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Blended transdiagnostic group CBT for emotional disorders: A feasibility trial protocol

Amanda Díaz-García [a,*], Alberto González-Robles [a], Azucena García-Palacios [b,c], Isabel Fernández-Felipe [b], Cintia Tur [b], Diana Castilla [c,d], Cristina Botella [b,c]

[a] Department of Psychology and Sociology, Universidad de Zaragoza (Campus de Teruel), Teruel, Spain
[b] Department of Basic and Clinical Psychology, and Psychobiology, Universitat Jaume I, Castellon, Spain
[c] CIBER Fisiopatología Obesidad y Nutrición (CIBERObn), Instituto Salud Carlos III, Madrid, Spain
[d] Department of Personality, Evaluation and Psychological Treatments, Universidad de Valencia, Valencia, Spain

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ABSTRACT

Introduction: Emotional disorders (anxiety and depressive disorders) are a relevant public health concern associated with high prevalence, high costs, and important disability. Therefore, research priorities include designing and testing cost-effective interventions to reach everyone in need. Internet-delivered interventions for emotional disorders are effective and can help to disseminate and implement evidence-based treatments. However, although these treatments are generally effective, not all patients benefit from this treatment format equally. Blended treatments are a new form of intervention that combines the strengths of face-to-face and Internet approaches. Nevertheless, research on blended interventions has focused primarily on individual therapy, and less attention has been paid to the potential of using this format in group psychotherapy. This study aims to analyze the feasibility of blended transdiagnostic group CBT for emotional disorders. The current article describes the study protocol for this trial.

Method and analysis: A one-armed pilot trial will be conducted. Participants will be 30 adults suffering from DSM-5 anxiety and/or depressive disorders. The treatment consists of a blended transdiagnostic group intervention delivered during a period of 24 weeks. Groups of 6 to 10 patients will attend a total of eight 2-hour, face-to-face sessions, alternated with the use of an online platform where they will find the contents of the treatment protocol. The intervention has four core components: present-focused awareness, cognitive flexibility, identification and modification of behavioral and cognitive patterns of emotional avoidance, and interoceptive and situational exposure. These components are delivered in 16 modules. Assessments will be performed at baseline, during the treatment, at post-treatment, and at 3-month follow-up. Clinical and treatment acceptability outcomes will be included. Quantitative and qualitative data (participants' views about blended group psychotherapy) will be analyzed.

Ethics and dissemination: The trial has received ethical approval from the Ethics Committee of Universitat Jaume I (September 2019) and will be conducted in accordance with the study protocol, the Declaration of Helsinki, and good clinical practice. The results of this study will be disseminated by presentation at conferences and will be submitted for publication in a peer-reviewed journal.

Trial registration: ClinicalTrials.gov Identifier: NCT04008576. Registered 05 July 2019, https://clinicaltrials.gov/ct2/show/NCT04008576

1. Introduction

Emotional disorders (anxiety and depressive disorders) (Bullis et al., 2019) are the most prevalent mental disorders (Ferrari et al., 2013; Kessler et al., 2005), and impact the lives of millions of people worldwide (Kohn et al., 2004; Steel et al., 2014). Moreover, emotional disorders are associated with high costs (Andlin-Sobocki and Wittchen, 2005; Cuijpers et al., 2012), disability (Baxter et al., 2014), chronicity

* Corresponding author.
E-mail addresses: amandadiaz@unizar.es (A. Díaz-García), gonzaleza@unizar.es (A. González-Robles), azucena@uji.es (A. García-Palacios), fernandi@uji.es (I. Fernández-Felipe), ctur@uji.es (C. Tur), diana.castilla@uv.es (D. Castilla), botella@uji.es (C. Botella).

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(Richards, 2011), and high comorbidity rates with other emotional disorders (Kroenke et al., 2007).

A large body of research shows the efficacy of cognitive-behavioral treatments (CBT) for emotional disorders (Nathan and Gorman, 2015). However, although there is little doubt about the efficacy and effectiveness of CBT for emotional disorders, the dissemination and effective implementation of these protocols is still a major challenge for research and clinical practice (McHugh and Barlow, 2010). In other words, despite research efforts to provide empirically supported treatments during the past three decades, there is still an important treatment gap in mental healthcare, leading to a large proportion of patients who do not receive treatment in mental healthcare services, especially those with anxiety and mood disorders (Kohn et al., 2004; Lilienfeld et al., 2013; Wang et al., 2007).

