Isolating the Effects of Mindfulness Training Across Anxiety Disorder Diagnoses in the Unified Protocol

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The Unified Protocol for Transdiagnostic Treatment (UP; Barlow et al., 2011) has recently demonstrated statistically equivalent therapeutic effects compared to leading cognitive behavioral therapy (CBT) protocols for anxiety disorders designed to address disorder-specific symptoms (i.e., single-disorder protocols [SDP]); Barlow et al., 2017). Although all treatment protocols included similar evidence-based CBT elements, investigation of those related to symptom improvement in the UP is warranted. Because the UP is unique from the SDPs for its inclusion of mindfulness, the present study evaluated mindfulness as a primary treatment element. We explored whether UP participants, compared to SDP, demonstrated greater improvements in mindfulness from pre- to posttreatment, and whether these improvements predicted posttreatment severity across anxiety disorder diagnoses. Participants were individuals with a principle anxiety disorder ($N = 179$) randomized to receive either the UP or SDP. Results indicated significant improvements pre- to posttreatment in mindfulness for participants receiving either the UP or SDP. However, at posttreatment, mindfulness scores were significantly greater for the UP condition. At the diagnosis level, posttreatment scores in mindfulness were significantly greater in the UP condition than the respective SDP conditions for principal Generalized Anxiety Disorder (GAD) and Social Anxiety Disorder (SOC). Moreover, results suggest that change in mindfulness is related to posttreatment severity, when moderated by treatment condition, but only for participants with principal GAD. Taken together, the UP is effective in improving mindfulness in a sample with heterogeneous anxiety disorders, but this change seems particularly relevant for reduction in symptom severity for individuals with principal GAD.

Keywords: mindfulness; transdiagnostic; cognitive-behavioral treatment; anxiety

DECADES OF RESEARCH ON cognitive behavioral therapy (CBT) for anxiety disorders supports its efficacy (Carpenter et al., 2018; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012), while growing literature continues to support mindfulness training, commonly defined as present-focused, nonjudgmental awareness (Kabat-Zinn, 1994), as a stand-alone treatment for anxiety and as an additional component to existing protocols (Blanck et al., 2018; Vøllestad et al., 2012). As such, research has sought to examine the combined effects of CBT components and mindfulness training in treatment protocols applied to anxious populations (e.g., Acceptance and Commitment Therapy [ACT; Hayes, Strosahl, & Wilson, 2011], Acceptance-Based Behavior Therapy [ABBT; Roemer, Orsillo, & Salters-Pedneault, 2008], Mindfulness-Based Stress Reduction [MBSR; Kabat-Zinn, 1994]), and has found growing support (Roemer et al., 2013). However, research has been limited in isolating the unique effects of mindfulness within these protocols, because they are fundamentally different from traditional CBT in

ways other than the inclusion of mindfulness (i.e., inclusion of additional non-CBT skills or exclusion of behavioral elements). In the present study, we propose the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al., 2017) as an ideal means to isolate the unique effects of mindfulness in CBT when compared to traditional CBT protocols in the treatment of anxiety disorders, because the UP contains all components of traditional CBT treatments (e.g., cognitive restructuring, exposures) with mindfulness as an added skill.

Several studies have compared interventions with mindfulness components to traditional CBT protocols in anxiety disorder samples. For example, in the context of a clinical trial comparing ACT (Hayes et al., 2011) to CBT in a sample of heterogeneous anxiety disorders, results suggest that ACT resulted in similar symptom reductions to CBT throughout treatment, but demonstrated significantly lower symptom severity ratings at follow-up time points for individuals in the ACT condition (Arch et al., 2012). Moreover, while other research has found that MBSR (Kabat-Zinn, 1994) and CBT both decreased symptom severity, MBSR appeared to reduce worry at a greater rate than CBT (Arch et al., 2013). This pattern of results suggests, unsurprisingly, that targeting mindfulness directly leads to greater improvements in this skill, and that mindfulness-based interventions may be particularly well suited to address particular symptoms (e.g., worry).

Research examining the effects of mindfulness training across specific diagnoses, however, is more mixed. Within the context of discrete *DSM* disorders, randomized control trials (RCTs) comparing mindfulness training to active, evidence-based comparison treatments are relatively few; of the existing studies, most of the work in this area has been conducted in the context of social anxiety and generalized anxiety disorder, whereas panic disorder and obsessive-compulsive disorder are not as frequently studied (Roemer et al., 2013). For example, an RCT comparing MBSR and CBT for social anxiety found that both treatments resulted in significant reductions in symptoms, but self-report and clinician-rated measures of social anxiety were significantly lower at posttreatment for individuals in the MBSR group (Koszycki, Benger, Shlik, & Bradwejn, 2007). In contrast, another RCT comparing ACT to CBT and a waitlist condition for social anxiety found that both active treatments equally outperformed waitlist controls on symptom outcomes (Craske et al., 2014). Although there has not been a trial directly comparing mindfulness-based treatment to CBT for GAD

samples, some studies have compared them to control conditions (e.g., Evans et al., 2008) or other evidence-based treatments, such as applied relaxation (Hayes-Skelton, Roemer, & Orsillo, 2013). In Hayes-Skelton et al. (2013), ABBT (Roemer et al., 2008) was compared to applied relaxation, and found large effects for GAD symptoms that were maintained out to 6 months posttreatment for those receiving ABBT.

