

## Translating CBM-I Into Real-World Settings: Augmenting a CBT-Based Psychiatric Hospital Program

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Cognitive bias modification for interpretation (CBM-I) is an appealing augmentation to cognitive-behavioral therapy (CBT) because it targets cognitive bias efficiently via computerized training. Few studies have tested the combination of CBM-I and CBT, and none have translated lab-based CBM-I protocols to an acute psychiatric setting. The present study describes the development and implementation of CBM-I as an augmentation to a CBT-based partial hospital. We developed a transdiagnostic CBM-I based on the word–sentence association paradigm (WSAP), which reinforces individuals for endorsing benign interpretations and rejecting negative interpretations of ambiguous sentences. Over two iterations of development, we randomly assigned patients ( $N = 127$ ;  $M$  age = 34.21; 58% female, 40% male, 2% nonbinary) to either CBM-I or a control group (Phase 1: neutral WSAP task; Phase 2: treatment as usual). CBM-I comprised daily sessions (10 minutes) completed during program hours, and number of sessions varied naturalistically according to patient length of stay. Primary outcomes included feasibility, acceptability, and target engagement (interpretation bias). CBM-I was feasible

and acceptable to acute psychiatric patients, and successfully shifted interpretation for novel stimuli. Patient feedback suggested that participants viewed CBM-I as bolstering their primary CBT-based care. Exploratory analyses examining clinical benefit revealed a small between-group effect on anxiety severity ( $d = 0.378$ ), but no group differences on depression outcomes ( $d = 0.008$ ). Findings indicate that CBM-I is a feasible and acceptable augmentation to CBT-based partial hospital care. Future studies are warranted to determine who is most likely to benefit from this low-intensity approach.

*Keywords:* cognitive bias modification; interpretation bias; CBT; hospital; effectiveness

DAILY LIFE OFTEN REQUIRES the resolution of ambiguity. For example, not getting a job or a friend not returning a call are situations that can be interpreted in multiple ways. The way in which individuals automatically resolve the countless ambiguous situations encountered each day impacts their affect and behavior. Theoretical models propose that a tendency to resolve ambiguity negatively (i.e., interpretation bias) maintains emotional disorders (see Hirsch, Meeten, Krahé, & Reeder, 2016, for a review). Interpretation bias contributes to a vicious cycle in which individuals experience the world as hopeless or threatening,

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which leads to negative affect, behavioral avoidance, and more biased cognition (e.g., Beck & Clark, 1997; Mathews & MacLeod, 2005). Robust data from animal (e.g., Enkel et al., 2010) and human studies (see Hirsch et al., 2016) have demonstrated that interpretation bias is a transdiagnostic mechanism in emotional disorders and a risk factor for developing psychopathology (e.g., Dearing & Gotlib, 2009).

Laboratory-based experimental studies suggest that interpretation bias plays a causal role in emotional disorders. Researchers have experimentally manipulated interpretation via repetitive training tasks, which are typically modified versions of tasks originally developed to assess interpretation. Referred to as cognitive bias modification for interpretation (CBM-I) or interpretation bias modification, such tasks can induce a negative bias in healthy individuals, leading to impaired emotion regulation in response to stress (Wilson, MacLeod, Mathews, & Rutherford, 2006). Moreover, CBM-I affects related cognitive biases, including attention (Amir, Bomyea, & Beard, 2010) and memory (Tran, Hertel, & Joormann, 2011).

CBM-I has grown exponentially over the past decade from its roots in experimental psychopathology testing causal relations between interpretation bias and emotional vulnerability (e.g., Mathews & MacLeod, 2002), to a potential treatment. Meta-analyses suggest that CBM-I has reliable effects on interpretation bias (see Hallion & Ruscio, 2011; Lau, 2013; MacLeod & Mathews, 2012; Menne-Lothmann et al., 2014, for reviews). CBM-I may also improve clinical symptoms when delivered over multiple sessions in a laboratory setting (e.g., Amir & Taylor, 2012)—however, a meta-analysis conducted by Cristea, Kok, and Cuijpers (2015) concluded that current CBM-I tasks' effects on anxiety and depression are small. While most CBM-I studies have targeted depression and various types of anxiety, studies also suggest promise for various populations including obsessive-compulsive disorder (OCD; e.g., Amir, Kuckertz, Najmi, & Conley, 2015), trauma reactions (Woud, Verwoerd, & Krans, 2017), body dysmorphic disorder (Summers & Cogle, 2016), and trait hostility (Hawkins & Cogle, 2013), though more research testing CBM-I in populations with severe mental health symptoms and co-occurring disorders is needed.

### Translation of Laboratory Findings Into Real-World Settings

There are numerous potential methods of implementing CBM-I in real-world clinical settings. For example, in several randomized controlled trials, home delivery of CBM-I via the Internet reduced

symptoms of general anxiety (e.g., Salemink, Kindt, Rienties, & van den Hout, 2014), social anxiety (Bretschneider, Neumann, Berger, Renneberg, & Boettcher, 2015), and depression (e.g., Blackwell et al., 2015; Pictet & Ceschi, 2016). Online CBM-I interventions delivered at home and in the classroom with adolescents and children have also shown promise (e.g., de Hullu, Sportel, Nauta, & de Jong, 2017; Reuland & Teachman, 2014). Additionally, a 1-week protocol of stand-alone CBM-I was effective in reducing depression symptoms in an outpatient psychiatric clinic (Torkan et al., 2014).

In addition to serving as a low-intensity stand-alone intervention, CBM-I is particularly well suited to augment cognitive-behavioral therapy (CBT). Interpretation bias often manifests in the form of negative automatic thoughts. CBT targets interpretation bias via cognitive restructuring, an explicit process involving “off-line” post hoc reappraisals of situations, and change in interpretation bias mediates symptom improvement in CBT (e.g., Goldin et al., 2012; Teachman, Marker, & Clerkin, 2010). CBM-I may help individuals more efficiently apply CBT concepts, such as identifying negative automatic thoughts, by helping individuals notice how often they automatically jump to a negative conclusion and illuminating the brain's process of efficiently resolving ambiguous situations “online” in daily life. This bottom-up manner of targeting of interpretation bias may produce a synergistic effect with the top-down approach of CBT.

A few studies to date have examined CBM-I as an adjunct to various forms of CBT with encouraging results across several populations, including depression (Williams, Blackwell, Mackenzie, Holmes, & Andrews, 2013; Williams, O'Moore, Blackwell, Smith, Holmes, & Andrews, 2015), OCD (Amir et al., 2015; Salemink, Wolters, & de Haan, 2015), and individuals with anxiety sensitivity and suicidal ideation (Schmidt, Norr, Allan, Raines, & Capron, 2017). Most of these studies evaluated CBM-I as an adjunct to a single-session, self-administered, and/or low-intensity version of CBT or as a precursor to starting CBT. Thus, information about how to translate laboratory-based CBM-I protocols to augment more intensive and face-to-face CBT are lacking.

