Behavioral Psychology / Psicología Conductual, Vol. 23, Nº 3, 2015, pp. 447-466

THE UNIFIED PROTOCOL FOR TRANSDIAGNOSTIC TREATMENT OF EMOTIONAL DISORDERS IN GROUP FORMAT IN A SPANISH PUBLIC MENTAL HEALTH SETTING

Jorge Osma[1], Cristian Castellano[1], Elena Crespo[2,3], and Azucena García-Palacios[2]

[1]University of Zaragoza; [2]Jaume I University; [3]CREOS, Psychotherapy and Training Center (Spain)

Abstract

The unified protocol for transdiagnostic treatment of emotional disorders (UP) includes therapeutic techniques and methods that have proven their efficacy and it is focused specifically on emotion regulation. Although the efficacy of UP has been proven in individual format, it is important to evaluate the delivery of the UP in other formats with the aim of improving cost-benefit. The aim of this pilot study was to evaluate the effectiveness and feasibility of UP in group format. Eleven patients with emotional disorders who attended a public mental health unit participated in the study. Primary outcomes were anxiety and depression symptoms, and secondary outcomes were positive and negative affect, impairment, general functioning, quality of life, and personality dimensions. At 12-month follow-up, 100% of the participants no longer met the diagnostic criteria for their main diagnosis, significant improvements were achieved in the primary outcomes and also in most secondary outcomes, including neuroticism scores. The administration of UP in a group format could be a suitable approach to treat emotional disorders in public mental health settings.

KEY WORDS: *unified protocol, transdiagnostic, group format, emotional disorders, public mental health*.

Resumen

El protocolo unificado para el tratamiento transdiagnóstico de los trastornos emocionales (PU) incluye las técnicas y métodos terapéuticos que han demostrado eficacia y se centra, específicamente, en la regulación emocional. La eficacia del PU ha sido demostrada en formato individual, pero es necesario investigar su aplicación en otros formatos, sobre todo con el objetivo de mejorar el coste-beneficio. El objetivo de este estudio piloto es evaluar la eficacia y viabilidad del PU en formato grupal. Participaron 11 personas con trastornos emocionales de

This study was partially supported by the Aragon Government, the European Social Fund, and CREOS, Psychotherapy and training center, S. L. Special thanks to the professionals from the Rafalafena Mental Health Center in Castellón (Spain) and all the participants who voluntarily participated in this pilot study.

Correspondence: Jorge Osma, Facultad de Ciencias Sociales y Humanas, Universidad de Zaragoza, c/ Ciudad Escolar, s/n 44003 Teruel (Spain). E-mail: osma@unizar.es

una unidad de salud mental pública. Las medidas de resultado primarias fueron síntomas de ansiedad y depresión, las secundarias, afecto positivo y negativo, inadaptación, funcionamiento general, calidad de vida y dimensiones de personalidad. A los 12 meses de seguimiento el 100% de los participantes no cumplía criterios de su diagnóstico principal, se obtuvieron mejoras en las medidas primarias y en muchas de las secundarias, incluyendo el neuroticismo. La utilización del PU en formato grupal puede ser un método adecuado para el tratamiento de los trastornos emocionales en contextos de salud mental pública.
PALABRAS CLAVE: *protocolo unificado, transdiagnóstico, formato grupal, trastornos emocionales, salud mental pública.*

Introduction

The epidemiological study of Eaton et al. (2008) reported the average 12-month prevalence and interquartile range of different mental disorders in the general population, including anxiety and mood disorders, called emotional disorders (ED). The average of 1-year prevalence varied from 0.9 in panic disorder (0.6-1.9 interquartile range) to 5.3 in major depressive disorder (3.6-6.5). The cost per annum associated with ED ranges from 10.6 (billion US dollars) for obsessive-compulsive disorder to 97.3 for major depressive disorder.

Given the high prevalence and the associated cost of ED, interest in the efficacy of treatment protocols has increased notably, leading to the emergence of evidence-based treatment (EBT). This term includes the most efficacious and effective treatments for each one of the mental disorders (e.g., Dozois et al., 2014). Thanks to the awareness of the importance of EBTs, their manualization, and the training of therapists in these protocols, satisfactory outcomes have been achieved in the treatment of many mental disorders. Despite the good results, there are still some barriers, such as the high comorbidity among ED, the still moderate efficacy of some EBTs, the relapse rates, and the elevated cost associated with the training of the therapists and the implementation of each EBT (Clark, 2009).

To overcome these limitations, and similarly to the proposals in the field of anxiety disorders (Norton, 2012), Barlow and colleagues have proposed a transdiagnostic perspective for the treatment of ED, *the unified protocol for transdiagnostic treatment of emotional disorders* (UP; Barlow, Ellard, et al. 2011; Barlow, Farchione, et al., 2011). Instead of focusing on each single disorder, this protocol focuses on the common features of ED, that is, on the psychopathological dimensions underlying both anxiety and mood disorders. This perspective is based on the idea that ED may share more features than the factors that differentiate them. This would explain the high comorbidity among them and the fact that treatment protocols designed for one disorder also affect the comorbid disorder (Brown, Antony, & Barlow, 1995). Brown and Barlow (2009) proposed a dimensional classification of ED that is linked to the triple vulnerability model also proposed by Barlow et al. (Suarez, Bennett, Goldstein, & Barlow, 2009) to explain the common bases of ED.

The UP was initially designed to target the core processes that contribute to the onset and maintenance of ED (Wilanowska et al., 2010) but, although the UP includes components of traditional cognitive behavioral therapy (CBT), it focuses on the deficit in emotion regulation common to all ED. With regard to this issue, the UP emphasizes the adaptive value of all emotions and promotes tolerance to intense emotions and the identification and modification of dysfunctional emotion regulation strategies. One of the main objectives of the UP is to help patients to cope with emotions more adaptively, identifying the dysfunctional emotion regulation strategies that interfere with their lives. The patients learn not to suppress their emotional experiences, to be more aware of them, and to identify the valuable information that emotions provide (Barlow, Ellard, et al., 2011).

The UP was designed to be administered in a variety of ED, including anxiety disorders, unipolar depression, and related disorders (Barlow, Farchione, et al. 2011). Since the first case study using the UP was published (Boisseau, Farchione, Fairholme, Ellard, & Barlow, 2010), some evidence has been accumulated about the efficacy of the individual format of the UP in the treatment of ED (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010; Farchione et al., 2012). Furthermore, a recent study provides preliminary support for the long-term benefits of the UP administered in individual format (18 months post-treatment) (Bullis, Fortune, Farchione, & Barlow, 2014). These results are very promising due to the more time- and cost-efficient characteristics of the UP not only for therapists (training) but also for patients (shorter waiting-lists).