Although these findings suggest that treatments with mindfulness components may be at least as effective in reducing symptomology, these existing treatments do not exclusively focus on mindfulness or traditional elements of CBT. For example, ACT contains some cognitive (e.g., cognitive diffusion) and behavioral techniques (e.g., targeting avoidance) that can be found in CBT, in addition to other features such as focus on values and language. Thus, it is difficult to isolate the effects of mindfulness when comparing this treatment to traditional CBT protocols as there are multiple elements that differ between them. The UP may represent a more ideal comparison treatment, as it is a CBT protocol with an added module for mindfulness; in other words, treatment components between the UP and traditional CBT (e.g., exposure, cognitive restructuring) are generally similar with the exception of mindfulness.

Traditional CBT protocols for anxiety disorders were designed to target disorder-specific symptoms, and thus, are largely single-diagnosis protocols (SDPs). As a transdiagnostic treatment, the UP incorporates similar cognitive-behavioral strategies as the SDPs, but emphasizes the experience of emotions, rather than discrete disorder symptoms. Specifically, the UP is designed to address patients' tendency to experience negative emotions (i.e., neuroticism) by reducing reliance on avoidant coping that paradoxically maintains these internal experiences and exacerbates symptoms (Abramowitz, Tolin, & Street, 2001; Gross & John, 2003; Sauer-Zavala et al., 2012). By fostering an approach-oriented stance toward emotions, the UP reduces these rebound effects, thereby decreasing the frequency of negative emotions (Sauer-Zavala et al., 2012; Sauer-Zavala et al., under review).

The modules included in the UP (e.g., monitoring, cognitive reappraisal, countering avoidant behaviors, interoceptive and situational exposure), described in detail elsewhere (Payne, Ellard, Farchione, & Fairholme, 2014), represent traditional cognitive-behavioral skills that are also incorporated into one or more of the SDPs; however, as noted previously, the emphasis of these skills is on dysregulated emotional experiences, broadly, rather than on discrete symptoms.

Additionally, given the overlap between cultivating a more willing, accepting relationship with emotions and the goals of mindfulness, the UP (but not the SDPs) includes formal mindfulness training. In the context of the UP, mindful attention (i.e., attention toward a present-moment experience, without judgment) is focused specifically on emotional experiences (e.g., physical sensations, thoughts, behavioral urges), in contrast to other mindfulness-based interventions cited earlier wherein this quality of attention can be directed toward a range of phenomena (e.g., showering, dishwashing, eating). Mindful principles are practiced via three exercises. First, patients take part in a guided meditation designed to introduce mindfulness while they are experiencing a relatively neutral mood. Next, patients are asked to choose a personally relevant piece of music that will likely induce a strong emotional response and to nonjudgmentally observe their internal experiences while listening to the song. Finally, the "anchoring in the present" exercise encourages patients to identify whether thoughts about the past and future are exacerbating a current emotional experience and to bring their response in line with the demands of the present moment.

In addition to mindfulness practice existing as a dedicated module, mindfulness principles are reinforced throughout the remainder of the UP in the more traditional cognitive-behavioral modules. For example, the Cognitive Flexibility module in the UP does not discourage or try to "change" patient's initial interpretations, implying "good" or "bad" thoughts; instead, nonjudgmental awareness of the automatic thought is encouraged, followed by the generation of other possible interpretations. In other words, "thoughts about the worst scenario can still be there, but they can 'coexist' with other possible assessments of the situation" (Barlow et al., 2018, p. 105). That mindfulness is in part used to bolster acquisition and application of subsequent skills further differentiates the UP from previous mindfulness-inclusive treatments, unlike some of the acceptance-based treatments previously cited that include mindfulness (e.g., ACT), the UP is still a change-oriented CBT treatment, and mindfulness is used as a means to facilitate change rather than accept symptoms without trying to change them.

Although there may be the perception that change-oriented CBT strategies and acceptance-oriented mindfulness techniques cannot exist harmoniously in a single treatment (Harrington & Pickles, 2009), there is emerging research to suggest that CBT protocols with a mindfulness component may result in greater symptom reduction for heterogeneous anxiety disorders (Arch et al., 2012). In a recent RCT, the UP (Barlow et al., 2017) was compared to four gold-standard cognitive-behavioral interventions each designed to target a single anxiety disorder (i.e., social anxiety, panic disorder with or without agoraphobia, generalized anxiety disorder, and obsessive-compulsive disorder). Results suggest that the UP produced equivalent symptom reduction on patients' primary diagnoses compared to the more targeted SDPs. Additionally, results from a component analysis of UP modules (Sauer-Zavala et al., 2017) indicate that the Mindful Emotion Awareness module indeed increases patients' self-reported levels of responding to negative emotions with a nonjudgmental and present-focused stance. However, how these changes in mindfulness relate to changes in clinical outcomes has yet to be examined within the UP. As such, it is of value to examine the unique influence of mindfulness within the UP compared to CBT protocols without this skill on clinical outcomes.

