

Article

Isolating the Unique Effects of the Unified Protocol Treatment Modules Using Single Case Experimental Design Behavior Modification 2017, Vol. 41(2) 286–307 © The Author(s) 2016 Reprints and permissions: sagepub.com/journalsPermissions.nav DOI: 10.1177/0145445516673827 journals.sagepub.com/home/bmo



Shannon Sauer-Zavala¹, Clair Cassiello-Robbins¹, Laren R. Conklin^{1,2}, Jacqueline R. Bullis^{1,3}, Johanna Thompson-Hollands^{1,4}, and Katherine A. Kennedy¹

Abstract

The Unified Protocol (UP) for the Transdiagnostic Treatment of Emotional Disorders is a cognitive-behavioral intervention designed to treat the range of anxiety, depressive, and related disorders. Thus far, the UP treatment modules have only been studied when they are delivered in their entirety and presented in a standard sequence. To personalize the presentation of the UP modules for a given patient's presentation (e.g., providing the modules in a varied order, dropping irrelevant modules), it is first necessary to establish that each module leads to change in the skill it is designed to promote, and that these changes can occur in the absence of the other modules. Using a multiple baseline design in accordance with the single-case reporting guidelines in behavioral interventions (SCRIBE), eight

Corresponding Author:

Shannon Sauer-Zavala, Center for Anxiety and Related Disorders, Boston University, 648 Beacon St., 6th floor, Boston, MA 02215, USA.

Email: shannonesauer@gmail.com

¹Boston University, MA, USA

²Chalmer's P. Wylie VA Ambulatory Care Center, Columbus, OH, USA

³McLean Hospital/Harvard Medical School, Boston, MA, USA

⁴VA Boston Healthcare System, MA, USA

patients with heterogeneous emotional disorders were randomly assigned to a I- or 3-week baseline assessment phase followed by four sessions of one of four UP modules (psychoeducation, emotional awareness, cognitive flexibility, and countering emotional behaviors). Results provide preliminary support for the notion that each UP module under study leads to change in its associated skill in the absence of the other modules (five of eight patients demonstrated reliable change in the module-specific skill). In addition, exploratory analyses suggest that the emotion awareness training and cognitive flexibility modules appeared to exhibit change specific to their associated skills, psychoeducation, and countering emotional behaviors demonstrated somewhat more broad-based change across skills.

Keywords

Unified Protocol, treatment personalization, treatment mechanisms

A large body of evidence exists to support the efficacy of time-limited psychotherapy for common mental disorders (Lambert & Bergin, 1994; Rachman, 2009). It has been suggested, however, that a minimum dose of psychotherapy is necessary to significantly improve symptoms; a systematic review of the clinical trials literature indicates that approximately 13 treatment sessions are necessary to observe improvement in two thirds of patients (Hansen, Lambert, & Forman, 2002). Unfortunately, the average number of sessions attended by patients in community practice is less than five (Garfield, 1994; Hansen et al., 2002). These data suggest the importance of increasing the efficiency of our treatment protocols such that important skills that are proven to drive therapeutic change are presented as early as possible.

There are several potential methods for increasing the efficiency of our treatment protocols. First, a transdiagnostic approach may represent a way to target the pervasive comorbidity commonly observed in community practice in a more streamlined manner. Instead of addressing co-occurring conditions sequentially, and thereby extending the length of treatment, mechanistically transdiagnostic interventions simultaneously address symptoms of multiple disorders by targeting the core, underlying processes that maintain comorbidity (Sauer-Zavala et al., 2017). In other words, patients are provided with a set of skills geared specifically toward common deficits that may ultimately lead to symptom change across a range of disorders. Transdiagnostic treatments, given their ability to handle comorbidity, may also increase patient engagement as they map better on to many patients' presenting concerns.

Another method for increasing treatment efficiency is to personalize the intervention delivered such that patients receive only the treatment components that best fit with their presentations. Modular interventions, popular in the child psychotherapy literature (e.g., Chorpita, Taylor, Francis, Moffitt, & Austin, 2004), represent an example of how personalized treatment can be accomplished. For example, the Modular Approach to Therapy for Children With Anxiety, Depression, or Conduct Problems (MATCH; Chorpita & Weisz, 2009) distills procedures from a variety of evidence-based treatments for problems of childhood into freestanding modules. Clinicians generate a problem list (e.g., anger outbursts, fear of spiders) and then choose specific modules from this bank of strategies to construct a treatment plan that conforms to their patients' unique constellation of presenting concerns. This approach circumvents the need to work through an entire treatment protocol that may not apply to a given patient in its entirety; only relevant skills, which can cut across diagnostic boundaries, are selected. MATCH has demonstrated steeper trajectories of improvement compared with traditional manualized care, suggesting that this approach may indeed be more efficient (Weisz et al., 2012). Not surprisingly, modular approaches have also been applied successfully in low- and middle-income countries (Murray et al., 2014) where treatment efficiency is paramount.

Perhaps the greatest gain in treatment efficiency could come from the combination of a personalized approach with a mechanistically transdiagnostic intervention. Transdiagnostic interventions often consist of multiple components, each designed to target one core vulnerability, some of which may be more or less beneficial to an individual patient. For example, in Cognitive Behavioral Therapy-Enhanced (CBT-E; Fairburn, 2008), a transdiagnostic intervention designed to address the range of eating disorders, several components (e.g., decreasing body checking, decreasing rigid eating rules, challenging distorted thinking) are utilized to target the core deficit of over-evaluation of shape and weight. Even within the framework of treating one psychopathological mechanism, the ability to determine what skills will lead to maximum change for a given individual may greatly increase treatment efficiency. Some work matching treatment components designed to address underlying mechanisms to unique patients has previously been conducted. For example, in Persons and colleagues' (e.g., Persons 2007; Persons, Beckner, & Tompkins, 2013) case formulation approach to psychotherapy, the therapist collaborates with the patient to develop a hypothesis about the factors that cause and maintain each of the patients' presenting problems; this hypothesis is then used to generate applicable intervention strategies, often drawing from the cognitive-behavioral tradition. The authors describe this approach as a form of collaborative empiricism, as it draws its strategies from

research-supported techniques but uses the patient's input to select specific strategies. A next step in this area is to begin establishing data-driven principles for choosing one transdiagnostic treatment skill over another, as an alternative or compliment to clinical decision making or patient preference (Fisher, 2015).