### Partial Hospital Treatment

One important real-world treatment setting that may benefit from a CBM-I augmentation is the partial hospital. Partial hospital programs are critical points of care for individuals experiencing acute symptoms who are at risk for suicide or deterioration, and therefore require a higher level of care (Forgeard, Kirakosian, Beard, & Björgvinsson,

2018). Partial hospitals serve as a bridge between inpatient and outpatient treatment. Individuals discharging from inpatient hospitalization frequently attend partial hospitals to facilitate their transition back to outpatient treatment. Additionally, partial hospitals are used in lieu of inpatient hospitalization. Partial hospitals deliver intensive, brief (e.g., 1–4 weeks), day treatment to individuals with a range of primary diagnoses and substantial comorbidity. Staff include psychology trainees, bachelor-level counselors, nurses, psychologists, social workers, and psychiatrists. Treatment is primarily group based and focused on teaching cognitive-behavioral coping skills (e.g., challenging dysfunctional thinking, behavioral activation; see Beard & Björgvinsson, 2013; Drymalski & Washburn, 2011, for detailed descriptions of partial hospital treatment).

There are several characteristics that make partial hospitals particularly appealing settings in which to examine CBM-I augmentation. Approximately 82% of mental health facilities or hospitals reportedly offer CBT (N-MHSS Report, 2010). However, as noted by Hirsch et al. (2016), individuals experiencing acute stress may find it challenging to learn and apply complex cognitive techniques, particularly given the brief length of stay in a partial hospital program. Thus, CBM-I is appealing for partial hospital programs because it is consistent with the cognitive restructuring component of CBT and may accelerate cognitive changes via a controlled opportunity to self-monitor and apply CBT concepts.

Additionally, as previously reviewed, CBM-I targets a transdiagnostic mechanism and has shown promise across a range of disorders. Given that partial hospital programs often treat transdiagnostic and comorbid populations, CBM-I is appealing because of its potential to efficiently alter cognitive biases across many forms of psychopathology. Finally, CBM-I possesses advantages for a partial hospital setting due to its computerized format, which does not require specialized training to administer and can be reliably delivered by any staff member, including bachelor's-level counselors.

### Current Study

The current study describes the development and preliminary evaluation of CBM-I as an augmentation to a CBT-based partial hospital treatment. We obtained patient feedback on a CBM-I protocol, made refinements, and tested the refined version in a second cohort. For both cohorts, we compared results with a priori targets for feasibility, acceptability, and change in interpretation bias. We hypothesized that CBM-I would be feasible and

acceptable to this population and for this setting based on its unique characteristics. We also hypothesized that at posttreatment, the CBM-I group would endorse more benign interpretations and fewer negative interpretations compared to a control group.

Although describing the treatment development process and obtaining data on real-world feasibility and acceptability were the primary aims in this pilot study, a secondary aim was to explore potential clinical utility to inform future trials. However, we did not expect to observe CBM-I augmentation effects on clinical outcomes for several reasons. First, large samples are required to detect clinical effects of a low-intensity augmentation of a powerful CBT-based treatment as usual (TAU). Thus, any statistical analyses in the current pilot study are underpowered. Second, all patients are required to have experienced symptom improvement to warrant discharge from partial hospital level of care, making it difficult to observe group differences at the discharge time point. Finally, given the demographic and clinical heterogeneity of a psychiatric hospital sample, it is likely that CBM-I will not benefit all patients.

Nonetheless, given that this is the first study to implement CBM-I in this type of sample and setting, we thought it was warranted to conduct exploratory analyses to test the potential clinical utility of CBM-I as an augmentation to CBT-based psychiatric care. We tested moderators to generate hypotheses about which subgroups might benefit from this augmentation. Specifically, we tested whether moderators found in studies of a different type of CBM (targeting attention bias) and different population (social anxiety disorder [SAD]) would replicate in the current study of CBM for interpretation bias in a transdiagnostic, psychiatric sample. Amir, Taylor, and Donohue (2011) found that individuals with greater baseline attention bias responded better to CBM for attention bias—thus, we expected that individuals with a greater baseline level of interpretation bias would respond better to CBM-I. Additionally, three recent meta-analyses of CBM found that CBM was only superior to control in younger individuals (Liu, Li, Han, & Liu, 2017; Mogoşe, David, & Koster, 2014; Price et al., 2016). Thus, we expected that younger individuals might benefit more from CBM-I in the current study. We also examined baseline symptom severity, diagnosis, and number of prior hospitalizations as potential moderators.

### Method

#### OVERVIEW OF STUDY

We adapted a lab-based CBM-I protocol for a transdiagnostic, acute psychiatric setting. We tested

this version of CBM-I in a small, pilot trial, compared feasibility and acceptability outcomes to our targets, and obtained qualitative feedback from participants. We made several refinements based on participant feedback and again obtained feasibility and acceptability data in a second small, pilot trial. Finally, to inform future, adequately powered trials, we explored potential effects of CBM-I on clinical outcomes, including moderators. Due to the small number of participants in each

phase of recruitment, we collapsed across the two phases for analyses involving clinical outcomes.

**Phase I**

**PARTICIPANTS**

Participants were individuals admitted to a partial hospital from December of 2013 to June of 2015, who provided informed written consent to the study (see [Figure 1](#) for flowchart and [Table 1](#) for demographics). The average age was 34.21 ( $SD =$