PRESENT STUDY

The goal of the present study is to determine the effect of the inclusion of mindfulness in the context of CBT for principal anxiety disorders. The large equivalence trial comparing the UP to SDPs for heterogeneous anxiety disorders described above provides an ideal context for this question, as both treatment approaches contain similar strategies (e.g., cognitive reappraisal, exposure), with a key difference being the inclusion of formal mindfulness training in the UP but not the SDPs. First, we sought to characterize pre- to posttreatment change in mindfulness as a function of condition (UP vs. SDP) in the full sample. Given the inclusion of a mindfulness module in the UP, we predicted that individuals in that condition would exhibit significantly greater change in mindfulness scores over the course of treatment and greater posttreatment scores than those in the SDP condition, regardless of principal diagnosis. Second, we sought to explore the extent to which change in mindfulness is associated with posttreatment symptom severity, and whether this effect is moderated by treatment condition. We hypothesized that changes in mindfulness would demonstrate a stronger relationship to posttreatment symptom severity for individuals in the UP condition; such results may suggest that increased mindfulness is important for symptom outcomes in the UP, but not necessarily in traditional CBT approaches. Finally, we compared changes in mindfulness and its association with posttreatment severity as a function of treatment condition within each of the four principal

diagnoses. To our knowledge, the present study is the first to compare a mindfulness-inclusive treatment to a full CBT protocol with multiple diagnoses separately. Thus, we did not identify specific hypotheses and considered these analyses exploratory.

Method

PARTICIPANTS

Participants were drawn from a larger randomized control trial (Barlow et al., 2017), which included 223 individuals randomized to one of two active treatments (UP or SDP) or waitlist control in a 2:2:1 allocation ratio, respectively. The study recruited from treatment-seeking individuals presenting at the Center for Anxiety and Related Disorders (CARD) at Boston University, Boston, Massachusetts. Participants received treatment free of charge, and were compensated for major assessments. Given that one of the aims of the current study was to compare treatment elements across active treatments, participants in the waitlist control were not included in our sample. The current sample is comprised of the intent-to-treat participants (all randomized participants) from UP ($n = 88$) and SDP ($n = 91$) conditions for a total sample size of $N = 179$. Demographic characteristics of the sample are displayed in Table 1.

Inclusion and Exclusion Criteria

Individuals were eligible to participate if they were assigned a clinically significant principal diagnosis of social anxiety (SOC), panic disorder with or without agoraphobia (PD/A), generalized anxiety disorder (GAD), or obsessive-compulsive disorder (OCD); diagnoses were made by trained independent evaluators who administered the Anxiety Disorder Interview Schedule (ADIS; Brown & Barlow, 2014; Di Nardo, Brown, & Barlow, 1994) for DSM-IV and DSM-5, and full procedures for maintaining reliability are described elsewhere (Barlow et al., 2017). Because the UP is transdiagnostic, participants with comorbid diagnoses of emotional disorders (e.g., anxiety and depression) were not excluded. Additionally, to be eligible, participants needed to be 18 years of age or older, fluent in English, and (if taking psychotropic medications) able to demonstrate stabilization on psychotropic medications for at least 6 weeks prior to enrollment, along with willingness to maintain that dose throughout the study.

Exclusion criteria included conditions that required more immediate attention and specialized treatment such as a primary or comorbid diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder, organic mental disorder, or current high risk of suicide. Additionally, we did not include participants with a history of substance abuse, with the exception of nicotine, marijuana, and caffeine. To better isolate the effects of the treatments utilized in the study, participants were excluded if they had received at least 8 sessions of CBT within the last 5 years, or if they were concurrently receiving non-CBT treatment for an emotional disorder.

INTERVENTIONS

Participants were randomized to either the UP or SDP condition, the latter dependent on principal diagnosis. Both treatment conditions, based on recommendations of the protocol authors, were delivered across 16 weekly sessions, with the exception of individuals with a principal diagnosis of PD/A, for which treatment lasted 12 sessions for

Table 1
Sample Characteristics at Baseline

Characteristic	Total	UP	SDP	Test Statistic for UP vs. SDP
Age, mean (SD)	30.66 (10.77)	30.95 (11.5)	30.37 (10.0)	$t(177) = 0.36$, $p > 0.05$
Female sex (n, %)	99 (55.31)	48 (54.55)	51 (56.04)	$\chi^2(1) = 0.04$, $p > 0.05$
Race (n, %)				$\chi^2(4) = 5.70$, $p > 0.05$
White	149 (83.24)	73 (82.95)	76 (83.52)	
Black	13 (7.26)	8 (9.09)	5 (5.49)	
Asian	12 (6.70)	6 (6.81)	6 (6.59)	
Pacific Islander	4 (2.23)	1 (1.14)	0 (0.00)	
Hispanic (n, %)	15 (8.38)	3 (3.41)	4 (4.40)	$\chi^2(1) = 5.57$, $p < 0.05$
Principal Dx (n, %)				$\chi^2(3) = 0.76$, $p > 0.05$
SOC	48 (26.82)	23 (26.14)	25 (27.47)	
PD/A	47 (26.26)	25 (28.41)	22 (24.18)	
GAD	49 (27.37)	22 (25.00)	27 (29.67)	
OCD	35 (19.55)	18 (20.45)	17 (18.68)	

Note. SOC = social anxiety disorder; PD/A = panic disorder with or without agoraphobia; GAD = generalized anxiety disorder; OCD = obsessive compulsive disorder; UP = Unified Protocol; SDP = single diagnosis protocol.

both UP and SDP conditions. Sessions lasted approximately 50 minutes each for SOC, PD/A, and GAD and 90 minutes for OCD. Treatments were administered by master-level or higher-level (post-doctoral, licensed psychologists) clinicians, without significant differences in competence and good to excellent fidelity scores (Barlow et al., 2017).