Present Study

The Unified Protocol (UP) for the Transdiagnostic Treatment of Emotional Disorders (Barlow, Farchione, et al., 2011) may represent an ideal intervention to explore the benefits of combining the two strategies described above to increase treatment efficiency. The UP is a mechanistically transdiagnostic treatment (for types of transdiagnostic treatments, see Sauer-Zavala et al., 2017) that purportedly targets the features maintaining symptoms across a range of common mental health conditions (e.g., anxiety and depressive disorders)—the frequent experience of negative emotions, coupled with aversive reactions to these emotions (Barlow, Sauer-Zavala, Carl, Bullis, & Ellard, 2014). The UP consists of eight modules, six¹ of which are thought to address the putative mechanisms maintaining symptoms across emotional disorders; the six core UP modules include psychoeducation and tracking of emotional experiences (Module 2), mindful emotion awareness (Module 3), cognitive flexibility (Module 4), countering emotional behaviors (Module 5), and interoceptive (Module 6) and situational (Module 7) emotion exposures. Module 1 and Module 8 (motivational enhancement and relapse prevention, respectively) are important components of cognitive-behavioral therapy but are not considered to address mechanisms that are the focus of change in the UP. There is promising empirical support for this intervention across the range of anxiety disorders (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010; Farchione et al., 2012), depression (Boswell, Anderson, & Barlow, 2014), bipolar disorder (Ellard, Deckersbach, Sylvia, Nierenberg, & Barlow, 2012), and borderline personality disorder (Sauer-Zavala, Bentley, & Wilner, 2016). In these treatment trials, the UP was administered in its entirety and in a sequential manner; a logical next step is to explore whether treatment with the UP can be customized such that modules are delivered in an order dictated by an individual's presenting difficulties at pre-treatment.

An important first step in determining whether the delivery of UP can be altered from its standard form is to establish whether this protocol can be considered "modular"—that is, can UP skills stand alone such that they can be presented in the absence of the other skills or in a varied order? Chorpita, Daleiden, and Weisz (2005) define modularity as the ability to "break up complex activities into simpler parts that may function independently" (p. 142)

and provide four criteria for determining whether a treatment approach can be considered modular. Specifically, modular treatments must have the ability to be divided into meaningful functional units (Criterion 1) and that each must have a specified purpose (Criterion 2). In addition, although modules should function independently when delivered in the absence of other modules (Criterion 3), they also must have the ability to be connected together in a meaningful way (Criterion 4). Available evidence suggests that the UP meets two of these four criteria; the UP is divided into functionally distinct skill modules and theses modules are already connected within standardized context of the UP framework (Criteria 1 and 4). It is unclear, however, whether each module achieves its specified purpose such that a given module indeed leads to expected changes in targeted skills and whether these changes can occur in the absence of the other UP modules (Criteria 2 and 3).

The purpose of the present study is to explore whether the UP achieves "modularity" by investigating the unique contributions of each UP module on skill acquisition; confirming that each module can stand alone is a necessary first step toward our long-term goal of personalizing the UP modules delivered to a given patient. Toward this end, each patient in this study received one of the core UP modules isolation, with the exception of Modules 6 and 7 (interoceptive and situational exposure, respectively). Given that previous work has established the independence of the UP's exposure-based modules (Brake et al., 2016), we limited our focus to the four remaining core UP modules: psychoeducation and tracking of emotional experiences (Module 2), mindful emotion awareness (Module 3), cognitive flexibility (Module 4), and countering emotional behaviors (Module 5). The primary goal of this project was to investigate whether the presentation of a given UP module indeed leads to change in its associated treatment skill (e.g., countering emotional behaviors leads to fewer instances of avoidant coping). An additional exploratory aim was to examine the module's effect on other UP skills.

Method

Participants

Participants were recruited from a pool of individuals seeking treatment at the Center for Anxiety & Related Disorders (CARD) at Boston University (BU). The study was fully approved by the BU Institutional Review Board. Inclusion criteria were consistent with eligibility requirements for adult outpatient treatment at CARD; specifically, participants met criteria for a *Diagnostic and Statistical Manual of Mental Disorders* (5th ed., *DSM-5*; American Psychiatric Association, 2013) emotional disorder diagnosis without a comorbid condition

requiring treatment prioritization (acute suicide risk, mania, psychotic features, a substance use disorder at a clinical level). The term emotional disorder refers to psychopathology that is driven by aversive reactions to strong, frequently occurring emotions that lead to maladaptive efforts to avoid experiencing such emotions (Sauer-Zavala & Barlow, 2014), and diagnoses typically considered within the purview of this group include anxiety, depressive, and related (e.g., dissociative, somatization) disorders (Barlow, 1991). Diagnostic inclusion and exclusion criteria were assessed by the *Anxiety and Depression Interview Schedule, 5th edition* (Brown & Barlow, 2014), on which CARD interviewers have been trained to meet rigorous reliability standards (for a detailed description of this process, see Brown, Di Nardo, Lehman, & Campbell, 2001). In addition, participants were required to be at least 18 years of age, fluent in English, and willing to maintain a stable dosage of medication (or lack of medication) for the duration of the study. Finally, individuals were required to refrain from seeking additional psychotherapy during the study.

A total of 10 participants consented to treatment. Two participants who consented were replaced during the study as the experimental design utilized required complete data from each participant; one participant dropped out of treatment following the second session and one participant's data were removed due to inconsistent questionnaire responses leading to the suspicion that the individual was not completing them accurately. Thus, complete post-treatment data were available for eight participants. Principal diagnoses included generalized anxiety disorder (GAD, n = 2), social anxiety disorder (n = 1), obsessive-compulsive disorder (OCD, n = 1), somatic symptom disorder (n = 1), agoraphobia (n = 1), other specified anxiety disorder (GAD, n = 1), and persistent depressive disorder (n = 1). Participants had zero (n = 2), one (n = 2), two (n = 2), or three (n = 2)comorbid clinical diagnoses. Comorbid diagnoses included social anxiety disorder (SOC, n = 4), specific phobia (n = 2), GAD (n = 2), OCD (n = 1), other specified eating disorder (atypical anorexia nervosa, n = 1), body dysmorphic disorder (n = 1), and post-traumatic stress disorder (n = 1). Given that the UP is a transdiagnostic treatment, participants with any emotional disorder were included as there is evidence to suggest that similar mechanisms are maintaining symptoms across diagnostic boundaries. In addition, the study design utilized (described in detail below) is equipped to deal with sample heterogeneity by using each participant as their own control. Fifty percent of our sample indicated that they were currently prescribed psychotropic medication, though they agreed to maintain a consistent dose for the duration of the study. Of these eight participants, one participant, randomized to immediate treatment, missed the third treatment assessment but completed her fourth treatment assessment; for feasibility reasons, we elected to retain these data with one missing point. Participants were primarily Caucasian (n = 6) and female (n = 6). Participants ranged from 18 to 50 years with a mean age of 27 years (SD = 10.49 years).

