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Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders: Protocol Development and Initial Outcome Data

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Abstract

Two studies present preliminary support for the Unified Protocol (UP), a transdiagnostic, emotion-focused cognitive-behavioral treatment developed to be applicable across the emotional disorders. Study 1 presents data from an open clinical trial of the initial version of the UP in a heterogeneous clinical sample, yielding large pre- to post-treatment effect sizes across disorders on measures of DSM-IV diagnostic category severity, and medium to large effect sizes on general measures of depression and anxiety, social adjustment, and levels of negative and positive affect. Following a period of further manual development resulting in specific modifications and enhancements to core treatment components, Study 2 presents data from an additional pilot study of this revised version of the UP. Results from Study 2 demonstrated more robust treatment effect sizes and greater changes across measures of depression, anxiety, positive and negative affect, social adjustment, and quality of life. Relatively similar treatment effects were again demonstrated across a full range of anxiety and mood disorders, suggesting roughly equivalent transdiagnostic efficacy. Implications for the treatment of emotional disorders, clinical practice, and dimensional conceptualizations of psychopathology are discussed.

Introduction

Anxiety and mood disorders disrupt the lives of millions of Americans each year, with lifetime prevalence rates for anxiety disorders estimated at 29% of the population, and mood disorders at 21% (Kessler, Berglund & Demler, 2005). Anxiety disorders alone represent a cost to this country of over $42 billion annually (Greenberg et al., 1999). Clearly, effective treatments for anxiety and mood disorders that can be widely disseminated are sorely needed to address this significant public health risk. In service of this goal, several evidenced-based cognitive-behavioral treatments targeting specific anxiety and mood disorders have been developed over the last 20 plus years (Antony & Stein, 2009; Barlow, 2002; Norton & Price, 2007). However, along with the development of these effective treatments has come a proliferation of disorder-specific treatment manuals, placing a significant burden on practicing clinicians who wish to deliver empirically-supported treatments to their patients,

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and hampering efforts at widespread dissemination of evidenced-based psychological treatments.

Recent scientific advances suggest that there may be more that unites anxiety and mood disorders than previously conceived, potentially making the need for numerous disorder-specific treatments obsolete and opening the possibility for a more parsimonious application of evidence based treatments in clinical practice. Recent research, particularly in the fields of neuroscience, emotion science and descriptive and functional psychopathology, has begun to identify common, higher order factors that underlie anxiety, mood and related emotional disorders. For example, using structural equation modeling, Brown, Chorpita and Barlow (1998) found that the covariance among latent factors corresponding to a range of emotional disorders including unipolar depression, social phobia, generalized anxiety disorder (GAD), obsessive-compulsive disorder (OCD), and panic disorder with agoraphobia (PDA) was explained by the higher order factors of negative and (low) positive affect. Specifically, negative affect loaded positively on all five DSM-IV disorder categories (Brown et al., 1998). Consistent with this structural model, preliminary investigations of anxiety and mood disorders emerging from the field of affective neuroscience consistently demonstrate increased activation in key neural structures implicated in the generation of negative affect across these disorders, relative to healthy controls (Etkin & Wager, 2007; Mayberg et al., 1999; Siegle, Thompson, Carter, Steinhauer, & Thase, 2007). For instance, a recent meta-analysis of fMRI studies of patients with post-traumatic stress disorder (PTSD), social phobia, and specific phobia consistently showed greater amygdala and insula activity (structures linked to the generation of negative emotional responses) in patient samples relative to matched healthy controls (Etkin & Wager, 2007). Behavioral investigations of emotion regulation and emotional processing have increasingly found that individuals suffering anxiety and mood disorders endorse more frequent and intense experiences of negative affect than healthy individuals (Campbell-Sills, Barlow, Brown, & Hoffman, 2006; Mennin, Heimberg, & Turk, 2005), and tend to view these experiences as more aversive (Roemer, Salters, Raffa, & Orsillo, 2005). Further, deficits in the ability to regulate emotional experiences, emerging out of unsuccessful efforts to avoid or dampen the intensity of negative emotions, have been found across the anxiety and mood disorders (Cambpell-Sills et al., 2006).

Taken together, these reports emerging from diverse fields of study provide mounting evidence for the role of increased negative affect as both a precipitating and maintaining factor across anxiety and mood disorders. Further, this evidence suggests that deficits in emotional processing and maladaptive regulation of emotional experiences may contribute to anxiety and mood disorders, representing a key target for therapeutic change (Barlow, Allen & Choate, 2004). In support of this theory, an investigation by Brown (2007) examining the temporal course and structural relationships between negative affect (represented by a factor of neuroticism/behavioral inhibition), positive affect (represented by positive affect/ behavioral activation), and the DSM-IV disorder constructs of unipolar depression, GAD, and social phobia found that of these five factors, negative affect evidenced the greatest amount of change following cognitive-behavioral treatment over a 2-year interval. Further, the temporal covariance of the DSM-IV disorder constructs was fully accounted for by change in negative affect. This suggests that 1) negative affect represents a unifying

construct accounting for the covariance of emotional disorders, and 2) negative affect may be responsive to therapeutic interventions, and may mediate the extent of change in the emotional disorders (Brown, 2007). Therefore, addressing the core affective processes contributing towards an increase in negative affect present across the emotional disorders, rather than discrete, disorder-specific heterogeneous symptoms, may more efficiently target the root of these disorders and result in reductions in co-occurring disorder symptoms.

