



Effectiveness of a blended group transdiagnostic treatment for emotional disorders: Study protocol for a randomized controlled trial

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ABSTRACT

Introduction: Emotional disorders (ED) (mood and anxiety disorders) are very prevalent and disabling, and often appear in comorbid presentations. Although there are effective treatments for these disorders, there is still a large gap between the number of people who need them and those who actually receive them. The combination of three strategies may help in this regard, facilitating the dissemination and accessibility of treatment: the transdiagnostic perspective of ED, the group format, and the use of technologies in a blended format (i.e., the combination of online and face-to-face therapy elements). This study intends to compare the efficacy of a new ED intervention, a transdiagnostic group treatment protocol administered in a blended format, with that of a face-to-face treatment. This article describes the study protocol for the randomized controlled trial.

Method and analyses: A two-arm, parallel-group, randomized controlled clinical trial (RCT) will be conducted. Participants ($N = 144$) will be adult volunteers suffering from DSM-5 anxiety and/or depressive disorders and will be randomly assigned to one of two conditions: Face-to-face Group Transdiagnostic Protocol or Blended Group Transdiagnostic Protocol. The face-to-face condition will consist of a total of 16 weekly face-to-face group sessions, while the blended condition will consist of 8 biweekly face-to-face group sessions in combination with self-applied work through a web platform. Clinical and acceptability measures will be included in both groups. Assessments will be performed at baseline, during the treatment, at post-treatment, and at 3-, 6- and 12-month follow-ups. This study received the approval of the Ethics Committee of Universitat Jaume I in October 2021 (CD/91/2021). Intention-to-treat analyses will be performed. Statistical analyses will be carried out using SPSS version 28.0. The results will be reported in accordance with CONSORT recommendations.

Discussion: This is the first RCT to compare the effectiveness of an ED treatment protocol based on the transdiagnostic perspective and applied in group and blended format. It will offer relevant data to continue moving forward towards treatment alternatives that are cost-effective and more accessible, so that all patients with ED who require them can benefit.

Trial registration: [ClinicalTrials.gov](https://clinicaltrials.gov/study/NCT05569018) Identifier: NCT05569018. Registered 06 October 2022, <https://clinicaltrials.gov/study/NCT05569018>

1. Introduction

The most common psychological disorders are emotional disorders (ED), i.e., anxiety and mood disorders (WHO, 2022). ED frequently appear together, being comorbid presentations more common than single disorders (Kessler et al., 2015; Kroenke et al., 2007). In addition,

these disorders entail significant social and economic costs and involve a great deal of disability (Javaid et al., 2023; Kessler, 2012). However, although there are effective evidence-based psychological treatments, there is a large gap between the number of people who need treatment and those who actually receive it (Moitra et al., 2022), due to, among other factors, geographic barriers and long waiting lists (Kazdin, 2017;

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Luo et al., 2020).

The transdiagnostic approach (Brown and Barlow, 2009) postulates that ED are different symptomatologic manifestations of a common vulnerability system, in which neuroticism/negative affect and extraversion/positive affect are key underlying dimensions. Therefore, treatment from this perspective focuses on addressing the underlying mechanisms common to ED rather than the specific symptoms of each anxiety or depressive disorder, so it can better account for the high rates of comorbidity and help with addressing these problems (Mansell et al., 2009; Sauer-Zavala et al., 2017). Some meta-analysis studies have demonstrated the efficacy of transdiagnostic treatments in different formats (individual, group and others), with comparable effects (Cuijpers et al., 2023; Schaeuffele et al., 2023). Additionally, the effect of transdiagnostic treatment appears to be equivalent to that of specific treatments and might even be greater (Schaeuffele et al., 2023). Moreover, it may result in lower costs and is therefore beneficial for the dissemination and implementation of these protocols (McEvoy et al., 2009; Murray et al., 2019), given that only one protocol is needed to address different disorders.

Internet-based therapy (i.e., the use of the Internet, in different methods or applications, to deliver psychological treatments, with more or less therapist involvement) has been very widespread in recent years and has become yet another strategy to bridge the treatment gap and improve the dissemination and implementation of evidence-based treatments. Internet-delivered therapies have a number of benefits. They are more widely available, involve less stigma and shorten the length of time patients must wait to start therapy (Griffiths and Christensen, 2007; Spurgeon and Wright, 2010). Furthermore, according to a meta-analysis that examined the effectiveness of online therapies in the treatment of anxiety and mood disorders (Hedman-Lagerlöf et al., 2023), online cognitive-behavioral treatment (CBT) is as effective as face-to-face CBT. The efficacy of online transdiagnostic CBT interventions has also been tested in randomized clinical trials (e.g., Díaz-García et al., 2021a; González-Robles et al., 2020) as well as in a recent meta-analysis (Kolaas et al., 2024). However, not all individuals benefit equally from online interventions and dropout rates are high, even in guided ones, mainly due to the lack of treatment personalization and therapeutic support (Fernández-Álvarez et al., 2017).