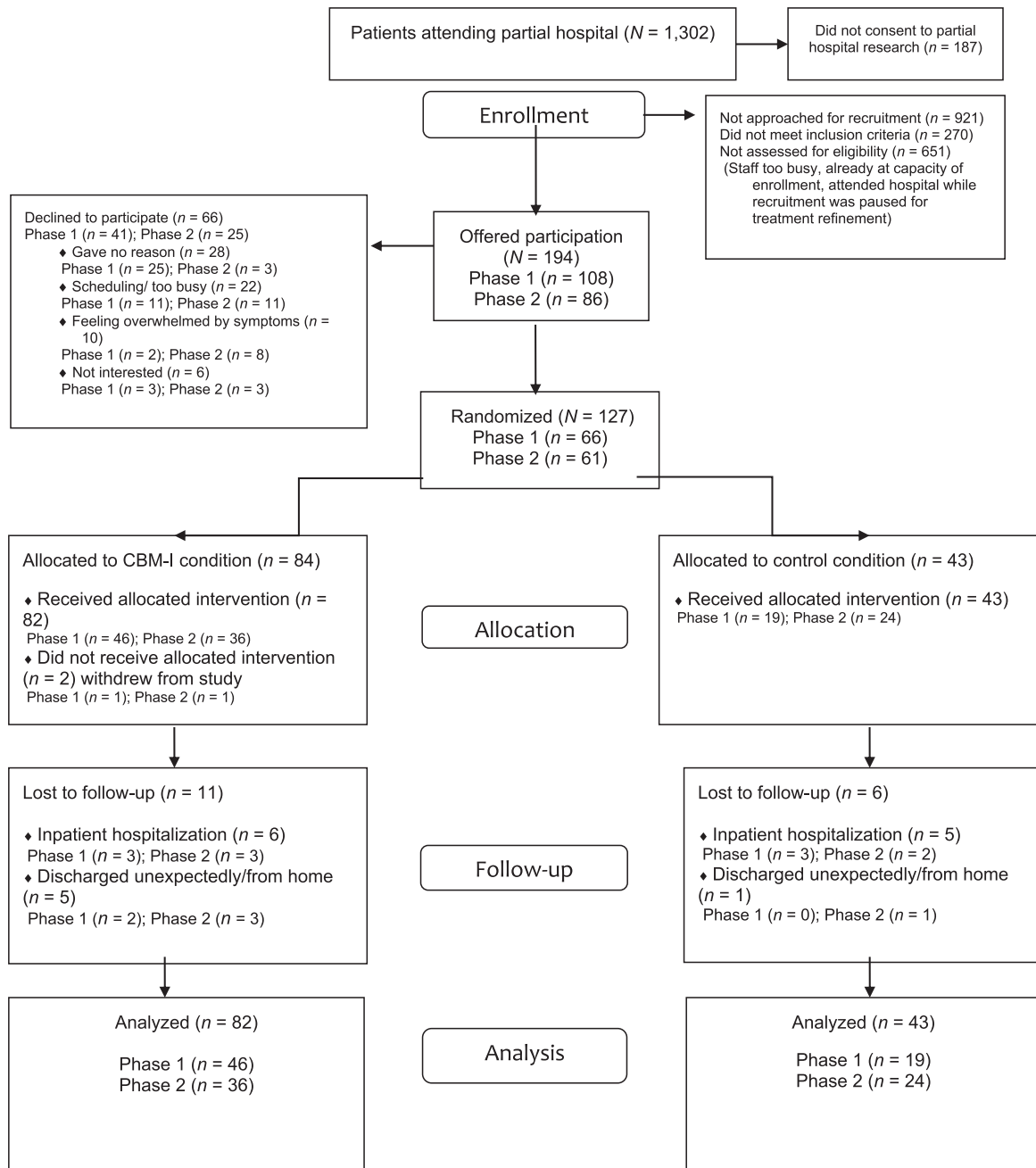


FIGURE 1 CONSORT diagram. Note. CMB-I = cognitive bias modification for interpretation.

Table 1  
Demographic Characteristics of Participants at Admission to the Partial Hospital Program

Demographic variables	Phase 1				Phase 2			
	CBM-I ( <i>n</i> = 46)		Control ( <i>n</i> = 19)		CBM-I ( <i>n</i> = 36)		Control ( <i>n</i> = 24)	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
<b>Gender</b>								
Female	28	(61%)	9	(47%)	22	(61%)	13	(57%)
Male	18	(39%)	10	(53%)	12	(33%)	10	(43%)
Nonbinary gender	0	(0%)	0	(0%)	2	(6%)	0	(0%)
Latinx	2	(4%)	0	(0%)	2	(6%)	0	(0%)
<b>Race</b>								
White	40	(87%)	17	(89%)	34	(94%)	20	(87%)
Black	0	(0%)	2	(11%)	0	(0%)	2	(9%)
Asian	3	(7%)	0	(0%)	1	(3%)	1	(4%)
Multiracial	2	(4%)	0	(0%)	1	(3%)	0	(0%)
American Indian/Alaskan Native	1	(2%)	0	(0%)	0	(0%)	0	(0%)
<b>Education level</b>								
Some high school	0	(0%)	0	(0%)	3	(8%)	0	(0%)
High school/GED	0	(0%)	1	(5%)	1	(3%)	1	(3%)
Some college	17	(37%)	8	(42%)	10	(28%)	4	(17%)
Four-year college graduate	11	(24%)	5	(26%)	15	(42%)	7	(30%)
Graduate degree	18	(39%)	5	(26%)	7	(19%)	11	(48%)

Note. CBM-I = cognitive bias modification for interpretation; GED = general equivalency diploma.

12.52, range = 18–68), and the average duration of treatment from admission to discharge (including nontreatment days such as weekends) was 12.6 (*SD* = 3.9) days.

Due to the group therapy format of partial hospitals, all patients were required to have sufficient English-language skills to attend. We did not have any exclusion criteria regarding diagnosis or functional ability. Although CBM-I has not been tested in individuals diagnosed with psychotic or bipolar disorders, we included such individuals as long as they were also experiencing significant depression symptoms that might benefit from CBM-I (see below), and were not experiencing current symptoms of psychosis or mania that would have prevented them from providing informed consent or completing the research procedures (e.g., sitting at a computer for 10 minutes). Although the partial hospital does not treat primary substance use disorders (SUDs), approximately 38% of the population meets criteria for a secondary SUD (including alcohol). Given that our aim was to develop CBM-I for a real-world, comorbid sample, we included individuals with comorbid SUDs, although CBM-I in the current study was not designed to target substance use. In contrast to most lab-based studies, we also included individuals with current, severe suicidality (i.e., recent suicide attempt, ideation intensity and/or intent so severe that the outpatient clinician referred the patient to a psychiatric hospital level of care). In

addition, we included individuals with concurrent pharmacotherapy (93% of sample) because excluding such individuals would exclude most of the partial hospital population.

Finally, inclusion criteria specified a score of 10 or greater on the Patient Health Questionnaire–9 (PHQ-9; Kroenke & Spitzer, 2002; indicating at least moderate depression symptom severity). While all individuals attending the partial hospital meet criteria for a DSM disorder, some individuals report low levels of symptoms upon admission because they have been stabilized during inpatient hospitalization prior to coming to the partial hospital. Thus, we wanted to ensure that participants were reporting significant symptoms in order to conduct preliminary tests of clinical effects of CBM-I. We chose a depression severity measure for this purpose because most patients meet criteria for major depressive disorder (MDD) or a depressive episode in the context of bipolar disorder (see below for diagnostic information).