Development of the Unified Transdiagnostic Treatment for Emotional Disorders

In response to these advances, we developed the Unified Protocol for the Treatment of Emotional Disorders (UP), a transdiagnostic, emotion-focused cognitive-behavioral treatment (CBT) (Barlow et al., 2008). The UP was developed to be applicable across anxiety and mood disorders, as well as other disorders in which anxiety and emotion dysregulation plays a significant role, such as many somatoform and dissociative disorders. The focus in the UP on common underlying factors reflects scientific advances leading to more dimensional conceptions of psychopathology, and represents a movement away from the extreme diagnostic splitting evident in DSM-IV that has resulted in the proliferation of disorder-specific treatments. Further, this approach renders moot the issues of comorbidity, not otherwise specified (NOS) diagnoses, and sub-threshold presentations among anxiety and mood disorders allowing for more focused and simplified treatment planning.

The development of the UP began with the distillation of key principles from traditional empirically-supported CBT treatments (e.g. Barlow, 1988, 2002; Beck, Rush, Shaw, & Emery, 1987) and advances in research on adaptive emotion regulation (e.g. Campbell-Sills et al., 2006; Gross, 1998; Mennin et al., 2005). Specifically, the UP has emerged out of decades of research leading to the development of effective cognitive and behavioral treatments for anxiety and mood disorders (Barlow, 2002). At the core of the UP are the fundamental principles of traditional CBT, including emphases on extinction learning through behavioral exposure and the identification and modification of maladaptive cognitions. However, the focus of extinction training now extends to anxiety focused on interoceptive cues, including those associated with intense emotions, an extension of a concept first utilized in panic disorder (Barlow, 1988; Barlow, Craske, Cerny, & Klosko, 1989; Craske, 1991). The UP also extends upon traditional CBT by explicitly focusing on the role of thoughts, feelings and behaviors in generating internal emotional experiences, and subsequently the role of emotional (dys)regulation in emotional disorders. As such, the UP emphasizes the adaptive, functional nature of emotions, helps facilitate greater tolerance of emotions, and seeks to identify and correct maladaptive attempts to regulate emotional experiences. The initial version of the UP treatment manual included sessions targeting antecedent cognitive reappraisal (emphasizing two core thinking traps – jumping to conclusions and thinking the worst; Craske & Barlow, 1989), the prevention of emotional avoidance and increased emotional awareness, and the identification and modification of emotion- driven action tendencies (Barlow, 1988; termed “emotion driven behaviors,” or “EDBs”). Treatment concepts were tied together in the final phase of treatment through engagement in interoceptive and situationally-based emotion exposures, emphasizing the

elicitation of and exposure to both situational and internal emotional experiences. For a more detailed description of the initial version of the UP, see Allen, McHugh, and Barlow (2008).

This first, early version of the UP was pilot-tested in a heterogeneous sample of 18 patients presenting for treatment at the Center for Anxiety and Related Disorders at Boston University and meeting diagnostic criteria for a range of anxiety disorders (see Study 1 below). Initial pilot-testing allowed us to acquire valuable clinical insight into how well patients acquired and adopted the core skills of the treatment, as well as how treatment concepts could be presented in a more logical progression. This in turn led us to consider ways in which the treatment could be improved upon further. Hence, initial pilot-testing was followed by revision of the treatment manual with the aim of enhancing patient learning and acquisition of core emotion regulation skills, thereby facilitating the extinction of both internally and situationally-cued anxiety. The revised version of the protocol was subsequently pilot-tested in an additional heterogeneous sample of 15 patients. Here, we present data from these two open trials of the UP.

Study 1 – Pilot-Test of Initial Version of the UP

The initial version of the UP was pilot-tested in a sample of patients whose principal diagnoses spanned the anxiety disorders, including GAD, OCD, social phobia, PTSD, and PDA, as well as major depressive disorder (MDD) and dysthymia. Patients carried on average at least one additional comorbid diagnosis. We hypothesized that treatment using the UP would result in reductions in clinical disorder severity across these disorder categories, as well as improvement in comorbid symptoms. We also hypothesized that treatment with the UP would result in improvement across the anxiety disorders on general measures of depression and anxiety, lower endorsement of negative affect and higher endorsement of positive affect, and improvements in social adjustment.