In this scenario, blended interventions emerge, a novel application format that combines elements of face-to-face therapy and Internet-based therapy (Erbe et al., 2017). This intervention format combines the advantages of both types of therapy and overcomes some barriers. One of the main advantages is that it allows reducing the number of sessions with the therapist. This implies saving a significant amount of therapist's time (e.g., Ly et al., 2015; Mathiasen et al., 2022) and decreases the number of dropouts (Rasing et al., 2020). It is also suggested that blended interventions allow a greater transfer of learned content to everyday life and that the combination of elements may lead to a greater likelihood of success (Erbe et al., 2017). Furthermore, blended treatments might be more effective than online interventions (Cuijpers et al., 2019) or even face-to-face treatments, although results are still contradictory in this regard (e.g., Rasing et al., 2021; Sethi et al., 2010; Thase et al., 2018), or at least be an alternative for those who do not benefit from or prefer other formats than face-to-face.

Several studies in the literature have already shown the efficacy of blended interventions for depression and anxiety. For example, a very recent European study (Kemmeren et al., 2023) has shown that CBT in blended format appears to be as effective as treatment as usual (in this case, CBT, interpersonal therapy, or problem-solving therapy) in reducing depressive symptoms and improving quality of life. Regarding the treatment of patients with anxiety disorders, Romijn et al. (2021) found no significant differences in efficacy measures between blended and face-to-face CBT at posttreatment nor at 1-year follow-up.

Research on blended treatments has primarily focused on individual formats and little is known about its potential in group formats. Nevertheless, group formats help treat a larger number of patients in a

shorter period of time, and it is an effective way to reduce the costs of psychotherapy. Previous literature suggests that group therapy is equal to individual treatment in terms of acceptance, attrition rates, remission, and improvement (Barkowski et al., 2016). In addition, CBT group formats have shown their effectiveness for different mental disorders with similar effect sizes to those of individual intervention (e.g., Burlingame et al., 2013; Jónsson et al., 2011). Transdiagnostic treatments applied in face-to-face group format have likewise demonstrated efficacy in several previous studies (e.g., Yan et al., 2022), and also the Unified Protocol (Osma et al., 2022; Peris-Baquero and Osma, 2023).

Despite the advantages offered by both formats, only a small number of studies (Gruber et al., 2001; Newman et al., 2014; Przeworski and Newman, 2004; Schuster et al., 2022, 2018) have combined the blended format with the group format to administer psychotherapy and, to our knowledge, no randomized studies have previously proposed the innovative combination of, on the one hand, the transdiagnostic perspective and, on the other hand, the group and blended formats. This strategy may contribute to evidence-based transdiagnostic CBT reaching people with ED in a more cost-effective way.

1.1. Objectives

The main aim of the present study is to compare the effectiveness of a blended transdiagnostic group treatment protocol with that of a standard (face-to-face) transdiagnostic group treatment protocol in a community sample of patients diagnosed with ED. The ED targeted in this study will be panic disorder, agoraphobia, social anxiety disorder, generalized anxiety disorder, major depressive disorder, dysthymia, obsessive-compulsive disorder, and non-specified anxiety/depression disorder. In this sense, the present study examines whether blended transdiagnostic treatment can achieve comparable clinical effects as standard transdiagnostic treatment, but at a lower cost. Moreover, it intends to analyze the acceptability of patients towards the two treatment conditions.

It is expected that: a) both treatment modalities will improve the symptoms of ED at post-treatment, reflected in the scores of the clinical measures, and these changes will be maintained over time in the two conditions (3-, 6-, and 12-month follow-ups); b) the blended condition will show equivalent effectiveness to the face-to-face intervention on clinical measures, and will be more cost-effective given that less therapist time will be needed to deliver the treatment; and c) the blended condition will show an acceptability comparable to the face-to-face condition (i.e., both modalities will be highly valued by the participants). In this article, the study protocol is presented.

2. Methods

2.1. Design

This study will be an equivalence two-arm, parallel-group, randomized controlled clinical trial (RCT). Trial participants will be randomly assigned to one of two conditions: 1) Face-to-face Group Transdiagnostic Protocol (FFGr-TP) or 2) Blended Group Transdiagnostic Protocol (BLGr-TP).

2.2. Study setting and participants

The study will take place at the university clinic of the Universitat Jaume I in Castellón, so the data will be collected in Spain from a community sample.

Participants will be adult volunteers who contact the Emotional Disorders Clinic at Universitat Jaume I or who write to the email enabled for the study looking for psychological assistance. The study flowchart is displayed in Fig. 1.