In the past two decades, different approaches have emerged to improve the dissemination and implementation of evidence-based treatments. In this regard, one important line of research is the transdiagnostic approach to the treatment of emotional disorders. The efficacy of transdiagnostic treatments has been shown in a growing number of meta-analytic studies (García-Escalera et al., 2016; Newby et al., 2015, 2016; Reinholt and Krogh, 2014). The main defining characteristic of transdiagnostic treatments is that they "apply the same underlying treatment principles across mental disorders, without tailoring the protocol to specific diagnoses" (McManus et al., 2010, p. 4). Broadly, transdiagnostic treatments are based on the premise that the commonalities of psychological disorders outweigh their differences, and that the observed differences (symptoms) are specific manifestations of broader, underlying common psychopathological processes. This approach has been called the "mechanistically transdiagnostic approach", and it has fueled the development of transdiagnostic treatments based on "shared mechanisms" (Sauer-Zavala et al., 2017). For these reasons, the use of transdiagnostic treatments has important implications for clinical practice. For example, comorbid presentations can be targeted more appropriately (Mansell et al., 2008), and training costs are lower because clinicians only have to be trained in one protocol instead of different protocols for each specific diagnosis (McEvoy et al., 2009).The goal of these treatments has typically been to train the individual in emotion regulation strategies to address the dimension of neuroticism or negative affect (Barlow et al., 2004; Norton, 2012; Titov et al., 2010, 2011). However, the interest in directly targeting positive affect in the context of emotional disorders has increased in more recent research (Carl et al., 2018; Taylor et al., 2017). For instance, Carl et al. (2018) proposed a module for the regulation of positive affectivity to be applied transdiagnostically across anxiety and depressive disorders. According to the authors, the module can be implemented flexibly, either integrated into a modular treatment program (e.g., the Unified Protocol) or as an adjunct treatment for patients who show deficits in positive affect at post-treatment.

Another approach that could enhance the dissemination and implementation of evidence-based CBT and considerably reduce the costs is the use of the Internet to deliver treatments. A number of systematic reviews have shown that Internet-delivered treatments for depression and anxiety disorders are more effective than different control groups, such as waitlist and treatment as usual groups (Andrews et al., 2018; Richards and Richardson, 2012; Spek et al., 2007), and that they work as effectively as face-to-face psychotherapy (Carlbring et al., 2018). In the context of Internet-delivered treatments, one possibility consists of the so-called "blended treatments", that is, the combination of face-to-face and Internet-delivered therapy (Kleiboer et al., 2016; Kooistra et al., 2014). Some of the advantages of these interventions include enhancing the learning process (e.g., retention of learned information or improvement of learned tasks), extending the reach of information by using the Internet, and optimizing development costs and time and cost-effectiveness (i.e., to offer learning strategies that reach large numbers of individuals quickly) (Cucciare et al., 2008). Moreover, by participating in a blended treatment, patients can work on their own mental health between sessions, increasing their ability to adapt and self-manage, which are core aspects in defining health (Huber et al., 2011). There is growing support in the literature for the claim that blended therapy may save clinician time, lead to lower dropout rates, help maintain the effects of inpatient therapy, and increase the effects of psychotherapy, compared to stand-alone face-to-face therapy (Erbe et al., 2017). Thus, another advantage of blended treatments is their lower cost in comparison with traditional face-to-face psychotherapy, suggesting that this treatment delivery format can help to save therapist time. For instance, the usual treatments include between 12 and 14 sessions, whereas blended treatments are shortened to 6–8 sessions, representing a 33–57% savings in terms of costs and time (Schuster et al., 2018). Furthermore, blended treatments might be a good alternative for those patients who are less likely to benefit from guided or unguided Internet-delivered treatments (with no face-to-face contact). Another way to reduce the costs of psychotherapy is through the use of the group format. The literature has shown that, for the treatment of anxiety and depressive disorders, different methods of implementation (individual vs. group CBT) have led to similar drop-out rates or satisfaction with the treatment (Bastien et al., 2004; Jónsson et al., 2011). Numerous advantages have been attributed to group therapy, such as support (the group become a valuable source of support), confidentiality (one of the ground rules for group therapy), or diversity (it makes it possible to discover a whole range of strategies to face problems) (APA, 2013; Sepúlveda et al., 2010). In addition, as the National Institute for Health and Care Excellence recommends, group CBT should be considered for people with mild to moderate depression who decline low-intensity psychosocial interventions such as Internet-based treatments (NIH, 2009). Furthermore, the literature suggests that the two treatment formats (individual vs. group) are comparable in terms of rates of treatment acceptance, dropout, remission, or improvement (Barkowski et al., 2016). Therefore, group therapy is an appropriate strategy to reduce the burden of these disorders in a more cost-effective manner.

A treatment strategy that may boost the cost-effectiveness relationship is the combination of the blended and group formats. In spite of the advantages of group CBT, in the specific field of transdiagnostic treatments, research has mainly focused on individual transdiagnostic treatments (González-Robles et al., 2018a, 2018b), with some exceptions (Norton, 2012; Reinholt et al., 2017). In Spain, Osma et al. (2019) are conducting arandomized controlled trial (RCT) that tests transdiagnostic group psychotherapy in specialized mental health care. However, to our knowledge, no studies have been published that combine blended (i.e., face-to-face plus Internet-delivered psychotherapy) and group delivery formats to provide transdiagnostic treatments for emotional disorders. The existing studies on blended group psychotherapy are quite scarce, and they focus only on the treatment of major depressive disorder (Schuster et al., 2018). Combining these two treatment approaches to deliver a transdiagnostic treatment might be a highly cost-effective treatment strategy for these disorders, which could ultimately contribute to the dissemination and implementation of evidence-based transdiagnostic CBT.