Examining the efficiency of the transdiagnostic treatment approach, some studies have shown that the group format is suitable for the treatment of anxiety disorders (e.g., Norton, 2012), and it has been administered in brief versions using internet (e.g., Dear et al., 2011). Regarding transdiagnostic protocols for anxiety and depression disorders administered in group format, we found some recent studies informing that such CBT transdiagnostic unified protocols were effective in the significant reduction of the anxiety and depression scores, and the outcomes also show improvements in quality of life and sexuality (de Ornelas, Azevedo, Aparecida, Egidio, & Cardoso, 2013; de Ornelas, Egidio, & Cardoso, 2015). Despite these promising results, these studies do not include in their outcomes the reduction of the diagnostic criteria of their samples after treatment or long-term follow-up assessments. Regarding the CBT transdiagnostic protocol used (de Ornelas et al., 2013), on the one hand and in contrast to the Barlow´s UP, these authors add some components, such as bibliotherapy, relaxation techniques, evaluation and training of social skills and problem-solving. On the other hand, it is not clear whether this UP incorporates some core variables underlying ED that are described in the original UP of Barlow´s team, such us present-focused awareness or interoceptive and in vivo exposure exercises (Barlow, Farchione, et al., 2011).

The recent study of Bullis et al. (2015) is the only one that has offered preliminary data about the application of the UP in group format with diagnostically diverse and severe patient population. All of the 8 modules of the UP protocol were delivered over the course of 12 sessions, two hours weekly in small groups of 5 to 6 patients. The participants used the workbook (Barlow, Ellard, et al., 2011) during the treatment. The results of this open clinical pilot trial

produced moderate to strong effects (Hedges´s *g* effect size) on anxiety and depressive symptoms, functional impairment, quality of life, and emotion regulation skills, as well as obtaining good acceptability and overall satisfaction ratings of the group therapy format. As the authors stated, the encouraging outcomes found must be interpreted with caution because of the small sample, the uncontrolled protocol evaluation, the exclusively self-report measures for outcome data used, and because they only provide pre-post assessment outcomes.

In summary, there is a high prevalence of ED in the general population (Eaton et al., 2008) and, although there are good treatment protocols for these disorders, there is still room for improvement (Clark, 2009). There is sound evidence of the shared psychopathological features of ED (Brown & Barlow, 2009), and the UP has provided promising evidence of its effectiveness in individual (Ellard et al., 2010; Farchione et al., 2012) and group format (Bullis et al., 2015). However, more evidence is needed in the field of the effectiveness of the UP in group administration, especially in public mental health settings and performing long-term assessments.

In the current study, we hypothesized that the UP delivery in group format could significantly reduce clinical symptoms and diagnostic criteria, and also increase positive affect in a heterogeneous sample of patients with ED. In this article, we present preliminary data testing the short- and long-term (12-month follow-up) effectiveness of the 10-session version of the UP administered in group format in a Spanish public mental health setting.

Method

Participants

The 11 participants in the study were from Spain and Caucasian, the age range was 28 to 66 years (*M*= 43.87; *SD*= 12.66). The rest of demographic features of the sample can be seen in Table 1. The participants' average time on medication was 6.75 years (*SD*= 8.05) with a range of 1 to 23 years.

Measures

a) "Anxiety Disorders Interview Schedule Lifetime Version for DSM-IV" (ADIS-IV-L; Brown, Di Nardo, & Barlow, 1994); Translated into Spanish by Botella and Ballester (1997). The ADIS-IV-L is a semistructured interview designed to assess anxiety, mood, somatoform, and substance use disorders according to the criteria of the diagnostic and statistical manual of mental disorders -4th ed (DSM-IV; American Psychiatric Association [APA], 1994). In this study we used the anxiety and mood disorder sections. Test-retest reliability varies, depending on the study from .68 to 1.00.

Table 1
Sociodemographic data

Variables	*n*	%
Sex		
Female	10	90.91
Male	1	9.09
Education		
Primary education	1	9.09
Secondary education level	8	72.73
University degree	2	18.18
Marital status		
Single	3	27.27
Married	6	54.55
Widowed	1	9.09
Divorced	1	9.09
Work status		
Active worker	4	36.36
Unemployed	2	18.18
Sick leave	2	18.18
Home-maker	2	18.18
Retired	1	9.09
Pharmacological treatment		
Anxiolytics	1	9.09
Antidepressant	3	27.27
Both	7	63.63

b) "Beck Depression Inventory" (BDI-II; Beck, Steer, & Brown, 1996); Spanish version by Sanz, Perdigón, and Vázquez (2003). The BDI-II is a commonly used measure for the evaluation of depressive symptomatology. Consists of 21 items, each one comprises four different sentences reflecting an increasing degree of depression. A score of 0 is given to the response indicative of lower depressive symptomatology and 3 to the response indicative of a higher level. The total score ranges from 0 to 63. The alpha coefficient obtained in the Spanish version (.87) indicates a good internal consistency.

c) "Beck Anxiety Inventory" (BAI; Beck & Steer, 1993); Spanish version by Magán, Sanz, and García-Vera (2008). The BAI includes 21 items to assess the severity of clinical anxiety symptomatology. Each item reflects an anxiety symptom and for each one, respondents rate the degree to which they were affected by it during the past week. Responses are obtained through a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*severely*). Total score ranges from 0 to 63. Internal consistency estimate for the Spanish version of the BAI was high, .93.

d) "Overall Depression Severity and Impairment Scale" (ODSIS; Bentley, Gallagher, Carl, & Barlow, 2014). The ODSIS is a five-item instrument designed to measure severity and impairment of depressive symptoms. Items are coded

from 0 to 4 and are summed to obtain one total score. Cronbach's alpha for the five ODSIS items was .94 in the outpatient sample, .91 in the student sample, and .92 in the community sample, all indicative of excellent internal consistency. For this study we used the Spanish translation of the original.

e) "Overall Anxiety Severity and Impairment Scale" (OASIS; Norman, Cissell, Means-Christensen, & Stein, 2006). The OASIS is a five-item continuous measure of anxiety-related severity and impairment. Items are coded from 0 to 4 and are summed to obtain one total score. The OASIS have shown high internal consistency, excellent test-retest reliability, and convergent and discriminant validity in clinical and non-clinical samples (i.e., Norman et al., 2006). In a recent study the internal consistency of the OASIS was good to excellent, ranging from .87 (student) to .91 (community) (Bentley et al., 2014). For this study we used the Spanish translation of the original.