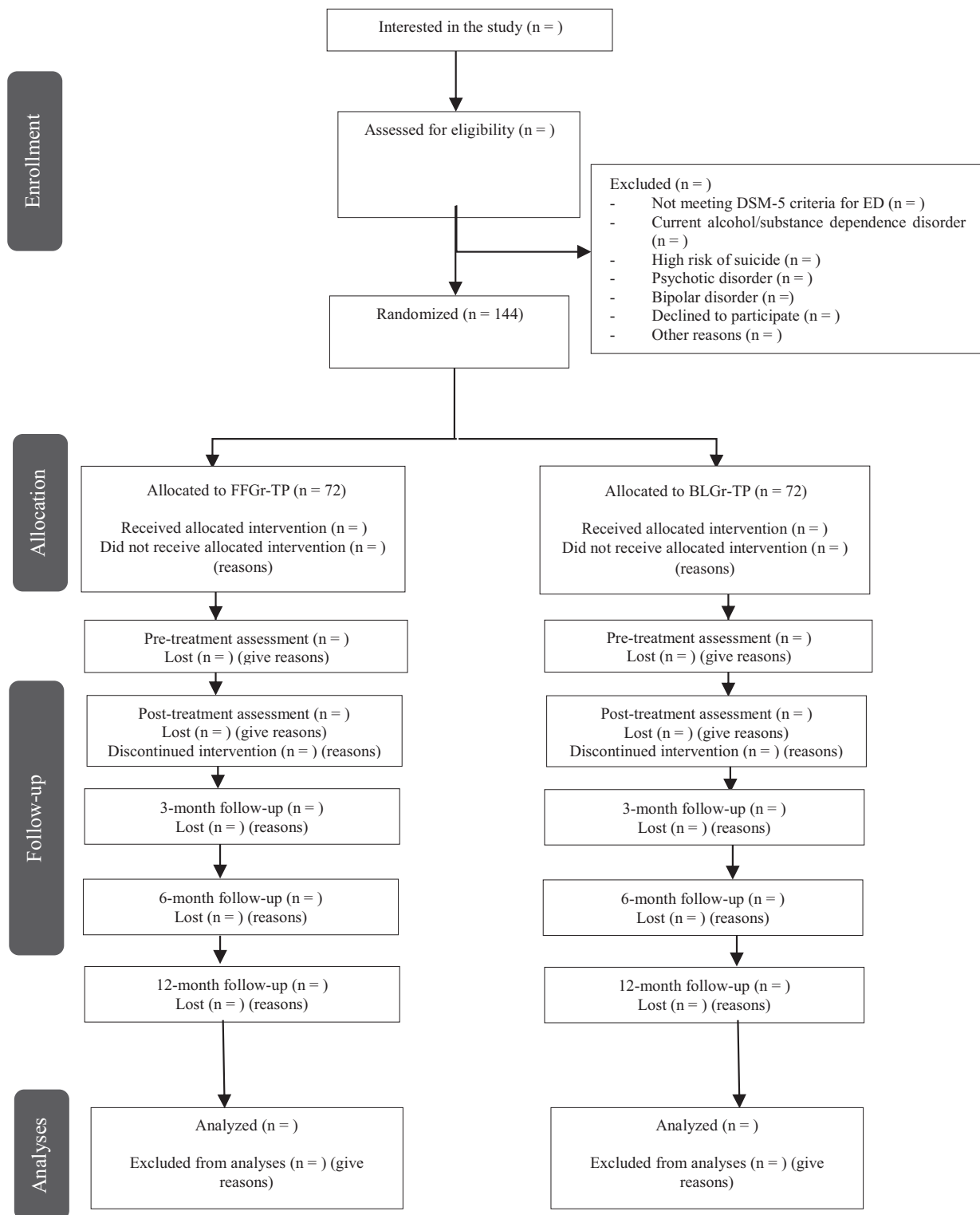


Fig. 1. Flow-chart of participants.

2.3. Eligibility criteria

To participate in this trial, participants must meet the following inclusion criteria: 1) ≥ 18 years old, 2) meeting DSM-5 (APA, 2013) diagnostic criteria for at least one of the aforementioned ED, 3) good understanding of Spanish, 4) access to the Internet and email address, and 5) signing an informed consent to participate. The following exclusion criteria will also be taken into account: 1) diagnosis of a severe

mental disorder (psychotic disorder, bipolar disorder, substance and/or alcohol dependence), 2) high risk of suicide, 3) having a serious medical illness or other condition that prevents treatment from being carried out, 4) receiving another psychological treatment during the study period, and 5) changes and/or increases in pharmacological treatment during the study period (a decrease is accepted).

2.4. Therapists

Two qualified therapists from the research team will lead each group. Both therapists will be licensed clinicians with experience in treating ED and who have received training in the use of the assessment protocol as well as the transdiagnostic treatment protocol. All therapists will have experience with group psychotherapy, and will be guided by expert clinicians with broad experience in the application of evidence-based CBT and this ED transdiagnostic approach. Each therapist will be familiar with both formats (face-to-face and blended) and will be able to work in both conditions.

2.5. Interventions

The transdiagnostic protocol designed by the research group, as well as its component modules, have been described in detail in previous studies (Díaz-García et al., 2021b, 2017; González-Robles et al., 2019). It consists of a transdiagnostic CBT protocol adapted from the Unified Protocol (Barlow, 2011) and with strategies based on Dialectical Behavioral Therapy (Linehan, 1993). The protocol also includes traditional therapeutic components of evidence-based treatment for ED. It consists of the following main components: 1) psychoeducation; 2) motivation for change; 3) awareness of emotional experiences; 4) cognitive flexibility; 5) psychoeducation and awareness of avoidance strategies that maintain ED; 6) interoceptive and emotional exposure (i. e., exposure to physical sensations and situations, places, etc.); 7) positive affect regulation strategies; and 8) relapse prevention.