Study Design

To achieve study aims, a single-case experimental design (SCED) was utilized. SCEDs elegantly use participants as their own control by presenting each participant with both conditions, with a goal of achieving internal validity through multiple observations of a single subject. Specifically, we employed a multiple baseline design, which is ideal for preliminary investigations of treatment mechanisms (Barlow, Nock, & Hersen, 2009) and report findings using the single-case reporting guidelines in behavioral interventions (SCRIBE; Tate et al., 2016). Participants were randomized to receive one of the four UP modules under examination in isolation. They were also randomized to a 1-week or a 3-week baseline period; in the context of a multiple baseline SCED, this allows us to observe whether change occurs when, and only when, a treatment module is introduced. Randomization was stratified so that two participants were assigned to each treatment module with one participant in each baseline condition (1-week or 3-week). Participants (N =8) completed all study measures via a secure, online survey platform on a weekly basis through both study phases (baseline and treatment). During the treatment phase, patients completed all measures at the start of each session and 1 week following the final session to reflect the effects of skills and content covered during the previous weeks' session and the practice of skills during the week following that session.

Treatment

As noted above, participants were randomized to one of four UP modules: psychoeducation and tracking of emotional experiences (Module 2), mindful emotion awareness (Module 3), cognitive flexibility (Module 4), or countering emotional behaviors (Module 5). A detailed description of each module is described elsewhere (Payne, Ellard, Farchione, Fairholme, & Barlow, 2014); however, a brief summary of skills hypothesized to develop as a function of the modules under study is provided. (a) Psychoeducation and tracking of emotional experiences (Module 2) provides patients with an understanding of the functional nature of emotions—specifically that they are adaptive and consist of three components (thoughts, physical sensations, and behaviors). The overarching goal of this module is demonstrate to patients (through monitoring) that their avoidant, intolerant responses to emotional experiences may

be perpetuating their symptoms. (b) Mindful emotion awareness (Module 3) cultivates a nonjudgmental, present-focused approach to experiencing emotions through a series of experiential exercises; the goal of this module is to facilitate emotional tolerance, rather than attempting to change one's emotional experience. (c) The cognitive flexibility module (Module 4) content is focused on helping patients develop greater flexibility in thinking by generating alternate appraisals of emotional situations. The goal here is to continue to promote tolerance of emotional stimuli, in this case thoughts, by allowing automatic appraisals to remain while considering more likely alternatives. Finally, (d) the countering emotional behaviors module (Module 5) content emphasizes the identification and prevention of emotion avoidance strategies and unhelpful emotion-driven behaviors. The goal of this module is to reduce the frequency of emotionally avoidant behaviors as a means to facilitate extinction of distress associated with the experience of strong emotions

Following the baseline phase, treatment lasted for 4 weeks with one 50- to 60-min individual session per week. For this preliminary investigation, a duration of four sessions was selected to allow for an adequate dose of treatment (given that participants were only receiving one module) to increase the likelihood skill acquisition could be clearly determined. The material covered in each session and associated homework assignments were consistent with the published UP patient workbook (Barlow, Ellard et al., 2011); however, references to previous UP skills/chapters were removed for this study. Study therapists (S.S.Z., L.R.C.) were certified experts in the provision of the UP. Treatment sessions were audio-recorded, and 20% of the tapes (n = 6) were randomly selected and evaluated for therapist competence (e.g., rapport, session management, therapist knowledge of content) and inclusion of disallowed treatment strategies (e.g., other UP module content, other intervention content). Overall, average competence ratings were high (4.77 on a 5-point scale), and none of the rated sessions included extraneous content outside the confines of the assigned UP module.

Measures

Beliefs About Emotions Scale (BES). The BES (Rimes & Chalder, 2010) was included to assess negative beliefs about emotions and was selected as the measure of skill acquisition for psychoeducation and tracking of emotional experiences (Module 2). The BES consists of 12 self-report items rated on a scale from 0 (totally disagree) to 6 (totally agree) including, "It is a sign of weakness if I have miserable thoughts" and "I should not let myself give in to negative feelings." The BES has demonstrated good validity, internal reliability, and sensitivity to change across treatment (Rimes & Chalder, 2010).

Southampton Mindfulness Questionnaire (SMQ). The SMQ (Chadwick et al., 2008) was included to assess a nonjudgmental, present-focused approach to emotions consistent with hypothesized skill acquisition in mindful emotion awareness (Module 3). The SMQ is a 16-item self-report measure with items beginning with, "Usually, when I have distressing thoughts or images" and continuing with a mindfulness-related response, such as, "I try just to experience the thoughts or images without judging them" and "I am able to accept the experience." Participants rate these items on a scale from 0 (strongly disagree) to 6 (strongly agree). The scale consists of a single factor structure and has demonstrated good internal consistency and validity (Chadwick et al., 2008).

UP-Cognitive Skills Questionnaire (UP-CSQ). The CSQ-UP (Conklin, Cassiello-Robbins, Wilner, & Sauer-Zavala, in press) is an eight-item measure that was developed explicitly to assess the skill of cognitive flexibility (Module 4) as it is taught in the UP as existing questionnaires assessing cognitive coping either included skills that are not emphasized in the UP or excluded key concepts covered in this module. Participants rated items including "I evaluated my thinking when I experienced a distressing emotion" and "I understood that my thoughts can have an effect on my feelings and behaviors" by indicating how often they use each skill on a scale from 1 (never) to 5 (always or when needed). This scale has demonstrated good internal consistency and validity (Conklin et al., in press).