f) "Positive and Negative Affect Scale" (PANAS; Watson, Clark, & Tellegen, 1988) Spanish version by Sandín et al. (1999). The PANAS has 20 items measuring both positive and negative affect, with 10 items per dimension. Participants are asked to rate in a 5-points Likert scale, from 1 (*very slightly or not at all*) to 5 (*extremely*), how much they experience different feelings and emotions, as "Enthusiastic" for positive affect or "Nervous" for negative affect. Internal consistency estimate for the Spanish version of the PANAS was high for both scales and also for both men (.89 [PA] and .91 [NA]) and women (.87 [PA] and .89[NA]).

g) "Spanish version of the Quality of Life Index" (QLI-Sp; Mezzich et al., 2000). This self-report is composed of 10 dimensions (10 items): physical well-being, emotional well-being, self-care and independent functioning, occupational and interpersonal functioning, social emotional support, community and services support, personal fulfilment, spiritual fulfilment, and overall quality of life. Each item is assessed according to the subject's personal perspective at the time. Responses are obtained through a 10-point line ranging from poor to excellent. The test-retest reliability correlation coefficient of the QLI-Sp mean score was .89. The discriminant validity of the QLI-Sp was documented by the highly significant difference obtained between the mean scores of the two samples selected (clinical and non-clinical) to represent quite different levels of quality of life.

h) "Maladjustment Inventory" (*Escala de inadaptación*, MI; Echeburúa, Corral, & Fernández-Montalvo, 2000). The MI reflects the extent to which the subject's current problems affect different areas of daily life: work, social life, free time, relationship with partner, family life, and overall maladjustment in everyday life. All dimensions are assessed through a 6-point line ranging from 0 (*nothing*) to 5 (*very severe*). The full range of the instrument is therefore 0 to 30, with 12 points representing the overall cut-off point. The higher the score, the greater the level of maladjustment. Test-retest reliability is .86, and the internal consistency alpha coefficient is .94.

i) "Global Assessment Functioning Scale" (GAF Axis V of DSM-IV-TR; APA, 2000). The GAF measures global mental health from the perspective of psychic, social, and functional ability. The scale has ten vignettes exemplifying

symptom severity and psychosocial functioning to be used as reference in rating, each vignette representing successive 10-point intervals in the semi-quantifying in the total scale range 1-100. Rating 1 represents the maximum dysfunction and 100 the best possible function. In each vignette, the first part exemplifies syndrome severity and the last part psycho-social functioning. GAF is a much used scale and its psychometric properties are documented in several studies (i.e., Söderberg & Tungström, 2007).

j) "NEO Five-Factor Inventory" (NEO-FFI; Costa & McCrae, 1999). NEO-FFI is a self-report inventory which offers a rapid and general measure of the Big Five personality factors: Neuroticism, Extraversión, Openess, Agreableness, and Conscientiousness. Consists of 60 items, 12-item for each personality factor. Responses are obtained through a 5-point Likert scale ranging from 0 (*totally agree*) to 4 (*totally disagree*). The internal consistency and factorial structure for the Spanish version were satisfactory (Costa & McCrae, 1999).

Procedure

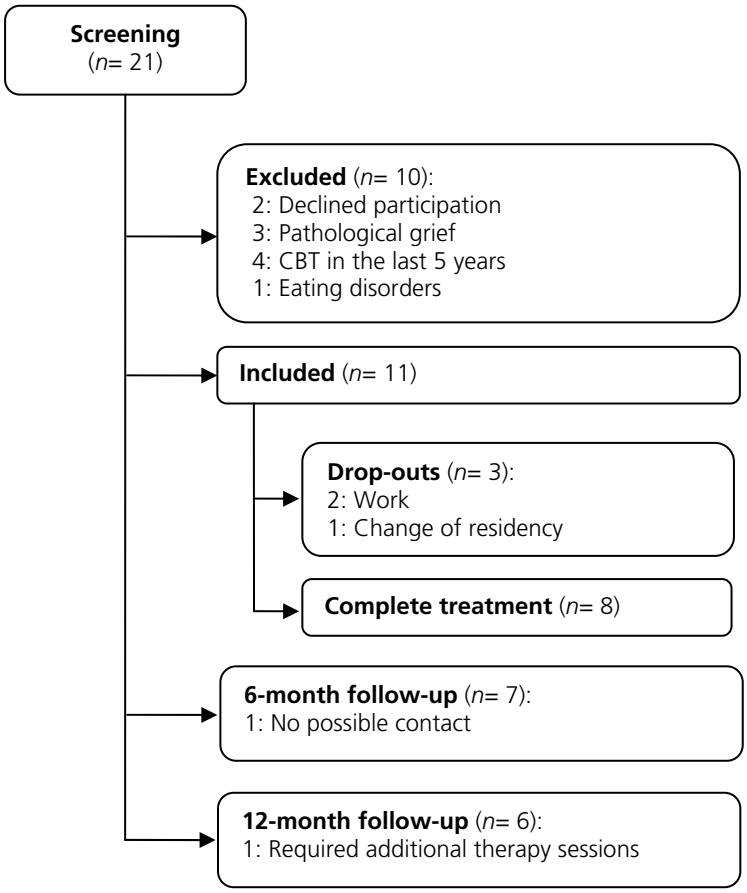
The eleven participants included in this study were recruited in the Rafalafena public mental health unit in Castellón (Spain). The ethical committee of the unit approved the study. Clinical psychologists and psychiatrists of the unit were informed about the study protocol and also about the inclusion and exclusion criteria (see Farchione et al., 2012). The inclusion criteria for patients were to be 18 years of age or older, to have a good comprehension of Spanish language, to have received a principal diagnosis (most severe or interfering) of anxiety or unipolar depression disorders, to sign the informed consent form to participate in the study, and to be able to attend all treatment sessions and assessments; regarding medication, participants were required to be stable on medication 3 months prior to beginning treatment and during treatment.