Method

Participants

Participants were recruited from a pool of individuals seeking treatment at the Center for Anxiety and Related Disorders at Boston University. All individuals were assessed using the Anxiety Disorders Interview Schedule for DSM-IV–Lifetime Version (ADIS-IV-L; DiNardo, Brown, & Barlow, 1994) and were contacted for participation if they received a principal diagnosis of an anxiety disorder (see below for a description). Individuals were excluded only if participation in a research study was contraindicated, for instance, current significant suicidal ideation, current substance dependence diagnosis, or a history of mania or a psychotic disorder.

Twenty-four patients consented to treatment. Two of the 24 who had consented dropped out of treatment. Of the remaining 22 patients, two did not complete post-treatment assessments. Therefore, post-treatment data were available for 20 participants and are included in the present study. Participants were 58.8% female ($n = 12$). The mean age was 30 years ($SD = 10.64$) and participants ranged from 18 to 54 years old. The sample was primarily Caucasian ($n = 17$). Nine individuals were taking psychotropic medications at the time of enrollment

and randomization. All individuals were stable on the same dose for at least 3 months prior to enrolling in the study and as part of participation in the study, all agreed to maintain these dosages and medications for the duration of the study. Sixteen individuals had received prior psychosocial treatment for anxiety or mood disorders. Principal diagnoses represented by the sample included: GAD (n = 4), social phobia (n = 4), OCD (n = 3), PDA (n = 5), PTSD (n = 1), MDD (n = 2), and hypochondriasis (n = 1). Three individuals had co-principal diagnoses (a diagnosis of equal severity). For these individuals the co-principal diagnoses were anxiety not otherwise specified (n = 1), MDD (n = 1), and social phobia (n = 1). Consistent with prior research, the present sample evidenced significant comorbidity (Brown et al., 2001). Participants in Study 1 had an average number of 3.3 diagnoses at pre-treatment (SD = 1.26; range 1 to 6 diagnoses). Additional or comorbid diagnoses included: GAD (n = 4), social phobia (n = 3), OCD (n = 2), MDD (n = 2), dysthymia (n = 3), specific phobia (n = 1), impulse control not otherwise specified (n = 1), and primary insomnia (n = 1).

Measures

Anxiety Disorders Interview Schedule for DSM-IV– Lifetime Version (ADIS-IV-L; DiNardo et al., 1994).—This semi-structured, diagnostic clinical interview focuses on DSM-IV diagnoses of anxiety, mood, somatoform, and substance use disorders. The information derived from the interview using the ADIS allows clinicians to determine differential diagnoses and gain a clear understanding of the level of impairment and severity of each diagnosis. Principal and additional diagnoses are assigned a clinical severity rating (CSR) on a scale from 0 (no symptoms) to 8 (severely disturbing/disabling), with a rating of 4 or above (definitely disturbing/disabling) passing the clinical threshold for DSM-IV diagnostic criteria. In instances where the patient meets criteria for two or more current diagnoses, the principal diagnosis is assigned as the diagnosis with the higher CSR, representing the greatest amount of interference and/or distress, and the remaining diagnoses become additional (comorbid) diagnoses. Occasionally, co-principal diagnoses are assigned when diagnoses are determined to be equally severe and interfering. This measure has demonstrated acceptable to excellent interrater reliability for the anxiety and mood disorders (Brown, DiNardo, Lehman, & Campbell, 2001).

The ADIS-IV-L was administered during the first assessment, and an abbreviated version assessing only current diagnoses was administered at post-treatment assessments. All assessments were administered by doctoral students at the Center for Anxiety and Related Disorders who had undergone extensive training (see Brown et al., 2001).

Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996).—The BDI-II is perhaps the most widely used measure to assess current depressive symptoms. It contains 21 items focusing on the levels of depressive symptoms over the past two weeks. Participants are asked to circle the number next to the statement that best corresponds to how they felt over the past week. Scores range from 0 to 63, with higher scores indicating greater depressive symptoms.

Beck Anxiety Inventory (BAI; Beck & Steer, 1990; Steer, Ranieri, Beck, & Clark, 1993).—The BAI also contains 21 items scored in a similar way and focuses on common symptoms that are more unique to anxiety, such as somatic and certain cognitive symptoms.

Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1998).—The PANAS is a brief, reliable and valid measure of positive and negative affect. It consists of 20 feeling or emotion words. Respondents rate each emotion word on a scale ranging from 1 = very slightly or not at all to 5 = extremely, indicating the extent to which they experienced that emotion or feeling during the past few weeks. The PANAS allows for the assessment of core negative affect as well as deficits in positive affect. The PANAS has shown excellent convergent and divergent validity.

Work and Social Adjustment Scale (WSAS; modification of scale introduced by Hafner & Marks, 1976).—The WSAS is a five-item measure asking participants to rate the degree of interference caused by their symptoms in work, home management, private leisure, social leisure, and family relationships. Interference is rated over the past week on a 0 to 8 scale (0 = not at all interfering to 8 = severe interference). The WSAS is a descriptive measure of subjective interference in various domains of living, and has been successfully used in previous studies (e.g., Brown & Barlow, 1995).