1.1. Current study

The objective of this study is to analyze the feasibility of blended transdiagnostic group CBT for emotional disorders. To this end, a transdiagnostic Internet-delivered treatment protocol will be delivered in combination with group psychotherapy sessions. The treatment protocol is a mechanistically transdiagnostic treatment that adds a specific component for the regulation of positive affectivity. Thus, the treatment contains strategies for the regulation of both negative affectivity and positive affectivity. The manualized version of this treatment protocol has already been pilot-tested in an individual face-to-face format (González-Robles et al., 2019), and results of a randomized controlled trial of the Internet-delivered version have already been published (González-Robles et al., 2020). Specifically, we aim to study the

adequacy of the different methods of recruitment and data collection (e.g., how broad or restrictive eligibility criteria are, how willing patients are to participate, time needed to collect data), to explore reasons for non-participation and for dropping out from the treatment, to analyze and select optimal outcome measures, and to explore patients' acceptability of the intervention (both quantitatively and qualitatively). Furthermore, a secondary aim of the study is to preliminary estimate the impact of the intervention at post-treatment and 3-month follow up.

These objectives will help to optimize the design of a future RCT and they are consistent with the recommendations found in the literature about feasibility studies (Eldridge et al., 2013, 2016). The current article describes the study protocol of this trial.

2. Method and analysis

2.1. Design

The current study uses a single-group, open-trial design with three measurement points: baseline (pre-treatment), immediately after the intervention (post-treatment), and at 3-month follow-up. A mixed-method design will be used (including quantitative and qualitative methodology) (Creswell and Clark, 2017), in line with guidelines for Good Reporting of a Mixed Method Study (O'cathain et al., 2008) and for complex interventions (Craig et al., 2008).This design is appropriate to evaluate an intervention before it is introduced in a clinical setting (Bowen et al., 2009). Quantitative data will be collected through the online platform using validated questionnaires. Qualitative data will be collected using the focus group method using in-depth questions. Quantitative data will be employed to explore changes in outcomes, while qualitative data will provide data on the participants' opinions about the treatment, the face-to-face sessions, and the online platform.

2.2. Participants, recruitment and procedure

Participants will be adults attending the Service of Psychological Assistance at Universitat Jaume I to seek psychological help. The main aim of this service is to provide evidence-based treatment protocols using Information and communication Technologies tools. After an initial screening session, an additional session will be arranged with those candidates interested in participating to confirm that they meet the eligibility diagnostic criteria, using the MINI International Neuropsychiatric Interview (MINI) (Ferrando et al., 1997; Sheehan et al., 1998). This session will be used to collect sociodemographic and other clinical data (e.g., medication). Moreover, patients will be asked about medication types and dose before starting the intervention, and these data will be monitored and recorded during the treatment and follow-up periods. Once the characteristics of the study have been explained to participants, they will be asked to sign an informed, written consent form. All the assessment instruments will be delivered through a web platform (https://www.psicologiaytecnologia.labpsitec.es), and assessments will take place at pre- and post-treatment and at 3-month follow-up. One week before the intervention starts (i.e., first group session), patients will be asked to complete pre-treatment assessment instruments. Post-treatment questionnaires will be completed 3 weeks after the last group session.

Groups will be led by two trained therapists (AD-G and AG-R), each of whom will have the support of a co-therapist (IF-F and CT). Both therapists and co-therapists are qualified clinicians with experience in the treatment of emotional disorders and have been trained in the use of the transdiagnostic treatment protocol as well as the study protocol. Moreover, the leading therapists (AD-G and AG-R) developed doctoral dissertations focused on the application of transdiagnostic CBT (Díaz-García et al., 2017; González-Robles et al., 2020). All the therapists have experience with group psychotherapy, and they will be supervised by expert clinicians with extensive experience in the application of evidence-based CBT and this transdiagnostic protocol for emotional disorders. All the therapists involved in participant assessments have already been trained in the use of the diagnostic interview (i.e., MINI). The study flowchart is shown in Fig. 1.

The study has been registered in Clinicaltrials.gov (https://clinicaltrials.gov/) as NCT04008576 (https://clinicaltrials.gov/ct2/show/NCT04008576) and received ethical approval from the Ethics Committee of Universitat Jaume I (Castellon, Spain).

Because the study is designed to assess the feasibility of conducting an RCT, a formal power calculation is not considered appropriate. A minimum of 30 participants is considered enough to cover the aims of this feasibility study and to provide data about a number of parameters (i.e., adherence, attrition, satisfaction with the online treatment and with the face-to-face group sessions, deterioration rate, platform usage, and so on) that will help to optimize the future RCT design.