Single Diagnosis Protocols (SDPs)
If randomized to the SDP condition, participants were assigned to receive one of the following CBT-based treatment protocols: *Managing Social Anxiety: A Cognitive-Behavioral Therapy Approach,* second edition (MSA; Hope, Heimberg, & Turk, 2006); *Mastery of Your Anxiety and Panic,* fourth edition (MAP; Barlow & Craske, 2007); *Mastery of Your Anxiety and Worry,* second edition (MAW; Zinbarg, Craske, & Barlow, 2006); *Treating Your Obsessive-Compulsive Disorder With Exposure and Response (Ritual) Prevention Therapy,* second edition (TOCD; Foa, Yadin, & Lichner, 2012). These protocols correspond to SOC, PD/A, GAD, or OCD, respectively.

Unified Protocol (UP)
The UP comes from the same cognitive-behavioral tradition as the SDPs, but rather than focusing on particular situations and symptoms associated with specific anxiety disorders, the UP uses skills like cognitive reappraisal and exposure, in addition to other skills (e.g., mindfulness), to encourage an approach-oriented attitude toward the experience of strong emotions more broadly, while reducing avoidance of them. In addition to psychoeducation and relapse prevention modules, the UP consists of five core modules: Understanding Emotions, Mindful Emotion Awareness, Cognitive Flexibility, Countering Emotional Behaviors, Understanding and Confronting Physical Sensations, and Emotion Exposures.

MEASURES
Diagnostic Assessment
Participants were assessed for *DSM-5* diagnoses using the Anxiety Disorders Interview Schedule (ADIS; Brown & Barlow, 2014; Di Nardo et al., 1994) semi-structured interview. Diagnoses receive a clinical severity rating (CSR) from 0 (*no symptoms*) to 8 (*extremely severe symptoms*), with 4 being the clinical threshold.

Mindfulness
Mindfulness was assessed at pre- and posttreatment for all participants using the Southampton Mindfulness Questionnaire (SMQ: Chadwick et al., 2008). The SMQ consists of 16 items measuring present-centered nonjudgmental awareness. Items are rated 0 (*strongly disagree*) to 6 (*strongly agree*) for statements describing distressing experiences (e.g., "Usually when I experience distressing thoughts and images, I judge the thought/image as good or bad" or "Usually when I experience distressing thoughts and images, I am able to accept the experience"). Items load onto a single factor, and demonstrate good internal consistency in the current sample ($\alpha = 0.89$), comparable to alphas found in other clinical samples ($\alpha = 0.82$; Chadwick et al., 2008).

Symptom Severity
Posttreatment severity scores were assessed using the Clinical Global Impression Scale for severity (CGI-S; Guy, 1976), which is a one-item clinician-rated measure: "Considering your total clinical experience with this particular population, how mentally ill is the patient at this time" with scores ranging from 1 (*not ill*) to 7 (*among most severely ill*). We chose this as an outcome measure in the present study because it is widely used, not diagnosis specific, and comprehensive in that it considers the presentation of the patient as a whole (e.g., symptoms, behavior, history; Busner & Targum, 2007).

VARIABLES IN ANALYSIS
All participants included in analyses had complete SMQ scores at pretreatment and posttreatment, and CGI-S scores at posttreatment ($N = 174$). Posttreatment for each variable was defined as the 16th session for all individuals except those with a primary diagnosis of PD/A, for whom posttreatment was the 12th session. Change scores in mindfulness (SMQ Δ) were computed by subtracting pretreatment scores from posttreatment. Although the ADIS was administered at pre- and posttreatment, and CSRs for each diagnosis were collected, CGI-S was selected as the primary measure of symptom severity in the present study because the CGI-S rating is not explicitly based on specific *DSM-5* criteria (Busner & Targum, 2007), thus allowing for more flexibility in a global assessment of patient symptom severity and functioning. For example, individuals who are rated a CSR of 4 at baseline and show some improvement in overall severity, but still meet diagnostic criteria at posttreatment, must still be rated a 4 because ratings lower than 4 are reserved for individuals who do not meet full diagnostic criteria. Additionally, CSR ratings are made for each diagnosis, whereas a single CGI-S rating is made to reflect all diagnoses (i.e., better accounts for comorbidity).

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Results

PRELIMINARY ANALYSES

Treatment conditions (i.e., UP and SDP) did not differ significantly on age, sex, race, or number of participants with each principal diagnosis (see Table 1). Similarly, within each principal diagnostic category (SOC, PD/A, GAD, and OCD), there were no between-condition (i.e., UP and SDP) differences on these demographic variables, with the exception of age; among individuals with GAD, those in the UP condition were significantly older than those in the SDP condition (see Table 2). As such, only age was considered as a covariate in subsequent analyses comparing treatment conditions for participants with a principal diagnosis of GAD. Treatment conditions also did not differ on number of participants currently taking psychotropic medications in the full sample, $\chi^2(1) = 0.63$, $p > 0.05$, or within principle diagnoses (PD/A [$\chi^2(1) = 0.47$, p > 0.05]; SOC [$\chi^2(1) = 0.92$, p > 0.05]; GAD [$\chi^2(1) = 0.63$, p > 0.05]; OCD [$\chi^2(1) = 0.12$, $p > 0.05$]). Further, participants in the UP and SDP conditions reported similar levels of mindfulness at baseline; however, collapsed across treatment condition, participants with a principal diagnosis of OCD began treatment with a significant deficit in mindfulness, compared to other diagnoses (see Table 3). Last, because the majority of participants presented with comorbid diagnoses ($N = 150$, 83.8%),

