Article

Unified Protocol in a Group Format for Improving Specific Symptoms of Emotional Disorders in the Spanish Public Health System

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Abstract

Background: The Unified Protocol (UP) for the transdiagnostic treatment of emotional disorders (EDs) has demonstrated its efficacy in improving dimensions shared by EDs, but there is insufficient evidence regarding the specific symptoms of each ED. The main objective of the study was to evaluate the efficacy of the UP applied in a group format compared with individual Treatment as Usual (TAU), in improving specific ED symptoms. **Methods:** The study sample (n=243) was a subset of participants of a randomized controlled trial conducted in the Spanish public health system. Specific symptoms assessed from pre-treatment to the six-month follow-up were: depressive, agoraphobic, generalized anxiety, panic, and obsessive-compulsive symptoms. Personality dimensions and quality of life were also measured. **Results:** There were statistically significant changes after the UP in all the study variables ($0.44 = d = 1.35$). Changes in depressive symptoms, obsessive-compulsive disorder, and perceived quality of life were superior in the UP. **Conclusions:** The results support the efficacy of group UP for improving both transdiagnostic dimensions and specific ED symptoms, as well as quality of life, through the public health-care system.

Keywords: Unified protocol, group format, transdiagnostic, emotional disorders, randomized controlled trial.

Resumen

Protocolo Unificado en Formato Grupal Para la Mejora de los Síntomas de los Trastornos Emocionales en el Sistema de Salud Público Español. **Antecedentes:** el Protocolo Unificado (PU) para el tratamiento transdiagnóstico de los trastornos emocionales (TEs) ha demostrado eficacia en la mejora de las dimensiones compartidas por los TEs, pero no hay suficiente evidencia respecto a los síntomas específicos de cada uno de los TEs. El objetivo principal de este estudio fue evaluar la eficacia del PU aplicado en formato grupal, en comparación con un Tratamiento Habitual (TH) individual, para mejorar los síntomas específicos de los TEs. **Método:** la muestra del estudio (n=243) fueron un subgrupo de participantes de un ensayo controlado aleatorizado en el sistema de salud público español. Los síntomas evaluados antes y hasta los 6 meses de seguimiento fueron: depresión, agorafobia, ansiedad generalizada, pánico y obsesivo-compulsivo. También se midieron dimensiones de la personalidad y la calidad de vida. **Resultados:** se produjeron cambios estadísticamente significativos tras el PU en todas las variables ($0.44 = d = 1.35$). Los cambios en síntomas de depresión, trastorno obsesivo-compulsivo y calidad de vida fueron superiores en el PU. **Conclusiones:** los resultados apoyan la eficacia del PU en grupo para mejorar tanto las dimensiones transdiagnósticas, como los síntomas específicos de los TEs, así como la calidad de vida en nuestro sistema público de salud.

Palabras clave: protocolo unificado, formato grupal, transdiagnóstico, trastornos emocionales, estudio controlado aleatorizado.

Emotional disorders (EDs), consisting of depressive and anxiety disorders and related disorders, are the most prevalent psychiatric disorders worldwide (World Health Organization [WHO], 2017) and people with EDs are the most common patients seeking treatment in the public health system in Spain (Navarro-Mateu et al., 2015). Furthermore, EDs are also commonly related to functional impairment and high socio-economic costs (WHO, 2017).

EDs have traditionally been conceptualized as relatively independent diagnostic syndromes (American Psychiatric

Association [APA], 2013). However, symptoms' overlapping (e.g., difficulties concentrating in depression, generalized anxiety disorder or posttraumatic stress disorder; presence of panic attacks in any ED) and high rates of comorbidity between EDs (Brown et al., 2001) have suggested the presence of shared mechanisms that may contribute to the development and maintenance of EDs (Wilamowska et al., 2010). Specifically, psychopathology research has shown evidence of two genetically based, temperamental dimensions of personality (neuroticism and extraversion) that can account for the etiology, course, and maintenance of the full range of EDs (Brown & Barlow, 2009).

Cognitive Behavioral Treatments (CBT) have generally focused on treating diagnosis-specific symptoms by helping patients cope with emotions associated with specific situations related to a single disorder (Barlow et al., 2018). Although CBT interventions have demonstrated efficacy for specific EDs (Barlow et al., 2007), they

also present several limitations (e.g., some patients do not respond well to CBT, manualized treatments for each disorder complicate treatment delivery, etc., see Wilamowska et al., 2010). Instead of focusing on every single disorder, transdiagnostic approaches are considered a unique treatment to address the common traits shared by all these disorders (Norton, 2012). For instance, the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al., 2018) is a transdiagnostic, cognitive-behavioral intervention that targets temperamental characteristics underlying all EDs by more explicitly focusing on the interaction of thoughts, feelings, and behaviors in generating internal emotional experiences, and the subsequent role of emotion dysregulation in modifying these experiences (Ellard et al., 2010).

Past research has generally focused on evaluating the effect of the UP in transdiagnostic outcomes (Cassiello-Robbins et al., 2020). However, recent research has highlighted the importance of assessing the impact of transdiagnostic interventions on specific symptoms of EDs to explore whether they can also perform as well as disorder-specific interventions when it comes to specific symptoms (Kristjánsdóttir et al., 2019). The UP had shown preliminary efficacy to improve specific symptoms of single anxiety disorders as well as major depressive disorder (e.g., Ellard et al., 2010; Farchione et al., 2012). A recent review also reported that both individual and group delivery formats of the UP tended to lead to improvements in the targeted symptoms, suggesting the feasibility of adapting the UP to different numbers of populations (Cassiello-Robbins et al., 2020).