Exclusion criteria consisted primarily of the conditions that, in a clinical context, would require immediate or simultaneous treatment, which could interact with the study treatment in unknown ways; for instance, current Diagnostic and statistical manual of mental disorders - 4th edition (APA, 1994) diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder, or organic mental disorder, clear and current suicidal risk, or current or recent (within 3 months) history of substance abuse or drug dependence, with the exception of nicotine, marijuana, and caffeine. Individuals were also excluded if they had previously received at least 8 sessions of psychological treatment consisting of clear and identifiable cognitive-behavioral principles, such as cognitive restructuring and exposure, within the past 5 years. Additionally, the authors considered as exclusion criteria to have required additional or more intensive treatment (i. e., individual therapy) during the group therapy or between the follow-up assessment periods (i.e., one case between the 6- and 12-month follow-ups) in order to evaluate the efficacy of 10 sessions of the UP in group format at short and long-term periods. Figure 1 displays a flow diagram of the study.

The health professionals of the unit conducted screening interviews and referred patients to two clinical psychologists of the research team, who

conducted the assessment. These two clinicians were advanced doctoral students with more than 3 years of training and supervision of CBT protocols. They conducted a clinical assessment of the patients in all the assessment periods, including the ADIS-IV-L (Brown et al., 1994) in the follow-ups. Participants who met the inclusion criteria were invited to participate and signed an informed consent. The patients who did not meet the inclusion criteria received the usual treatment offered in the mental health unit.

Figure 1
Flow diagram of the pilot study



Participants received 10 therapy sessions with all the UP modules (Barlow, Ellard, et al., 2011) in a group format. The main therapist (first author) had been trained in CBT protocols for ED in a specialized research group of Jaume I University from 1999 to 2011. The UP therapist guide and client workbook

(Barlow, Ellard, et al., 2011; Barlow, Farchione, et al., 2011) was translated into Spanish and used it in this pilot study. In Table 2, we provide the content and homework of each session. The treatment lasted three months (considering vacation time) and the patients received one weekly 2-hour session.

Table 2
Description of UP group format protocol

Session	Contents	Homework
1	Motivation enhancement for treatment engagement. Setting specific treatment goals.	Establish objectives and goals of the treatment if they could not finish in session.
2	Understanding emotions: Functional and adaptive nature of emotions. Three-component model of emotions.	Complete the Three-Component Model form by selecting one emotional experience that occurs during the week.
3	Recognizing and tracking emotional responses. ARC model of emotional experiences.	Use the Monitoring Emotions and EDBs in Context form to begin monitoring the ARC of their emotional experiences.
4	Emotion awareness training. Nonjudgmental present-focused emotion awareness exercises.	Complete several forms of mood induction, anchor in the present, and emotion awareness.
5	Cognitive appraisal and reappraisal. Reciprocal relationship between thoughts and emotions. Automatic appraisal and thinking traps. Cognitive reappraisal to increase flexibility in thinking	Use the Identifying and Evaluating Automatic Appraisals form and begin the reappraisal process.
6	Emotion avoidance. Types of emotion avoidance strategies and their short- and long-term contribution to the negative cycle of emotional responding.	Use the List of Emotion Avoidance Strategies form to begin identifying the ways they attempt to avoid uncomfortable emotions.
7	Emotion-driven behaviors (EDBs). Identifying maladaptive EDBs and developing alternative action tendencies.	Use the Changing EDBs form to identify and change their maladaptive emotion-driven behaviors.
8	Awareness and tolerance of physical sensations. Role of internal physical sensations in the emotional response.	Practice the symptoms induction exercises.
9	Interoceptive and situational emotion exposure. Emotional and situational avoidance hierarchy. Emotion exposure practice.	Generate a list of emotional situations that they currently avoid. Practice emotion exposures of these situations.
10	Relapse prevention. Review of progress on the protocol and of skills for coping with emotions.	Continue their progress through the practice of treatment components.

All patients received a client workbook as an aid to read the content of each session, do the exercises recommended between sessions and after completing the treatment. Sessions were structured, beginning with a brief review of the contents of the previous session (except for the first one), review of the homework, presentation of the new content, in-session exercises, review of the present content through a test, and they concluded with the homework assignment. Participants who were not able to attend one or more sessions were given the manual with the content of the missed session, and this content was reviewed at the beginning of the following session. In this way, all participants who completed the treatment protocol received all the contents of the UP and practiced all the exercises. As shown in Figure 1, 8 participants completed the treatment (being present in at least 6 sessions). The average number of sessions completed by participants was 7.75 (range: 6 to 10).

Regarding the diagnoses, all participants were assessed with ADIS-IV (Brown et al., 1994) based on the DSM-IV (APA, 2000) criteria. One patient presented obsessive compulsive disorder, four patients had from anxiety disorder not otherwise specified (three of them had mixed anxiety depressive disorders and in one case, it was impossible to establish whether the anxiety symptoms were of a primary nature or induced by a medical condition or substance use), one patient had panic disorder with agoraphobia, three had major depression, and two presented depressive disorder not otherwise specified (they had had fewer than five depressive symptoms for at least two weeks). Three participants had a comorbid diagnosis, two of major depression disorder, and one of panic disorder without agoraphobia.

In this study, assessment was conducted at pretest, posttest, and 6- and 12-month follow-up. Except for one, none of the participants received any additional psychological treatment during the follow-up periods (see Figure 1).

Data analysis

Statistical analyses were performed with the SPSS 21.0 (SPSS 21.0; IBM, 2012). Descriptive statistics were used for demographic data. Given the small sample size, we chose non-parametric tests to explore effectiveness, concretely, the Wilcoxon test, establishing statistical significance at $p < .05$. In addition, effect size was calculated with Cohen's *d*. Lastly, clinical significance was also calculated for the primary outcome measures, BDI and BAI.

Results

Treatment retention

Treatment retention achieved was high, that is, 8 of the 11 participants who started the treatment, completed it. Seven participants completed the 6-month follow-up and six the 12-month follow-up.

Diagnostic criteria

Table 3 presents the primary and secondary diagnoses of the study participants. Six to 8 participants who completed the treatment no longer met the primary diagnosis criteria at posttest (ADIS-IV; Brown et al., 1994). This percentage increased to 7 at the 6-month follow-up and 6 at the 12-month follow-up (of the 6 participants who completed the follow-up assessment). Regarding comorbid diagnosis, all participants no longer met the criteria for this diagnosis at posttest, and this outcome was maintained at the 12-month follow-up.

