day of treatment, without requiring availability or resources from clinical staff. Our results provide further evidence for the feasibility and acceptability of this type of protocol as an adjunctive intervention in a naturalistic setting, as had been shown previously with patients in a transdiagnostic acute psychiatric hospital setting (Beard et al., 2019; 2020) and inpatient and residential alcohol settings (Eberl et al., 2013; Manning et al., 2016; Wiers et al., 2015).

Acceptability of CBM-I was also supported. Responses in the exit interviews were largely positive, with the mean responses for all questions above 4 (on a scale ranging 0-7); most items

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met the benchmarks. Themes that emerged from the qualitative feedback (Table 3) suggested that the scenarios in the CBM-I trainings were relevant to participants' symptoms, and that overall it was helpful in increasing awareness, challenging thinking, cognitive restructuring, cognitive defusion, normalizing intrusive thoughts, and through the use of repeated practice.

The qualitative data also provides several examples of how the program could be enhanced. First, due to OCRDs being a highly heterogeneous group of disorders in terms of symptom presentations, some of the feedback spoke to this and how some participants may not have found the trainings as helpful. For example, when asked what was least helpful about the task, participants stated some of the scenarios were irrelevant to their symptoms or too repetitive. This speaks to how different symptom presentations within OCRDs can be, and how personalizing the stimuli is an important future direction.

Additionally, when asked how the program could improve, 32% (n = 7) of participants pointed out typographical and grammatical errors in the program. Many of the comments appeared detailed-oriented and seem to align with perfectionism, a common symptom presentation in OCRDs, especially related to excessive concern with making mistakes (Frost & Steketee, 1997; Frost et al., 2002; Moretz & McKay, 2009). In an IRT program for OCRDs, it is likely that the sample was higher in perfectionism than in participants in the majority of prior CBM studies, potentially leading these seemingly small content errors to urges to correct mistakes and lower acceptability for the CBM-I training. Relatedly, some participants reflected on being focused on providing "the best" answers due to perfectionism.

Overall, this qualitative data reinforces the importance of doing careful pilot testing of CBM programs and making refinements accordingly prior to conducting large-scale RCTs. Additionally, our study contributes to the small body of CBM research examining patient attitudes

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towards the intervention (Beard et al., 2012; 2019; 2020). The feedback suggests that this CBM-I was relevant to participants' symptoms, helpful with practicing cognitive techniques, and that future adaptations may benefit from including personalized stimuli.

We randomized a smaller number of patients to a psychoeducation condition to evaluate the feasibility of using this as a comparison arm in a future larger trial. Our data supports psychoeducation as a strong control condition, which was credible and acceptable to patients, yet did not target interpretation. Credibility and expectancy scores were similar across CBM-I and psychoeducation, both meeting our a priori benchmarks, suggesting participants believed both programs were credible and they expected them to be helpful. Acceptability ratings for psychoeducation were similar to those for CBM-I. Qualitative comments suggest how the program was helpful in that it provided, *"helpful building blocks"* and *"did a good job of explaining some of the 'crazy' things I do that are actually common OCD things."*

As expected, the CBM-I group met the benchmark for target engagement, whereas the psychoeducation group did not. CBM-I had a large effect on interpretation bias, whereas psychoeducation had a trivial effect. Importantly, the change in foil bias scores showed a smaller effect size than change in target bias scores. This suggests participants in CBM-I had greater improvements over time in their abilities to make adaptive versus maladaptive interpretations, while there was no effect on interpretation of generally positive or negative situations. Further examination revealed that the effects were generally largest in magnitude between pre-intervention and mid-intervention as opposed to mid-intervention and post-intervention, suggesting that the intervention has its largest impact after the first half of the eight training sessions. This is consistent with several recent studies supporting early gains in treatment in IRT for OCD (Brennan et al., 2014; Krompinger et al., 2017; Falkenstein et al., 2019). Possible reasons for these gains during

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the first four sessions could include that participants' levels of motivation and willingness to engage in the training may have been highest during this time, along with having recently heard the rationale for CBM-I, and the training being more novel and less repetitive to the participants at this stage.