2.3. Eligibility criteria

The selection of participants will be based on the following eligibility criteria: a) age 18 years old or older; b) fluency in Spanish; c) daily access to the Internet at home and an email address; d) meeting DSM-5 diagnostic criteria (DSM-5 American Psychological Association, 2013) for at least one of the following emotional disorders (Bullis et al., 2019): major depressive disorder, dysthymic disorder, other specified/unspecified depressive disorder, panic disorder, agoraphobia, social anxiety disorder, generalized anxiety disorder, other specified/unspecified anxiety disorder, and obsessive-compulsive disorder; e) absence of schizophrenia, bipolar disorder and/or alcohol and/or substance dependence disorder; f) absence of high suicide risk; g) not receiving any additional psychological treatment during the study period; and h) no changes and/or increases in pharmacological treatment during the treatment and follow-up periods (decreases in medication will be accepted).

2.4. Treatment

The treatment consists of a blended transdiagnostic group intervention delivered during a period of 24 weeks. Groups of 6 to 10 patients will attend a total of eight 2-hour, face-to-face sessions, alternated with the use of an online platform where they will find the contents of the treatment protocol. The treatment is a 16-module transdiagnostic CBT Internet-delivered protocol adapted from the Unified Protocol (Barlow et al., 2011a, 2011b) and treatment strategies derived from Dialectical Behavioral Therapy (Linehan, 1993). The treatment was initially developed and structured in a patient and therapist handbook (Botella et al. Transdiagnostic Treatment for Emotion Disorders: Manualized Treatment Protocol, unpublished) and, later, adapted to a multimedia web platform designed by our research group (https://www.psicologiaytecnologia.labpsitec.es). The intervention has four core components that aim to: a) increase present-focused awareness, b) promote cognitive flexibility, c) identify and modify behavioral and cognitive patterns of emotional avoidance, and d) promote interoceptive and situational graded exposure. Additionally, it also contains a treatment component aimed at regulating positive affect (modules 12 to 15). These components are preceded by three modules containing psychoeducation about emotions and emotion regulation, and a module to facilitate patients' readiness to change (motivation for change) (modules 1 to 3), and they are followed by a relapse prevention module (module 16). More details about the online treatment platform and the contents of the modules have been published elsewhere (Díaz-García et al., 2017; González-Robles et al., 2019).

Each group will meet once every three weeks. During the three weeks between group sessions, participants will be asked to access the online platform to review the treatment contents and do the homework tasks. Attendance of participants to the face-to-face sessions as well as program usage will be monitored throughout the whole study period. Overall, group sessions will be divided in two parts: the first part will focus on

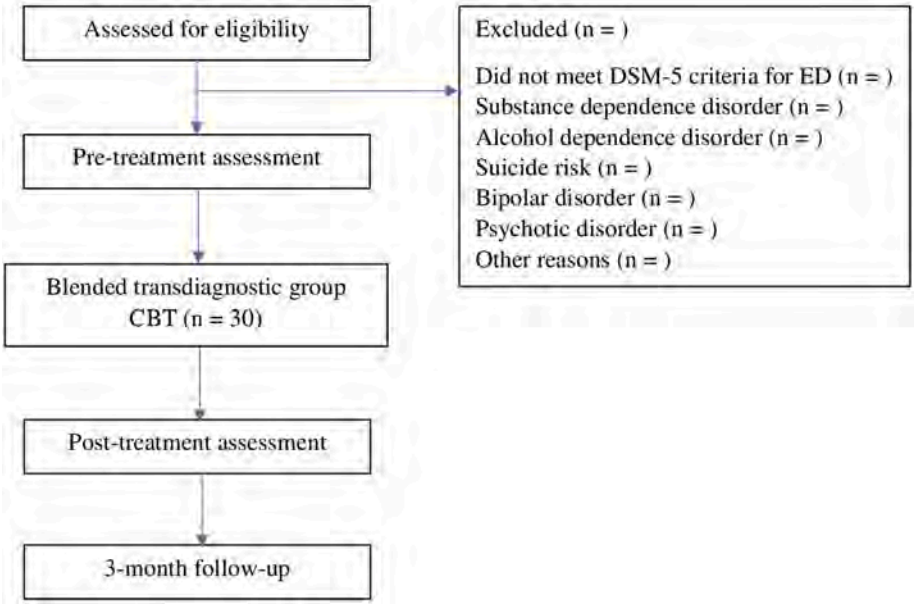

Fig. 1. Flowchart of participants.

discussing the contents of the modules already targeted, whereas the second part will be devoted to presenting the contents of the modules to be addressed in the following three weeks. In order to make the sessions more dynamic and appealing to patients, a practical and participative approach will be followed. The structure of the face-to-face group sessions and the contents of the online modules are described in greater detail in Table 1.

In order to promote the use of the online platform between the group sessions, all the participants will be sent two automatized emails (e.g., "We encourage you to review the modules and carry out all the tasks described in the program as many times as necessary. Remember, the more you practice, the more you will benefit from the treatment") and two mobile phone text messages (e.g. "Hi there! Don't give up on your module tasks! Dedicate some time and effort to them. Remember, practice makes perfect!") once a week during the treatment period. In general, the purpose of these messages is to encourage the practice of the treatment strategies, increase the time the participants spend using the platform, and provide positive reinforcement.