the presence of comorbidity and number of comorbid diagnoses were evaluated as potential covariates. In the current sample, there were no differences between treatment conditions in the presence of comorbidity, $\chi^2(1) = 0.48$, $p > 0.05$, or average number of diagnoses, $t(177) = -0.38$, $p > 0.05$, and these were not related changes in mindfulness ($r = -0.08$, $p > 0.05$, and $r = -0.07$, $p > 0.05$, respectively) in the full sample. Additionally, previous research found that there were not significant between-group differences in reduction of comorbid conditions, but that comorbidity was significantly reduced in both conditions at posttreatment (Steele et al., 2018). As such, comorbidity was not considered in subsequent analyses.

CHANGE IN MINDFULNESS AS A FUNCTION OF TREATMENT CONDITION IN THE FULL SAMPLE

Effect size estimates reflecting between condition (UP vs. SDP) differences in mindfulness at pre- and posttreatment can be seen in Table 3. Hedges's g, a variation of Cohen's d that corrects for biases due to small sample size (Rosenthal, 1991), was used to evaluate the magnitude of group differences in SMQ scores at both pre- and posttreatment. As noted above, levels of mindfulness did not differ significantly as a function of treatment condition at baseline. In contrast, results suggest a significant difference in

Table 2

Sample Characteristics at Baseline Within Diagnostic Groups

Demographic Variables	Full Sample (UP and SDP)	UP	SDP	Test Statistic for UP vs. SDP
SOC $n = 48$				
Age (*M, SD*)	30.06 (10.95)	31.09 (13.47)	29.12 (8.15)	$t(46) = 0.62$, $p > 0.05$
Female Sex (*n*, %)	23 (47.92)	13 (56.52)	10 (40.00)	$\chi^2(1) = 1.31$, p > 0.05
Hispanic (*n*, %)	6 (12.50)	1 (4.35)	5 (20.00)	$\chi^2(1) = 2.68$, p > 0.05
Non-White (*n*, %)	14 (29.17)	6 (26.09)	8 (32.00)	$\chi^2(3) = 2.03$, p > 0.05
PD/A $n = 47$				
Age (*M, SD*)	34.11 (12.47)	31.72 (11.32)	36.82 (13.41)	$t(45) = -1.41$, $p > 0.05$
Female Sex (*n*, %)	28 (59.57)	13 (52.00)	15 (68.18)	$\chi^2(1) = 1.27$, p > 0.05
Hispanic (*n*, %)	2 (4.3)	0 (0.00)	2 (9.09)	$\chi^2(1) = 2.37$, p > 0.05
Non-White (*n*, %)	4 (8.51)	3 (12.00)	1 (4.55)	$\chi^2(2) = 1.84$, p > 0.05
GAD $n = 49$				
Age (*M, SD*)	29.49 (9.97)	33.00 (12.79)	26.63 (5.70)	$t(47) = 2.33$, $p < 0.05$
Female Sex (*n*, %)	30 (61.22)	15 (68.18)	15 (55.56)	$\chi^2(1) = 0.81$, p > 0.05
Hispanic (*n*, %)	5 (10.20)	1 (4.55)	4 (14.81)	$\chi^2(1) = 1.40$, p > 0.05
Non-White (*n*, %)	8 (16.33)	4 (18.18)	4 (14.81)	$\chi^2(3) = 5.15$, p > 0.05
OCD $n = 35$				
Age (*M, SD*)	28.49 (8.20)	27.22 (6.51)	29.82 (9.70)	$t(33) = -.093$, $p > 0.05$
Female Sex (*n*, %)	18 (51.43)	7 (38.89)	11 (64.71)	$\chi^2(1) = 2.33$, p > 0.05
Hispanic (*n*, %)	2 (5.71)	1 (5.56)	1 (5.88)	$\chi^2(1) = 0.00$, p > 0.05
Non-White (*n*, %)	4 (11.43)	2 (11.11)	2 (11.76)	$\chi^2(3) = 4.00$, p > 0.05

Note. SOC = social anxiety disorder; PD/A = panic disorder with or without agoraphobia; GAD = generalized anxiety disorder; OCD = obsessive compulsive disorder; UP = Unified Protocol; SDP = single diagnosis protocol.

mindfulness between the UP and SDP conditions at posttreatment ($g = 0.70$, 95% CI [0.33, 1.07]), and the magnitude of this difference was medium. Standardized mean gain effect sizes were calculated to determine significance and strength of pre- to posttreatment change in mindfulness within each condition (Becker, 1988). Effect size change for both UP ($ES_{sg} = -1.40$, 95% CI [-1.83, -0.98]) and SDP ($ES_{sg} = -0.72$, 95% CI [-1.01, -0.44]) conditions was significant, though the size of the effect was large for the UP and medium for the SDP condition. Taken together, these analyses suggest that levels of mindfulness increased in both conditions, but the magnitude of this change may be greater in the UP condition.