Concerning UP derived individually, in a randomized clinical trial (RCT; n=223) comparing UP to gold-standard, single-disorder evidence-based protocols (SDPs) for anxiety disorders, no differences were found between the transdiagnostic UP intervention and the SDPs in symptom reduction of the principal diagnosis after treatment (Barlow et al., 2017) and at the 12-month follow-up (Eustis et al., 2020). However, participants' attrition in the UP group was superior after treatment (Barlow et al., 2017). A secondary study by the same team selected a subset of patients with depressive disorders (n=44) from a larger RCT. Participants in the UP condition showed significantly lower levels of depression than a waiting-list condition at post-treatment and the 12-month follow-up, but no differences were found between the UP and SDPs interventions (Sauer-Zavala et al., 2020).

Regarding the effectiveness of UP delivered in group, few but promising results have been found. A multicenter RCT is being conducted in the Spanish public health system to demonstrate the cost-effectiveness of UP in a group format (Osma et al., 2018). UP in group format is being compared to a Treatment as Usual (TAU) in a non-inferiority design. Preliminary results of this study showed moderate to large effect sizes in reducing depression and anxiety as well as in personality dimensions after the UP intervention and at the 3-month follow-up in a community sample (n=157) with EDs (Osma, Peris-Baquero, Suso-Ribera, Sauer-Zavala et al., 2021). A more recent study (n=488) showed a larger effect of the UP (vs. TAU) on the general symptoms and quality of life at the 6-month follow-up (Osma, Peris-Baquero, Suso-Ribera, Farchione et al., 2021). Finally, another work evaluated the UP in a group format compared to diagnosis-specific CBT in a non-inferiority RCT for patients with ED (n=291). The findings confirmed that the UP was not inferior to CBT in reducing symptoms overtime, thus suggesting that the UP would be acceptable for its implementation in similar clinical settings (Reinholt et al., 2021).

Several other studies have found promising outcomes for improving general transdiagnostic symptoms of EDs after the UP in a group format (e.g., Grill et al., 2017; Laposa et al., 2017; Ornelas-Maia et al., 2015; Osma, Peris-Baquero, Suso-Ribera, Sauer-Zavala, et al., 2021; Reinholt et al., 2017). Recent results of the UP in group format have also evidenced promising results for diagnosis-specific symptoms (Reinholt et al., 2021). To our knowledge, however, no published studies have evaluated the effectiveness of the UP in a group format, compared to a TAU carried out under the conditions of clinical practice, to address diagnosis-specific symptoms in Spanish patients with EDs. Therefore, the main aim of this research was to evaluate the effectiveness of UP in a group format compared with the treatment delivered in the routine practice, i.e. TAU (individual non-structured CBT), to improve specific symptoms of several ED diagnoses: depression, generalized anxiety disorder, panic disorder, agoraphobia, and obsessive-compulsive disorder. A secondary aim was to assess two transdiagnostic personality dimensions (neuroticism and extraversion) and quality of life to confirm if the UP would also improve general symptoms. Considering the non-inferiority design of the RCT, and the previous evidence of the UP versus single-diagnosis protocols for EDs, we hypothesized that UP would be as effective as the TAU in decreasing symptoms of depression, generalized anxiety, panic, agoraphobia, and obsessive-compulsive disorders, as well as improving the transdiagnostic personality dimensions and perceived quality of life. Cost-effectiveness and clinical implications of using UP in a group format are also discussed.

Method

Participants

Participants in the present study were selected from different public mental health centers of the Spanish public system. The sample consists of a subset of participants from an ongoing RCT (for more details, see the published study protocol, Osma et al., 2018). The sample was composed of 243 participants with a primary diagnosis of an ED. Patients were either allocated to the UP (n=131) or the TAU (n=112) conditions. The flowchart of participant enrollment can be seen in Figure 1.

Mean age of the participants in the UP group was 43.14 years (Range: 18-70; SD=12.46) and 82.4% (n=108) of them were women. In the TAU condition, the mean age was 43.09 years (Range: 18-77; SD=13.16) and 75.9% (n=85) were also women. The sociodemographic information of the sample is reported in Table 1. The chi-square did not reveal statistically significant within-group differences in gender ($\chi^2(1) = .98$, $p = .323$), and MANOVA found no differences in age ($F = 0.00$, $p = .976$).

Principal and comorbid ED diagnosis can be found in Table 2. There were no between group differences in the principal diagnoses ($\chi^2(12) = 17.16$, $p = .144$).

Instruments

The diagnostic interview and primary and secondary outcome measures used in the study are reported in Table 3.

Procedure

The design was a non-inferiority two-group multicenter RCT conducted in a naturalistic setting, the Spanish national public health

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                          │  Assessed for eligibility (n = 246) │
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     │    Enrollment      │                ├─────────▶│ Excluded                               │
     └───────────────────┘                │          │  □  Not meeting inclusion criteria (n = 3) │
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                          │      Randomized (n = 243)         │
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Allocated to UP intervention (n = 131)	Allocated to TAU intervention (n = 112)
– Dropped out in the initial stages of treatment (n = 30) – Dropout before starting treatment (n = 14) Received allocated intervention (n = 87)	– Dropped out in the initial stages of treatment (n = 12) – Dropout before starting treatment (n = 19) Received allocated intervention (n = 81)

3-Month Follow-Up

Lost to follow-up (n = 8) Continued research (n = 79)	Lost to follow-up (n = 13) Continued intervention (n = 68)