Although this study was not adequately powered for between-group comparisons, descriptive data does not suggest that the CBM-I group experienced stronger reductions in maladaptive beliefs compared to psychoeducation. During the treatment program, patients undergo interventions which target mechanism-specific symptoms of OCRDs, such as obsessive beliefs. Thus, we expected all participants' obsessive beliefs to change over time as a function of being admitted to a treatment program during the course of the study, though we hypothesized CBM-I would augment the amount of change. It is possible that such a low-intensity intervention was not powerful enough to achieve 'far transfer' outcomes of interpretation bias engagement such as obsessive beliefs in people already receiving intensive treatment. The prior study which examined CBM-I as an augmentation for adolescents in treatment for OCD discusses the possibility that treatment may be so effective that "there is no room" to detect any additional benefits of CBM-I (Salemink et al., 2015). Additionally, it may be that the current study did not allow for enough time to pass to observe the putative distal effect of CBM-I which would need to be tested with mediation with a larger sample and over a longer time period. A prior meta-analysis demonstrated that CBM-I effect sizes for emotional outcomes are small (Cristea et al., 2015). This is likely especially the case in a study such as the current one, in which the intervention is a low-intensity augmentation to a powerful evidence-based treatment, ERP.

Preliminary examination of descriptive data shows that Y-BOCS scores improved across both conditions, as expected, and with what appears to be more improvement from pre-to post-

Journal Pre-proofs

intervention in the CBM-I group. This pilot study was not adequately powered to detect the effect of CBM-I on clinical outcomes, and would require a large sample to do so. The current pattern of symptom reduction suggests that a larger trial is warranted.

Limitations

First, as a feasibility and acceptability trial, this study was not designed to statistically compare groups, and included unbalanced randomization to learn more about the CBM-I intervention. Thus, we cannot conclude anything about CBM-I's superiority or lack thereof to psychoeducation. Relatedly, this study was not powered to examine the effects of comorbid diagnoses, which will be important in future studies with larger samples. Second, there was a lack of diversity in racial/ethnic identities among participants due to the demographic characteristics of the hospital where the study took place. Therefore, these results must be interpreted with caution with regard to generalizability to patients who identify as BIPOC. Third, while this study has ecological validity in that it was conducted in a naturalistic sample, all patients were seeking IRT levels of care, and therefore findings may not generalize to patients seeking once-weekly outpatient treatment. To increase generalizability, additional studies of feasibility and acceptability would need to be conducted with more diverse samples and patients in outpatient settings, and modified accordingly. Fourth, as presented in the qualitative data, because of the heterogeneity of OCD, participants provided feedback that the least helpful part of the program for them was scenarios targeting symptoms they did not have (i.e., contamination, scrupulosity, and perfectionism). Future studies should consider personalizing the stimuli according to participants' specific symptom domains. Fifth, although our eligibility criteria were not limited to OCD and we anticipated better representation of non-OCD OCRDs, only one participant in both the feasibility and RCT trials had an OC-related disorder. Lastly, approximately one third of participants noted

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typographical and grammatical errors in the CBM-I trainings, which could have had an effect on engagement during the sessions.

Conclusions

The current study found CBM-I is a feasible and acceptable augmentation to treatment as usual for patients undergoing IRT, and it led to improvement in interpretation. Establishing the feasibility of this intervention constitutes an important step towards refining augmentation strategies for severe OCRD cases, but also is in keeping with a broader push in the field to move to interventions that target underlying processes thought to maintain symptom presentations (cf., Hoffmann & Hayes, 2018). This push calls for renewed emphasis on idiographic functional analysis, including an interrogation of patients' belief systems and the contexts in which they arise. In the case of severe and/or treatment-refractory OCD, it may be that traditional ERP is rendered less effective should the patients' underlying relationship to cognitions be unaddressed (e.g., Arch et al., 2012). For example, a patient who is strongly fused to thoughts that an objectively non-threatening situation is threatening, even amidst repeated exposure, may experience limited symptom change. CBM-I may constitute a path to directly address this process and promote greater flexibility amidst the experience of threatening interpretations.