CHANGE IN MINDFULNESS AS A FUNCTION OF TREATMENT CONDITION WITHIN EACH PRINCIPAL DIAGNOSIS

Effect size estimates reflecting between group (UP vs. SDP) differences within each principal diagnosis are also displayed in Table 3. Again, we used Hedges's g to evaluate differences in mindfulness scores at pre- and posttreatment between the UP and each individual SDP (e.g. MAP, MAW, TOCD, MSA). As noted above, there were no significant differences in pretreatment levels of mindfulness as a function of treatment condition (UP vs. SDP) within each diagnosis, with the exception of OCD (higher pretreatment mindfulness among UP

Table 3
Main Results for Mindfulness (SMQ) Between and Within Conditions

Treatment Group	Means		Within Condition Pre-Post Effect Size Change	Effect Size Pre (Hedges g)	Effect Size Post (Hedges g)
	Pre	Post			
Full Sample					
UP	M = 36.45 N = 87 SD = 14.90	M = 56.40 N = 68 SD = 14.13	ES_{sg} = -1.37 (large) CI [0.98, 1.76]	g = 0.09 CI [-0.21, 0.39]	g = 0.62 (medium) CI [0.26, 0.97]
SDP	M = 35.00 N = 87 SD = 16.83	M = 47.31 N = 59 SD = 15.27	ES_{sg} = -0.76 (medium) CI [0.47, 1.05]		
SOC					
UP	M = 36.70 N = 23 SD = 15.66	M = 57.47 N = 17 SD = 11.13	ES_{sg} = 1.49 (large) CI [0.61, 2.37]	g = 0.01 CI [-0.59, 0.61]	g = 0.87 (large) CI [0.19, 1.55]
SDP	M = 36.61 N = 20 SD = 14.81	M = 45.75 N = 20 SD = 14.67	ES_{sg} = 0.62 (medium) CI [0.13, 1.11]		
PD/A					
UP	M = 38.75 N = 24 SD = 14.23	M = 54.55 N = 20 SD = 17.70	ES_{sg} = 0.99 (large) CI [0.43, 1.56]	g = 0.01 CI [-0.56, 0.59]	g = 0.02 CI [-0.66, 0.70]
SDP	M = 38.50 N = 22 SD = 20.48	M = 54.21 N = 14 SD = 16.61	ES_{sg} = 0.82 (large) CI [0.24, 1.41]		
GAD					
UP	M = 39.18 N = 22 SD = 13.55	M = 56.67 N = 18 SD = 14.15	ES_{sg} = 1.27 (large) CI [0.48, 2.05]	g = 0.20 CI [-0.37, 0.77]	g = 1.03 (large) CI [0.33, 1.74]
SDP	M = 36.23 N = 26 SD = 15.64	M = 42.13 N = 17 SD = 13.32	ES_{sg} = 0.40 (small) CI [-0.07, 0.87]		
OCD					
UP	M = 29.72 N = 18 SD = 15.49	M = 57.46 N = 13 SD = 12.71	ES_{sg} = 1.93 (large) CI [0.92, 2.93]	g = 0.25 CI [-0.42, 0.93]	g = 0.51 CI [-0.35, 1.37]
SDP	M = 25.88 N = 16 SD = 13.97	M = 50.13 N = 8 SD = 15.91	ES_{sg} = 1.66 (large) CI [0.43, 2.89]		

Note. SOC = social anxiety disorder; PD/A = panic disorder with or without agoraphobia; GAD = generalized anxiety disorder; OCD = obsessive compulsive disorder; UP = Unified Protocol; SDP = single diagnosis protocol.

participants). However, at posttreatment, participants in the UP condition with principal diagnoses of GAD and SOC demonstrated significantly higher mindfulness scores than participants with these diagnoses in the SDP condition; these differences were both large. There were no significant differences in mindfulness at posttreatment as a function of treatment condition for individuals with principal diagnoses of PD/A and OCD. Again, standardized mean gain effect sizes were used to evaluate the strength and significance of change on mindfulness within each condition. For each principal diagnosis, both UP and SDP conditions diagnosis exhibited medium to large, significant change, with the exception of the SDP for GAD (MAW). Although larger effect size change was generally found in the UP condition for each principal diagnosis, the effect size for the UP for GAD was very large, while there was no significant change for the corresponding SDP (MAW).

RELATIONSHIPS BETWEEN MINDFULNESS AND SYMPTOM CHANGE

Next, we examined whether there was a difference in the extent to which increases in mindfulness predicted posttreatment symptoms as a function of treatment condition. Prior to conduction this analysis, preliminary analysis reflected that there were no significant differences in posttreatment CGI-S scores between treatment conditions (Hedges's g = -0.19, CI [-0.54, 0.16]). The structure for moderation analysis, which was conducted in SPSS using the PROCESS macro (Hayes, 2014), can be seen in Figure 1. In the full sample, treatment condition did not moderate the relationship between SMQ Δ and CGI-S (coefficient of interaction term = 0.44, SE = 0.01, 95% CI [-0.02, 0.04]), with treatment condition only accounting for 0.50% of the unique variance in posttreatment CGI-S scores.