Checklist of Emotional Avoidance Strategy Engagement (CEASE). The CEASE (Kennedy, 2015) was designed to assess the degree to which individuals engage in 68 specific strategies to avoid or reduce the intensity of strong emotions (e.g., "Avoid parties or social events" and "Distract yourself by thinking about or imaging something else"). This measure was selected to correspond to the types of changes expected following the countering emotional behaviors module of the UP (Module 5). The CEASE's self-report items are rated on a scale from 0 (never used to manage emotions) to 4 (always used to manage emotions), and the total score was used. This measure demonstrates adequate internal consistency and significantly correlates with measures of behavioral and emotional avoidance (Kennedy, 2015).

Data Analytic Strategy

In accordance with analytic guidelines for SCEDs, data were primarily analyzed using visual inspection techniques (Barlow et al., 2009). The first

participant in each condition served as the primary experiment with the additional case representing an opportunity for replication. The goal of SCED is to focus on internal validity by taking multiple observations of a single subject to evaluate hypotheses; if the experiment shows effects upon replication, one begins to get a sense that the manipulation is robust and generalizable. The primary outcome of interest was whether change in the module-relevant measure (e.g., the BES for the psychoeducation and tracking of emotional experiences module) occurred when and only when the treatment module was introduced. To examine this outcome, data from relevant measures were plotted graphically for each participant and visually assessed for changes in level and/or slope across the two study phases: (a) assessment-only baseline phase and (b) treatment phase. To aid in the interpretation of the data, all measures were scored so that higher scores indicated better functioning, and increases in scores over the course of treatment were considered indicative of improvement. Thus, the raw scores for the CEASE and BES (for which higher scores typically represent lower functioning) were reverse scored by subtracting the raw score from the maximum score for the measure so that higher scores would reflect better functioning.

To provide an additional, more stringent test of the findings, a reliable change index (RCI) score was calculated for each measure pre/post-treatment. The RCI statistic provides an indication of whether change in an individual's score is significant above and beyond the fluctuations associated with imprecise measurement tools and is calculated by dividing the change in an individual's score pre/post an intervention by the standard error of the difference of the test (Jacobson & Truax, 1991). Values greater than 1.96 represent statistically significant change. RCI scores were used to (a) assess whether the change produced on a module-relevant measure was reliable and (b) explore changes in other domains that occurred as a result of receiving a given module (i.e., does the psychoeducation module produce changes in mindful emotion awareness, emotional behaviors, and cognitive flexibility).

To maximize interpretability, participants will be referred to by the first letter of their assigned module, with the exception of the countering emotional behavioral module given the overlap in first letter with the cognitive flexibility module (P = Psychoeducation and tracking of emotional experiences, M = Mindful emotion awareness, C = Cognitive flexibility, and B = Countering emotional Behaviors). In addition, the first patient assigned to each module (main experiment) will be denoted with the number one (i.e., P1, M1, C1, B1) and the second patient (replication) will be labeled with the number two (i.e., P2, M2, C2, B2).

Results

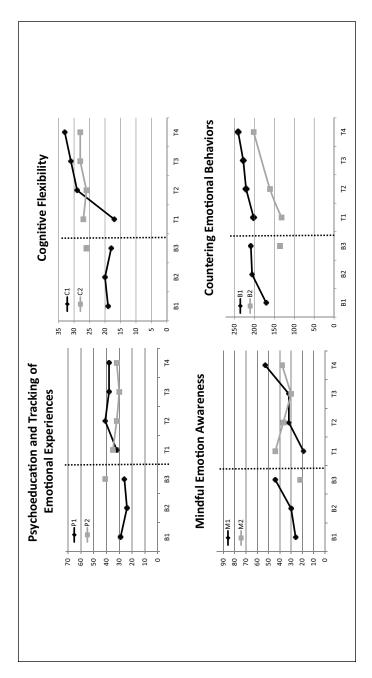
Visual Inspection

Data in Figure 1 represent the primary analyses to assess whether individual UP modules, when presented in isolation, indeed lead to change in their associated skill; summary data for these figures are presented in Table 1. The first participant in each module, who served as the primary experiment (highlighted in bold in the figures), demonstrated changes in level and/or slope in the expected direction after the introduction of the treatment module. With one exception, the second participant in each module similarly showed change in the module-relevant measure, thus replicating the results; participant P2's scores showed change in level and slope, but opposite of the predicted direction. Taken together, these data suggest that each module produce change in its intended domain and that this change is likely due to the effects of the intervention.

RCI

RCI scores (see Table 2) suggested that for five out of the eight participants (P1, M2, C1, B1, and B2), administration of the treatment module produced significant and reliable change in the targeted domain. Despite demonstrating change in level and/or slope per our visual inspection criteria, participants M1 and C2 did not achieve our more stringent criteria of reliable change. Finally, as noted above, participant P2 demonstrated change in the opposite of the predicted direction; however, this change was not significant per our RCI analyses.

As an exploratory study aim, RCI scores were used to investigate changes in non-targeted domains that occurred as a result of receiving a given treatment module (Table 2). Despite evidence that the UP module presented was associated with change in its relevant skill (seven of eight participants per visual inspection, five of eight participants per RCI), patterns in changes on other UP skill domains as a function of module were somewhat less clear. For participants receiving the psychoeducation and tracking of emotional experiences module, P1 achieved reliable change in all three non-targeted domains, while P2 demonstrated additional reliable improvements on cognitive skills. In the mindful emotion awareness module, neither M1 nor M2 achieved reliable change in any additional domain. Similarly, in the cognitive flexibility module, C1 did not achieve reliable change in any non-targeted domains whereas C2 achieved reliable change with regard to avoidance behaviors. Finally, in the countering emotional behaviors module, B1 achieved reliable change in all



specific measures: psychoeducation and tracking of emotional experiences—BES, mindful emotion awareness—SMQ, cognitive flexibility—UP-CSQ, Note. Each graph presents the module-relevant measure alone to evaluate whether the module produced change in the intended domain. Modulecountering emotional behaviors—CEASE. P = Psychoeducation, M = Mindful emotion awareness, C = Cognitive flexibility, and B = Countering emotional Behaviors. BES = Beliefs About Emotions Scale; SMQ = Southampton Mindfulness Questionnaire; UP-CSQ = UP-Cognitive Skills Figure 1. Change in module-relevant measure across the baseline and treatment phases of the study. Questionnaire; CEASE = Checklist of Emotional Avoidance Strategy Engagement.