To streamline the description of participants, we report diagnostic information here for the total sample collapsed across phases. Primary diagnoses assigned by the program psychiatrists included MDD (73%), bipolar disorders (18%), posttraumatic stress disorder (PTSD; 4%), anxiety disorder (3%), and OCD (2%). Comorbidity was common, with 97% of individuals meeting criteria for more than one disorder (*M* = 2.62, *SD* = 1.57, range = 1–11). Together, primary and comorbid diagnoses



included MDD (82%), generalized anxiety disorder (GAD; 36%), SAD (34%), panic disorder (PD; 28%), bipolar disorder (16%), PTSD (15%), OCD (10%), and psychotic disorders (3%).

#### TREATMENTS AND SETTING

The partial hospital is an insurance-based (including Medicare and Medicaid) program in a non-profit, freestanding psychiatric hospital located in a suburb of the northeast region of the United States. The psychiatric hospital is affiliated with an academic medical school. The program delivers intensive, brief CBT skill-based treatment to individuals with a range of psychiatric disorders (principally mood, anxiety, personality, and psychotic disorders). Clinical team managers and program psychiatrists oversee treatment and develop aftercare plans for each patient. Patients attend the program during weekdays (8:30 a.m.–2:50 p.m.) and return home each evening.

#### *Cognitive-Behavioral Therapy*

TAU at the partial hospital comprises individual and group therapy focused on the acquisition of CBT skills. Group content was derived from empirically supported behavioral manuals (e.g., behavioral activation adapted from Martell, Dimidjian, & Herman-Dunn, 2013; identifying and challenging negative automatic thoughts adapted from Beck, 1979; and interpersonal effectiveness adapted from Linehan, 1993). Patients attend up to five 50-minute groups each day. Patients also attend two to three 30-minute individual treatment sessions each week to practice skills.

#### *CBT Treatment Fidelity*

Group leaders follow detailed treatment protocols designed for each group, derived from established treatment manuals. Twice per year, trained research assistants rate group leaders for adherence to the protocols. Ratings occur in vivo, and group leaders are not informed ahead of time. During the data collection period for the current study, ratings revealed that group leaders addressed 92% of protocol components, confirming that providers adhered to the protocols.

#### *CBT Treatment Providers*

Typical of real-world clinical settings, level of training and supervision varied among clinicians. Mental health counselors, nurses, psychologists, social workers, and psychology trainees (postdoctoral fellows, predoctoral interns, and practicum students) delivered the group CBT. Bachelor-level and trainee providers received individual and group supervision from licensed clinical psychologists. In addition to the CBT skills work, patients also met with a case

manager for treatment and aftercare planning, and a psychiatrist for medication consultation.

#### *CBM-I Task*

The CBM-I intervention was a modified version of the word–sentence association paradigm (WSAP) designed to extinguish negative interpretations and encourage benign interpretations of ambiguous situations (Beard & Amir, 2008). A WSAP trial began with a fixation cross that appeared on the computer screen for 500 ms. Second, a word representing either the negative (“embarrassing”) or benign (“funny”) interpretation of an ambiguous sentence (“People laugh after something you said”) that followed appeared in the center of the computer screen for 500 ms. Third, the ambiguous sentence appeared. The computer keyboard had a sticker with the letter “Y” placed on top of the “J” key and the letter “N” placed on top of the “L” key. Participants were instructed to press “Y” if they thought the word and sentence were related, or to press “N” if the word and sentence were not related. Participants received positive feedback (“Correct!” in green font) when they endorsed the benign interpretation or rejected the negative interpretation of the ambiguous sentence. Participants received negative feedback (“Incorrect” in red font) when they endorsed the negative interpretation or rejected the benign interpretation. Approximately half of the participants assigned to the CBM-I condition completed a nearly identical task in which the sentence appeared first. Participants pressed the space bar after reading the sentence. The word then flashed for 500 ms, and participants were instructed to respond. Results from tests including word–sentence order as a factor when predicting the primary outcomes (interpretation bias; Clinical Global Improvement Scale—Self-Report [CGIS], Guy, 1976; PHQ-9; Generalized Anxiety Disorder–7 Scale [GAD-7], Spitzer, Kroenke, Williams, & Löwe, 2006) did not differ according to word–sentence order ( $ps > .05$ )—thus, we collapsed across these versions of CBM-I to streamline the presentation of results. Participants completed 100 trials (50 sentences paired once with a benign interpretation and once with a negative interpretation) in random order during each session.

#### *CBM-I Rationale*

During the first CBM-I session on participants’ second day in the partial hospital program, all participants received a packet providing brief psychoeducation about depression, anxiety, and cognitive biases (referred to as mental habits), as well as a CBM-I treatment rationale (see Supplemental Information). Participants were told that

with repeated practice, CBM-I would help them to develop healthier mental habits. Participants were encouraged to apply what they learned in CBM-I to situations in their actual life. Staff made a point to acknowledge that in real life there are not necessarily correct or incorrect interpretations of situations, but that we think people will benefit more if they use the feedback provided by the program to complete the task as quickly and accurately as possible.

#### ACUTE PSYCHIATRIC SETTING CONSIDERATIONS

##### *Stimuli*

As already mentioned, an acute psychiatric setting requires an intervention suitable for a transdiagnostic and highly comorbid sample. Thus, we included ambiguous situations relevant to a variety of daily situations and potential threat domains. We drew upon previously used CBM-I stimuli related to social and general anxiety (Beard & Amir, 2008; Beard, Weisberg, & Amir, 2011), and created new stimuli that were relevant to depression, such as failure-relevant experiences (see Supplemental Information for examples).

##### *Hospital Staff and Resources*

We sought to use staff and resources intrinsic to the partial hospital to deliver the CBM-I intervention. The partial hospital program employs a full-time, bachelor's-level staff member who collects self-report data from all patients for routine clinical monitoring. We trained this staff member to recruit, schedule sessions, and deliver the intervention in the clinical monitoring office on an existing laptop.

##### *Number and Scheduling of Sessions*

Patients' duration of treatment typically varies from 1 to 14 days based on their level of improvement (or deterioration), insurance provider, and outpatient aftercare plan. Thus, the common CBM-I protocol of eight sessions completed over 4 weeks was not possible. We allowed the number of CBM-I sessions to vary naturalistically and offered CBM-I each day patients attended the program, starting on their second day. Thus, on the second day in the program, participants completed the WSAP baseline assessment and the first CBM-I training sessions. Participants completed the 10-minute sessions primarily during their lunch hour; some participants completed sessions at the end of the program day (2:50 p.m.).

##### *Neutral Control Condition*

Participants received the same psychoeducation and rationale. The neutral control task presented words that were related or unrelated to a superficial aspect

of the ambiguous sentences (e.g., "chuckle"; "people laugh after something you said"). Thus, words were not related to the emotional interpretation of the sentence. Like the CBM-I task, participants received positive or negative feedback about the accuracy of their responses.