6-Month Follow-Up

Lost to follow-up (n = 15) Continued research (n = 64)	Lost to follow-up (n = 22) Continued intervention (n = 46)

Dropout reasons: No reply or not answering the phone: *n* = 16 (12.03%); Incompatibility with work schedules: *n* = 6 (4.5 %); Improvement in symptomatology (without medical discharge) *n* = 4 (3.01%); Medical discharge for Health problems: *n* = 3 (2.26%); Asked for private treatment: *n* = 3 (2.26%); No data available: *n*=101 (75.94%)
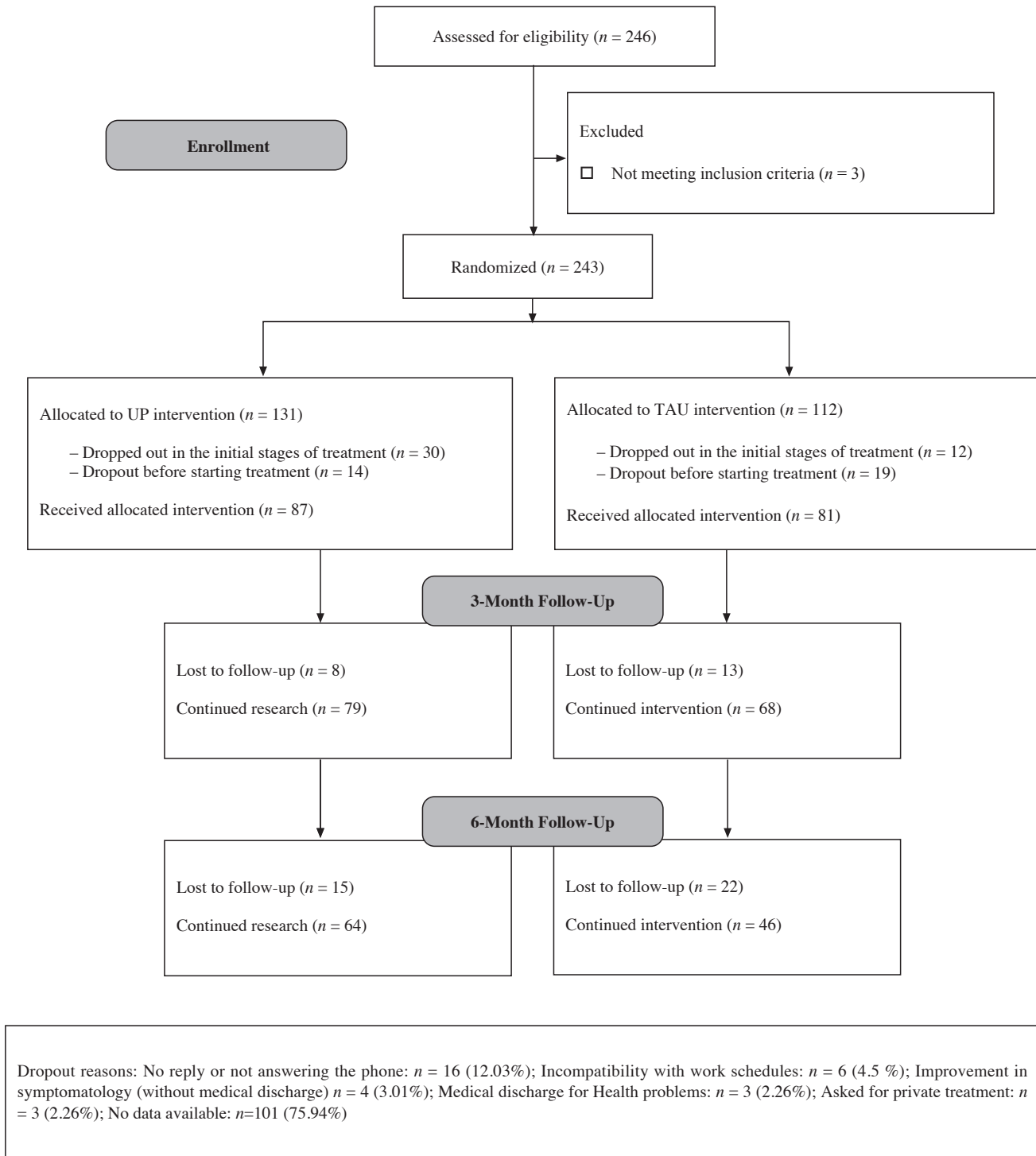
Figure 1. Flow chart showing distribution of participants at each time point

system. Secondary outcomes of the RCT were used for this study. Patients seeking treatment were referred to the study by licensed clinical psychologists, psychiatrists, and clinical psychology residents working at the different mental health units of the public health system. Participants meeting eligibility criteria (for more details, see the study protocol in Osma et al., 2018) were asked to voluntarily participate in the study and were provided with an information sheet and an informed consent form. After participation acceptance, they completed a baseline assessment protocol that consisted of a battery of questionnaires to evaluate, depending on participant's diagnosis, specific symptoms of each ED as well as personality dimensions and quality of life. Next, participants were randomly assigned in each collaborating center, using a computer-generated sequence (Randomizer), to receive one of the two following conditions:

Table 1
Socio-demographic characteristics of participants (n = 243)