Participant	Measure	ВІ	B2	В3	ΤI	T2	Т3	T4
Psychoeduca	ıtion							
PI	BES	29	24	26	32	41	38	38
P2				41	35	32	30	32
Emotion awa	areness							
MI	SMQ	26	30	44	19	32	32	53
M2				22	44	37	30	38
Cognitive fle	xibility							
CI	UP-CSQ	19	20	18	17	29	31	33
C2				26	27	26	28	28
Countering	emotional be	haviors						
ВІ	CEASE	170.51	206	209	202	221	228	241
B2				136	132	161		202

 Table I. UP Module-Relevant Questionnaire Score as a Function of Assessment

 Time-Point.

Note. Module-specific measures: psychoeducation and tracking of emotional experiences—BES, mindful emotion awareness—SMQ, cognitive flexibility—UP-CSQ, countering emotional behaviors—CEASE. All measures are scored such that higher scores indicate better functioning. P = Psychoeducation and tracking of emotional experiences, M = Mindful emotion awareness, C = Cognitive flexibility, and B = Countering emotional Behaviors. UP = Unified Protocol; BES = Beliefs About Emotions Scale; SMQ = Southampton Mindfulness Questionnaire; UP-CSQ = UP-Cognitive Skills Questionnaire; CEASE = Checklist of Emotional Avoidance Strategy Engagement.

three non-targeted domains, while B2 replicated these results with regard to the changes in beliefs about emotions, but not mindfulness and cognitive skills. Taken together, there is preliminary evidence to suggest that the psychoeducation and countering emotional behaviors modules may produce change somewhat more broadly in non-targeted domains, while the mindful emotion awareness and cognitive flexibility modules appear to be more specific.

Discussion

The goal of the present study was to explore the unique contributions of four UP modules on skill acquisition; specifically, we sought supportive evidence that a given UP module leads to change in its associated treatment skill (e.g., psychoeducation and tracking of emotional experiences [Module 2] leads to beliefs about the adaptive nature of emotions). The purpose of this aim was to determine whether the UP modules meet Chorpita et al.'s (2005) definition of modularity and could potentially be delivered in any order or in the absence of the others. The UP previously satisfied two of four criteria for modularity:

Table 2. RCI Scores Pre-/Post-Treatment for All Measures Administered to Each Participant.

Participant	Measure	Pre-treatment score	Post-treatment score	Reliable change statistic
PI	BES	26	38	2.51*
	SMQ	35	58	3.23*
	CSQ	18	26	2.69*
	CEASE	194	252	5.30*
P2	BES	41	32	-1.88
	SMQ	48	45.5	-0.35
	CSQ	15	31	5.39*
	CEASE	267	254	-1.19
MI	BES	43	46	0.63
	SMQ	44	53	1.26
	CSQ	17	21	1.35
	CEASE	254	269	1.37
M2	BES	12	20	1.67
	SMQ	22	38	2.24*
	CSQ	24	24	0
	CEASE	124	129	0.46
CI	BES	21	23	0.42
	SMQ	54	54	0
	CSQ	18	33	5.05*
	CEASE	232	234	0.18
C2	BES	35	37	0.42
	SMQ	40	48	1.12
	CSQ	26	28	0.67
	CEASE	127	165	3.47*
ВІ	BES	13	44	6.47*
	SMQ	23	63	5.61*
	CSQ	22	29	2.36*
	CEASE	209	241	2.92*
B2	BES	16	34	3.76*
	SMQ	37	50	1.82
	CSQ	29	202	-1.35
	CEASE	136	70	6.03*

Note. Module-specific measures: psychoeducation and tracking of emotional experiences—BES, mindful emotion awareness—SMQ, cognitive flexibility—UP-CSQ, countering emotional behaviors—CEASE. Module-relevant measure is bolded. All measures are scored such that higher scores indicate better functioning. P = P sychoeducation and tracking of emotional experiences, M = M indful emotion awareness, C = C ognitive flexibility, and B = C ountering emotional B ehaviors.

RCI = reliable change index; BES = Beliefs About Emotions Scale; SMQ = Southampton Mindfulness Questionnaire; CSQ = Cognitive Skills Questionnaire; CEASE = Checklist of Emotional Avoidance Strategy Engagement.

^{*}p < .05.

(a) This intervention can be divided into meaningful functional units reflecting each skill, and (b) each unit fits together within a standardized interface. Our data provide preliminary evidence that the UP has the potential to achieve the final two criteria for modularity: (c) Each module appears to achieve its specified purpose (i.e., change in the module-relevant skill), and (d) these changes can occur in the absence of the other UP modules. In sum, seven of eight participants passed our visual inspection criteria suggesting change in level and/or slope in the module-relevant measure occurs when, and only when, the treatment module was introduced. Lending further support to our conclusions, five of eight participants passed our more stringent test of reliable change in the module-relevant measures. Overall, these data provide initial support for the notion that the UP can be considered a modular intervention, suggesting UP skills could potentially be presented in any order as a means to enhance treatment efficiency based on individual patient needs, however replication with a larger sample is necessary. In addition, further research would be needed to determine whether treatment efficacy or efficiency is enhanced when modules are reordered.

An exploratory aim of the present study was to examine each module's effect on the other UP skill domains not explicitly targeted. For the mindful emotion awareness (Module 3) and cognitive flexibility (Module 4), change appeared to be largely specific to the skill associated with those modules. Three of the four participants (both mindful emotion awareness participants and one cognitive flexibility patient) assigned to these modules did not demonstrate reliable change in any additional skill domain, with the remaining participant (cognitive flexibility) achieving reliable change in one additional skill (decreased emotional behaviors). In contrast, reliable change was demonstrated across all four skills measured for one participant in both the psychoeducation and tracking of emotional experiences (Module 2) and countering emotional behaviors (Module 5) modules. The remaining two participants demonstrated reliable change in two of four domains; specifically, cognitive flexibility improved significantly for the second psychoeducation participant and negative beliefs about emotions decreased significantly for the second countering emotional behaviors participant. In sum, these data suggest that the mindful emotion awareness and cognitive flexibility modules may lead to more specific change associated with their relevant skill domains, while psychoeducation and countering emotional behaviors demonstrated somewhat more broad-based change. These conclusions, however, should be accepted with caution given the small sample size in the present study; results may have more to do with individual differences among patients, rather than due to the module they received.