Table 3
Proportion of treatment initiators who achieved recovery or remission on all diagnoses at post-treatment and 12-month follow-up assessment

Diagnoses at pretreatment assessment	Post-treatment			12-month follow-up		
	n	% Recovery	% Remission	*n*	% Recovery	% Remission
Principal diagnoses						
All principal diagnoses	8	75	25	6	100	0
OCD	1	0	100	1	100	0
MDD	2	100	0	1	100	0
Anx. NOS	3	66.6	33.3	3	100	0
DDNOS	2	100	0	1	100	0
Comorbid diagnoses						
All comorbid diagnoses	2	100	0	1	100	0
PDA	1	100	0	0		
MDD	1	100	0	1	100	0

Notes: A person is considered to be *recovered* when he/she no longer meets the diagnostic criteria for the disorder, whereas *remission* refers to some improvement but he/she continues to meet diagnostic criteria. OCD= obsessive-compulsive disorder; MDD= major depressive disorder; PDA= panic disorder with agoraphobia; Anx. NOS= anxiety disorder not otherwise specified; DDNOS= depressive disorder not otherwise specified.

Regarding pharmacological treatment, all participants reduced dosage at posttreatment. At the 12-month follow-up, 3 of the participants did not take any medication and the remaining 3 had reduced dosage considerably, and all of them were in the process of ceasing to take medication.

Clinical improvement

In table 4 we can observe the mean and standard deviation of the clinical measures at different assessment periods. Table 5 shows the mean differences and effect size of the clinical measures and as we can observe, there were significant differences from pretest to posttest in the primary and secondary outcome measures (BDI, BAI, ODSIS and OASIS), with medium effect sizes, and in agreeableness and general functioning, with large effect sizes.

From posttest to 6-month follow-up, the primary outcome measures continued to show significant differences, with small effect sizes, and of the

secondary outcome measures, anxiety severity and impairment (OASIS) scores improved, with a large effect size, and impairment (MI), neuroticism and responsibility (NEO-FFI) scores improved, with a small effect size.

From posttest to 12-month follow-up, anxiety symptoms (BAI and OASIS) continued to decrease significantly, with medium to large effect sizes, as did impairment (MI) and neuroticism (NEO-FFI), with a large effect size. Quality of life (QLI) also increased, with a large effect size.

Table 4
Mean and standard deviation of the clinical measures at pretest, postest, 6- and 12-month follow-up

Variables	Pre-test (*n*= 8)	Post-test (*n*= 8)	6 MFU (*n*= 7)	12 MFU (*n*= 6)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)
GAF (AXIS V)	47.87 (6.17)	66.0 (8.73)	79.0 (15.85)	83.33 (15.05)
BDI	15.37 (11.86)	9.50 (8.21)	7.00 (6.58)	5.66 (6.31)
BAI	20.00 (10.12)	13.25 (11.20)	8.28 (10.85)	6.00 (8.04)
MI	14.37 (6.61)	9.12 (6.31)	6.28 (6.10)	3.5 (4.59)
LQI	6.53 (1.02)	6.20 (1.00)	6.92 (1.19)	7.5 (1.22)
PANAS				
Positive affect	23.37 (6.16)	26.37 (7.08)	30.42 (8.71)	31.33 (7.20)
Negative affect	18.37 (5.95)	17.62 (3.50)	16.42 (3.4)	14.00 (5.01)
NEO-FFI				
Neuroticism	22.38 (8.56)	23.75 (7.32)	20.42 (8.61)	15.5 (4.96)
Extraversion	31.50 (4.14)	30.75 (4.26)	34.00 (5.71)	33.33 (3.07)
Openness	24.50 (9.54)	25.00 (8.26)	25.71 (6.87)	25.16 (7.80)
Agreeableness	35.63 (2.06)	32.75 (3.80)	33.85 (3.84)	32.83 (3.31)
Responsibility	30.38 (6.63)	29.75 (6.64)	30.28 (5.43)	29.33 (7.94)
ODSIS	5.00 (3.85)	3.12 (4.12)	2.71 (5.31)	1.00 (2.44)
OASIS	8.25 (3.05)	6.37 (3.73)	2.57 (1.98)	1.83 (2.63)

Note: GAF= Global Assessment Functioning Scale-Axis V of DSM-IV-TR; BDI= Beck Depression Inventory; BAI= Beck Anxiety Inventory; MI= Maladjustment Inventory; LQI= Life Quality Index; PANAS= Positive and Negative Affect Schedule; NEO-FFI= NEO-Five Factor Inventory; ODSIS= Overall Depression Severity and Impairment Scale; OASIS= Overall Anxiety Severity and Impairment Scale; MFU= month follow-up.

The comparison between pretreatment and the 12-month follow-up revealed significant differences in the primary outcome measures and in most secondary outcome measures, reaching large effect sizes (from ≥ .8 to ≥ 1.20), with the exception of the NEO-FFI personality dimensions and quality of life. There were also significant differences in positive affect, with a large effect size, and negative affect, with a medium effect size.

Clinical significance: reliable change index (RCI)

Clinical significance was calculated for the primary outcomes, depression and anxiety (Table 6). The results comparing pre-treatment to the 12-month follow-up scores are very similar for both variables. Three of the participants can be

considered to be recovered (reaching functional scores), 2 improved but significant changes could not be observed because they already had low scores at pre-treatment. Finally, 1 improved significantly despite their scores still being closer to the dysfunctional level.

Table 5
Wilcoxon test results and effect size (Cohen's *d*)

Variables	Pre-Post	Post-6 MFU	Post-12 MFU	Pre-12 MFU
	Z (*d*)	*Z* (*d*)	*Z* (*d*)	*Z* (*d*)
GAF (AXIS V)	-2.52* (-2.46)	-1.78 (-.97)	-1,84 (-1.36)	-2.20* (-3.08)
BDI	-2.11* (0.57)	-2.20* (.33)	-1.37 (.08)	-2.20* (1.02)
BAI	-2.20* (0.63)	-2.20* (.45)	-2.22* (.74)	-2.21* (1.53)
MI	-1.68 (0.81)	-2.23* (.45)	-1.99* (1.01)	-2.20* (1.91)
LQI	-.33 (0.32)	-1.77 (-.65)	-1.99* (-1.16)	-1.57 (-.86)
PANAS				
Positive affect	-1.54 (-.45)	-1.35 (-.51)	-1.75 (-.69)	-1.99* (-1.18)
Negative affect	-.42 (.15)	-.95 (.34)	-1.48 (.83)	-2.03* (.79)
NEO-FFI				
Neuroticism	-.51 (.17)	-2.04* (.41)	-2.20* (1.31)	-1.68 (.98)
Extraversion	-.08 (.17)	-1.18 (-.64)	-.94 (-.69)	-1.08 (-.50)
Openness	-.16 (-.05)	-.67 (-.09)	-.21 (-.01)	-0,31 (-0,07)
Agreeableness	-2.20* (.94)	-.53 (-.28)	-.53 (-.02)	-1.62 (1.01)
Responsibility	-.69 (.09)	-2.00* (-.08)	-.31 (.05)	-.13 (.14)
ODSIS	-2.01* (.47)	-.73 (.08)	-1.34 (.62)	-2.04* (1.24)
OASIS	-2.28* (.55)	-2.20* (1.27)	-2.20* (1.40)	-2.20* (2.25)