Treatment

A maximum of fifteen 60-minute individual treatment sessions were allowed in Study 1. Patients who completed a full course of treatment were seen on average 13 total sessions (range 8–15) of 15 total allowable sessions. Treatment was comprised of four main components: 1) psychoeducation about emotions, including a review of the functional nature of emotions; 2) alteration of antecedent cognitive misappraisals; 3) prevention of emotional avoidance; and 4) modification of emotion-driven behaviors (EDBs). Treatment emphasized emotion exposures (provoking emotion expression) through situational, internal, and somatic (interoceptive) cues, as well as standard mood inductions. For a more complete description of treatment, see Allen et al., 2008.

Therapists and Treatment Integrity

Therapists for the study were six doctoral students with one to four years of experience, providing treatment under the close supervision of a licensed senior team member. Treatment adherence was monitored during weekly supervision and manual development meetings.

Results

Efficacy at Post-Treatment Assessment

Descriptive statistics and effect size estimates for the primary study variables are shown in Table 1. All effect size estimates were calculated using Cohen's *d*, where 0.2 indicates a small effect size, 0.5 indicates a medium effect size, and 0.8 indicates a large effect size (Cohen, 1988). Of course, because of the small N in most calculations effect sizes are only rough estimates as indicated by the confidence intervals, also supplied (Kraemer & Kupfer,

2006). A large treatment effect size for the ADIS CSR for the principal or co-principal diagnoses was found at post-treatment (d = 1.15, n = 18). Moderate effect sizes were evidenced for general measures of depression (BDI-II; d = 0.57, n = 19) and anxiety (BAI; d = 0.64, n = 19). A moderate effect size was also evidenced at post-treatment for negative affectivity (PANAS-N; d = 0.50), while a small to moderate effect size was evidenced for positive affectivity (PANAS-P; d = −0.31). Post-treatment effect size for a measure of social adjustment was also in the moderate to large range (WSAS; d = 0.69).

Effects on Comorbidity

In order to evaluate the effect of the UP on additional or comorbid diagnoses, a separate variable was calculated by creating a mean of the CSRs for all additional or comorbid diagnoses at both pre- and post-treatment (n = 12). Effect sizes were then calculated using these values. The UP evidenced a large effect size on comorbid clinical diagnoses (d = 1.15).

Applicability Across the Anxiety Disorders

One of the central tenets of the UP is its hypothesized applicability across the range of anxiety and mood disorders. In order to evaluate this hypothesis, separate effect size estimates were calculated for each of the primary anxiety disorders, regardless of whether the disorder was principal or comorbid status. As shown in Table 2, the UP evidenced comparable large effect sizes for social phobia (d = 1.21; n = 8), OCD (d = 0.93; n = 5), and PDA (d = 1.14; n = 4). However, effect size estimates for GAD were more modest (d = 0.63; n = 7). Large effect sizes were also evidenced on comorbid depression diagnoses (MDD and dysthymia; d = 1.58; n = 6).

Summary

Results from the Study 1 pilot-test of the initial version of the treatment manual provided preliminary support for the efficacy of the UP in the treatment of a range of anxiety and mood disorders including GAD, social phobia, panic disorder, OCD, social phobia, PTSD, and depression. Treatment with the UP lead to an overall reduction in the frequency and severity of both principal and co-occurring disorders from pre- to post-treatment. Further, a separate analysis of treatment effects for specific disorders revealed reductions in clinical severity in every diagnosis represented by the sample, including depression.

While these initial results were promising, overall effect sizes in Study 1 nevertheless fell below what is typically seen in disorder-specific CBT treatments for anxiety (d = 1.58; Norton & Price, 2007). In addition, while reductions in clinical severity were evidenced across disorders, diagnoses on average remained at a clinical level (defined as an ADIS CSR at “4” or above) at post treatment (mean post-treatment CSR = 4.02; SD = 2.11). Finally, despite evidence suggesting that a high proportion of individuals treated for GAD fail to meet criteria for high end-state functioning (Waters & Craske, 2005), the GAD response to treatment with the UP nevertheless fell below our expectations. Thus, these preliminary results highlighted the need for continued treatment refinement and protocol testing. Following an extensive period of further treatment manual development and refinement, the

UP was pilot tested in an additional sample of patients. We present these results below in Study 2.

Study 2 – Pilot-Test of the Revised Version of the UP

Following the initial pilot-test presented in Study 1, and prior to advancing to a more complex randomized controlled trial (RCT), the UP manual underwent several modifications in an effort to improve upon these initial promising results. As suggested by Rounsaville, Carroll, and Onken (2001), this additional treatment manual development phase and further pilot testing allows for thorough testing of the theoretical rationale behind treatment components, and allows for important modifications informed by clinical experience and judgment to be made and treatment efficacy to be established before moving on to effectiveness testing.