	UP (n = 131)	TAU (n = 112)	Total (n = 243)
	n (%)	n (%)	n (%)
Educational level			
Less than 12 years of education received	56 (42.7)	47 (42.0)	103 (42.4)
Secondary studies	28 (21.4)	22 (19.6)	50 (20.6)
Primary studies	25 (19.1)	23 (20.5)	48 (19.8)
No studies	3 (2.3)	2 (1.8)	5 (2.1)
More than 12 years of education received	75 (57.3)	65 (58.0)	140 (58.6)
Vocational training	29 (22.1)	27 (24.1)	56 (23.0)
University studies	33 (25.2)	23 (20.5)	56 (23.0)
High school	13 (9.9)	15 (13.4)	28 (11.5)
Marital status			
Married/living w partner	73 (55.7)	56 (50.0)	129 (53.1)
Not Married/not living w partner	58 (44.3)	56 (50.0)	114 (46.9)
Single	33 (25.2)	36 (32.1)	69 (28.4)
Separated/ Divorced	19 (14.5)	16 (14.3)	35 (14.4)
Widowed	6 (4.6)	4 (3.6)	10 (4.1)
Job status			
Working	47 (35.9)	47 (42.0)	94 (38.7)
Not-working	84 (64.1)	65 (58.0)	149 (61.3)
Unemployed	29 (22.1)	24 (21.4)	53 (21.8)
Sick leave	22 (16.8)	27 (24.1)	49 (20.2)
Home-maker	15 (11.5)	4 (3.6)	19 (7.8)
Student	11 (8.4)	6 (5.4)	17 (7.0)
Retiree	7 (5.3)	4 (3.6)	11 (4.5)

Note: UP: Unified Protocol; TAU: Treatment as usual

Table 2
Primary and secondary diagnoses of participants (N=243)

	UP (n = 131)	TAU (n = 112)	Total (n = 243)
	n (%)	n (%)	n (%)
Primary diagnosis			
Anxiety disorders	72 (55.0)	59 (52.7)	131 (54.0)
Generalized anxiety disorder	20 (15.3)	18 (16.1)	38 (15.6)
Panic disorder with agoraphobia	22 (16.8)	12 (10.7)	34 (14.0)
Panic disorder without agoraphobia	9 (6.9)	13 (11.6)	22 (9.1)
Obsessive-compulsive disorder	7 (5.3)	7 (6.3)	14 (5.8)
Agoraphobia	11 (8.4)	2 (1.8)	13 (5.3)
Non-specific anxiety disorder	1 (0.8)	3 (2.7)	4 (1.6)
Posttraumatic stress disorder	–	2 (1.8)	2 (0.8)
Hypochondria	2 (1.5)	–	2 (0.8)
Social phobia	–	2 (1.8)	2 (0.8)
Mood disorders	57 (43.5)	51 (45.5)	108 (44.4)
Major depressive disorder	42 (32.1)	38 (33.9)	80 (32.9)
Dysthymia	15 (11.5)	12 (10.7)	27 (11.1)
Unspecified mood disorder	–	1 (1.2)	1 (.4)
Mixed disorders	2 (1.5)	2 (1.8)	4 (1.6)
Adjustment disorder	2 (1.5)	2 (1.8)	4 (1.6)
Secondary diagnosis			
Anxiety disorders	45 (34.3)	39 (34.8)	84 (34.5)
Non-specific anxiety disorder	36 (27.5)	22 (19.6)	58 (23.9)
Obsessive-compulsive disorder	11 (8.4)	11 (9.8)	22 (9.0)
Generalized anxiety disorder	5 (3.8)	3 (2.7)	8 (3.3)
Social phobia	7 (5.3)	1 (0.9)	8 (3.3)
Hypochondria	6 (4.6)	1 (0.9)	7 (2.9)
Panic disorder without agoraphobia	2 (1.5)	2 (1.8)	4 (1.6)
Panic disorder with agoraphobia	2 (1.5)	4 (3.6)	6 (2.5)
Posttraumatic stress disorder	2 (1.5)	–	2 (0.8)
Mood disorders	1 (0.8)	–	1 (0.4)
Major depressive disorder	7 (5.3)	12 (10.7)	19 (7.8)
Mixed disorders	7 (5.3)	12 (10.7)	19 (7.8)
Adjustment disorder	2 (1.5)	5 (4.5)	7 (2.9)
	2 (1.5)	5 (1.2)	7 (2.9)
Psychotropic medication			
Taking psychotropic medication	108 (82.4)	88 (78.6)	196 (80.3)
Not taking psychotropic medication	23 (17.6)	24 (21.4)	47 (19.3)

Note: UP: Unified Protocol; TAU: Treatment as usual

1) *UP intervention:* consisted of 8 modules of treatment of the first edition of the Spanish manual of the UP (Barlow et al., 2011), adapted to be implemented in a group format. The adaptation consisted of 12 two-hour treatment sessions, at a rate of one session per week. The intervention was applied for approximately 3 months. The treatment groups consisted of 8-10 participants, and the intervention was conducted by 2 clinicians (therapist and co-therapist) previously trained in UP and supervised by a UP certificate expert (Osma et al., 2018).

2) *TAU condition:* consisted of individual non-structured CBT with a variable number of sessions (average duration of the sessions was around 30 to 40 minutes; for more details, see Osma et al., 2018) determined by their therapist according to their clinical judgment, duration of specific treatment applied, and availability of care at the public health center. Therefore, participants in this condition received fewer sessions in the same time period in comparison with participants in the UP condition.

Three months after the pre-treatment assessment, and coinciding with the ending of the UP treatment, therapists again provided the participants of each treatment group with the same battery of post-treatment questionnaires. Additionally, instruments were also administered at the three- and six-month follow-ups. This research was approved by the ethical and research committees of all collaborating centers.