#### MEASURES

We assessed interpretation bias with the WSAP (Beard & Amir, 2009). The WSAP was identical to the CBM-I task, with the exception that participants did not receive feedback about their responses. Similar to the CBM-I task, the WSAP assessment included 120 word-sentence pairs that were modified from the original WSAP task to represent situations relevant for a transdiagnostic sample. Novel word-sentence pairs not used in the training were presented in the assessment. The WSAP has demonstrated adequate test-retest reliability (e.g., Martinelli, Holzinger, & Chasson, 2014), and internal consistency was adequate in the current sample (split-half reliability  $\rho = .86$  for negative interpretations;  $\rho = .69$  for benign).

The PHQ-9 (Cronbach's  $\alpha = .69$ ) and the GAD-7 (Cronbach's  $\alpha = .84$ ) assess the frequency of symptoms of MDD and GAD, respectively, over the past 2 weeks. The PHQ-9 and the GAD-7 have both been well validated in numerous populations, including in a psychiatric hospital sample (Beard & Björgvinsson, 2014; Beard, Hsu, Rifkin, Busch, & Björgvinsson, 2016). Given the need to streamline assessments in this brief, acute treatment setting, we were unable to include separate measures for each anxiety disorder. Thus, we selected the GAD-7 because its items (e.g., "feeling nervous, anxious, or on edge") are most relevant to this transdiagnostic sample and has been validated in this same partial hospital population as a general severity measure (Beard & Björgvinsson, 2013).

The CGIS is a 7-point scale assessing improvement following treatment (1 = *very much improved* to 7 = *very much worse*). Patient ratings are correlated with provider ratings (ICC = .65) with comparable validity (Forkmann et al., 2011).

An exit questionnaire asked participants to rate aspects of CBM-I on a 7-point Likert-type scale (1 = *completely disagree* to 7 = *completely agree*) and included prompts to write about the most helpful and least helpful aspects of CBM-I and suggestions for improvement. Staff recorded spontaneous participant comments during sessions. Two of us (LSR, ALS) independently reviewed qualitative data and generated an initial coding framework, which was refined iteratively. We resolved any discrepancies and developed broader categories. We also coded each comment as positive, neutral, or negative.

Because the two coders met to resolve any discrepancies and refined the codes iteratively until consensus was reached, we did not calculate interrater reliability.

#### PROCEDURE

Participants completed self-report measures as part of standard clinical care using Research Electronic Data Capture (REDCap), a secure, web-based application (Harris et al., 2009). The local Institutional Review Board approved all procedures. On the second day of treatment, patients completed a baseline interpretation assessment (WSAP), were randomized to condition by a random number generator, and completed their first session. Since our primary aim was to evaluate the feasibility and acceptability of CBM-I, we assigned 66% of individuals to CBM-I and 33% to the control condition. Both participants and staff were blind to condition. Participants completed the WSAP, symptom measures, and the exit questionnaire on their discharge day. Participants were not compensated for participation.

#### DATA ANALYTIC STRATEGY

The primary aims of this pilot study were to develop and refine a CBM-I protocol for an acute psychiatric hospital setting. Thus, our primary outcomes were the feasibility and acceptability of CBM-I in this novel sample and setting. We selected a priori targets for feasibility, acceptability, and target engagement based on face validity, clinical experience of what would be meaningful in the partial hospital setting (e.g., five sessions as a target for dosage given the brief duration of TAU), and,

when available, relevant literature (e.g., interpretation bias targets based on healthy groups' scores cited in previous studies). We calculated descriptive data and compared the obtained data to the a priori targets (see Table 2). To test whether CBM-I induced the expected changes in interpretation bias, we also conducted linear regression models predicting posttreatment WSAP accuracy ("yes" to benign and "no" to negative interpretations), with condition as the predictor, controlling for baseline accuracy.

Given the transdiagnostic sample, we selected the CGIS as the primary clinical outcome because it assesses global improvement, regardless of diagnosis. Following standard definitions of treatment response, we classified responders as those with a rating of "1" or "2" (e.g., Storch, Lewin, De Nadai, & Murphy, 2010). Additionally, because both the CBT-based partial hospital TAU and the CBM-I augmentation primarily target mood and anxiety symptoms, we also examined the PHQ-9 and GAD-7 as secondary symptom severity outcomes.

We collapsed across the two phases of recruitment to test clinical outcomes. Even after collapsing across the two phases of recruitment, the current study is underpowered to detect small effects due to the relatively smaller number of participants assigned to control conditions. Given these issues of power in a pilot trial and the fact that all patients have to improve to be discharged, these analyses were considered exploratory. First, we conducted logistic regressions for the dichotomous posttreatment outcome (CGIS responder vs. not) with condition as the predictor. We then conducted linear regressions to test whether condition predicted posttreatment

Table 2  
A Priori Benchmarks and Actual Outcomes for Feasibility, Acceptability, and Target Engagement

Domain	Goal	Phase 1 outcome	Phase 2 outcome
<b>Feasibility</b>			
Consent rate	≥ 50	62%	71%
Dropout (i.e., did not complete CBM sessions after enrolling)	< 25%	2%	3%
Average number of sessions completed	≥ 5	8.23	7.5
<b>Acceptability (exit questionnaire)</b>			
"I felt the computer program was helpful."	Mean ≥ 5 "Slightly agree"	5.27	5.38
"The sentences described situations that were relevant to me."	Mean ≥ 5 "Slightly agree"	5.32	5.31
"The program was user-friendly."	Mean ≥ 5 "Slightly agree"	5.95	6.48
"The program helped me practice what I learned in groups."	Mean ≥ 5 "Slightly agree"	5.37	5.55
<b>Target engagement (change in interpretation bias)</b>			
WSAP: Benign and negative interpretation accuracy	75% of CBM-I group moves into normal range of interpretation (70% accuracy for both benign and negative trials)	87%	94%

Note. CBM = cognitive bias modification; WSAP = word-sentence association paradigm; CBM-I = cognitive bias modification for interpretation.



PHQ-9 and GAD-7 scores, controlling for baseline scores on these measures.

To inform future studies, we examined the following potential moderators of CBM-I outcome: age, gender, baseline level of interpretation bias (benign, negative), baseline level of symptom severity (PHQ-9, GAD-7), number of prior hospitalizations, and diagnosis (yes/no) (MDD, GAD, SAD). Treatment condition (CBM-I or control), moderator, and the Condition  $\times$  Moderator interaction term were entered as predictor variables into regression models predicting responder status (CGIS) and posttreatment scores on the PHQ-9 and GAD-7, controlling for baseline scores on the same measure. Continuous predictors (age, baseline interpretation bias, baseline symptom severity, number of hospitalizations) were centered. Given the exploratory nature of these analyses and the number of moderators examined ( $10 \times$  three clinical outcomes), we controlled for a 25% false discovery rate following recommended procedures (Benjamini & Hochberg, 1995). We calculated the Benjamini and Hochberg threshold for  $p$  values for the 30 moderator tests.