The next step in this line of research is to conduct a larger, adequately-powered RCT to examine 'far transfer' tasks and clinical outcomes. It will be important to have a larger number of participants with different types of OCRD symptoms (i.e., perfectionism, scrupulosity, BDD) to be able to learn for which subtypes CBM-I may be most helpful. Ultimately, if interpretation bias is found to be a promising mechanism of response, future work will translate these findings to develop augmentations to ERP for patients with OC-related disorders.

Journal Pre-proofs

Journal Pre-proofs

References

Alshurafa, M., Briel, M., Akl, E. A., Haines, T., Moayyedi, P., Gentles, S. J., … Guyatt, G. H. (2012). Inconsistent definitions for intention-to-treat in relation to missing outcome Data: Systematic review of the methods literature. *PLoS ONE, 7(11), e49163.*

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders (DSM-5)*.

Amir, N., Kuckertz, J. M., Najmi, S., & Conley, S. L. (2015). Preliminary evidence for the enhancement of self-conducted exposures for OCD using cognitive bias modification. *Cognitive Therapy and Research, 39(4), 424–440.* doi:10.1007/s10608-015-9675-7

Angelakis, I., Gooding, P., Tarrier, N., & Panagioti, M. (2015). Suicidality in obsessive compulsive disorder (OCD): A systematic review and meta-analysis. *Clin.Psych.Rev, 39.*

Arch, J. J., Wolitzky-Taylor, K. B., Eifert, G. H., & Craske, M. G. (2012). Longitudinal treatment mediation of traditional cognitive behavioral therapy and acceptance and commitment therapy for anxiety disorders. *Behaviour Research and Therapy, 50(7-8), 469–478.*

Beadel, J. R., Smyth, F. L., & Teachman, B. A. (2014). Change processes during cognitive bias modification for obsessive compulsive beliefs. *Cognitive Therapy and Research, 38.*

Beard, C., McHugh, R. K., Björgvinsson, T., Ramadurai, R., & Pollak, J. P. (2020). HabitWorks: Development of a CBM-I smartphone app to augment and extend acute treatment. *Behavior Therapy.* doi:10.1016/j.beth.2020.04.013

Beard, C., Rifkin, L. S., Silverman, A. L., & Bjorgvinsson, T. (2019). Translating CBM-I into real-world settings: Augmenting a CBT-based psychiatric hospital program. *Behavior Therapy, 50*(3), 515-530. doi: 10.1016/j.beth.2018.09.002

Beard, C., Weisberg, R. B., & Primack, J. (2011). Socially anxious primary care patients'

Journal Pre-proofs

attitudes toward cognitive bias modification (CBM): A qualitative study. *Behavioural and Cognitive Psychotherapy, 40(05), 618–633.* doi:10.1017/s1352465811000671

Brennan, B. P., Lee, C., Elias, J. A., Crosby, J. M., Mathes, B. M., Andre, M.-C., … Hudson, J. I. (2014). Intensive residential treatment for severe obsessive-compulsive disorder: Characterizing treatment course and predictors of response. *J. Psych.Res., 56, 98–105.*

Clarke, P. J. F., Nanthakumar, S., Notebaert, L., Holmes, E. A., Blackwell, S. E., & MacLeod, C. (2013). Simply imagining sunshine, lollipops and rainbows will not budge the bias: The role of ambiguity in interpretive bias modification. *Cog. Ther. and Res., 38, 120–131.*

Clerkin, E. M., & Teachman, B. A. (2011). Training interpretation biases among individuals with symptoms of obsessive compulsive disorder. *J. Behav. Ther. & Exp. Psych., 42*, 337–343.