Key Modifications to the Unified Treatment Protocol

The revised version of the UP treatment manual was modified to anchor treatment concepts more explicitly within the three-component, modal model of emotion (see Fairholme, Boisseau, Ellard, Ehrenreich, & Barlow, in press), and to place a greater emphasis upon increasing patient awareness of the interaction of each of these components within the context of present moment experience. As the treatment proceeds in the revised manual, the domains of thoughts, feelings, and behaviors are each explored in detail within the context of their contribution to present moment emotional experiences, focusing specifically on exploring dysfunctional emotion regulation strategies that the patient has developed over time within each of these domains, and teaching patients more adaptive emotion regulation skills (for a more detailed description of how emotion regulation skills are addressed in the UP, we refer the reader to Fairholme et al., in press). Treatment sessions from the original protocol were reordered, so that the presentation of core treatment concepts progressed in a more clinically useful and theoretically consistent way.

Specific modifications were as follows: 1) Enhancements were made to the original session one material to expand patients' understanding of the adaptive function of emotions and to promote the development of skills for monitoring their emotional experiences. A description of the ABCs of emotions (antecedent triggers, behavioral responses, and consequences of these responses) was included, as well as specific definitions of the adaptive function of a range of negative emotions, including anger, anxiety, and sadness, and enhanced examples of EDBs triggered by these specific emotions. 2) Emotional awareness training was moved from session five to session two in the revised protocol, emphasizing present-focused, non-judgmental emotion awareness as an important core skill serving to enhance acquisition of subsequent treatment concepts including interoceptive exposure. A formal, in-session mindful awareness exercise was also added (adapted from Segal, Williams, & Teasdale, 2002), followed by an emotion-induction exercise using music selected by the patient as emotion provoking. 3) While sessions three and four of the initial protocol emphasized antecedent cognitive reappraisal, the revised protocol was modified to reflect more explicitly an emphasis on increasing cognitive flexibility, employing reappraisal strategies not only before but also during and after emotionally-laden situations. Additionally, a greater

emphasis was placed on teaching patients to recognize how thoughts influence emotions, physical sensations, and behaviors, and vice versa. 4) Session 5 of the revised protocol placed a greater emphasis on using interoceptive exercises not only as a method of exposure to internal cues, but also to build an awareness of how physical sensations interact with and influence thoughts and behaviors. All patients, regardless of diagnosis, were taken through three core interoceptive exposure exercises (breathing through a thin straw, spinning in circles, and hyperventilating). 5) Finally, the revised version of the UP included optional additional "booster sessions," wherein patients solidified acquired emotion regulation skills through additional emotion exposure practice. This revised protocol was then pilot-tested in an additional sample of 15 patients seeking treatment at our Center.

Method

Participants

Eighteen patients consented to treatment. Two patients dropped out after the first session of treatment, and one patient completed five sessions but was forced to drop out due to transportation difficulties. Therefore, post-treatment data were available for 15 individuals and are reported here. Participants in Study 2 were comparable to Study 1 participants on all demographic variables. Participants in Study 2 were 53.3% female (n = 8), with 4 males in the immediate treatment and 3 in the waitlist control condition. The mean age was 29.73 years (SD = 7.11) and participants ranged from 18 to 44 years old. The sample for study 2 was primarily Caucasian (n = 12), with two participants self-identifying as Asian and one participant self-identifying as multi-racial. Six individuals were taking psychotropic medications at the time of enrollment and randomization. All individuals were stable on the same dose for at least 3 months prior to enrolling in the study and as part of participation in the study, all agreed to maintain these dosages and medications for the duration of the study. Nine individuals had received prior treatment for anxiety or mood disorders. Overall, the characteristics of Study 2 participants were comparable those included in Study 1.

As in Study 1, any individual with a principal diagnosis of an anxiety disorder (other than a specific phobia) was eligible to participate. Principal diagnoses included: GAD (n = 3), social phobia (n = 5), OCD (n = 3), and PDA (n = 2). Two individuals had co-principal diagnoses. For these individuals the co-principal diagnoses were, GAD and agoraphobia without panic (n = 1) and GAD and social phobia (n = 1). Participants in study 2 had an average number of 2.2 comorbid diagnoses at pre-treatment (SD = 1.01; range 1 to 4 diagnoses). Additional or comorbid diagnoses included: GAD (n = 2), social phobia (n = 3), OCD (n = 2), PDA (n = 2), MDD (n = 3), dysthymia (n = 1), specific phobia (n = 2), hypochondriasis (n = 1), and anxiety disorder not otherwise specified (n = 1).