All analyses were intent-to-treat. Participants completed the admission and discharge assessments used for outcome analyses regardless of the number of CBM-I sessions completed or days in the program. To handle missing data (see Figure 1), we used the SPSS 25 multiple imputation function to generate 20 imputed data sets. Variables included in the model to generate imputed data sets included age, gender, baseline and discharge scores (GAD-7, PHQ-9, WSAP), number of prior inpatient hospitalizations, CGIS, and baseline scores on a measure of well-being. We report test statistics from pooled data.

### Phase I Results

All feasibility and acceptability benchmarks were met (see Table 2). The most common reasons for declining study participation were scheduling difficulties or feeling too busy with TAU. We selected five CBM-I sessions as a minimal a priori target dose, and almost all participants met this target (CBM-I = 93%, control = 95%). Participants assigned to the CBM-I condition completed an average of 8.24 sessions ( $SD = 2.55$ , mode = 8, range = 1–15). Participants assigned to the control condition completed an average of 7.68 sessions ( $SD = 2.33$ , mode = 8, range = 2–12), and this did not differ from the CBM-I group,  $t(63) = 0.817$ ,  $p = .417$ ,  $d = 0.22$ , 95% CI [-0.51, 1.27].

The CBM-I group also met the target for shifting interpretation bias into the healthy range (see Table 2). There was a significant effect of condition for benign interpretations,  $B = .118$ ,  $SE = .033$ ,  $t = 3.63$ ,  $p < .001$ , 95% CI [.054, .182], and negative interpretations,  $B =$

.269,  $SE = .069$ ,  $t = 3.91$ ,  $p < .001$ , 95% CI [.133, .404] (see Table 4), suggesting that the CBM-I group shifted their responses on the WSAP task as intended.

Qualitative feedback revealed several themes (see Table 3). Of 115 comments, 64 (56%) were positive, 38 (33%) negative, and 13 (11%) neutral. Of note, participants were specifically asked to comment on the most helpful and least helpful aspects of the intervention. Regarding patient experiences, participants noted that the CBM-I program was simple, easy to use, fun, gamelike, and motivating. Participants also commented that the CBM-I stimuli were personally relevant. Participants noted several perceived mechanisms of action of CBM-I, including increased awareness of cognitive bias, increased cognitive flexibility, and facilitated psychological distance from thoughts. Participants also noted that CBM-I increased their objectivity and mastery.

Negative attitudes centered on the rigid feedback. Being told one was incorrect repeatedly in a short amount of time resulted in some participants feeling inadequate and excessively stressed. Additionally, some participants commented that the positive interpretations were too positive and not believable for them personally. Some participants noted that the task was too easy. Participants provided many suggestions for improvement. Some participants recommended that the stimuli include more variety, be personalized, and be more realistic. Participants suggested adding a score counter so that people could better track their performance over time. Finally, many participants recommended that we make the program more accessible via online or smartphone delivery.

### REFINEMENTS TO CBM-I

We made several modifications to the CBM-I intervention and study design based on initial participant feedback (see Table 5 for a full list). Specifically, we changed the CBM-I feedback from “Incorrect” to “Try again next time” to soften the experience of making an error. To make the task more engaging, we added points to the feedback after each trial (i.e., correct +1). At the end of each session the program displayed participants’ accuracy for that session (i.e., percentage of correct trials) and average reaction time. We also revised the stimulus set to include more neutral interpretations. Specifically, we modified the program to present neutral interpretations in initial sessions and gradually introduce more positive interpretations as sessions progressed. This modification also ensured variety in the stimuli. We created eight different stimuli sets for the first eight sessions of the CBM-I program that gradually became more

Table 3  
Qualitative Feedback From Phase 1

Theme	Example quote
Positive experience	
Fun, gamelike, motivating	"It became like a video game and I wanted to win or get all of the green 'correct!'"
Stimuli were personally relevant	"Many of these situations . . . were ones that I personally have had negative thoughts/emotions toward."
Easy to use	"The program was very easy to use and quick."
Negative experience	
Rigid feedback	"This is bogus!" "The use of 'correct' and 'incorrect' designations seemed both inaccurate and judgmental. . . ."
Task was too easy	"By the end it was barely necessary to read the sentences: you could just answer 'Y' or 'N' based on if the word given was positive or negative."
Mechanism of action	
Awareness of cognitive bias	"It helped me reflect on how much my automatic thoughts shape me." "It pointed out situations where I assume the worst."
Changed cognitive bias	"It helped me to think about things in new, creative ways that I would have never thought of before." "It broadened my interpretation of what certain situations mean."
Facilitated psychological distance	"It helped me to take a step back."
Increased objectivity	"It was training me to be more rational and objective."
Increased mastery	"It made me feel like I accomplished something."
Generalizing to daily life	"The other day I woke up from a noise outside my window. Instead of thinking the worst-case scenario right away, my brain went back to this software and told me it could be a cat or a truck."
Suggestion for improvement	
More variety in stimuli	"Change the situations covered every couple of sessions."
Personalize	"Ask questions prior to the first session to ensure the sentences have meaning and interest to the individual."
More realistic stimuli	"More neutral words"; "New statements that are more realistic."
Score counter	"Include a counter . . ."
Delivery via online or smartphone	"Make it web based . . . make it mobile."
Appearance	"Make it prettier."

positive. Participants who completed more than eight sessions repeated the eighth stimulus set for all subsequent sessions.

Finally, we changed the control group. In Phase 1, participants assigned to the control condition completed a similar computer task as participants assigned to CBM-I. The computer presented words that were related or unrelated to some superficial aspect of the ambiguous sentences (e.g., "chuckle"; "People laugh after something you said"). Thus, words were not related to the emotional interpretation of the sentence. Like the CBM-I task, participants received positive or negative feedback about the accuracy of their responses. We originally selected this neutral/nonemotional interpretation control group due to concerns about other control groups (e.g., training toward 50% benign and 50% negative) being a diluted form of interpretation bias modification (Clerkin, Beard, Fisher, & Schofield, 2015). However, comments from numerous participants assigned to the neutral control suggested that this task may also be an active interpretation training. For example, participants stated that the neutral control helped

them ("recognize that different situations could be seen in both a positive or negative way"). In hindsight, it seems obvious that repeatedly requiring individuals to focus on the neutral and nonemotional aspects of emotionally relevant situations could be an active form of CBM-I training. In addition to potentially influencing interpretation bias, it may also serve as a form of psychological distancing. Consequently, in the second iteration of pilot testing, we compared the revised CBM-I intervention to a test-retest, TAU control group. Participants assigned to this control group completed TAU in the partial hospital, as well as the same pre- and posttreatment assessments as the CBM-I group. This control group allowed a better test of any potential augmentation effects of the CBM-I intervention above and beyond standard CBT-based partial hospital treatment. We retained the same randomization schedule (66% to CBM-I/33% to TAU).