Data Analysis

Statistical analyses were carried out using SPPS version 22.0 statistical analysis software (IBM Corp., 2013). Firstly, characteristics of the sample were analyzed (*n*=243). Subsequently, pre-treatment differences in clinical and demographic characteristics of the two treatment samples were analyzed by multivariate analysis of variance (MANOVA) for continuous variables and chi-square test for categorical variables.

Next, a linear mixed model analysis was carried out, using compound symmetry as a covariance structure (AL-Marshadi, 2014) to analyze the main effects of time. Means, standard deviations, and effect sizes at each evaluation time were also included. Additionally, treatment condition and number of sessions were also included as main effects in this study to evaluate the influence of these variables on the results and to calculate the interaction effects between Treatment Condition*Time and Treatment Condition*Number of Sessions* Time.

Finally, post hoc analyses were performed based on the statistically significant results of the linear mixed model analyses.

Results

Between-group differences

The MANOVA indicated no statistically significant differences either in the primary or secondary outcomes when comparing the TAU and the UP at baseline (*p* > .05).

Table 3	
Assessment measures used in the study	
Instruments	**Construct and psychometrics**
Diagnosis	
• Anxiety Disorders Interview Schedule for DSM-IV-Lifetime Version (ADIS-IV-L; Di Nardo, Brown, & Barlow, 1994; Botella & Ballester, 1997)	• Semi-structured diagnostic clinical interview designed to assess anxiety, mood, somatoform, and substance use disorders • Test-retest reliability varies depending on the study from .68 to 1.00 (Brown et al., 2001)
Primary outcomes measures	
• Beck Depression Inventory (BDI-II; Beck et al., 1996; Sanz et al, 2003)	• Depressive symptom severity • Internal consistency of the Spanish version for clinical population was α =.89 (Sanz et al., 2003)
• Agoraphobia Inventory (IA; Echeburúa et al., 1992)	• Motor, psychophysiological, and cognitive dimensions of agoraphobia and the variability of responses according to factors that contribute to increase or reduce anxiety • Internal consistency varies from α =.87 (Cognitive subscale) to α =.94 (Psychophysiological subscale). Echeburúa et al. (1992)
• Panic Disorder Severity Scale (PDSS; Shear et al., 1997; Bulbena Vilarrasa et al., 2000)	• Clinical features and symptoms of panic disorder • The internal consistency of the Spanish validation was α = .65 (Bulbena Vilarrasa et al., 2000)
• Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990; Nuevo et al., 2002)	• General tendency to worry or worry-trait in the generalized anxiety disorder • The Cronbach's alpha coefficient of the Spanish validation was α = .95 (Nuevo et al., 2002)
• Yale-Brown Obsessive-Compulsive Scale (Y-BOCS; Bobes et al., 1996; Goodman et al.,1989; Vega-Dienstmaier et al., 2002).	• Obsession and compulsion severity of the obsessive-compulsive disorder • Internal consistency of the scale for the Spanish validation ranged from α = .87 to α = .94 (Vega-Dienstmaier et al., 2002)
Secondary outcomes measures	
• NEO Five-Factor Inventory (NEO-FFI; Costa & McCrae, 1999)	• Neuroticism (Neurotic temperament) and Extraversion (Positive temperament) • The internal consistency and factor structure of the Spanish version have been satisfactory (Costa & McCrae 1999)
• Quality of Life Index (QLI; Ferrans & Powers, 1985; Mezzich et al., 2000)	• Evaluates 10 dimensions related to the global perception of quality of life • The scale has an adequate test-retest reliability (r = .89; Mezzich et al., 2000)

Treatment doses

The average number of treatment sessions between the pre- and post-assessment was 9.99 (SD = 1.80, range= 6-12) in the UP group and 2.71 (SD = 1.30, range= 1-5) in the TAU condition. The average number of treatment sessions until the 6-month follow-up in the UP was 12.09 (SD = 2.11, range = 8-15), and 6.43 (SD = 2.68, range = 3-14) in TAU condition. In the UP-treatment condition, 13 participants received additional sessions in an individual format (M = 1.61 sessions, SD = 0.96, range = 1-4). The number of sessions received at each evaluation time can be seen in Figure 2.

Main effects of time through treatment conditions

The results of the main effect of time can be seen in Table 4. For the UP treatment, the results showed a main effect of time in all study outcomes: depression (BDI-II; "$F_{(240.34)}$ = 58.03, p < .001), agoraphobia (IA; $F_{(52.26)}$ = 10.72, p < .001), panic disorder (PDSS; $F_{(67.67)}$ = 18.94, p < .001), generalized anxiety disorder (PSWQ; $F_{(46.57)}$ = 4.84, p = .005), obsessive-compulsive disorder (Y-BOCS; $F_{(19.40)}$ = 8.59, p = .001), neuroticism (NEO-FFI; $F_{(241.87)}$ = 27.89, p < .001), extraversion (NEO-FFI; $F_{(238.86)}$ = 11.90, p < .001), and quality of life (QLI; $F_{(246.08)}$ = 32.54, p < .001).

Regarding the TAU condition, the results of the linear mixed model showed statistically significant effects of time on depression ($F_{(195.16)}$ = 16.18, p < .001), panic disorder ($F_{(5.91)}$ = 5.91, p = .002), neuroticism ($F_{(198.83)}$ = 5.24, p = .002), and quality of life ($F_{(204.32)}$

= 8.66, p < .001). The effects of time on the remaining variables were non-significant.