Conley & Wu, 2018; Conley, S. L., & Wu, K. D. (2018). Experimental modification of dysfunctional interpretations in individuals with contamination concerns. *Journal of Behavior Therapy and Experimental Psychiatry, 59, 56–64.*

Cristea, I., Kok, R., & Cuijpers, P. (2015). Efficacy of cognitive bias modification interventions in anxiety and depression: Meta-analysis. *British Journal of Psychiatry, 206*(1), 7-16.

Devilly, G. J., & Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *Journal of Behavior Therapy and Experimental Psychiatry, 31*(2), 73-86.

Eberl, C., Wiers, R. W., Pawelczack, S., Rinck, M., Becker, E. S., & Lindenmeyer, J. (2013). Approach bias modification in alcohol dependence: Do clinical effects replicate and for whom does it work best? *Developmental Cognitive Neuroscience, 4,* 38-51.

Falkenstein, M. J., Nota, J. A., Krompinger, J. W., Schreck, M., Garner, L. E., Potluri, S., … Elias, J. A. (2019). Empirically-derived response trajectories of intensive residential treatment in obsessive-compulsive disorder: A growth mixture modeling approach.

Journal Pre-proofs

Journal of Affective Disorders, 245, 827–833. doi:10.1016/j.jad.2018.11.075

First, M. B., Williams, J. B. W, Karg, R.S., Spitzer, R. L. (2015). Structured Clinical Interview for DSM-5— Research Version (SCID-5 for DSM-5). Arlington, VA, APA.

Fisher, P. L., & Wells, A. (2005). How effective are cognitive and behavioral treatments for obsessive–compulsive disorder? A clinical significance analysis. *BRAT, 43, 1543–1558.*

Foa, E. B., Hembree, E. A., Cahill, S. P., Rauch, S. A. M., Riggs, D. S., Feeny, N. C., & Yadin, E. (2005). Randomized trial of prolonged exposure for posttraumatic stress disorder with and without cognitive restructuring: Outcome at academic and community clinics. *Journal of Consulting and Clinical Psychology, 73*(5), 953–964.

Fontenelle, I. S., Fontenelle, L. F., Borges, M. C., Prazeres, A. M., Rangé, B. P., Mendlowicz, M. V., & Versiani, M. (2010). *Quality of life and symptom dimensions of patients with obsessive–compulsive disorder. Psychiatry Research, 179(2), 198–203.*

Frost, R. O., Novara, C., & Rhéaume, J. (2002). Perfectionism in obsessive compulsive disorder. In *Cognitive Approaches to Obsessions and Compulsions* (pp. 91-105). Pergamon.

Frost, R. O., & Steketee, G. (Eds.). (2002). *Cognitive approaches to obsessions and compulsions: Theory, assessment, and treatment*. Elsevier.

Gagné, J.-P., Van Kirk, N., Hernandez-Vallant, A., Potluri, S., Krompinger, J. W., Cattie, J. E., … Elias, J. A. (2018). Validating an abbreviated version of the Obsessive Beliefs Questionnaire. *Journal of Clinical Psychology.* doi:10.1002/jclp.22629

Goodman, W. K., Price, L. H., Rasmussen, S. A., Mazure, C., Fleischmann, R. L., Hill, C. L., ... & Charney, D. S. (1989). The Yale-Brown obsessive compulsive scale: I. Development, use, and reliability. *Archives of General Psychiatry*, *46*(11), 1006-1011.

Grafton, B., MacLeod, C., Rudaizky, D., Holmes, E. A., Salemink, E., Fox, E., & Notebaert, L.

Journal Pre-proofs

(2017). Confusing procedures with process when appraising the impact of cognitive bias modification on emotional vulnerability. *British Journal of Psychiatry, 211(05), 266–71.*

Grisham, J. R., Becker, L., Williams, A. D., Whitton, A. E., & Makkar, S. R. (2014). Using cognitive bias modification to deflate responsibility in compulsive checkers. *Cognitive Therapy and Research, 38(5), 505–517.* doi:10.1007/s10608-014-9621-0

Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap). *Journal of Biomedical Informatics. 42.*

Holmes, E. A., Lang, T. J., & Shah, D. M. (2009). Developing interpretation bias modification as a "cognitive vaccine" for depressed mood: imagining positive events makes you feel better than thinking about them verbally. *Journal of Abnormal Psychology*, *118*(1), 76.