Measures

Measures included in Study 2 were identical to those included in Study 1, with the following additions:

Structured Interview Guide for the Hamilton Anxiety Rating Scale (SIGH-A; Shear et al., 2001).—The SIGH-A was developed to create a structured format for

administering the Hamilton Anxiety Rating Scale (HARS; Hamilton, 1959). The SIGH-A includes specific instructions on administration and anchor points for assigning severity ratings. This measure demonstrated good inter-rater and test-retest reliability. In addition, scores are similar to (although consistently higher than) the HARS.

Structured Interview Guide for the Hamilton Depression Rating Scale (SIGH-D; Williams, 1988).—Similar to the SIGH-A, the SIGH-D was developed to provide more specific instructions for administration and scoring of the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960). The SIGH-D also demonstrated good inter-rater and test-retest reliability and produces scores similar to the HRSD.

Quality of Life Inventory (QOLI; Frisch, Cornell, Villaneuva, & Retzlaff, 1992).—The QOLI consists of 32 items relevant to overall life satisfaction, including items related to work, love relationships, friendships, self-regard, standard of living, recreation, community, home, etc. Respondents rate each item on its importance to overall happiness and satisfaction. Test-retest reliability coefficients have ranged from 0.80 to 0.91 and internal consistency coefficients from 0.77 to 0.89 across three clinical and 3 nonclinical samples. Validity of the QOLI was demonstrated by significant positive correlations with seven related measures of well-being and significant negative correlations with measures of general psychopathology, but in all cases the QOLI was not redundant with these other measures (Frisch et al., 1992).

Treatment

A maximum of eighteen 60-minute individual treatment sessions were allowed in Study 2. Patients in Study 2 were seen an average of 17 sessions out of the allowable 18 (range 12-18). Treatment included the same four components as the treatment provided in Study 1, with the following modifications: 1) increased emphasis on adaptive function of emotions and emotion driven behaviors; 2) an increased focus on present-focused emotion awareness, including formal mindful awareness practice; 3) increased focus on cognitive flexibility; 3) increased emphasis on the contribution of physiological sensations to emotional experiences; 4) increased emotion exposure practice.

Therapists & Treatment Integrity

Similar to Study 1, therapists for the study were five doctoral students with one to three years of experience, and one licensed doctoral-level psychologist with six years of experience. All therapists provided treatment under the close supervision of licensed senior team members. Treatment adherence was monitored during weekly supervision and manual development meetings.

Results

Efficacy at Post-Treatment Assessment

Descriptive statistics and effect size estimates for the primary study variables are shown in Table 3. As in Study 1, all effect size estimates were calculated using Cohen's *d* (Cohen, 1988). At post-treatment, there was a large treatment effect size for the ADIS CSR for the

principal or co-principal diagnoses (d = 1.94). Moderate to large effect sizes were also evidenced for general measures of depression; specifically, the SIGH-D (d = 0.92), and BDI-II (d = 0.43). Moderate effect sizes were evidenced for anxiety; specifically, the SIGH-A (d = 0.45), and BAI (d = 0.62). Moderate to large effect sizes were also evidenced at post-treatment for negative affectivity (PANAS-N; d = 0.76), and positive affectivity (PANAS-P; d = −0.54). Post-treatment effect sizes were also in the moderate to large range for quality of life (QOLI; d = −0.42), and overall functioning (WSAS; d = 0.81).

Effects on Comorbidity

As in Study 1, in order to evaluate the effect of the UP on additional or comorbid diagnoses, a separate variable was calculated by creating a mean of the CSRs for all additional or comorbid diagnoses at both pre- and post-treatment (n = 9). Effect sizes were then calculated using these values. The UP evidenced a large effect size on comorbid clinical diagnoses (d = 2.14), indicating that the UP targets not only the principal disorder that is most impairing at pretreatment, but also comorbid conditions that are also impairing the individual's life.

Applicability Across the Anxiety Disorders

Following the same statistical procedures as Study 1, separate effect size estimates were calculated for each of the primary anxiety disorders, regardless of whether the disorder was principal or comorbid status. As shown in Table 4, the UP evidenced comparable large effect sizes for each of the primary anxiety disorders, GAD (d = 1.70; n = 6), social phobia (d = 1.73; n = 9), OCD (d = 3.13; n = 4), and PDA (d = 1.26; n = 4). Consistent with Study 1, the UP also evidenced large effect sizes on comorbid depression diagnoses (MDD and dysthymia; d = 1.71; n = 4).

Summary and Limitations

The results from Study 2 appear to be more robust than from Study 1 on measures of clinical severity, general symptoms of depression and anxiety, levels of negative and positive affect, and measures of social adjustment and quality of life. The treatment effect size for clinician-rated CSRs for principal diagnoses is strong and larger than what is typically seen in disorder-specific CBT treatments for anxiety (d = 1.58; Norton & Price, 2007) and other transdiagnostic CBT treatments (d = 1.29; Norton & Philipp, 2008), as they were for co-morbid disorders. On average, the severity levels of principal diagnoses dropped below diagnostic threshold so that individuals no longer met criteria. A considerable increase in treatment effects across specific diagnoses was also observed, resulting in much larger treatment effect sizes (see Table 4). For example, the post-treatment effect size for GAD increased from d = 0.63 in Study 1 to d = 1.70 in Study 2. The effect size for social phobia increased from d = 1.21 to d =1.73. Notably, the post-treatment effect size for OCD increased from d = 0.93 to d = 3.13, well above the average effect size for CBT treatment of OCD reported in a recent review (d = 2.02; Norton & Price, 2007). Once again, these results should be interpreted with caution because of the small sample size.