The intervention will consist of the application of this transdiagnostic protocol composed by 16 modules focused on regulating both negative and positive affect. The intervention will be administered over a 16-week period. Both conditions will be developed in a group format and in both cases the groups will have 6 to 10 patients. Table 1 shows the distribution of sessions in each treatment condition. In both cases, the pace of progress is one module per week.

2.5.1. Face-to-face group transdiagnostic protocol (FFGr-TP)

The intervention will be carried out in a face-to-face group format, in which patients will attend a total of 16 weekly face-to-face sessions of 2 h each. During the period between sessions (1 week), patients will work on the content of the modules seen in the face-to-face sessions through homework assignments (traditional paper format).

2.5.2. Blended group transdiagnostic protocol (BLGr-TP)

The treatment in this condition will be administered in blended (face-to-face + online) format. Face-to-face group sessions will be combined with the autonomous work of patients through a web platform (<https://psicologiyatecnologia.labpsitec.es/>) where they will find the contents of the program. The participants will attend a total of 8 face-to-face 2-h sessions. The objective of the face-to-face sessions in this condition is to present and explain the upcoming modules in a general way (also performing some activities together), to answer questions about the previous modules and homework assignments, and to address possible difficulties. The online part of the treatment will consist of working the contents exposed in the face-to-face sessions during the period between sessions (2 weeks). It is an interactive program easy to use with multimedia elements that allow individuals to carry out the modules from home and at their own pace. The platform offers different tools (Home, Calendar, Review and How am I doing?) that allow users to see their progress in the treatment, to visualize the days they have accessed the platform and the tasks completed and pending, to access the modules that have already been completed to review them as many times as needed, and to see their evolution in terms of measures of anxiety, depression and positive/negative affect, respectively (they can be seen in Fig. 2). In the BLGr-TP condition, a message of support (a SMS) will be sent to participants every week during the treatment administration.

Table 1
Treatment schedule in the two conditions.

Week	FFGr-TP*	BLGr-TP	
			First part:
			<ul style="list-style-type: none"> • Therapists' introduction • Schedule of sessions, advantages of group therapy and rules • Introduction of patients, their problems and goals
			Second part:
			<ul style="list-style-type: none"> • Session agenda • Module 1 <ul style="list-style-type: none"> • ED and transdiagnostic perspective • Role of emotional regulation (ER) • Contents and structure of the program • Importance of assessments and homework/practice • Module 2 <ul style="list-style-type: none"> • Importance of motivation • Decisional balance exercise • Importance of identify objectives • Module 3 <ul style="list-style-type: none"> • The adaptive function of emotions • Three components of emotion
Week 1	GS 1 (module 1)	GS 1 (modules 1-3)	
Week 2	GS 2 (module 2)	AW on the OP (modules 1-3)	First part:
			<ul style="list-style-type: none"> • Session agenda • Doubts and questions of modules 1-3
			Second part:
			<ul style="list-style-type: none"> • Module 4 <ul style="list-style-type: none"> • What is mindfulness? • Primary and secondary reactions • Techniques what and how • "Observing the breath" exercise • Module 5, mindfulness of <ul style="list-style-type: none"> • Physical sensations • Thoughts • Emotions (exercise on induction of emotions) • Activities of daily life
Week 3	GS 3 (module 3)	GS 2 (modules 4-5)	
Week 4	GS 4 (module 4)	AW on the OP (modules 4 and 5)	First part:
			<ul style="list-style-type: none"> • Session agenda • Doubts and questions of modules 4-5
			Second part:
			<ul style="list-style-type: none"> • Module 6 <ul style="list-style-type: none"> • Role of automatic thoughts • Identification of core beliefs • Main thinking traps • Module 7 <ul style="list-style-type: none"> • Cognitive reappraisal • Intrusive and obsessive thoughts (difference with negative thoughts)
Week 5	GS 5 (module 5)	GS 3 (modules 6-7)	
Week 6	GS 6 (module 6)	AW on the OP (modules 6 and 7)	First part:
			<ul style="list-style-type: none"> • Session agenda • Doubts and questions of modules 6-7
			Second part:
			<ul style="list-style-type: none"> • Module 8 <ul style="list-style-type: none"> • Emotional avoidance, consequences, and maladaptive emotional avoidance strategies • Exercise to identify maladaptive ER strategies
Week 7	GS 7 (module 7)	GS 4 (modules 8-9)	

(continued on next page)

Table 1 (continued)