## Phase 2

Participants were patients at the partial hospital program from July of 2015 to August of 2016 (see

Table 1 for characteristics). Similar to Phase 1, all feasibility, acceptability, and interpretation bias benchmarks were met (see Tables 2 and 4). Also similar to Phase 1, almost all participants were able to complete at least five CBM-I sessions (94%). Participants completed an average of 7.5 CBM-I sessions ( $SD = 2.54$ , mode = 9, range = 1–14). Additionally, three out of four acceptability targets improved from Phase 1 to Phase 2.

#### Clinical Outcomes: Phase 1 and 2 Combined

Treatment condition did not predict treatment response (defined as “much” or “very much” improved) in the logistic regression,  $B = -.095$ ,  $SE = .43$ ,  $OR = .910$ , 95% CI [.392, 2.113],  $p = .826$ . In the CBM-I group, 56 out of 72 participants (78%) were classified as responders. In the control group, 28 out of 37 participants (76%) were responders. Condition was not a significant predictor of post-treatment depression,  $B = .427$ ,  $SE = 1.42$ ,  $t = 0.344$ ,  $p = 0.731$ , or anxiety severity,  $B = .33$ ,  $SE = .826$ ,  $t = 0.40$ ,  $p = .690$ . Given the underpowered nature of this pilot study, we also examined between-group effect sizes. The between-group Cohen’s  $d$  for change in depression was near zero,  $d = 0.008$ , 95% CI [–.0879, 0.896], whereas the effect for anxiety symptoms was small in magnitude,  $d = 0.378$ , 95% CI [–0.451, 1.207]. Because the two phases differed in the type of control group used, we also conducted analyses comparing CBM-I versus only the TAU control group. A similar pattern of results emerged.

Several variables initially appeared to be significant moderators of clinical outcome. Specifically, GAD diagnosis moderated response on the CGIS,  $B = -2.284$ ,  $SE = 1.078$ ,  $OR = .102$ ,  $p = .034$ , 95%

CI [.012, .844]. There was also a trend for age to moderate response on the CGIS,  $B = -.065$ ,  $SE = .036$ ,  $OR = .937$ ,  $p = .071$ , 95% CI [.937, 1.006], and on the GAD-7,  $B = .117$ ,  $SE = .061$ ,  $t = 1.924$ ,  $p = .054$ , 95% CI [–.002, .237]. Baseline negative interpretation bias also moderated response on the GAD-7,  $B = -7.825$ ,  $SE = 3.845$ ,  $t = -2.035$ ,  $p = .042$ , 95% CI [–15.360, –0.289]. No other variables moderated response on the CGIS, GAD-7, or PHQ-9. We included all 30  $p$  values from the moderator analyses in a Benjamini and Hochberg calculator. None of the  $p$  values exceeded the Benjamini and Hochberg threshold for significance based on a .25 false discovery rate. Consequently, we did not conduct follow-up analyses to probe any interactions.

#### Discussion

The present study describes an iterative treatment development process to translate a lab-based CBM-I protocol to augment CBT-based psychiatric hospital care. Our primary aim was to determine whether CBM-I would be feasible and acceptable to individuals attending a psychiatric hospital characterized by acute suicidality, severe symptoms, and comorbidity. As expected, CBM-I demonstrated excellent feasibility as an augmentation to CBT-based TAU. Linking to acute treatment likely contributed to high retention rates (97%). CBM-I’s brevity made it possible to deliver during breaks in patients’ busy schedules. CBM-I was also feasible to implement because it did not require additional clinician time or resources. However, completing CBM-I on a laptop substantially limited the number of patients who could receive the intervention at

Table 4  
WSAP Accuracy Scores at Pre- and Posttreatment Assessments

Phase 1	Pretreatment $M$ ( $SE$ )	Posttreatment $M$ ( $SE$ )	$t$	$p$	$d$
Benign					
TAU + CBM	67% (2.38)	93% (1.57)	9.801	<.001	2.30
TAU + neutral comparison	66% (3.87)	81% (4.08)	2.932	.004	1.10
Negative					
TAU + CBM	48% (3.25)	91% (4.00)	9.224	<.001	2.58
TAU + neutral comparison	48% (5.89)	64% (7.76)	2.147	.034	0.70
Phase 2					
Benign					
TAU + CBM	72% (2.38)	94% (2.03)	7.343	<.001	1.95
TAU	71% (2.78)	84% (3.23)	3.615	<.001	0.95
Negative					
TAU + CBM	40% (2.69)	90% (4.25)	9.890	<.001	3.01
TAU	54% (4.03)	63% (6.41)	1.286	.199	0.39

Note. Means represent accuracy (not endorsement of benign or negative interpretations). All values represent pooled estimates. Standard deviations for within-group Cohen’s  $d$  effect size estimates were derived from original data. WSAP = word–sentence association paradigm; TAU = treatment as usual; CBM = cognitive bias modification.

Table 5  
Refinements Made in Response to Phase 1 Feedback

Feedback/problem from phase 1	Modification for phase 2
Many patients did not meet the PHQ-9 cutoff for inclusion but endorsed clinical levels of anxiety symptoms that would potentially benefit from CBM-I “Incorrect” feedback is distressing Need more gamelike features	Expanded the inclusion criteria to include individuals scoring 10 or greater on the seven-item Generalized Anxiety Disorder Scale (GAD-7).  Changed CBM-I feedback from “Incorrect” to “Try again next time.” Added points to the feedback after each trial (“Correct! + 1” or “Try again next time! + 0”). At the end of each session, the program displayed accuracy for that session (i.e., percentage of correct trials) and average reaction time.
Interpretations are unrealistically positive	Revised the stimulus set to include more neutral interpretations. Presented neutral interpretations in initial sessions and gradually introduced more positive interpretations as sessions progressed, which also ensured variety in the stimuli. Created eight different stimuli sets for the first eight sessions of the CBM-I program that gradually became more positive. Participants who completed more than eight sessions repeated the eighth stimulus set for all subsequent sessions.
Neutral control group was an active form	Test-retest, treatment as usual (TAU) control group of interpretation training

Note. PHQ-9 = Patient Health Questionnaire–9; CBM-I = cognitive bias modification for interpretation.

any one time. Delivery via a smartphone app would allow all patients attending the partial hospital to receive CBM-I. Smartphone delivery would also have allowed participants who found CBM-I useful to continue using it following discharge from acute care.