2.5. Outcome measures

2.5.1. Clinical outcomes

2.5.1.1. Diagnostic interview. Mini International Neuropsychiatric Interview Version 7.0.2 (MINI). It is a widely used structured diagnostic psychiatric interview to determine DSM-5 and ICD-10 diagnoses. This interview is a brief and accurate structured interview that can be administered by clinicians after a brief training session and in a short period of time. It can also be administered by nonclinical interviewers after more intensive training. The MINI has excellent test-retest and inter-rater reliability (k = 0.88–1.00) and adequate concurrent validity with the Composite International Diagnostic Interview (Lecrubier et al., 1997). This interview has been translated and validated in Spanish (Ferrando et al., 1997).

2.5.1.2. Primary outcomes measures. Overall Anxiety Severity and Impairment Scale (OASIS) (Campbell-Sills et al., 2009). The OASIS is a 5-item questionnaire that assesses the severity and functional impairment caused by anxiety symptoms during the previous week. Items are rated on a scale ranging from 0 to 4, added together to obtain a score that ranges between 0 and 20. Previous studies have shown good internal consistency (α = 0.80), test-retest reliability, and convergent and discriminant validity. The Spanish version has shown good internal consistency (α = 0.86) and construct validity in patients with emotional disorders (González-Robles et al., 2018a, 2018b).

Overall Depression Severity and Impairment Scale (ODSIS) (Bentley et al., 2014). The ODSIS is a brief scale made up of 5 items for the assessment of the severity and impairment associated with depressive symptoms during the previous week. The responses are coded on a 5-point scale (0 to 4), and scores can range between 0 and 20 points. The instrument has demonstrated excellent internal consistency in different samples (α = 0.91 to 0.94) and good convergent and discriminant validity. The Spanish validation has also shown excellent internal consistency (α = 0.93) and convergent and discriminant validity (Mira et al., 2019).

2.5.1.3. Secondary outcomes measures. Positive and Negative Affect Schedule (PANAS) (Watson et al., 1988). The PANAS is a 20-item scale that assesses the dimensions of positive affectivity and negative affectivity. The scale contains 10 descriptors for each dimension (e.g., "enthusiastic", "inspired", or "proud" in the positive affectivity scale; "scared", "irritable", or "guilty" in the negative affect scale). For each item, responses are rated on a 5-point scale (1–5), and the scores on each scale (10 items on each) can range from 10 to 50. The scale has shown excellent convergent and discriminant validity. The Spanish version has demonstrated good psychometric properties (Díaz-Garcia et al., 2020; Sandín et al., 1999).

NEO-five factor Inventory (NEO-FFI) (Robins et al., 2001). The NEO-FFI is a shorter version of the NEO-PI-R composed of 60 items that evaluate the personality dimensions of the five-factor personality model (Costa and McCrae, 1992). Because this study is focused on a mechanistically transdiagnostic treatment that emphasizes the dimensions of neuroticism and extraversion (McManus et al., 2010), only the scores in these dimensions will be used. The NEO-FFI has shown good test-retest reliability. The Spanish version of the questionnaire also showed good psychometric properties (Aluja et al., 2005).

Quality of Life Index (QLI) (Mezzich et al., 1986). The QLI is a scale containing 10 items that assesses quality of life in the following ten areas: psychological well-being, physical well-being, emotional and social support, interpersonal functioning, self-care and independent functioning, community and service support, occupational functioning, self-realization, spiritual satisfaction, and an overall assessment of

Table 1
Structure of face-to-face sessions and multimedia elements.