Despite caution in interpreting data from the present study, the pattern of change as a function of module observed makes strong conceptual sense. For example, the psychoeducation and tracking of emotional experiences (Module 2) module covers the interactive role of thoughts, physical feelings, and behaviors in contributing to the experience of strong emotions; although skills to change thoughts and behaviors are not explicitly taught, patients may take steps challenge their emotion-provoking thinking patterns and counter emotional avoidance after observing the consequences of their emotional reactions, including how these processes are maintaining their symptoms. In addition, a major component of this module in the UP is highlighting the adaptive, functional nature of emotions, which may have led to more accepting attitudes toward emotions demonstrated on our measure of mindfulness. Similarly, somewhat more broad-based change was seen for patients who received the countering emotional behaviors (Module 5) module. It is possible that asking patients to act counter to their various forms of emotional avoidance and unhelpful emotion-driven behaviors may have served as behavioral experiments, allowing patients to disconfirm beliefs about their ability to handle distressing situations and leading to change in cognitive skills (Salkovskis, Clark, Hackmann, Wells, & Gelder, 1999). Additional evidence suggests that coming in contact with the emotions provoked when acting counter to avoidant behavior may serve to provide new learning about the emotions themselves, thereby extinguishing distress in response to emotional experiences (Brake et al., 2016; Craske & Barlow, 2007) and leading to changes in negative beliefs about emotions and present-focused, nonjudgmental awareness.

There is also a theoretical rationale to account for more specific change in the mindful emotion awareness (Module 3) and cognitive flexibility (Module 4) modules. The mindful emotion awareness module, for example, encourages patients to observe their thoughts and associated action tendencies without judgment and without attempts to change their experience in any way; the explicit goals of this module underscore limited movement on measures of cognitive and behavioral skills. Similarly, focusing on flexibility of thinking within the cognitive flexibility module appears to exact change only on patients' ability to challenge their emotional thinking patterns with limited movement on measures of other UP skills.

The present study was conceptualized as a preliminary step in enhancing the efficiency of mechanism-based transdiagnostic interventions, specifically the UP. Given initial evidence suggesting that the UP can be successfully delivered as individual modules, several next steps become apparent. First, understanding the best method for selecting and ordering UP modules for a given patient must be explored. Unfortunately, research in this area has been

sparse. One possibility for personalization involves using any baseline and demographic data that may be predictive to develop an algorithm to match patients to modules that will likely lead to the greatest symptom improvement (e.g., DeRubeis et al., 2014). Another possibility is using self-reported skill use at pre-treatment to determine whether it is necessary to focus on a particular skill in treatment and, within this framework, whether to prioritize ameliorating deficits or capitalizing on existing strengths (Cheavens, Strunk, Lazarus, & Goldstein, 2012; Wingate, Van Orden, Joiner, Williams, & Rudd, 2005). Future research on personalizing the UP for more efficient delivery must explore these options for selecting and ordering skills modules.

The findings of the present study must be interpreted within the context of its limitations. First, the sample size of the present study was quite small. Although it is reasonable and customary within an SCED framework to include one participant per condition (in this case, one participant per UP module) with the other participant assigned to that condition serving as a replication, additional replications would have made our findings more robust and allowed for the use of additional non-parametric analyses. Furthermore, participants in the present study were fairly heterogeneous in terms of diagnoses and baseline functioning. Given the discrepancies in individual responses to the intervention in the present study, there may be a number of individual differences that influence whether someone is likely to benefit from a given module or from treatment at all, thus limiting generalizability. As noted above, the goal of SCEDs is to achieve internal validity in the preliminary evaluation of treatment mechanisms with less of a focus on external validity; future studies with larger samples that allow for group comparisons may answer questions regarding the generalizability of the findings. Another compromise to generalizability is the fact that four sessions per module were administered, which differs from the recommended module lengths in the UP Therapist Guide (Barlow Farchione et al., 2011) and how this treatment is likely to be provided in clinical practice. Although the decision to provide four sessions was made to ensure a dose of treatment to detect effects on skill acquisition, the majority of patients (six of eight) showed scores on their module-related skills that were non-overlapping with their baseline scores after the second session of treatment, consistent with UP recommendations. Finally, participants were randomly assigned to a given module, rather than being assigned based on presenting needs (e.g., high or low scores on module-relevant measures), making it difficult to draw conclusions about how to prioritize module presentation.

In addition, two patients failed to achieve reliable change in their module-specific measure (despite change in level and/or slope per visual inspection). One patient (P2) demonstrated change in the opposite of the predicted

direction on the module-specific measure per visual inspection, though this change was not significant per the RCI analyses. Of note, this patient's baseline assessment occurred within a few days of returning from a relaxing vacation, and she explicitly indicated that the way she responded to questions differed from how she usually felt in a more positive, adaptive direction. In addition, this patient, who was assigned to the psychoeducation and tracking of emotional experiences module (Module 2), expressed a good level of familiarity with the adaptive nature of emotions and had a good ability to identify components of her emotional experience from the outset; she indicated the material was not particularly new to her. Thus, there may not have been much room for her to improve her scores in the treatment phase.

Conclusion

Overall, findings from the present study provide preliminary support for the notion that the modules included in the UP indeed to lead to changes on the skills they were intended to affect. These changes were achieved when the modules were presented in isolation, rather than within the context of the entire UP treatment package, suggesting that each module can stand on its own. The UP is already an efficient form of psychotherapy as its transdiagnostic nature allows for the simultaneous consideration of comorbid conditions. The present findings represent a preliminary step in furthering the UP's efficiency as the establishment of UP skills as stand-alone modules allows for a personalized presentation of this treatment in which modules are reordered or excluded based on patients' presenting concerns and time constraints. Future research should determine best practices for personalization of the UP.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Note

 The Unified Protocol (UP) has previously been described as consisting of five core modules (e.g., Farchione et al., 2012); however, both clinical experience and empirical data (Boswell, Anderson, & Barlow, 2014) suggest that Module 2 indeed engages the putative UP mechanisms and should be considered core.