Week	FFGr-TP*	BLGr-TP
Week 8	GS 8 (module 8)	AW on the OP (modules 8 and 9)
		<ul style="list-style-type: none"> Behavioral experiment of thought suppression Module 9 Emotion-driven behaviors and consequences Technique of opposite action
		<p>First part:</p> <ul style="list-style-type: none"> Session agenda Doubts and questions of modules 8–9 <p>Second part:</p> <ul style="list-style-type: none"> Module 10 Role of physical sensations in emotions Avoidance of physical sensations: exercise of holding the breath 30 s Explanation of the interoceptive avoidance test and hierarchy of interoceptive exposure
Week 9	GS 9 (module 9)	GS 5 (modules 10–11)
		<ul style="list-style-type: none"> Module 11 Exposure to emotion In-vivo and imagined exposure Hierarchy of exposure to emotion and self-monitoring worksheet
Week 10	GS 10 (module 10)	AW on the OP (modules 10 and 11)
		<p>First part:</p> <ul style="list-style-type: none"> Session agenda Doubts and questions of modules 10–11 <p>Second part:</p> <ul style="list-style-type: none"> Module 12 Role of activity in our well-being Importance of getting involved with life Importance of social support Introduction to diary of daily activities
Week 11	GS 11 (module 11)	GS 6 (modules 12–13)
		<ul style="list-style-type: none"> Module 13 Role of positive emotions Induction of positive emotions Importance of smiling
Week 12	GS 12 (module 12)	AW on the OP (modules 12 and 13)
		<p>First part:</p> <ul style="list-style-type: none"> Session agenda Doubts and questions of modules 12–13 <p>Second part:</p> <ul style="list-style-type: none"> Module 14 Psychological well-being Psychological strengths: exercise Importance of identifying values and important life goals
Week 13	GS 13 (module 13)	GS 7 (modules 14–15)
		<ul style="list-style-type: none"> Module 15 Discuss about what strengths are important to each person and which they want to enhance Strategies to enhance strengths Exercise on identify, maintain and enjoy vital moments of well-being
Week 14	GS 14 (module 14)	AW on the OP (modules 14 and 15)
Week 15	GS 15 (module 15)	GS 8 (module 16)
		<p>First part:</p> <ul style="list-style-type: none"> Session agenda

Table 1 (continued)

Week	FFGr-TP*	BLGr-TP
Week 16	GS 16 (module 16)	AW on the OP (module 16)
		<ul style="list-style-type: none"> Doubts and questions of modules 14–15 <p>Second part:</p> <ul style="list-style-type: none"> Module 16 Evaluating progress: in-session round Review of skills learned Fluctuation of emotions, setbacks and relapses Strategies for maintaining and consolidating achievements Exercise on preparation for high-risk situations (What would you do if...?)

Note. GS: Group Session; AW: Autonomous Work; OP: Online Platform.
 * The contents of the group sessions in the FFGr-TP condition coincide with that indicated for each module in the BLGr-TP condition. What changes between the two conditions is the format of administration.

2.6. Outcomes

Participants will be assessed before and after treatment, as well as at follow-up assessments at 3, 6 and 12 months after completion of the treatment. Post-module measures will be also collected.

2.6.1. Clinical outcomes

2.6.1.1. Primary outcome measures. Anxiety and depression symptoms will be assessed using the *Overall Anxiety Severity and Impairment Scale* (OASIS) (Campbell-Sills et al., 2009) and the *Overall Depression Severity and Impairment Scale* (ODSIS) (Bentley et al., 2014). Both are a 5-item scale used to assess the degree and functional impairment of this type of symptomatology over the course of the previous week. Each item is scored on a 5-point scale (0–4) and total score can be between 0 and 20. The Spanish version of OASIS (González-Robles et al., 2018) and ODSIS (Mira et al., 2019) have demonstrated strong convergent and discriminant validity, as well as high internal consistency ($\alpha = 0.86$ and $\alpha = 0.93$ respectively). In addition, we will add an item to explore the frequency of thoughts about suicide during the past week, also ranging from 0 (“absence of thoughts of suicide”) to 4 (“thoughts of suicide most of the time”).

2.6.1.2. Secondary outcome measures. The *Multidimensional Emotional Disorders Inventory* (MEDI) (Rosellini and Brown, 2019) will also be used. It is a self-report questionnaire that assesses the nine transdiagnostic dimensions (Neurotic Temperament, Positive Temperament, Depressive Mood, Autonomic Arousal, Somatic Anxiety, Social Anxiety, Intrusive Thoughts, Traumatic Re-experiencing and Avoidance) proposed in the hybrid dimensional-categorical approach to the classification of ED (Brown and Barlow, 2009). It consists of a 49-item scale with a 9-point Likert-type response (from 0 = “It is not characteristic of me” to 8 = “Totally characteristic of me”). The Spanish validation (Osma et al., 2023) shows good psychometric properties and strong internal consistency indices ($\alpha = 0.66$ to 0.91).