We selected minimally clinically significant benchmarks for acceptability appropriate for the acuity of partial hospital patients. Overall, CBM-I was acceptable to this acute, transdiagnostic sample, as very few participants dropped out and all acceptability benchmarks were met. However, participants in Phase 1 provided both negative feedback and suggestions about several aspects of the intervention. We made several modifications to the intervention based on participant feedback, and subsequently, three out of four acceptability targets improved from Phase 1 to Phase 2.

As expected, results revealed that participants effectively learned the CBM-I contingencies. Both CBM-I and control groups showed improvement in interpretation bias, likely due to the CBT they received and symptom improvement. However, the CBM-I group showed larger changes than the control group with large between-group effect sizes. These findings provide initial evidence of target engagement and a near transfer of training effects to the same interpretation bias task using novel stimuli. However, it is unclear whether CBM-I shifted interpretive style outside of this training task. Conducting this trial as part of standard clinical care required that all study procedures fit within a 30-minute session during the lunch hour—thus, we were unable to include independent

measures of interpretation bias. It will be important for future studies to test the generalization of interpretation change to other measures.

The current pilot study was not designed or powered to detect CBM-I’s effect on clinical outcomes. There are several reasons why a very large sample size would be required to detect clinical effects of CBM-I above and beyond the CBT-based TAU. First, participants in the current study received intensive CBT-based treatment and large symptom reductions following such TAU are typical (e.g., Björgvinsson et al., 2014). Moreover, prior meta-analyses suggest that, consistent with the low-intensity nature of CBM-I, effect sizes for clinical or emotional outcomes are likely small (Cristea et al., 2015). Thus, very large samples would be required to detect a small augmentation to a powerful TAU. Second, such a targeted intervention is not likely to be indicated for all individuals in such a heterogeneous population. Thus, it is likely that CBM-I will be a useful augmentation for only some subgroups of this broader population. Large sample sizes are thus required to test potential moderators. Finally, patients are only eligible for discharge after symptoms have stabilized. Thus, we should not expect to see any group differences on clinical outcomes at the point of discharge. A more relevant time point is likely in the month following discharge, a period well-known for increased risk of relapse (e.g., Qin & Nordentoft, 2005).

Consistent with these caveats, CBM-I was not superior to control groups on global clinical improvement, and most participants in both groups rated themselves as “much or very much improved”



(78% CBM-I vs. 76% control). Groups also did not differ on improvement in depression symptom severity ( $d = 0.008$ ). However, there was a small, between-group effect size for improvement in anxiety symptom severity ( $d = 0.378$ ). Although not statistically significant in this small pilot trial, this between-group effect size is in line with meta-analyses comparing stand-alone CBM-I to various controls. This discrepancy in effect sizes between depression and anxiety symptoms is also consistent with prior reviews that suggested CBM-I effects are more robust for anxiety than depression (see Jones & Sharpe, 2017). Should larger trials replicate this pattern of clinical outcomes, CBM-I may be useful in acute hospital settings as an additional method for targeting anxiety. Such an augmentation could be quite valuable, given that the majority of acute hospital treatment focuses on stabilizing mood and suicide risk, and comorbid anxiety disorders may not be prioritized in TAU. Thus, even a small effect may be clinically meaningful given the high-risk population and ease of CBM-I delivery. These findings, along with the primary feasibility and acceptability outcomes, suggest that future, fully-powered trials that include a follow-up assessment are warranted to determine the clinical utility of CBM-I in this setting.

Future studies are also needed to confirm which patient characteristics are suited for CBM-I augmentation. Age has been found to moderate effects in CBM specifically for SAD (Liu et al., 2017; Price et al., 2016), although another broader meta-analysis did not find any effect of age (Menne-Lothmann et al., 2014). Some researchers have speculated that younger individuals may find a computerized or smartphone-delivered mental health treatment to be more credible, which may affect outcome (Mogoşe et al., 2014). A different explanation is that younger individuals' cognitive biases may be more malleable (Mogoşe et al., 2014). A similar trend effect for age was observed in the current study, although none of these tests were significant after considering all analyses together with a 25% false discovery rate. Future studies examining age should include measures to better understand the mechanisms underlying this effect to inform the tailoring of CBM-I protocols to be more effective in older individuals.

Strengths of this study include the clinically acute, transdiagnostic sample, and naturalistic setting. These features allowed us to test CBM-I in the real world with individuals and a setting that differed substantially from typical lab-based studies. The availability of therapist fidelity data ensure that patients received CBT as intended in this naturalistic setting. The current partial hospital is

consistent with the standard structure of partial hospital and day programs across the United States. Therefore, findings should generalize to similar day treatment settings that offer CBT.

The limitations also stem from this naturalistic setting. Given the extreme demands on patients and clinicians, we did not include an independent measure of interpretation bias or a clinician-rated measure of improvement. We were also unable to manipulate the number of CBM-I sessions because they varied according to patients' length of stay. Controlling for this variable in a naturalistic treatment setting is also complicated because it is affected by an individual's insurance carrier, having an outpatient treatment provider in place, and speed of improvement or deterioration. Additionally, all participants saw the same stimuli in this study. Stronger effects might have been observed had we personalized stimuli. Future studies should consider this when translating CBM-I into heterogeneous patient populations.

Conclusions about feasibility and acceptability should be interpreted in the context of the sample, which was relatively well educated. Although the reading level required by the WSAP task was very low, it is nonetheless possible that samples with lower educational attainment might respond differently. Due to the hospital's demographic characteristics, the sample also lacked ethnorracial diversity. Although benefits have been observed in more representative samples (e.g., Amir et al., 2011; Beard et al., 2011), it is crucial to study the feasibility and acceptability of CBM-I in less educated and more ethnorracially diverse samples. Moreover, researchers testing CBM-I in some minority populations may need to modify stimuli to avoid suggesting reappraisals of stigma-related experiences (e.g., feeling like you are being watched in a store).

Selecting an appropriate control condition has been a challenge in the CBM-I field (e.g., Clerkin et al., 2015). We quickly realized that, like the typical 50/50 control, the Phase 1 neutral control likely included several active ingredients, making it an interpretation training itself. A TAU control group provided the best test of our ultimate question: Does CBM-I confer clinical benefit above and beyond TAU? However, patients were no longer blind to their condition assignment. Finally, given the pilot nature of this study, we were not able to include a follow-up assessment. As previously mentioned, a follow-up assessment is crucial for determining whether CBM-I buffers individuals from the stressful transition from hospital care to outpatient care. Future studies are warranted to establish whether continued use of CBM-I during the postacute period would lead to better long-term outcomes.

## Appendix A. Supplementary Data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.beth.2018.09.002>.

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