Kamath, P., Reddy, Y. C., & Kandavel, T. (2007). Suicidal behavior in obsessive-compulsive disorder. *The Journal of Clinical Psychiatry*, *68*, 1741-1750.

Krompinger, J. W., Monaghan, S. C., Gironda, C. M., Garner, L. E., Crosby, J. M., Brennan, B. P., & Elias, J. A. (2017). Early response is predictive of outcome in intensive behavioral treatment for obsessive compulsive disorder. *J. OC & Related Disorders, 15, 57–63.*

Lang, P., & Bradley, M. M. (2007). The International Affective Picture System (IAPS) in the study of emotion and attention. *Handbook of emotion elicitation & assessment*, *29*, 70-3.

Manning, V., Staiger, P. K., Hall, K., Garfield, J. B. B., Flaks, G., Leung, D., … Verdejo-Garcia, A. (2016). Cognitive bias modification training during inpatient alcohol detoxification reduces early relapse: A randomized controlled trial. *Alcoholism:Clin.Exp.Res.,40.*

Markarian, Y., Larson, M. J., Aldea, M. A., Baldwin, S. A., Good, D., Berkeljon, A., … McKay, D. (2010). Multiple pathways to functional impairment in OCD. *Clin.Psych.Review, 30.*

Mathews, A., & Mackintosh, B. (2000). Induced emotional interpretation bias and anxiety.

Journal Pre-proofs

Journal of Abnormal Psychology, 109(4), 602–615. doi: 10.1037/0021-843X.109.4.602

Menne-Lothmann, C., Viechtbauer, W., Höhn, P., Kasanova, Z., Haller, S. P., Drukker, M., … Lau, J. Y. F. (2014). *How to boost positive interpretations? A meta-analysis of the effectiveness of cognitive bias modification for interpretation. PLoS ONE, 9(6).*

Moretz, M. W., & McKay, D. (2009). The role of perfectionism in obsessive–compulsive symptoms: "Not just right" experiences and checking compulsions. *J.Anxiety. 23*, 640-44.

Obsessive Compulsive Cognitions Working Group. (1997). Cognitive assessment of obsessive-compulsive disorder. *Behaviour Research and Therapy, 35*(7), 667-681.

Obsessive Compulsive Cognitions Working Group. (2001). Development and initial validation of the obsessive beliefs questionnaire and the interpretation of intrusions inventory. *Behaviour Research and Therapy, 39*(8), 987-1006.

Onken, L. S., Carroll, K. M., Shoham, V., Cuthbert, B. N., & Riddle, M. (2014). Reenvisioning clinical science: Unifying the discipline to improve the public health. *ClinPsychSci, 2.*

Premo, J. E., Sarfan, L. D., & Clerkin, E. M. (2016). Training interpretation biases among individuals with body dysmorphic disorder symptoms. *Body Image, 16, 54–62.*

Price, R. B., Wallace, M., Kuckertz, J. M., Amir, N., Graur, S., Cummings, L., ... & Bar-Haim, Y. (2016). Pooled patient-level meta-analysis of children and adults completing a computer-based anxiety intervention targeting attentional bias.*Clin.Psych.Rev., 50,*37-49.

Rachman, S. (1997). The evolution of cognitive behaviour therapy. In: S*cience and Practice of Cognitive Behaviour Therap*y, Eds: D. Clark. C. G. Fairburn & M. G. Gelder, pp. 1–26.

Radomsky, A. S., Alcolado, G. M., Abramowitz, J. S., Alonso, P., Belloch, A., Bouvard, M…., & Wong, W. (2014). Part 1- You can run but you can't hide: Intrusive thoughts on six continents. *Journal of Obsessive-Compulsive and Related Disorders, 3*(3), 269-279.