Given that there were significant differences in magnitude of change in mindfulness as a function of treatment condition for participants with GAD and SOC, we next explored whether the relationship between change in mindfulness and posttreatment clinical severity was moderated by treatment condition within these diagnoses. First, preliminary analyses reflected no significant difference in posttreatment CGI-S scores between conditions for participants with either GAD (Hedges's g = -0.32, CI [-0.98, 0.35]) or SOC (Hedges's g = -0.49, CI [-0.21, 1.18]). For participants with GAD, treatment condition trended toward significantly moderating the relationship between SMQ Δ and CGI-S (coefficient of interaction term = 0.06, SE = 0.02, 95% CI [0.00, 0.10]), such that change in mindfulness scores from pre- to posttreatment were more strongly associated with lower posttreatment clinical severity in the UP condition. Specifically, there was a significant negative association between these variables for individuals the UP condition, whereas there was a positive, nonsignificant association for those in the SDP condition (Figure 2). Approximately 10.18% of the variance in posttreatment CGI-S scores can be explained uniquely by treatment condition. Despite significant between-group differences in posttreatment mindfulness scores, for participants with SOC, we failed to find a significant relationship between SMQ Δ and CGI-S (r = -0.02, p = 0.15), even when including treatment condition as a moderator (coefficient of interaction term = -0.00, SE = 0.02, 95% CI [-0.05, 0.05]).

Discussion

The goal of the present study was to better understand the effect of mindfulness in the context of CBT for principal anxiety disorders. The first objective was to determine whether the inclusion of formal mindfulness training was associated with increased levels of present-focused nonjudgmental
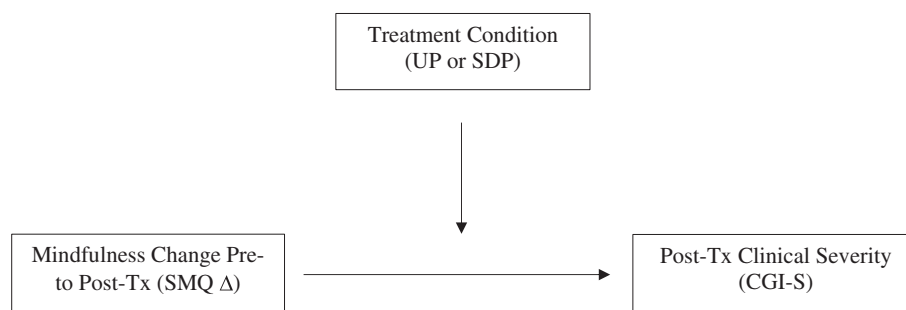
FIGURE 1   Moderation Analysis Structure
Note. UP = Unified Protocol; SDP = single diagnosis protocol; GAD = generalized anxiety disorder;
SMQ = Southampton Mindfulness Questionnaire; CGI-S = Clinical Global Impression Severity.
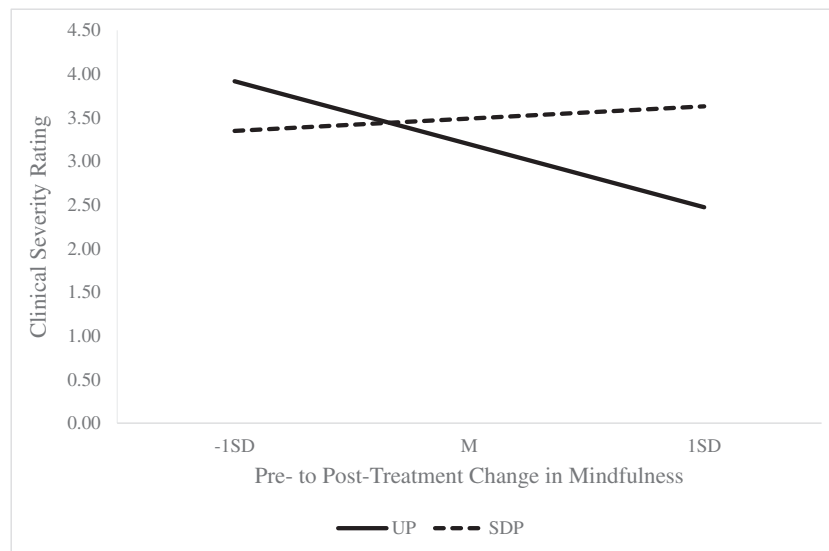
FIGURE 2 Posttreatment Clinical Severity Ratings at Levels of Pre- to Posttreatment Change in Mindfulness for GAD
Note. UP = Unified Protocol; SDP = single diagnosis protocol; GAD = generalized anxiety disorder.

attention above traditional CBT-components. Toward that end, we predicted that those receiving the UP would demonstrate greater pre-to-posttreatment change in mindfulness compared to those receiving an SDP. This hypothesis was confirmed, as change in mindfulness was large in magnitude for individuals in the UP condition, compared to medium in magnitude for SDP participants. Additionally, we found that post-treatment mindfulness levels were significantly higher in the UP condition compared to the SDP condition, and this difference was medium in magnitude. A second objective was to determine whether the UP had unique advantages in cultivating mindfulness compared to specific SDPs across diagnoses. Results suggest that, at posttreatment, significant differences in mindfulness between the UP and SDP conditions were observed only for individuals with principal SOC and GAD, and these effects were both large in magnitude. Overall, these findings confirmed our expectations that formal mindfulness training results in larger improvements in this skill, and that these effects were more pronounced for individuals with SOC and GAD.