To assess positive and negative affectivity, the Spanish version of *Positive and Negative Affect Schedule* (PANAS) (Díaz-García et al., 2020) will be used. Also, the Spanish version of the *NEO-Five Factor Inventory* (NEO-FFI) (Aluja et al., 2005) will be administered to evaluate neuroticism and extraversion as temperament variables. The emotional regulation will be assessed using the Spanish validation of *Difficulties in Emotion Regulation Scale* (DERS) (Hervás and Jódar, 2008) and the perceived self-efficacy will be also evaluated using the *General Self-*

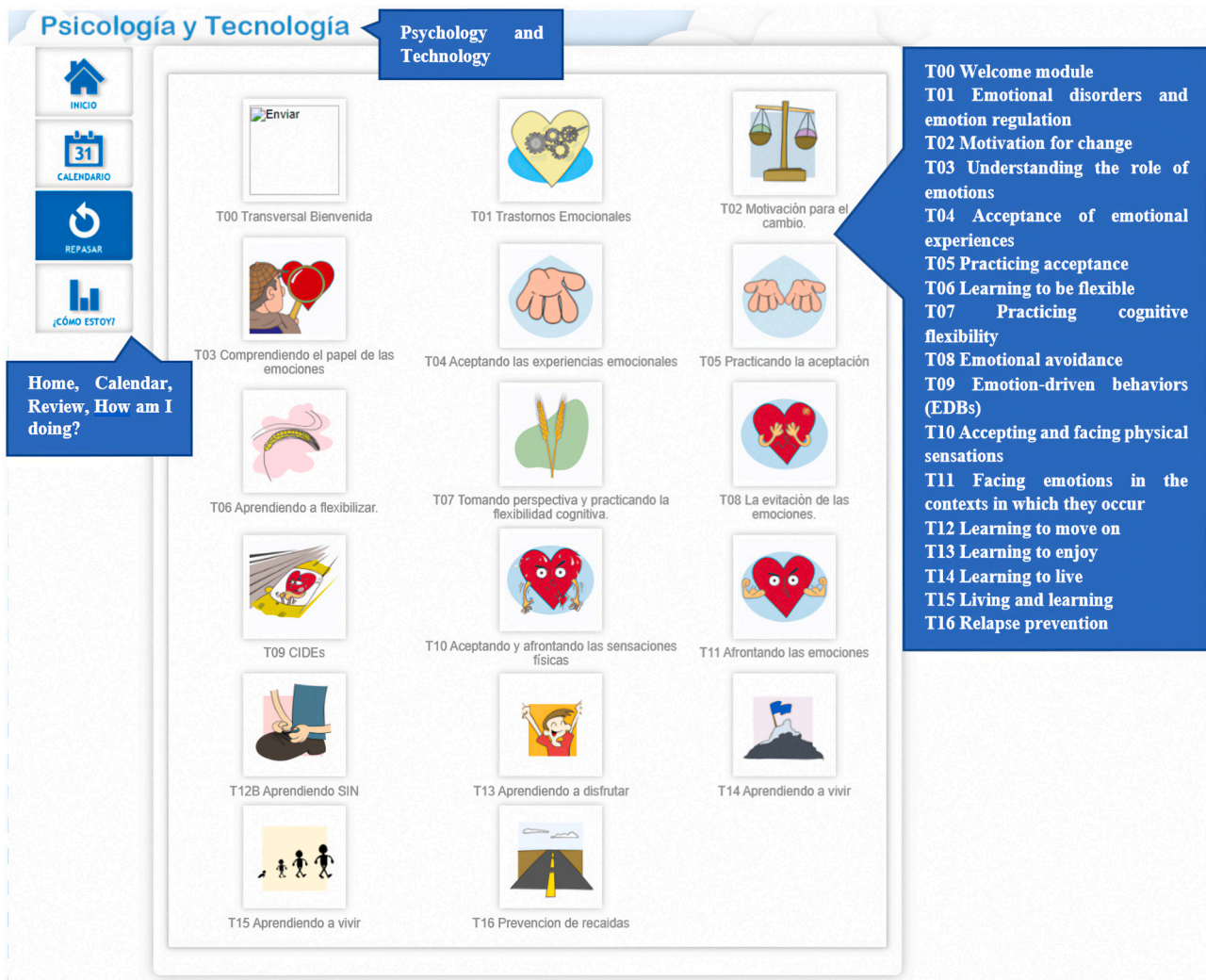


Fig. 2. Tools and modules on the online platform.

Efficacy Scale (GSES) (Sanjuán et al., 2000). The Modulate subscale of the S-DERS (Lavender et al., 2017) will also be used as a measure of state emotional regulation throughout the treatment. Finally, some measures of functioning will be collected using the Spanish adaptation of *Quality of Life Index* (QLI; Mezzich et al., 2000) and *Work and Social Adjustment Scale* (WSAS; Echezarraga et al., 2018).

2.6.2. Acceptability outcomes

Participants' acceptance will be assessed with *Expectations and Opinion of Treatment scales* adapted from Borkovec and Nau (1972) and usability with the *System Usability Scale* (SUS; Castilla et al., 2023). Patients' therapeutic alliance will also be measured in both conditions with the Spanish version of the *Working Alliance Inventory short format* (WAI-S) (Corbella et al., 2011). An ad hoc opinion questionnaire will also be administered on satisfaction with the group sessions, and an opinion question will be asked after each module to find out its usefulness.

2.6.3. Other outcome measures

The system-collected data will be used to assess patients' participation and usage of the online treatment platform. These details will include the total number of modules finished, the number of days spent in each module, the number of logins and the number of reviews.

The study variables and assessment times are summarized in Table 2.