Journal Pre-proofs

Reuther, E. T., Davis, T. E., III, Rudy, B. M., Jenkins, W. S., Whiting, S. E., & May, A. C. (2013). Intolerance of uncertainty as a mediator of the relationship between perfectionism and obsessive-compulsive symptom severity. *Depression and Anxiety, 30*(8), 773-777.

Salemink, E., Wolters, L., & de Haan, E. (2015). Augmentation of treatment as usual with online cognitive bias modification of interpretation training in adolescents with obsessive compulsive disorder: a pilot study. *J. of Behav. Ther. and Exp. Psychiatry*, *49*, 112-119.

Salkovskis, P. M. (1985). Obsessional-compulsive problems: A cognitive-behavioural analysis. *Behaviour Research and Therapy, 23*(5), 571-583. doi: 10.1016/0005-7967(85)90105-6

Stanley, I. H., Hom, M. A., & Joiner, T. E. (2018). Modifying mental health help-seeking stigma among undergraduates with untreated psychiatric disorders: A pilot randomized trial of a novel cognitive bias modification intervention. *Behaviour Research and Therapy*.

Summers, B. J., & Cougle, J. R. (2016). Modifying interpretation biases in body dysmorphic disorder: Evaluation of a brief computerized treatment. *Beh. Res. and Ther.*, *87*, 117-127.

Tolin, D. F., Woods, C. M., & Abramowitz, J. S. (2003). Relationship between obsessive beliefs and obsessive–compulsive symptoms. *Cognitive Therapy and Research, 27*, 657–669.

Wiers, C. E., Ludwig, V. U., Gladwin, T. E., Park, S. Q., Heinz, A., Weirs, R. W…., & Bermpohl, F. (2015). Effects of cognitive bias modification training on neural signatures of alcohol approach tendencies in male alcohol-dependent patients. *Add. Bio., 20*, 990-99.

Wilhelm, S., & Steketee, G. S. (2006). *Cognitive therapy for obsessive compulsive disorder: A guide for professionals*. New Harbinger Publications.

Wilver, N. L., & Cougle, J. R. (2019). An Internet-based controlled trial of interpretation bias modification versus progressive muscle relaxation for body dysmorphic disorder. *Journal of Consulting and Clinical Psychology*, *87*(3), 257.

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Table 1. *Pre-Intervention Demographic and Clinical Characteristics*

	Feasibility (*N* = 4) *M (SD)*	CBM-I (*n* = 22) *M (SD)*	Psychoeducation (*n* = 8) *M (SD)*
Age	28.50 (*9.85*)	30.36 (*8.44*)	27.25 (*3.77*)
	N (%)	*N (%)*	*N (%)*
Gender			
Female	4 (100%)	11 (50%)	4 (50%)
Male	---	10 (46%)	4 (50%)
Not listed: participant's write-in response "none"	---	1 (5%)	---
Race/Ethnicity			
White	4 (100%)	19 (86%)	7 (88%)
Multiracial	---	2 (9%)	---
Hispanic, Latino, or Spanish Origin	---	1 (5%)	---
Middle Eastern or North African	---	---	1 (13%)
Education			
Some high school	1 (25%)	1 (5%)	---
High school graduate/GED	---	1 (5%)	---
Some college	1 (25%)	5 (23%)	---
Bachelor's degree	---	10 (46%)	4 (50%)
Graduate or professional degree	2 (50%)	5 (23%)	4 (50%)
Sexual Orientation			
Heterosexual	1 (25%)	18 (82%)	8 (100%)
Gay	---	2 (9%)	---
Bisexual	3 (75.0%)	1 (5%)	---
Not Listed		1 (5%)	---

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Table 2. *Trial Benchmarks and Descriptive Data of Target Engagement and Clinical Outcomes*