Notes: GAF= Global Assessment Functioning Scale - Axis V of DSM-IV-TR; BDI= Beck Depression Inventory; BAI= Beck Anxiety Inventory; MI= Maladjustment Inventory; LQI= Life Quality Index; PANAS= Positive and Negative Affect Schedule; NEO-FFI= NEO-Five Factor Inventory; ODSIS= Overall Depression Severity and Impairment Scale; OASIS= Overall Anxiety Severity and Impairment Scale; MFU= month follow-up. *d*= Cohen's *d*. *p< .05; **p< .01; ***p< .001.

Satisfaction with and utility of the contents and format treatment

The UP in group format was rated by participants as a treatment of excellent quality. All participants rated the usefulness of the content and skills learned during the treatment as over 8 (score ranging from 0 to 10). Regarding the group format, 5 participants reported that they would choose a group format if they needed psychological help in the future.

At the 12-month follow-up, participants rated the extent to which the treatment helped them to regulate their emotions during the past 6 months on a scale ranging from 0 (*Not at all*) to 10 (*Very much so*). The mean score was 8.3. Regarding the perceived utility of each one of the main UP strategies, the participants reported that the strategy that helped them the least was interoceptive exposure (mean score of 4.3, on a 0-10 scale range), and the strategies that helped them the most (with a score over 8) were identifying and evaluating automatic appraisals and thinking traps, identifying emotion avoidance, and learning and performing alternative behaviors to emotion-driven behaviors.

Table 6
Clinical change in primary outcomes

	BDI						BAI					
n	Pre	12 MFU	State	Range	RCI	Interpretation	Pre	12 MFU	State	Range	RCI	Interpretation
1	24	7	Improvement	Non-Clinical	4.34	Reliable improvement-recovered	17	6	Improvement	Non-Clinical	2.85	Reliable improvement-recovered
2	25	17	Improvement	Clinical	2.04	Reliable improvement -not recovered	26	22	Improvement	Clinical	1.03 (No change)	No change within dysfunctionality
3	12	2	Improvement	Non-Clinical	2.55	Reliable improvement-recovered	7	3	Improvement	Non-Clinical	1.03 (No change)	No change within functionality
4	18	7	Improvement	Non-Clinical	2.82	Reliable improvement-recovered	21	1	Improvement	Non-Clinical	5.19	Reliable improvement-recovered
5	4	1	Improvement	Non-Clinical	.76 (No change)	No change within functionality	23	3	Improvement	Non-Clinical	5.19	Reliable improvement-recovered
6	6	0	Improvement	Non-Clinical	1.53 (No change)	No change within functionality	6	1	Improvement	Non-Clinical	1.3 (No change)	No change within functionality

Note: BDI= Beck Depression Inventory; BAI= Beck Anxiety Inventory; RCI= reliable change index; Pre= Pretest; 12 MFU= 12-month follow-up.

Discussion

This is the first study showing preliminary effectiveness with data at 12-month follow-up of the application of the UP in group format, as well as its feasibility in a public mental health setting. These findings show that the UP in group format was effective in the treatment of ED at short- and long-term.

Clinical improvement was obtained in different variables. First, all the participants who completed the 12-month follow-up (n=6) no longer met diagnostic criteria for a mental disorder. The study of Bullis et al. (2015) did not present the effects on diagnostic criteria of the 11 participants that were treated with the UP in a small group format. The study by Farchione et al. (2012), which tested the efficacy of the UP in individual format and included a 6-month follow-up assessment, reported outcomes similar to ours (71% of the participants no longer met criteria for the primary diagnosis).

Second, a significant improvement was obtained in primary and secondary outcomes. After the administration of the group UP, the participants experienced a significant decrease in anxiety and depression symptomatology that was maintained and that decreased even more at the follow-up assessments. These findings have also been found in the comparison from pretest and posttest in the administration of the UP in group format (Bullis et al., 2015) and in individual format (Ellard et al., 2010; Farchione et al., 2012).

With regard to global functioning, we underline that there was a large discrepancy between the GAF rating at pretest and the scores on self-reported measures. The clinicians considered serious symptoms such as suicidal ideation, severe obsessive rituals, difficulties maintaining a job, and the important social life limitation in some of the patients. The clinicians also point out the long-term on medication treatments (ranging from 1 to 23 years) of most of the patients as an essential variable that could affect this discrepancy. Some of the patients had adapted to their serious symptoms over time and did not reflect their impairment in the self-reported measures. Despite this, the scores in general functioning and quality of life also improved significantly, although the changes occurred later, at the follow-up assessments. In Bullis et al.'s (2015) study, after treatment, only one of the nine patients with impairment or severe impairment in overall life enjoyment and satisfaction continued to report severe impairment.

Positive and negative affect as measured by the PANAS achieved significant changes only at the 12-month follow-up. These findings suggest that, once anxiety and depressive symptoms decrease, the assimilation and practice of the strategies learnt to regulate emotions over time have an impact on more general processes associated with quality of life and general functioning. Improvement in quality of life after administration of the UP has also been reported by Gallagher et al. (2013).

These results regarding statistical differences were reinforced by the analyses conducted to explore clinical improvement in the primary outcome measures by means of the Reliable Change Index. The majority of the participants achieved scores close to normality in depression (BDI) and anxiety (BAI). We highlight that the training in emotion regulation within the UP produced not only a decrement in

negative affect at the 12-month follow-up, but also a significant increase in positive affect. Similar results have been reported in other studies in individual format (regarding negative affect in Ellard et al. 2010; Sauer-Zavala et al., 2012; and regarding positive affect in Farchione et al., 2012). The preliminary data of this study show that, despite including techniques mainly addressing negative affect/neuroticism (Barlow et al., 2013), the UP can also modify positive affect. We underline that the use of skills to regulate emotions adaptively not only allows decreasing the frequency and intensity of negative emotions, but also leads to increasing the frequency and intensity of positive affect.