Discussion

In this article, we present preliminary data emerging from the development of the Unified Treatment Protocol for Emotional Disorders (UP), a transdiagnostic treatment designed to be applicable across anxiety and mood disorders. Results from a pilot-study of the initial version of the treatment manual, represented in Study 1, provided preliminary support for the efficacy of the UP in the treatment of a range of anxiety and mood disorders including GAD, social phobia, panic disorder, OCD, social phobia, PTSD, and depression, leading to an overall reduction in the frequency and severity of both principal and co-occurring disorders at post-treatment, and modest to large effect sizes on general measures of depression and anxiety, social adjustment, and quality of life. After further manual development and modifications to session content, a revised version of the UP was tested in an additional heterogeneous sample of patients, yielding more robust results, including large pre-post treatment effect sizes for both principal and co-morbid disorders, and medium to large decreases in overall negative affectivity.

These results are intriguing for several reasons. First, these studies offer preliminary data to suggest that a transdiagnostic treatment developed to specifically target underlying vulnerabilities representing common diathesis across anxiety and mood disorders may be as effective as individual treatments that target disorder-specific symptoms. In addition, targeting core affective factors in this way may result in clinical improvement that subsequently generalizes across co-morbid disorders, resulting in improvement not only in the most clinically interfering disorder a patient may present with but additional co-occurring disorders as well. If this is the case, clinicians are afforded a much more parsimonious approach to treatment planning. By focusing on core affective factors contributing to psychopathology, clinicians may target several co-occurring disorders simultaneously, thereby eliminating the need for multiple disorder-specific treatment manuals and more cumbersome treatment planning. This approach to the treatment of emotional disorders may prove valuable in the dissemination of evidence-based treatments, removing some of the traditional barriers to their implementation, such as the significant time and cost required for adequate training in multiple treatment manuals (Addis, Wade, & Hatgis, 1999). Moreover, as clinicians are often faced with the task of treating patients with complex clinical presentations, the use of a single protocol eliminates the need to use multiple protocols to tackle several problems at once, which has been shown to result in poorer treatment outcome (Craske, Farchione, Allen, Barrios, Stoyanova, & Rose, 2007).

Second, the results of these studies lend support to a more dimensional conceptualization of psychopathology. In the present study, targeting core affective factors rather than disorder-specific symptoms resulted in clinically significant changes across a range of anxiety and mood disorders, including both principal and co-occurring diagnoses. As comorbidity in clinical samples tends to be the rule rather than the exception (Brown Campbell, Lehman, Grisham, & Mancill, 2001), the arbitrary splitting brought about through categorical methods of diagnosis may not accurately capture or address the dynamic and interacting nature of these disorders, or the true holistic experience of these patients. Moving away from targeting disorder-specific symptoms and towards factors existing along the full “neurotic

spectrum" may prove both more parsimonious and more experientially accurate (Brown & Barlow, 2005; Brown & Barlow, in press).

Finally, our results speak to the necessity of testing and refining treatments to improve their feasibility, acceptability, and clinical utility. Refining our protocol based on the results from Study 1 and the clinical experience accrued from administering the protocol resulted in a revised protocol that was both more feasible and, seemingly, efficacious. Currently in its final stages of development and testing, the UP (version 3.0) has undergone additional changes informed by the outcomes data presented above, and direct use of the protocol in clinical practice. The principal changes in UP Version 3.0 include additional techniques for enhancing motivation to engage in treatment, drawing from the work of Miller and Rollnick (1991, 2002) and Arkowitz and Westra (2004); a greater focus on the role of positive emotion, both as a trigger for maladaptive emotion avoidance and as a target for emotion exposures; and expanded discussion of several key principles.

In addition to these changes, the latest version of the UP includes a shift from session-by-session content to a modular approach to treatment. Each of the core treatment concepts (i.e. present-focused awareness, cognitive flexibility, countering emotional avoidance and emotion driven behaviors, interoceptive and situation-based emotion exposures) are encapsulated within individual modules, intended to be delivered within a range of one to three sessions. Consistent with the defining principles of modularity as described by Chorpita, Viesselman, and Hamilton (2005), the modularized version of the UP is expected to provide clinicians with greater flexibility in the presentation to patients of core treatment concepts and skills, thus enhancing opportunities for skill acquisition and promoting more individualized patient care. In addition, the modular approach opens the possibility for a more "prescriptive" approach to treatment, wherein deficits in core skills corresponding to specific modules can be assessed in order to determine which of the modules ought to be applied or the amount of time that ought to be spent on each particular module. This prescriptive approach offers a number of possible advantages over using multiple manualized protocols, including greater efficiency in the administration of treatment procedures, greater cost-effectiveness, improved transportability across treatment contexts, and potentially improved treatment efficacy.