	Benchmark	CBM-I *M (SD)*	Psychoeducation *M (SD)*
Trial Benchmarks			
Feasibility			
Consent rate	≥ 50%	63.3%	
Dropout rate	≤ 25%	0%	0%
Completion of 6 or more of the 8 sessions	≥ 75%	95.5%	95.5%
At least moderate credibility	≥ 5 on CEQ #1	6.05 (1.25)	6.63 (1.51)
Acceptability (Exit Interview)			
"I felt the computer program was helpful"	Mean ≥ 4.5	4.18 (1.82)	4.57 (1.72)
"The program included content and/or situations that were relevant to me."	Mean ≥ 4.5	4.73 (1.72)	5.00 (1.63)
"The program was user-friendly	Mean ≥ 4.5	6.14 (1.28)	6.14 (.690)
"[It] helped me practice what I learned with my behavior therapist, coaching, and/or groups"	Mean ≥ 4.5	4.27 (1.72)	4.86 (.690)
"I enjoyed the computer task that I completed."	Mean ≥ 4.5	5.10 (1.60)	4.50 (2.12)
Target Engagement: pre to post target bias	*d* ≥ *.2* in CBM-I	*d* = .90	*d* = .06
Descriptive Data of Target Engagement and Clinical Outcomes			
Target Bias Index: Pre-Intervention	---	-0.72 (.77)	-1.02 (1.09)
Target Bias Index: Mid-Intervention	---	0.22 (1.07)	-0.87 (-.77)
Target Bias Index: Post-Intervention	---	0.33 (0.75)	-0.96 (1.05)
OBQ-9: Pre-Intervention	---	43.18 (10.46)	39.25 (10.67)
OBQ-9: Post-Intervention	---	31.23 (14.48)	28.38 (9.30)
Y-BOCS: Pre-Intervention	---	26.18 (5.31)	25.25 (5.65)
Y-BOCS: Post-Intervention	---	18.18 (4.22)	20.00 (4.41)
Y-BOCS: 1-Month Follow-Up	---	18.64 (5.82)	18.63 (7.07)

Note. CBM-I: *n* = 22; Psychoeducation: *n* = 8. For item, *"I enjoyed the computer task that I completed."* CBM-I *n* = 10, Psychoeducation *n* = 2 due to item being added after study began.
Higher, positive values for the Target Bias Index indicate lower levels of interpretation bias.

Table 3. *Qualitative Feedback from RCT*

Theme	Example Quotes
Perceived Benefits of CBM-I	
Increasing awareness	*"Seeing negative patterns" "Helped me realize how much my thoughts changed over time"*
Challenging thinking	*"Made me question why I think the way I think" "It makes me think about different scenarios, seeing other solutions - instead of always negative"*
Cognitive restructuring	*"Forced you to look at situations from a perspective I don't normally take"*
Cognitive defusion	*"Put me in the mind frame that they're just thoughts and don't define you or your behaviors" "Everyday life can go on even if you have intrusive thoughts"*
Repeated practice	*"Constantly facing those situations and having the right answer be opposite of what I feel" "Changing my thinking about those thoughts each week"*
Relevance of scenarios	*"Could relate to all of them even if I didn't struggle with those thoughts"*
Suggestions for Improvement	
Not enough relevant scenarios	*"[Least helpful parts] were the scenarios that didn't apply to me (i.e., contamination)" "Scrupulosity and perfectionism situations were the least helpful"*
Triggered perfectionism	*"I was very aware of what answers I should provide to get a good score and not doing so was difficult due to my perfectionism; I wanted to get the best score"*
Program errors	*"Typos and grammatical errors were mildly distracting"*