In this regard, the scores in the personality dimension neuroticism decreased at the 6- and 12-month follow-ups. Although significant differences were not found from pretest to the 12-month follow-up, the scores show a progressive decrement in this variable. The same occurred with extraversion scores: although significant differences were not found from pretest to the 12-month follow-up, the scores tend to increase over time. These results are in line with those of Carl, Gallagher, Sauer-Zavala, Bentley, and Barlow (2014), who concluded that the treatment with the UP facilitates improvement in neuroticism and extraversion temperaments, with more stable change shown in neuroticism. We agree with these authors' statement that maybe a greater number of sessions are needed in order to produce durable changes in temperament.

The UP in group format seems to have an influence on the personality dimension most closely associated with ED, that is, neuroticism. The rest of personality dimensions did not show important changes at the 12-month follow-up. This finding supports the idea that the UP, as Barlow proposes (Barlow et al., 2013), is specific to modify the personality dimension neuroticism. Our findings indicate the importance of incorporating the personality assessment in research studies to gather evidence that supports the idea that the UP can modify neuroticism and also extraversion and maintain this effect over time.

In this study, some participants with depressive symptoms did not perceive the interoceptive exercises to be as helpful as cognitive reappraisal, and some of the participants with prior anxiety symptoms said they could not feel similar physical sensations to those they fear in "real" life. These facts may have affected the low perceived utility scores. In spite of this, we agree with the recommendation of Barlow´s team to carry out the interoceptive exercises in order to facilitate greater awareness of physical sensations (Barlow, Farchione, et al., 2011).

The findings obtained in this pilot study show the feasibility of including this intervention in the services offered by the public mental health system. In this sense, these promising results encourage us to conduct a multicenter randomized clinical trial in public health settings to demonstrate, on the one hand, the efficacy of the UP in group format for the transdiagnostic treatment of ED and, on the other hand, to show that group interventions could help to improve cost-benefit in contexts with very limited resources, such as the public mental health systems. Feasibility and efficiency are important variables in the dissemination of psychological treatments in order to reach a higher number of individuals who could benefit from EBT.

This study has some limitations that deserve to be mentioned. Regarding the assessment protocol, we did not include specific instruments for specific disorders, such as the Panic Disorder Severity Scale (PDSS; Houck, Spiegel, Shear, & Rucci, 2002) for panic disorder. Regarding the treatment, we considered 10 sessions to be suitable for the application of the UP in the specific context where we applied it, a public mental health unit. It is important to administer EBTs in the least possible time without losing efficacy in contexts with scarce resources in order to achieve better dissemination. After this experience, it will be possible to explore this issue in future studies, given that some components, such as emotional awareness, cognitive reappraisal, and emotional exposure, could have benefited from a longer time interval. In this regard, extending the time interval between sessions and also adding some more sessions to the protocol, like Bullis et al. (2015), may help to increase practice of these specific elements and to resolve any problem that may arise during the practice at home. The study is an effectiveness and feasibility study using a small sample and with no comparison with a control condition. It would have been better to include a large sample in order to reinforce the promising findings we found. Another limitation is that most participants were women. Also, the measure of general functioning was conducted by the clinicians and not by independent assessors. In summary, it is important to replicate these findings with larger samples and to conduct randomized clinical trials.

This study shows promising data about the efficacy and feasibility of delivering the UP in a public mental health setting. These preliminary data encourage us to conduct a clinical trial to establish the efficacy and effectiveness of the UP in group format.

References

American Psychiatric Association (1994). *Diagnostic and statistical manual of mental disorders* (4th ed.) DSM-IV. Washington, DC: Author.

American Psychiatric Association (2000). *Diagnostic and statistical manual of mental disorders* (4th ed., text rev.) DSM-IV-TR. Washington, DC: Author.

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., Farchione, T. J., Fairholme, C. P., Ellard, K. K., Boisseau, C. L., Allen, L. B., & Ehrenreich-May, J. (2015). *Protocolo unificado para el tratamiento transdiagnóstico de los trastornos emocionales: Manual del terapeuta y manual del paciente* [The unified protocol for transdiagnostic treatment of emotional disorders: Client workbook and Therapist guide]. Madrid: Alianza Editorial. (Orig., 2011).

Barlow, D. H., Sauer-Zavala, S., Carl, J. R., Bullis, J. R., & Ellard, K. K. (2013). The nature, diagnosis, and treatment of neuroticism: Back to the future. *Clinical Psychological Science, 2*, *344-365*.

Beck, A. T., & Steer, R. (1993). *Beck Anxiety Inventory manual*. San Antonio, TX: Psychological Corporation.

Beck, A. T., Steer, R. A., & Brown, G. K. (1996). *Manual for the Beck Depression Inventory-II*. San Antonio, TX: Psychological Corporation.

Bentley, K. H., Gallagher, M. W., Carl, J. R., & Barlow, H. D. (2014). Development and Validation of the Overall Depression Severity and Impairment Scale. *Psychological Assessment, 26*, 815-830.

Boisseau, C. L., Farchione, T., Fairholme, C. P., Ellard, K. E., & Barlow, D. H. (2010). The development of the unified protocol for the transdiagnostic treatment of emotional disorders: A case study. *Cognitive and Behavioral Practice, 17*, 102-113.

Botella, C. y Ballester, R. (1997). *Trastorno de pánico, evaluación y tratamiento* [Panic disorder, assessment and treatment]. Barcelona: Martínez Roca.

Bullis, J. R., Fortune, M. R., Farchione, T. J., & Barlow, D. H. (2014). A preliminary investigation of the long-term outcome of the unified protocol for transdiagnostic treatment of emotional disorders. *Comprehensive Psychiatry,* 55, 1920-1927.

Bullis, J. R., Sauer-Zavala, S., Bentley, K. H., Thompson-Hollands, J., Carl, J. R., & Barlow, D. H. (2015). The unified protocol for transdiagnostic treatment of emotional disorders: Preliminary exploration of effectiveness for group delivery. *Behavior Modification, 39*, 295-321.

Brown, T. A., Antony, M. M., & Barlow, D. H. (1995). Diagnostic comorbidity in panic disorder: Effect on treatment outcome and course of comorbid diagnoses following treatment. *Journal of Consulting and Clinical Psychology, 63*, 408-418.

Brown, T. A., & Barlow, D. H. (2009). A proposal for a dimensional classification system based on the shared features of the DSM-IV anxiety and mood disorders: Implications for assessment and treatment. *Psychological Assessment*, *21*, 256-271.