Main and interaction effects of treatment condition and number of sessions

The main and interaction effects of treatment condition and number of sessions can be seen in Table 5. A main effect of treatment condition was observed for depression ($F_{(591.19)}$ = 8.51, p = .004), obsessive-compulsive disorder ($F_{(44.06)}$ = 7.70, p = .008), and quality of life ($F_{(589.66)}$ = 7.55, p = .006). Post hoc analyses of the main effect of treatment condition showed statistically significant differences in favor of the UP for depression at post-treatment (F = 10.04, p = .002) and at the 3- and 6-month follow-ups (F = 7.81, p = .006 and F = 5.38, p = .022, respectively), at post-treatment for obsessive-compulsive disorder (F = 4.82, p = .042), and at post-treatment and the 6-month follow-up for quality of life (F = 8.35, p = .004 and F = 4.82, p = .030, respectively).

In terms of the main effect of number of sessions, the results showed a statistically significant main effect in agoraphobia ($F_{(94.19)}$ = 4.39, p = .039) and obsessive-compulsive disorder ($F_{(41.72)}$ = 10.14, p = .003). However, post hoc analyses did not find a statistically significant relationship regarding the number of sessions and these scores (all p > .05).

Finally, the interaction effects of Time*Condition showed a significant interaction for depression ($F_{(411.54)}$ = 3.79, p = .010), obsessive-compulsive disorder ($F_{(30.67)}$ = 3.23, p = .036), and
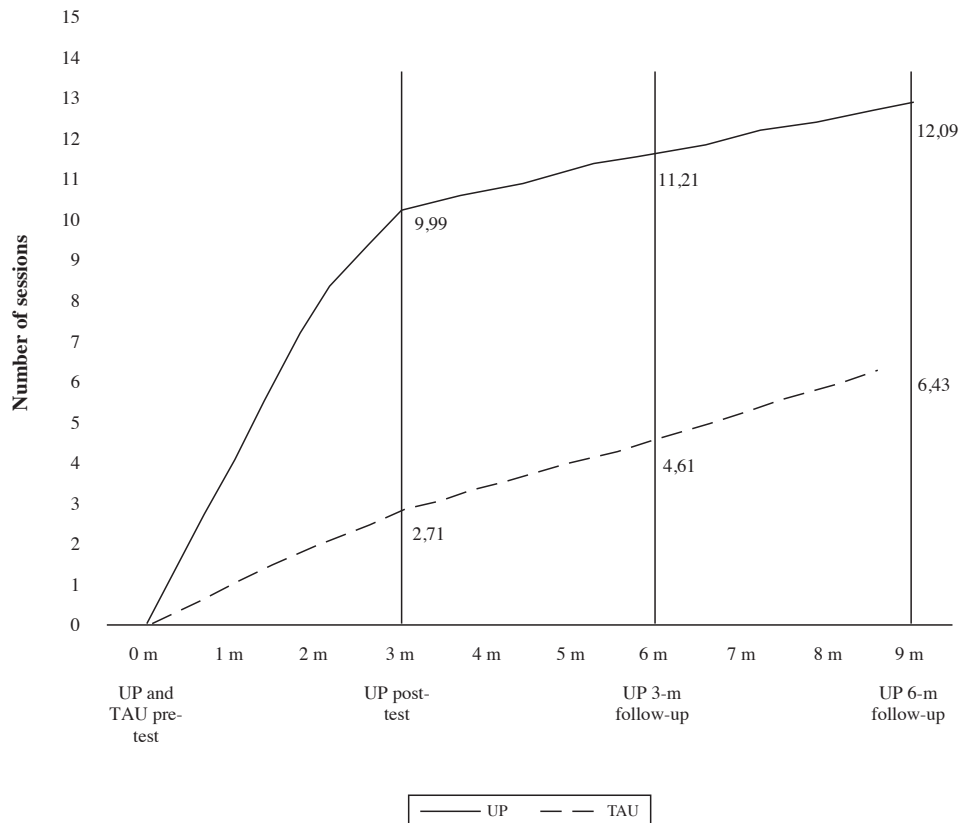
Figure 2. Distribution of the number of sessions over the course of treatment

quality of life ($F_{(441.86)}$ = 3.81, p = .010). The UP achieved larger improvements in depression, obsessive-compulsive disorder, and quality of life compared to the TAU condition. The results obtained in both conditions were comparable for the remaining variables. No interaction effect of Time*Condition*Sessions was found (p > .05).

Discussion

The main goal of this study was to evaluate the effectiveness of the UP, applied in a group format, as a transdiagnostic approach to address all the EDs together, compared to a non-structured CBT (TAU) focused on each single disorder, to improve diagnosis-specific symptoms of EDs in a naturalistic setting. Based on the non-inferiority design of the RCT, and the previous evidence of UP versus single-diagnosis protocols for EDs, we hypothesized that UP in a group format would obtain comparable results to the TAU in the decrease of symptoms of depression, generalized anxiety disorder, panic disorder, agoraphobia, and obsessive-compulsive disorder, as well as of neuroticism, and in the increase of extraversion and perceived quality of life.

Contrary to our hypotheses, results indicate statistically significant differences between the two interventions across time. The UP group showed a significant improvement in all the study variables from pre-treatment to the six-month follow-up, whereas participants who received the TAU intervention did not significantly improve symptoms of agoraphobia, generalized anxiety, or obsessive-compulsive symptoms. Effect sizes were also higher in the UP group. These findings are surprising, considering previous

studies comparing the UP in an individual and group format with active interventions, where no between-group differences were found (e.g., Barlow et al., 2017; Reinholt et al., 2021; Sauer-Zavala et al., 2020; Steele et al., 2018).