Additionally, we sought to explore the extent to which change in mindfulness is associated with posttreatment symptom severity, along with whether this effect is moderated by treatment condition, particularly within the SOC and GAD subsamples that exhibited significantly higher posttreatment mindfulness scores than the SDP condition. Collapsed across treatment condition, the full,

diagnostically heterogeneous sample and the GAD subsample exhibited a significant positive association between mindfulness change scores and post-treatment clinical severity, whereas this relationship was not observed for individuals with SOC. Further, treatment condition moderated this relationship at a trend level for individuals with principal GAD. These results suggest that mindfulness training is not only important in producing improvements in GAD symptoms, but also that this change in mindfulness may be a key treatment component in the UP (but not the SDP for GAD). It is, however, important to note that the moderation effect of treatment condition on the relationship between mindfulness and symptom severity was significant at a trend level with the inclusion of age as a covariate, and must be replicated to be considered reliable.

The results of the present study suggest that the inclusion of mindfulness may be particularly important for patients with GAD. Although CBT has demonstrated efficacy in treating GAD, evidence suggests that, among the anxiety disorders, it is least responsive to treatment (Cuijpers et al., 2014; Waters & Craske, 2005). Theory suggests that this may be due to having a more generalized focus, making the design of exposure more difficult, along with the pervasiveness and commonplace nature of the anxiety (i.e., not just in triggering situations; Roemer & Orsillo, 2002). Additionally, individuals with GAD have high levels of intolerance and reactivity to worry, as well as high levels of negative evaluation of those experiences (Lee, Orsillo, Roemer, & Allen, 2011; Mennin, Heimberg,

Turk, & Fresco, 2005). Given these unique difficulties, Roemer et al. (2008) developed Acceptance-Based Behavior Therapy (ABBT) specifically to address these areas of difficulty for GAD, an adaptation of traditional CBT treatments to include acceptance/mindfulness principles. ABBT and other nondiagnosis-specific acceptance/mindfulness-inclusive treatments, such as Mindfulness-based Cognitive Therapy (MBCT; Segal, Williams, & Teasdale, 2013) and ACT, have also gained empirical support in GAD samples (Arch et al., 2012; Evans et al., 2008) when compared to techniques traditionally used in CBT protocols for this disorder (e.g., applied breathing). Results from the present study support this existing literature that mindfulness may be particularly relevant and beneficial for treating GAD.

To our knowledge, this is the first study to compare a mindfulness-inclusive treatment to full CBT protocols with multiple diagnoses examined separately and collectively as a heterogenous sample. This permitted further evaluation of the UP as a transdiagnostic treatment. A proposed advantage of the UP is that it reduces training burden in clinical settings, allowing providers to utilize one manual for a range of principal diagnoses and comorbid conditions. The present results suggest further advantage in this context, such that providers can use the UP as a means to deliver effective mindfulness training and CBT skills across diagnoses in a way that does not increase training burden, and may actually relate to improvements in symptoms.

Future research should explore additional ways the inclusion of the mindfulness module in the UP may be relevant transdiagnostically. In particular, as the UP identifies aversive reactions to frequently occurring negative emotions as a primary mechanism in the maintenance of emotional disorders (Bullis, Boettcher, Sauer-Zavala, Farchione, & Barlow, 2019), examining the relationship between change in mindfulness and change in negative affectivity (rather than clinical severity) may point to the mechanism of this module across diagnoses. Additionally, future research can explore the inclusion of mindfulness in the UP transdiagnostically as it relates more specifically to comorbidity. For example, is mindfulness more or less related to symptom severity for individuals when GAD is the principal diagnosis or when GAD is present at a clinical level regardless of principal diagnosis? Further, the present study was not designed to allow for consideration of the potential for interaction between mindfulness training and other active CBT components, but doing so could expand our understanding of how mindfulness operates in the larger context of treatment. For example, it is possible that improvements in mindfulness may increase effectiveness of cognitive restructuring or exposure, and this interaction is how mindfulness may affect symptom change.

The results of the present study must be interpreted in light of its limitations. First, exploring the effects of mindfulness within each principal anxiety disorder resulted in reduced sample size, though this was accounted for using appropriate statistical tests. Furthermore, our sample was largely White, reducing the likelihood that our results are generalizable to the larger population. Nevertheless, this study adds to the limited literature comparing CBT with mindfulness to more traditional CBT approaches; in fact, a significant strength of the present study is that mindfulness is evaluated by comparing the UP to gold-standard SDPs used for anxiety disorders. Further, we were able to evaluate the inclusion of mindfulness in a CBT treatment for a diagnostically heterogeneous sample and specific anxiety disorders.

CONCLUSION

The present study found that the inclusion of mindfulness in the UP resulted in significant changes in mindfulness across disorders, with significantly greater scores on this skill at posttreatment compared to the SDP condition. Further, changes in mindfulness were related to posttreatment clinical severity for the full sample (collapsed across treatment condition), as well as participants with principal GAD. Additionally, for participants with principal GAD, there was a trend toward a significant moderation effect of treatment condition, suggesting a stronger relationship between improvements in mindfulness and clinical severity for those receiving the UP. In sum, results suggest that the UP does result in improved mindfulness compared to leading single diagnosis CBT-treatments, and that improved mindfulness may be particularly important for reducing clinical severity in GAD.

Mayo Clinic, and various American universities. Todd J. Farchione reported receiving royalties from Oxford University Press for one of the treatment manuals included in this study. Brittany K. Woods and Shannon Sauer-Zavala did not report any conflicts of interest.

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