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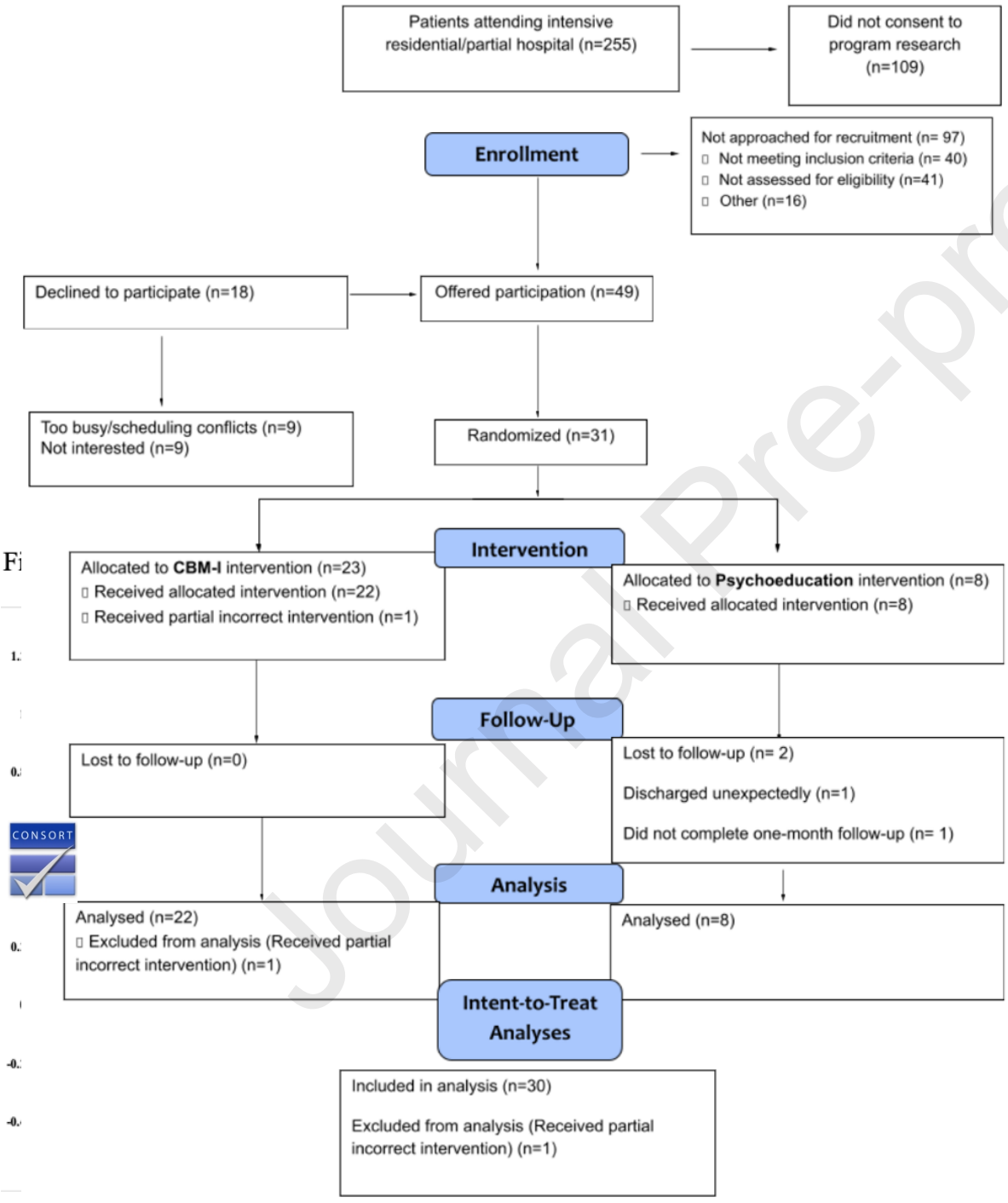
Figure 1. *CONSORT Flow Diagram for RCT*



Highlights

- First study of CBM-I in naturalistic treatment setting for adults with OCRDs
- Benchmarks were met for feasibility, acceptability, and target engagement
- Findings support larger RCT to determine if CBM-I enhances OCRD treatment response

CONSORT 2010 checklist of information to include when reporting a randomised trial*

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Section/Topic	Item No	Checklist item	Re on
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-1
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	n/a f
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7-8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7-8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8

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Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15-1
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	15-1
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	31
	13b	For each group, losses and exclusions after randomisation, together with reasons	31
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	26-2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	31
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-1
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17-1
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	23
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	23
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-2
Other information			
Registration	23	Registration number and name of trial registry	15
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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