Concerning the between-group differences on the primary variables of the study (i.e., specific symptoms of EDs), the findings showed that the UP is statistically superior to the TAU group when reducing depression and obsessive-compulsive symptoms. These finding are promising given that depression and obsessive-compulsive disorders are considered complex and severe presentations of EDs (Eisen et al., 2010; Richards, 2011). According to the transdiagnostic perspective, the clinical symptoms in all EDs have the same etiology, that is, an inability in tolerating the intense discomfort of the patients (Ellard et al., 2010). Therefore, the UP focuses on emotion regulation as a major therapeutic goal (e.g., Joormann & Stanton, 2016), which is a component that is not usually included in diagnosis specific treatment protocols for these disorders. This emphasis in emotion regulation might explain, for example, why the UP in our study was superior to the TAU condition in improving some treatment outcomes, such as the severity of depressive and obsessive-compulsive symptoms and quality of life. The differences in effectiveness, however, may be also due to the greater intensity of the UP treatment (weekly sessions instead of sessions occurring every month and a half) and the characteristics of group therapy (e.g., sharing experiences with others). On the other hand, the fact that the UP does not show statistical superiority for the other anxiety disorders confirms our non-inferiority hypothesis and the results of previous studies (e.g., Barlow et al., 2017; Eustis et al., 2020; Sauer-Zavala et al., 2020).

Table 4
Main effects of the linear mixed models through treatment periods and treatment conditions (N = 243)

Dependent variable		Pre-T	Post-T	3-MFU	6-MFU	F	p	Cohen's d			
								Pre-to-post-T	Post-T to 3-MFU	3-MFU to 6-MFU	Pre-T to 6-MFU
		M (SD)	M (SD)	M (SD)	M (SD)						
BDI-II	UP	29.21 (12.10)	18.38 (12.21)	17.38 (12.47)	16.26 (13.03)	58.03	< .001	0.89	0.08	0.09	1.03
	TAU	29.92 (12.94)	24.68 (13.49)	23.90 (15.84)	21.97 (17.28)	16.64	< .001	0.40	0.05	0.12	0.52
IA	UP	247.12 (100.35)	189.55 (114.40)	147.74 (98.39)	149.73 (119.22)	10.72	< .001	0.53	0.39	-0.02	0.88
	TAU	215.89 (128.21)	209.22 (166.23)	200.00 (144.95)	159.28 (144.68)	2.49	.086	0.04	0.05	0.28	0.41
PDSS	UP	16.38 (5.75)	9.22 (7.69)	8.43 (6.51)	8.05 (6.52)	18.94	< .001	1.05	0.11	0.06	1.35
	TAU	13.97 (6.59)	10.94 (6.89)	11.17 (7.30)	8.20 (8.05)	5.91	.002	0.44	-0.03	0.38	0.78
PSWQ	UP	63.54 (10.54)	61.68 (10.38)	55.00 (17.44)	55.63 (16.92)	4.84	.005	0.30	0.35	-0.04	0.56
	TAU	59.17 (13.55)	60.23 (11.69)	59.00 (12.78)	56.75 (16.39)	2.23	.104	-0.08	0.10	0.15	0.16
Y-BOCS	UP	21.73 (9.64)	14.67 (9.22)	12.43 (8.46)	11.57 (7.95)	8.59	.001	0.75	0.25	0.10	1.15
	TAU	27.09 (7.98)	25.00 (11.06)	23.43 (10.45)	18.60 (12.32)	2.43	.095	0.22	0.14	0.42	0.82
Neuroticism	UP	33.33 (7.38)	29.66 (7.68)	28.04 (8.46)	26.31 (9.83)	27.89	< .001	0.49	0.20	0.19	0.81
	TAU	32.80 (7.62)	31.18 (7.65)	30.15 (8.29)	29.42 (8.02)	5.23	.002	0.21	0.13	0.09	0.43
Extraversion	UP	20.86 (8.38)	23.05 (8.78)	24.60 (8.83)	24.69 (8.96)	11.90	< .001	-0.25	-0.18	-0.01	-0.44
	TAU	20.40 (8.45)	19.85 (8.97)	19.76 (8.72)	20.48 (8.46)	0.36	.785	0.06	0.01	-0.08	-0.01
QLI	UP	4.35 (1.53)	5.47 (1.90)	5.60 (1.82)	5.95 (2.02)	32.54	< .001	-0.65	-0.07	-0.18	-0.89
	TAU	4.33 (1.58)	4.68 (1.59)	5.23 (1.98)	5.14 (1.94)	8.66	< .001	-0.22	-0.31	0.04	-0.46

Note: UP: Unified Protocol; TAU: Treatment as usual; BDI-II: Beck Depression Inventory; IA: Agoraphobia Inventory; PDSS: Panic Disorder Severity Scale; PSWQ: Penn State Worry Questionnaire; Y-BOCS: Yale-Brown Obsessive Compulsive Scale; QLI: Quality of life index. T: Treatment, MFU: Month follow-up

Table 5
Main effects of the linear mixed models (N = 243)