References

- American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.
- Barlow, D. H. (1991). Disorders of emotion. *Psychological Inquiry*, 2(1), 58-71. doi: 10.1207/s15327965pli0201 15.
- Barlow, D. H., Ellard, K. K., Fairholme, C. P., Farchione, T. J., Boisseau, C. L., Allen, L. B., & Ehrenreich-May, J. (2011). The unified protocol for transdiagnostic treatment of emotional disorders: Client workbook. New York, NY: Oxford University Press.
- Barlow, D. H., Farchione, T. J., Fairholme, C. P., Ellard, K. K., Boisseau, C. L., Allen, L. B., & Ehrenreich-May, J. (2011). The unified protocol for transdiagnostic treatment of emotional disorders: Therapist guide. New York, NY: Oxford University Press.
- Barlow, D. H., Nock, M. K., & Hersen, M. (2009). Single case experimental designs: Strategies for studying behavior change (3rd ed.). Boston, MA: Allyn & Bacon.
- Barlow, D. H., Sauer-Zavala, S., Carl, J. R., Bullis, J. R., & Ellard, K. K. (2014). The nature, diagnosis, and treatment of neuroticism: Back to the future. *Clinical Psychological Science*, 2, 344-365. doi:10.1177/2167702613505532
- Boswell, J. F., Anderson, L. M., & Barlow, D. H. (2014). An idiographic analysis of change processes in the unified transdiagnostic treatment of depression. *Journal* of Consulting and Clinical Psychology, 82, 1060-1071. doi:10.1037/a0037403
- Brake, C. A., Sauer-Zavala, S., Boswell, J. F., Gallagher, M. W., Farchione, T. J., & Barlow, D. H. (2016). Mindfulness-based exposure strategies as a transdiagnostic mechanism of change: An exploratory alternating treatment design. *Behavior Therapy*, 47, 225-238. doi:10.1016/j.beth.2015.10.008
- Brown, T. A., & Barlow, D. H. (2014). *Anxiety and Related Disorders Interview Schedule for DSM-5 (ADIS-5)*. New York, NY: Oxford University Press.
- Brown, T. A., Di Nardo, P., Lehman, C., & Campbell, L. (2001). Reliability of DSM-IV anxiety and mood disorders: Implications for classification of emotional disorders. *Journal of Abnormal Psychology*, 110, 49-58. doi:10.1037/0021-843X.110.1.49
- Chadwick, P., Hember, M., Symes, J., Peters, E., Kuipers, E., & Dagnan, D. (2008). Responding mindfully to unpleasant thoughts and images: Reliability and validity of the Southampton mindfulness questionnaire (SMQ). *British Journal of Clinical Psychology*, 47, 451-455. doi:10.1348/014466508X314891
- Cheavens, J. S., Strunk, D. R., Lazarus, S. A., & Goldstein, L. A. (2012). The compensation and capitalization models: A test of two approaches to individualizing the treatment of depression. *Behaviour Research and Therapy*, 50, 699-706. doi:10.1016/j.brat.2012.08.002
- Chorpita, B. F., Daleiden, E. L., & Weisz, J. R. (2005). Modularity in the design and application of therapeutic interventions. *Applied & Preventive Psychology*, 11, 141-156. doi:10.1016/j.appsy.2005.05.002

Chorpita, B. F., Taylor, A. A., Francis, S. E., Moffitt, C., & Austin, A. A. (2004). Efficacy of modular cognitive behavior therapy for childhood anxiety disorders. *Behavior Therapy*, *35*, 263-287. doi:10.1016/S0005-7894(04)80039-X

- Chorpita, B. F., & Weisz, J. R. (2009). Modular approach to therapy for children with anxiety, depression. Trauma and conduct problems (MATCH-ADTC). Satellite Beach, FL: Practicewise.
- Conklin, L. R., Cassiello-Robbins, C., Wilner, J. G., & Sauer-Zavala, S. (in press). Assessment of skill acquisition in the Unified Protocol: Validation of measures of cognitive flexibility and emotional avoidance.
- Craske, M. G., & Barlow, D. H. (2007). *Mastery of your anxiety and panic: Therapist guide* (4th ed.). New York, NY: Oxford University Press.
- DeRubeis, R. J., Cohen, Z. D., Forand, N. R., Fournier, J. C., Gelfand, L. A., & Lorenzo-Luaces, L. (2014). The personalized advantage index: Translating research on prediction into individualized treatment recommendations. A demonstration. *PLoS ONE*, 9, e83875. doi:10.1371/journal.pone.0083875
- Ellard, K. K., Deckersbach, T., Sylvia, L. G., Nierenberg, A. A., & Barlow, D. H. (2012). Transdiagnostic treatment of bipolar disorder and comorbid anxiety with the unified protocol: A clinical replication series. *Behavior Modification*, 36, 482-508. doi:10.1177/0145445512451272
- Ellard, K. K., Fairholme, C. P., Boisseau, C. L., Farchione, T. J., & Barlow, D. H. (2010). Unified protocol for the transdiagnostic treatment of emotional disorders: Protocol development and initial outcome data. *Cognitive and Behavioral Practice*, 17, 88-101. doi:10.1016/j.cbpra.2009.06.002
- Fairburn, C. G. (2008). Cognitive behavior therapy and eating disorders. New York, NY: Guilford Press.
- Farchione, T. J., Fairholme, C. P., Ellard, K. K., Boisseau, C. L., Thompson-Hollands, J., Carl, J. R., & Barlow, D. H. (2012). Unified protocol for transdiagnostic treatment of emotional disorders: A randomized controlled trial. *Behavior Therapy*, 43, 666-678. doi:10.1016/j.beth.2012.01.001
- Fisher, A. J. (2015). Toward a dynamic model of psychological assessment: Implications for personalized care. *Journal of Consulting and Clinical Psychology*, 83, 825-836. doi:10.1037/ccp0000026
- Garfield, S. L. (1994). Research on client variables in psychotherapy. In A. E. Bergin & S. L. Garfield (Eds.), *Handbook of psychotherapy and behavior change* (4th ed., pp. 190-228). Oxford, UK: John Wiley.
- Hansen, N. B., Lambert, M. J., & Forman, E. V. (2002). The psychotherapy doseresponse effect and its implications for treatment delivery services. *Clinical Psychology: Science and Practice*, 9, 329-343. doi:10.1093/clipsy.9.3.329
- Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting* and Clinical Psychology, 59, 12-19.
- Kennedy, S. (2015). Assessing behavioral and emotional avoidance in adolescents: A psychometric validation study (Open Access Theses Paper No. 572). Retrieved from http://scholarlyrepository.miami.edu/oa_theses/572