Brown, T. A., Di Nardo, P. A., & Barlow, D. H. (1994). *Anxiety Disorder Interview Schedule for DSM-IV (ADIS-IV). Adult and Lifetime version. Clinical Manual*. San Antonio, TX: Psychological Corporation.

Carl, J. R., Gallagher, M. W., Sauer-Zavala, S. E., Bentley, K. H., & Barlow, D. H. (2014). A preliminary investigation of the effects of the unified protocol on temperament. *Comprehensive Psychiatry, 55*, 1426-1434.

Clark, D. A. (2009). Cognitive behavioral therapy for anxiety and depression: Possibilities and limitations of a transdiagnostic perspective. *Cognitive Behaviour Therapy*, *38,* 29-34.

Costa, P. T., & McCrae, R. R (1999). *Revised NEO Personality Inventory (NEO-PI-R) and NEO Five-Factor Inventory (NEO-FFI).* Madrid: TEA.

de Ornelas, A. C., Azevedo, A., Aparecida, C., Egidio, A., & Cardoso, A. (2013). Transdiagnostic treatment using a unified protocol: Application for patients with a range of comorbid mood and anxiety disorders. *Trends in Psychiatry and Psychotherapy, 35*, 134-140.

de Ornelas, A. C., Egidio, A., & Cardoso, A. (2015). The utilization of unified protocols in behavioral cognitive therapy in transdiagnostic group subjects: A clinical trial. *Journal of Affective Disorders, 172*, 179-183.

Dear, B. F., Titov, N., Schwencke, G., Andrews, G., Johnston, L., Craske, M. G., & McEvoy, P. (2011). An open trial of a brief transdiagnostic internet treatment for anxiety and depression. *Behavioral Research and Therapy, 49*, 830-837.

Dozois, D. J. A., Mikail, S. F., Alden, L. E., Bieling, P. J., Bourgon, G., Clark, D. A, Drapeau, M., Gallson, D., Greenberg, L., Hunsley, J., & Johnston, C. (2014). The CPA Presidential Task Force on evidence-based practice of psychological treatments. *Canadian Psychology, 55*, 153-160.

Eaton W. W., Martins, S. S., Nestadt, G., Joseph Bienvenu, O., Clarke, D., & Alexandre, P. (2008). The burden of mental disorders. *Epidemiologic Reviews, 30*, 1-14.

Echeburúa, E., Corral, P., & Fernández-Montalvo, J. (2000). Maladjustment Inventory (MI): Psychometric properties in clinical contexts. *Análisis y Modificación de Conducta*, *26*, 325-340.

Ellard, K. K., Fairholme, C. P., Boisseau, C. L., Farchione, T., & 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.

Farchione, T. J., Fairholme, C. P., Ellard, K. K., Boisseau, C. L., Thompson-Hollands, J., Carl J. R., Gallagher, M. W., & Barlow, D. H. (2012). The Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders: A randomized controlled trial. *Behavior Therapy*, *3*, 666-678.

Gallagher, M. W., Sauer-Zavala, S. E., Boswell, J. F, Carl, J. R., Farchione, T. J., & Barlow, D. H. (2013). The impact of the unified protocol for emotional disorders on quality of life. *International Journal of Cognitive Therapy, 6*, 57-72.

Houck, P. R., Spiegel, D. A., Shear, M. K., & Rucci, P. (2002). Reliability of the self-report version of the Panic Disorder Severity Scale. *Depression and Anxiety*, *15*, 183-185.

IBM Corp. Released (2012). IBM SPSS Statistics for Windows (Version 21.0) [software computer]. Armonk, NY: IBM Corp.

Magán, I., Sanz, J., & García-Vera, M. P. (2008). Psychometric properties of a Spanish version of the Beck Anxiety Inventory (BAI) in general population. *The Spanish Journal of Psychology*, *11*, 626-640.

Mezzich, J. E., Ruipérez, M. A., Pérez, C., Yoon, G., Liu, J., & Mahmud, S. (2000). The Spanish version of the Quality Of Life Index: Presentation and validation. *The Journal of Nervous and Mental Disease*, *188*, 301-305.

Norman, S. B., Cissell, S., Means-Christensen, A. J., & Stein, M. B. (2006). Development and validation of an Overall Anxiety Severity and Impairment Scale (OASIS). *Depression and Anxiety*, *23*, 245-249.

Norton, P. J. (2012). *Group-cognitive-behavioral therapy of anxiety: A transdiagnostic treatment manual*. New York, NY: Guilford.

Sandín, B., Chorot, P., Lostao, L., Joiner, T. E., Santed, M. A., & Valiente, R. M. (1999). PANAS Positive and Negative Affect Schedule: Factorial validation and transcultural convergence. *Psicothema*, *11*, 37-51.

Sanz, J., Perdigón, A. L., & Vázquez, C. (2003). The Spanish adaptation of the Beck's Depression Inventory-II (BDI-II): 2. Psychometric properties in the general population. *Clínica y Salud, 14*, 249-280.

Sauer-Zavala, S., Boswell, J. F., Gallagher, M. W., Bentley, K. H., Ametaj, A., & Barlow, D. H. (2012). The role of negative affectivity and negative reactivity to emotions in predicting outcomes in the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders. *Behaviour Research and Therapy*, *50*, 551-557.

Söderberg, P., & Tungström, S. (2007). *Outcome in psychiatric outpatient services. Reliability, validity and outcome based on routine assessments with the GAF scale* (Doctoral dissertation, Umeå University, Sweden). Retrieved from: http://www.diva-portal.org/smash/get/diva2:145230/FULLTEXT01.pdf

Suárez, L., Bennett, S., Goldstein, C., & Barlow, D. H. (2009). Understanding anxiety disorders from a "triple vulnerabilities" framework. In M. M. Antony, & M. B. Stein (Eds.), *Oxford handbook of anxiety and related disorders* (pp. 153-172). New York, NY: Oxford.

Watson, D., Clark, L. A., & Tellegen, A. (1988). Development and validation of brief measures of positive and negative affect: The PANAS scales. *Journal of Personality and Social Psychology*, *54*, 1063-1070.

Wilamowska, Z. A., Thompson-Hollands, J., Fairholme, C. P., Ellard, K. K., Farchione, T. J., & Barlow, D. H. (2010). Conceptual background, development, and preliminary data from the unified protocol for transdiagnostic treatment of emotional disorders. *Depression and Anxiety, 27,* 882-890.

RECEIVED: December 9, 2014
ACCEPTED: March 2, 2015