We are currently in the process of collecting data on the most recent version of the UP in a National Institute of Mental Health supported RCT. In addition, future studies are needed to examine the effectiveness and transportability of the transdiagnostic approach, as well as the applicability of the UP to other disorders in which emotion plays a key role, such as somatoform and dissociative disorders. Further, follow up data are needed to determine long-term clinical utility of the UP. In addition, dismantling studies are needed to evaluate whether all of the core skills presented in the UP are necessary for treatment gains. Finally, it remains an empirical question whether taking a modular approach could lead to a more prescriptive approach to treatment, wherein specific decision rules lead to more individualized delivery and "dosing" of treatment concepts. In anticipation of these important future investigations, these initial findings lend encouraging preliminary support for the UP as an efficacious, transdiagnostic treatment for emotional disorders.

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Table 1

Descriptive Statistics and Effect Size Estimates for Primary Study Variables – Study 1

		Pre-Tx		Post-Tx			95% Confidence Intervals	
Measure	**N**	**Mean**	**SD**	**Mean**	**SD**	**Cohen's *d***	**Lower**	**Upper**
ADIS (Co-)Principal Dx CSR	18	5.67	0.69	4.06	2.11	1.15	0.84	2.13
BDI	18	18.00	11.91	11.61	10.63	0.57	−4.94	5.48
BAI	18	20.72	8.46	15.17	8.83	0.64	−3.26	4.72
PANAS - NA	18	26.17	6.71	22.39	8.28	0.50	−2.59	4.33
PANAS - PA	18	27.33	6.81	29.39	6.27	−0.31	−3.46	2.58
WSAS	18	3.10	1.49	2.02	1.63	0.69	0.00	1.45
ADIS Mean CSR Comorbid Dx	13	4.27	0.44	3.00	1.77	1.15	0.91	2.11

Table 2

ADIS CSRs for Specific Clinical Diagnoses – Study 1

		Pre-Tx		Post-Tx			95% Confidence Intervals	
Diagnosis	**N**	**Mean**	**SD**	**Mean**	**SD**	**Cohen's *d***	**Lower**	**Upper**
GAD	7	4.86	1.07	3.86	2.12	0.63	−0.16	2.20
SOC	8	5.00	0.93	3.13	2.17	1.21	0.57	2.71
OCD	5	5.20	1.10	3.80	1.92	0.93	−0.03	2.61
PDA	4	5.50	1.00	4.00	1.63	1.14	0.16	2.74
DEP	6	5.00	0.63	2.33	2.73	1.58	1.08	3.77

Table 3

Descriptive Statistics and Effect Size Estimates for Primary Study Variables – Study 2

		Pre-Tx		Post-Tx			95% Confidence Intervals	
Measure	**N**	**Mean**	**SD**	**Mean**	**SD**	**Cohen's *d***	**Lower**	**Upper**
ADIS (Co-)Principal Dx CSR	15	5.60	0.83	3.13	1.72	1.94	1.52	2.81
SIGH-D	13	13.62	5.64	8.00	6.58	0.92	−2.14	4.50
SIGH-A	13	14.69	6.74	11.54	7.22	0.45	−3.21	4.38
BDI	14	17.71	9.06	13.00	12.78	0.43	−4.31	7.13
BAI	14	20.86	13.41	12.50	13.48	0.62	−6.40	7.68
PANAS - NA	14	28.93	7.60	22.29	10.00	0.76	−3.23	5.99
PANAS - PA	14	29.79	5.60	32.57	4.80	−0.54	−3.47	1.98
WSAS	14	3.57	2.24	1.91	1.86	0.81	−0.36	1.78
QOLI	14	0.41	2.10	1.15	1.40	−0.42	−1.52	0.31
ADIS Mean CSR Comorbid Dx	9	4.43	0.39	2.65	1.27	2.14	1.88	2.97

Table 4

ADIS CSRs for Specific Clinical Diagnoses – Study 2

		Pre-Tx		Post-Tx			95% Confidence Intervals	
Diagnosis	**N**	**Mean**	**SD**	**Mean**	**SD**	**Cohen's *d***	**Lower**	**Upper**
GAD	6	5.17	0.75	3.00	1.79	1.70	1.10	3.14
SOC	9	5.22	0.83	3.00	1.73	1.73	1.19	2.86
OCD	4	6.00	0.82	2.75	1.26	3.13	2.33	4.37
PDA	4	4.75	0.96	3.00	1.83	1.26	0.32	3.05
DEP	4	4.50	0.58	2.25	2.06	1.71	1.14	3.73