Sessions	Group session	Modules	Multimedia elements
S1	Part 1 (45′):	M1. Emotional disorders and emotion regulation	Videos 1–5. Objectives of the module; the transdiagnostic approach; emotion regulation; contents of the program; the importance of homework tasks
	– Therapists' introduction	M2. Motivation for change	Videos 6–12. Examples of patients with different emotional disorders
	– Discussion of the advantages and rules of group therapy	M3. Understanding the role of emotions	Multiple-choice check questions *PDF1 questions for reflection*
	– Patients' introduction		*PDF2 summary of M1*
	Part 2 (75′):		
	– Presentation of M1 to M3		Videos 1–6. Objectives of the module; ambivalence about change; identifying objectives and goals; pros and cons of changing (example); identifying objectives and goals (example); the importance of homework tasks Multiple-choice check questions *PDF1 questions for reflection* *PDF2 decisional balance worksheet* *PDF3 treatment goal setting worksheet* *PDF4 summary of M2*
			Videos 1–4. Objectives of the module; what are emotions?; the adaptive role of emotions; the three-component model of emotions; Multiple-choice check questions *PDF1 the function of emotions* *PDF2 three component model of emotions worksheet* *PDF3 summary of M2*
S2	Part 1 (30′):	M4. The acceptance of emotional experiences	Videos 1–5. Objectives of the module; primary and secondary emotional response; present-focused emotional awareness; observe the breath; the five senses exercise
	– Presentation of the agenda	M5. Practicing acceptance	Multiple-choice check questions
	– Doubts and questions about M1 to M3		*PDF1 "what" techniques* *PDF2 "how" techniques*
	– Emphasis on self-monitoring, practice and homework		*PDF3 summary of M4*
	Part 2 (90′):		Videos 1–4. Objectives of the module; present-focused awareness of physical sensations; present-focused awareness of thoughts; present-focused awareness of emotions
	– Presentation of M4 and M5		Multiple-choice check questions *PDF1 present-focused awareness of physical sensations worksheet* *PDF2 present-focused awareness of thoughts worksheet* *PDF3 present-focused awareness of emotions worksheet* *PDF4 present-focused awareness of the daily life worksheet* *PDF5 web links with videos to practice present-focused awareness of emotions* *PDF6 summary of M5*
S3	Part 1 (30′):	M6. Learning to be flexible	Videos 1–8. Objectives of the module; cognitive appraisal; how interpretations influence emotions; how the same situation can be interpreted in different ways; how emotions influence interpretations; negative thoughts (catastrophizing); downward arrow technique; identification and reappraisal of automatic thoughts (example)
	– Presentation of the agenda	M7. Practicing cognitive flexibility	Multiple-choice check questions
	– Doubts and questions about M4 and M5		*PDF1 downward arrow technique worksheet* *PDF2 identification and reappraisal of automatic thoughts worksheet*
	– Emphasis on self-monitoring, practice and homework		*PDF3 summary of M6*
	Part 2 (90′):		
	– Presentation of M6 and M7		Videos 1–5. Objectives of the module; cognitive reappraisal; techniques for cognitive reappraisal; strategies for the reappraisal of automatic thoughts (example); evaluating obsessive, intrusive, nonsensical thoughts Multiple-choice check questions *PDF1 strategies for the reappraisal of automatic thoughts worksheet* *PDF2 identification and reappraisal of automatic thoughts worksheet* *PDF3 downward arrow technique worksheet* *PDF4 identification and reappraisal of automatic thoughts worksheet* *PDF5 summary of M7*
S4	Part 1 (30′):	M8. Emotional avoidance	Videos 1–3. Objectives of the module; types of maladaptive emotional regulation strategies; consequences of maladaptive emotional regulation strategies
	– Presentation of the agenda	M9. Emotion-driven behaviors	Multiple-choice check questions
	– Doubts and questions about M6 and M7		*PDF1 maladaptive emotional regulation strategies worksheet* *PDF2 consequences of emotional avoidance worksheet*
	– Emphasis on self-monitoring, practice and homework		*PDF3 emotional avoidance strategies worksheet* *PDF3 summary of M8*
	Part 2 (90′):		
	– Presentation of M8 and M9		Videos 1–3. Objectives of the module; emotion-driven behaviors; the opposite action Multiple-choice check questions *PDF1 emotion-driven behaviors worksheet* *PDF2 the opposite action* *PDF3 Summary of M9*
S5	Part 1 (30′):	M10. Accepting and facing physical sensations	Videos 1–3. Objectives of the module; the role of physical sensations in emotion; the avoidance of physical sensations
	– Presentation of the agenda	M11. Facing emotions in the contexts where they occur	Multiple-choice check questions
	– Doubts and questions about M8 and M9		*PDF1 exercises to generate physical sensations* *PDF2 symptoms associated with the different exercises*

(*continued on next page*)

Table 1 (*continued*)

Sessions	Group session	Modules	Multimedia elements
	– Emphasis on self-monitoring, practice and homework Part 2 (90′): – Presentation of M10 and M11		*PDF3 symptom induction test worksheet* *PDF4 interoceptive exposure self-monitoring worksheet* *PDF5 summary of M10* Videos 1–4. Objectives of the module; what is graded exposure?; Situational exposure; exposure in the imagination Multiple-choice check questions *PDF1 emotional exposure hierarchy worksheet* *PDF2 exposure self-monitoring worksheet* *PDF3 summary of M11*
S6	Part 1 (30′): – Presentation of the agenda – Doubts and questions about M10 and M11 – Emphasis on self-monitoring, practice and homework Part 2 (90′): – Presentation of M12 and M13	M12. Learning to move on M13. Learning to enjoy	Videos 1–6. Objectives of the module; the relationship between inactivity and emotional distress; how being active can improve emotional well-being; the importance of short- and long-term significant life goals; the role of social support in emotional well-being; difficulties with and recommendations for behavioral activation Multiple-choice check questions *PDF1 recommendations for setting short- and long-term significant life goals* *PDF2 activity planning and social support form* *PDF3 diary of daily activities form* *PDF4 summary of M12* Videos 1–5. Objectives of the module; the role of positive emotions in life; the induction of positive emotions; the importance of smiling; exercise: smile to others Multiple-choice check questions *PDF1 summary of M13*

quality of life. The QLI has shown high test-retest reliability ($r = 0.87$). The Spanish version of the QLI has shown good internal consistency ($\alpha = 0.87$) and test-retest reliability in a clinical sample (Mezzich et al., 2000).

Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002). The WSAS is a 5-item scale that evaluates the degree of interference associated with the patients' symptoms in the following five domains: work, home management, private leisure, social leisure, and family relationships. Items are coded on a scale from 0 (not at all) to 8 (very severely), and higher scores are indicative of greater interference in the different areas. The scale has shown good to excellent internal consistency ($\alpha = 0.70$ to 0.94), test-retest reliability, and sensitivity to change. The Spanish version has demonstrated excellent internal consistency and good concurrent validity (Echezarraga et al., 2018).

2.5.2. Treatment acceptability

2.5.2.1. Expectations and opinion of treatment. Expectations and opinion of treatment scales (Borkovec and Nau, 1972). Each scale contains 5 items rated from 0 ("nothing at all") to 10 ("completely"). The expectation scale is applied after the treatment rationale has been explained. It aims to assess subjective patient expectations about this treatment. The opinion scale is administered after the patient has completed the treatment, and its objective is to evaluate the patient's satisfaction with this treatment. The items cover how logical the treatment is ("How logical do you think this treatment is?"), the degree of satisfaction with the treatment ("How satisfied are you with the treatment?"), whether the patient would recommend it to a person with similar problems ("To what extent do you feel confident recommending this treatment to a friend who has the same problems?"), how useful the treatment would be in treating other psychological problems ("To what extent do you think this treatment could be useful in treating other psychological problems?"), and how useful the treatment is for the patient ("To what extent do you think this treatment will be/was helpful to you?").Our team has used this scale in a number of research studies (Botella et al., 2009, 2016; Campos et al., 2018; Mira et al., 2017).

2.5.2.2. Satisfaction with the group sessions. In order to evaluate the participant's satisfaction with each of the different face-to-face group sessions, an ad hoc questionnaire was developed with seven questions rated on a Likert scale. The questions, rated from 0 (not at all) to 10 (extremely), include the following: 1) How helpful do you think the contents of this session can be for your problems?; 2) How useful do you think the contents of this session can be for your psychological problems at other times in your life?; 3) How logical do the contents of this session seem to you?; 4) How difficult/boring do the contents of this session seem to you?; 5) How interesting/enjoyable do the contents of this session seem to you?; 6) How clear/understandable were the contents of this session to you?; and 7) What overall score would you give the session?

Table 2
Study variables and assessment times.

Measure	Area of assessment	Time of assessment
Diagnostic interview		
MINI	Psychiatric diagnosis	BL
Primary outcomes		
OASIS	Severity of anxiety	BL, post-M, post-T and FU
ODSIS	Severity of depression	BL, post-M, post-T and FU
Secondary outcomes		
PANAS	Positive and negative affect	BL, post-M, post-T, FU,
NEO-FFI	Neuroticism and extraversion	BL, post-T and FU
QLI	Quality of life	BL, post-T and FU
WSAS	Work and social adjustment	BL, post-T and FU
Expectations scale	Expectations of treatment	BL
Opinion scale	Opinion of treatment	Post-T
Satisfaction scale	Satisfaction with group sessions	Post-F2F group sessions
SUS	Usability of the program	Post-T
Platform usage indicators	Number of modules completed, number of logins, number of times each module has been accessed/reviewed	Throughout the study period

Note. MINI: MINI Neuropsychiatric Interview; BL: Baseline; OASIS: Overall Anxiety Severity and Impairment Scale; Post-M: Post-module; Post-T: Post-treatment; FU: Follow-up; ODSIS: Overall Depression Severity and Impairment Scale; PANAS: Positive and Negative Affect Schedule; NEO-FFI: NEO Five Factor Inventory; QLI: Quality of Life Inventory; WSAS: Work and Social Adjustment Scale; F2F: Face-to-face; SUS: System Usability Scale.

2.5.2.3. Usability of the program. The System Usability Scale (SUS) (Bangor et al., 2008; Brooke, 1996) is applied in order to assess the usability of a service or product and the acceptance of technology by the people who use it. The SUS is a simple, ten-item scale that indicates the degree of agreement or disagreement with the statements on a 5-point scale (1 = strongly disagree; 5 = strongly agree). The final score is obtained by adding the scores on each item and multiplying the result by 2.5. Scores range from 0 to 100, where higher scores indicate better usability.

2.5.3. Other outcome measures

2.5.3.1. Assessment of barriers and facilitators. A focus group method will be used in order to obtain a wider range of answers and greater detail about the participants' opinions of the treatment, the face-to-face sessions, and the online platform. This methodology involves the use of in-depth questions about a given topic in a dynamic group with the aim of providing abundant information about the perspectives, perceptions, opinions, feelings, and thoughts individuals have about a certain issue, in this case, a blended group transdiagnostic treatment (Krueger and Casey, 2000). For this purpose, with the participants' consent, we will record the focus group interviews on audiotapes, and we will conduct qualitative data analyses. Specifically, we will use the Consensual Qualitative Research (CQR) methodology to gather information within certain thematic areas and subsequent domains (Hill et al., 2005). CQR was developed by psychotherapy researchers, and there is a data analysis protocol with a clear explanation about how to analyze the raw data (McLeod, 2013).