- Lambert, M. J., & Bergin, A. E. (1994). The effectiveness of psychotherapy. In A. E. Bergin & S. L. Garfield (Eds.), *Handbook of psychotherapy and behavior change* (4th ed., pp. 143-189). Oxford, UK: John Wiley.
- Murray, L. K., Dorsey, S., Haroz, E., Lee, C., Alsiary, M. M., Haydary, A., . . . Bolton, P. (2014). A common elements treatment approach for adult mental health problems in low- and middle-income countries. *Cognitive and Behavioral Practice*, 21, 111-123. doi:10.1016/j.cbpra.2013.06.005
- Payne, L. A., Ellard, K. K., Farchione, T. J., Fairholme, C. P., & Barlow, D. H. (2014). Emotional disorders: A unified transdiagnostic protocol. In D. H. Barlow (Ed.), Clinical handbook of psychological disorders: A step-by-step treatment manual (5th ed., pp.237-274). New York, NY: The Guilford Press.
- Persons, J. B. (2007). Psychotherapists collect data during routine clinical work that can contribute to knowledge about mechanisms of change in psychotherapy. *Clinical Psychology: Science and Practice*, 14(3), 244-246. doi:10.1111/j.1468-2850.2007.00083.x
- Persons, J. B., Beckner, V. L., & Tompkins, M. A. (2013). Testing case formulation hypotheses in psychotherapy: Two case examples. *Cognitive and Behavioral Practice*, 20, 399-409. doi:10.1016/j.cbpra.2013.03.004
- Rachman, S. (2009). Psychological treatment of anxiety: The evolution of behavior therapy and cognitive behavior therapy. *Annual Review of Clinical Psychology*, 5, 97-119. doi:10.1146/annurev.clinpsy.032408.153635
- Rimes, K. A., & Chalder, T. (2010). The Beliefs about Emotions Scale: Validity, reliability and sensitivity to change. *Journal of Psychosomatic Research*, 68, 285-292. doi:10.1016/j.jpsychores.2009.09.014
- Salkovskis, P. M., Clark, D. M., Hackmann, A., Wells, A., & Gelder, M. G. (1999). An experimental investigation of the role of safety-seeking behaviours in the maintenance of panic disorder with agoraphobia. *Behaviour Research and Therapy*, 37, 559-574. doi:10.1016/S0005-7967(98)00153-3
- Sauer-Zavala, S., & Barlow, D.H. (2014). The case for borderline personality disorder as an emotional disorder: Implications for Treatment. Clinical Psychology: Science & Practice, 21, 118-138. 10.1111/cpsp.12063
- Sauer-Zavala, S., Bentley, K. H., & Wilner, J. G. (2016). Transdiagnostic treatment of borderline personality disorder and comorbid disorders: A clinical replication series. *Journal of Personality Disorders*, 30, 35-51. doi: 10.1521/pedi 2015 29 179.
- Sauer-Zavala, S., Gutner, C. A., Farchione, T. J., Bullis, J. R., Boettcher, H. T., & Barlow, D. H. (2017). Current definitions of "transdiagnostic" in treatment development: A search for consensus. *Behavior Therapy*, 48(1), 128-138.
- Tate, R., Perdices, M., Rosenkoetter, U., McDonald, S., Togher, L., Shadish, W., . . . Vohra, S. (2016). The Single-Case Reporting Guideline in Behavioural Interventions (SCRIBE). Archives of Scientific Psychology, 4, 10-31.
- Weisz, J. R., Chorpita, B. F., Palinkas, L. A., Schoenwald, S. K., Miranda, J., Bearman, S. K., . . . Gibbons, R. D. (2012). Testing standard and modular designs for psychotherapy treating depression, anxiety, and conduct problems in youth:

A randomized effectiveness trial. *Archives of General Psychiatry*, 69, 274-282. doi:10.1001/archgenpsychiatry.2011.147

Wingate, L. R., Van Orden, K. A., Joiner, T. E. J., Williams, F. M., & Rudd, M. D. (2005). Comparison of compensation and capitalization models when treating suicidality in young adults. *Journal of Consulting and Clinical Psychology*, 73, 756-762. doi:10.1037/0022-006X.73.4.756.

Author Biographies

Shannon Sauer-Zavala, PhD, is a research assistant professor in the Department of Psychological and Brain Sciences at Boston University. Her research is focused on mechanisms of change in empirically supported treatment, particularly in the context of transdiagnostic interventions for emotional disorders.

Clair Cassiello-Robbins, MA, is a doctoral student in clinical psychology at Boston University. Her research focuses on dysregulated anger in the context of emotional disorders, with an emphasis on understanding treatment mechanisms relevant to this problem.

Laren R. Conklin, PhD, is a staff psychologist at the Chalmer's P. Wylie VA Ambulatory Care Center in Columbus, Ohio. Her research interests involve the exploration of characteristics that are associated with improved treatment outcomes, with a particular focus on understanding ways that current cognitive-behavioral treatments might be improved in anxiety and depressive disorders.

Jacqueline R. Bullis, PhD, is a senior research fellow in the Division of Depression and Anxiety Disorders at McLean Hospital/Harvard Medical School. Her research is aimed at increasing the public health impact of existing psychological treatments by applying a transdiagnostic, interdisciplinary approach to the diagnosis, treatment, and prevention of emotional disorders.

Johanna Thompson-Hollands, PhD, is a postdoctoral fellow at the Boston University School of Medicine/VA Boston Healthcare System. Her research interests are in emotional disorders, particularly post-traumatic stress disorder, and the bidirectional impact of psychopathology and family behaviors/distress.

Katherine A. Kennedy, BS, is a research assistant in Boston University's Department of Psychological and Brain Sciences. She was recently accepted to Fordham University's doctoral program in clinical psychology.