2.7. Timeline and recruitment

The study will be disseminated through posters and flyers, as well as announcements through professional and non-professional social networks. People interested in participating in the study will have to complete an online pre-screening questionnaire to check the exclusion criteria and to preliminary explore if there is any emotional disturbance. If no exclusion criteria are detected, they will be contacted by therapists who will conduct a diagnostic interview to establish diagnoses according to DSM-5 (APA, 2013) criteria.

Participants who meet the inclusion criteria will be requested to sign a written consent form after being informed of the details of the study and subsequently be randomly assigned to one condition. Patients will be required to complete the pre-treatment assessment one week before the intervention begins and post-treatment evaluation three weeks after the final group session. In both groups, all assessment questionnaires (pre, post, post-module, and follow-ups) will be completed online.

2.8. Sample size

This study was designed as an equivalence trial with two independent variables: the two types of treatment (a between-groups factor: BLGr-TP vs. FFGr-TP) and the five measurement occasions (a within-group factor with pretest, posttest, and 3-, 6-, and 12-months follow-ups). The main question that this investigation intends to answer is

Table 2
Enrolment, interventions, and assessments.

TIMEPOINT	STUDY PERIOD								
	Enrolment	Allocation	Post-allocation						Close-out
			Pre-treatment	Post-module (1 – 16) measures	Post-treatment	3-month follow-up	6-month follow-up	12-month follow-up	
ENROLMENT:									
Pre-screening	X								
Diagnostic interview	X								
Informed consent	X								
Allocation		X							
INTERVENTIONS:									
FFGr-TP			←————→						
BLGr-TP			←————→						
ASSESSMENTS:									
Sociodemographic variables	X								
<u>Primary outcomes</u>									
OASIS			X	X	X	X	X	X	
ODSIS			X	X	X	X	X	X	
<u>Secondary outcomes</u>									
MEDI			X		X	X	X	X	
PANAS			X	X	X	X	X	X	
NEO-FFI			X		X	X	X	X	
DERS			X		X	X	X	X	
Modulate of S-DERS				X					
GSES			X	X	X	X	X	X	
QLI			X		X	X	X	X	
WSAS			X		X	X	X	X	
<u>Acceptability outcomes</u>									
Expectations Scale			X						
Opinion Scale					X				
SUS				X (post-module 1)	X				
WAI-S				X (post-module 3)					
Opinion on modules and group sessions			←————→						
<u>Other outcomes</u>									
Platform usage indicators			←————→						
STATISTICAL ANALYSES									X

whether the two treatments exhibited similar efficacy through the five measurement occasions on the primary outcomes. With this purpose, two-way mixed ANOVAs will be applied, with the interaction effect being the main result. In particular, a non-statistically significant result for the interaction between the two factors will be evidence of equivalence between the two treatments. As a consequence, to a priori determine the sample size required, the interaction effect was the prioritized effect. In an equivalence trial it is needed to a priori define the margin of equivalence (Ranganathan et al., 2022). In the context of a two-way ANOVA where the main question is to assess the interaction effect between the type of treatment and time occasions, the equivalence between the two treatments implies that the mean profiles of both interventions will be similar. In this context, the effect size index typically used is the proportion of variance accounted for (usually, *Eta squared*, η^2) by the effect in question (cf., e.g., Grissom and Kim, 2012). Following Cohen's (1988), pp. 284–288) guidelines, proportions of variance explained of about 0.01, 0.06, and 0.14 can be assumed as reflecting a low, moderate, and large effect size, respectively. In order to warrant a good control for the Type I error rate (i.e., to accept equivalence when the treatments are, in fact, not equivalent), an effect size of $\eta^2 = 0.01$ was assumed as the margin of equivalence to a priori determine the sample size. G*Power 3.1.9.2 software was used to do this calculation. As this program implement as effect size index 'f' in place of

η^2 , it was translated in to f giving $f = 0.10$. With this effect size and assuming a significance level of 5 % and a statistical power of 80 %, the total sample required was 122 patients. Considering an estimated dropout rate of 15 % based on previous studies (e.g., Monreal-Bartolomé et al., 2019; Rasing et al., 2020) a total sample of 144 patients will be required (72 per group).

2.9. Allocation

Participants will be randomly assigned to one of the two treatment conditions by an independent researcher who is unaware of the characteristics of the study. Randomization will be stratified by principal diagnosis and block randomization will be performed within each stratum to ensure that all principal diagnoses are equally represented in all conditions. The Research Randomizer tool (<https://www.randomizer.org/>) will be used to generate the random sequence.

2.10. Statistical methods

The two groups will first be compared to ensure that there are no significant baseline differences between them and that both are comparable after randomization. This will be done using independent two-groups t-tests for continuous variables and chi-square tests for

categorical variables. In order to address missing data, intent-to-treat statistical analyses will be conducted. With this purpose, Linear Mixed Models will be applied in the context of two-way ANOVAs (Graham, 2009). This approach has been suggested because it can handle missing data more efficiently than the General Linear Model (Gueorguieva and Krystal, 2004). The main result to assess equivalence between the two treatments will be the interaction effect. In addition, standardized effect sizes (Cohen's *d*) will be used to estimate changes within and between groups. Cohen's *d* will be interpreted as small at 0.20, moderate at 0.50, and large at 0.80 and above (Cohen, 1988). The statistical analyses will be carried out using the IBM SPSS package version 28.0. The results will be reported in accordance with CONSORT recommendations (Schulz et al., 2010).