	BDI-II			IA			PDSS			PSWQ			Y-BOCS			Neuroticism			Extraversion			QLI		
	F	p	Cohen's d	F	P	Cohen's d	F	P	Cohen's d	F	P	Cohen's d	F	P	Cohen's d	F	p	Cohen's d	F	p	Cohen's d	F	p	Cohen's d
Time	7.70	< .001	0.43	4.61	.005	0.33	3.05	.032	0.27	0.75	.523	0.13	5.56	.004	0.37	3.35	.019	0.28	1.05	.370	0.16	6.78	< .001	0.40
Condition	8.51	.004	0.45	0.30	.588	0.08	0.48	.490	0.11	0.17	.677	0.06	7.70	.008	0.43	1.22	.269	0.17	2.59	.108	0.25	7.55	.006	0.43
Sessions	0.02	.881	0.02	4.39	.039	0.32	0.28	.599	0.08	0.02	.889	0.02	10.14	.003	0.49	0.11	.743	0.05	0.38	.539	0.10	0.31	.577	0.09
Time*Condition	3.79	.010	0.30	1.70	.174	0.20	0.49	.687	0.11	0.65	.583	0.12	3.23	.036	0.28	0.77	.512	0.14	1.38	.248	0.18	3.81	.010	0.30
Time*Condition*Sessions	1.60	.159	0.20	0.99	.430	0.15	0.31	.903	0.09	0.39	.851	0.10	1.12	.372	0.16	0.45	.810	0.10	0.73	.603	0.13	1.88	.097	0.21

Note: BDI-II: Beck Depression Inventory; IA: Agoraphobia Inventory; PDSS: Panic Disorder Severity Scale; PSWQ: Penn State Worry Questionnaire; Y-BOCS: Yale-Brown Obsessive Compulsive Scale; QLI: Quality of life index

With respect to the secondary variables, the results indicated a statistically superior difference of the UP compared to TAU on quality of life. A recent study found that UP in an individual format showed significant increases in quality of life when examining both within-individual effect sizes and between-condition effect sizes compared to a wait-list condition, and that post-treatment levels of quality-of-life predicted levels of functional impairment independently of diagnostic severity (Gallagher et al., 2013). Results of the current study provide evidence about the effectiveness of UP in a group format to increase the quality of life in people who suffer ED, highlighting the importance of examining mental health indicators in conjunction with markers of psychopathology.

In addition to the encouraging findings of this study to quality of life, and consistent with recent studies (Osma et al., 2021), UP showed a significant change over time in the improvement of the transdiagnostic-assessed personality dimensions (i.e., neuroticism and extraversion). Although there are no statistically significant between-group differences, the TAU condition did not achieve a significant improvement in extraversion. These results suggest that UP might be an adequate intervention not only to regulate negative but also positive affect by increasing extraversion, something that does not seem to occur in the TAU intervention.

Another interesting finding was that the improvement in outcomes for both the UP and the TAU conditions tended to converge over time. These findings indicate that an individual, non-

structured CBT intervention (TAU) could be effective for EDs in the National Health System (NHS); however, this TAU condition required a longer time to achieve the desired clinical changes. This may be due to differences in both the time spent during appointments (longer sessions in the group format) and between sessions (shorter time between sessions in the group format). This means that the UP achieved clinically significant improvements in a shorter time frame and these changes were maintained for up to 6 months after treatment termination. Regarding the TAU, scores tended to converge with the UP over time as patients gradually accumulated more sessions. These findings are promising since they suggest that the UP might reduce patient suffering faster than the TAU delivered in the NHS.

Despite these positive findings, the study has several limitations mostly due to its naturalist design (Leichsenring, 2004). As described above, the main goal of this study was to evaluate whether a transdiagnostic treatment (UP) in a group format would be superior to the treatment that was available in public centers to address specific symptoms of persons with EDs. Due to its naturalistic nature, there may be uncontrolled factors in the present investigation that need to be assessed in future studies to robustly demonstrate the efficacy of the UP for disorder-specific outcomes. Firstly, the interventions differed in the amount of treatment time offered. However, the results of this study show that there were no Time*Condition*Sessions interaction effects for any of the variables; that is, participants did not show a different evolution according to the number of sessions they received. Another factor that should be taken into account in relation to treatment effectiveness is treatment modality. In particular, in the present study the UP was implemented in a group format and the TAU was administered in an individual format. Individual treatment was the only treatment available at the NHS at the time of the study, which makes the comparison group representative of the usual treatment in the Spanish system. However, the fact that the UP in group was compared with an individual treatment makes it difficult to know whether the group differences found in effectiveness are due to the type of therapy employed or to the modality. Difficulties exist when attempting to conduct studies with two active group conditions in the Spanish NHS because this would imply creating disorder-specific groups that could be treated with the traditional specific

intervention for each type of disorder in the TAU condition. Future large RCTs may consider controlling for treatment modality if a sufficient number of participants with specific disorders can be recruited in a given period. Finally, another limitation may be the use of self-reports only to evaluate specific single-disorder symptoms. As suggested in a recent study (Osma, Peris-Baquero, Suso-Ribera, Farchione et al., 2021), including structured interviews, such as the ADIS, or a shorter version like the MINI (Sheehan et al., 2015), might provide interesting information on whether a change in diagnosis status occurred thanks to the treatment. In the present study this was not done due to time restrictions and to reduce the burden of assessments both in the patients and the clinicians.

In conclusion, and acknowledging some study limitations, the emotional regulation skills taught in UP seem to be effective, not only in the treatment of transdiagnostic dimensions associated with the onset and maintenance of EDs (neuroticism and extraversion), but also when improving specific symptoms of the different psychopathological manifestations. Moreover, UP improves the quality of life of patients regardless of the psychopathology that each one presents. This naturalistic study included a representative sample of patients from the Spanish community suffering from EDs, which may contribute to the research of the effectiveness of these treatments in the field of routine psychotherapeutic practice. These findings also suggest that the treatment components included in UP might target psychological mechanisms associated with how individuals with EDs perceive and react to daily emotional experiences (Barlow et al., 2014) independently of their diagnosis. This might help reduce the economic costs of delivering interventions focused on individual diagnoses by including transdiagnostic interventions to address all the EDs.

Acknowledgments

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