3. Ethics

This study has been approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain) (ref CD/91/2021, October 2021) and will be conducted in accordance with national and international norms (Declarations of Helsinki and Tokyo, as well as the World Psychiatric Association's Declaration of Madrid). All participants will be volunteers and they will have given their consent after being fully informed about the study. In addition, participants will have the possibility of withdrawing from the study at any time.

The confidentiality and rights of the subjects included in the study will be guaranteed in accordance with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of the digital rights (LOPDgdd), which adapts Spanish legislation to the General Data Protection Regulation (GDPR) of the European Union. Data protection is a crucial component of a project of this sort. Regarding the technological platform, personal passwords and advanced encryption will be used as security measures to protect data. To constantly guarantee the right to privacy, data will be separated into two completely independent systems that access two equally independent databases. Thus, users' personal data will be separated from their clinical data and replaced by codes, so patient data will be completely unbundled and only available to researchers who are responsible for the study.

The study will be conducted following the CONSORT (Consolidated Standards of Reporting Trials, <http://www.consort-statement.org>) statement (Moher et al., 2010) and CONSORT-EHEALTH guidelines (Eysenbach et al., 2011) and has been registered in [ClinicalTrials.gov](https://clinicaltrials.gov) with NCT05569018 identifier number (<https://clinicaltrials.gov/study/NCT05569018>).

4. Discussion

In the present study, our main objective is to analyze the comparative efficacy of this transdiagnostic, group and blended intervention for the treatment of ED in a community sample. Therefore, this study will make it possible to advance in the field of transdiagnostic treatments by testing a novel form of administering these interventions. In addition, it will provide relevant information to continue advancing towards treatment options that are cost-effective and more accessible, so that they can reach all people with ED who need them.

Blended format plays an important role in this regard. Due to the multiple benefits they provide, blended treatments are currently a growing field of research. In their systematic review, Erbe et al. (2017) concluded that, although blended format is a potentially effective alternative, the field of study is still small and more RCTs on efficacy and cost-effectiveness are needed to compare them, not only to control groups, but also to traditional non-blended psychotherapies. So far, studies generally find comparable clinical effects between blended interventions and other therapies (e.g., Kemmeren et al., 2023). Nevertheless, the results in this regard remain unclear and do not allow clear conclusions to be drawn.

In this study, a blended intervention will be compared to the same intervention in standard format, thus contributing to answering this question. If our hypotheses are verified, this type of intervention would be an effective way of approaching ED, with results comparable to traditional interventions, but more cost-effective, because it allows therapists to save time (50 % less of group sessions) and to treat more patients in the same period through groups. If this proposed intervention proves to be effective for the treatment of ED and well accepted by patients, it would be an ideal alternative particularly for public mental health care providers, because it would allow treating more people in less time and shortening long waiting lists. So, the next steps would be to seek its implementation in the different health systems.

To the best of our knowledge, this is the first study that will investigate the efficacy of a transdiagnostic group treatment applied in blended format in patients with ED in an RCT, and compare it with the transdiagnostic group protocol applied in standard format (face-to-face).

We are aware that this study has some limitations. On the one hand, the blended condition sessions will only take place once every two weeks, so some patients may use the online platform less frequently than expected. To counteract this, we created a support protocol that includes automated text messages (such as ones that emphasize the value of completing homework assignments, practicing various techniques, and so on). On the other hand, due to the size of the sample needed and the fact that some people might prefer an individual format, we may encounter problems in recruitment. For this reason, we will widely disseminate the study through various media (social networks, posters, brochures, etc.).

In summary, this study investigates the efficacy of a novel intervention for the regulation of ED: a transdiagnostic group and blended treatment (face-to-face group sessions and online self-administered therapy). In this sense, the intervention combines the advantages of transdiagnostic treatments and group and blended formats mentioned previously. The study will determine if the number of sessions proposed is sufficient to minimize costs while maintaining efficacy with the support of technology, and also if the therapeutic alliance is maintained in this administration format. In addition, it will contribute to broadening the research on blended interventions, in which depression is the most extensively studied disorder and group formats have been studied much less than individual ones, despite being more cost-effective. All in all, it can contribute to solving some of the challenges in the field of mental health, specifically it can help the dissemination and implementation of evidence-based psychological treatments so that all people in need can receive them (Díaz-García et al., 2021b; Kazdin, 2017).

5. Conclusions

The results of this study will provide insight into the short- and long-term efficacy of a novel intervention for ED: a transdiagnostic group treatment protocol administered in a blended format. It may have an important impact on both the design and the dissemination of future treatments aimed at addressing the vulnerabilities common to these disorders.

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CRedit authorship contribution statement

NJ-O: Writing - Original Draft, Conceptualization, Methodology. AD-G: Conceptualization, Methodology, Supervision. AG-P:

Conceptualization, Methodology, Supervision. JB-L: Conceptualization, Methodology, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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