2.5.3.2. Online platform usage measures. Participants' engagement and use of the online treatment platform will be assessed using several measures collected by the online system. These data will include information such as the total number of modules completed, the number of days spent in each module, the number of times each module was accessed (i.e., every time the user logs on to the platform), and the number of times each module was reviewed.

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

3. Ethics and dissemination

The trial has received ethical approval from the Ethics Committee of Universitat Jaume I (September 2019) and will be conducted in accordance with the study protocol, the Declaration of Helsinki, and good clinical practice. All participants will be volunteers, and they will sign a written, informed consent before their participation in the study. The security and confidentiality of the data will be guaranteed, i.e., all transferred data will be secured via AES-256 encryption (Advanced Encryption Standard). The web platform will be accessed through a unique username-password combination that will be available on a 24/7 basis. Only participants will have access to their password. In order to protect patients' privacy, sensitive information, i.e., personal data, will be replaced by codes and stored separately from clinical data (e.g. clinical outcomes). Only researchers directly involved in the current study will have access to these data. The results of this study will be disseminated by presentation at conferences and will be submitted for publication in a peer-reviewed journal.

4. Data analysis plan

Because the goal of this study is to analyze the feasibility of a blended transdiagnostic group intervention for ED, the analysis will be performed through descriptive statistics rather than formal hypothesis testing. To preliminary estimate the impact of the intervention, means, standard deviations, effect sizes and their corresponding confidence intervals will be calculated for both principal and secondary measures. The software SPSS version 26.0 will be used to conduct these analyses. Finally, qualitative data analyses will be conducted following the COnsolidated criteria for REporting Qualitative research (COREQ) (Tong et al., 2007).

5. Discussion

This study investigates the feasibility of a novel, blended (face-to-face and Internet-delivered therapy), group intervention for the regulation of emotional disorders. First, we aim to study the adequacy of the recruitment and data collection processes (e.g. whether inclusion and exclusion criteria should be adjusted; patients' willingness to participate in the trial). Second, another goal is to explore the reasons of patients that refuse to participate (e.g., the patient prefers an individual format). Relatedly, compliance with both the treatment and assessment protocols, retention and attrition rates, as well as reasons for drop out will be studied. Therefore, the psychometric data obtained in this trial will be helpful to define the assessment protocol in anticipation of a future RCT. Finally, both quantitative (i.e., expectations and opinion of treatment, usability of the treatment platform) and qualitative data (i.e., interviews about participants' opinions) will be collected and analyzed. In our own experience as clinical researchers, qualitative analysis procedures can provide critical data to improve the design and development of clinical trials (Fernández-Álvarez et al., 2017). On the other hand, this study seeks to preliminary estimate the impact of the intervention in a number of clinical measures at post-treatment and 3-month follow up. Taken together, these objectives will help to optimize the design of a future RCT. The present study seeks to contribute to solving some of the challenges in the mental health field, specifically to transform the healthcare system and policy responses in order to disseminate and implement evidence-based treatments (EBTs) around the world (Collins et al., 2011) and provide psychological support to all those in need (Kazdin, 2015). In line with this, the intervention described in this study combines the advantages of transdiagnostic treatments for emotional disorders (better management of comorbid presentations, higher cost-effectiveness, and dissemination) (Mansell et al., 2009; McEvoy et al., 2009; Sauer-Zavala et al., 2017) and Internet-delivered treatments (accessibility, versatility, and anonymity) (Andrews et al., 2010; Richards and Richardson, 2012; Spek et al., 2007).

Although Internet-delivered treatments are generally effective for depression and anxiety disorders, not all patients benefit from this treatment delivery format equally (e.g., patients who need more personal contact or those less likely to benefit from Internet-delivered treatments) (Fernández-Álvarez et al., 2017). Consequently, face-to-face therapy remains an important aspect of mental healthcare. Blended interventions have been developed to cover the research priority of delivering cost-effective interventions. It is not surprising, therefore, that combining these two approaches (i.e., face-to-face and Internet-delivered treatments) into one integrated treatment may be a way to take advantage of the best aspects of these two treatment modalities (Kooistra et al., 2014; Van der Vaart et al., 2014; Wentzel et al., 2016). Nevertheless, research on blended interventions has focused primarily on individual therapy, and less attention has been paid to the potential of using this format in group psychotherapy and, more specifically, in group transdiagnostic treatments, which have already shown their efficacy in several RCTs (Norton, 2012; Reinholt et al., 2017). Adding the group format intervention to a transdiagnostic treatment for emotional disorders and delivering it in a blended therapy format could contribute to some of the research priorities, such as the implementation of EBTs and the dissemination and sustainability of mental health promotion (Forsman et al., 2015; Wykes et al., 2015).

Despite the existence of effective evidence-based treatments, their transfer to routine practice is often quite scarce (Cunningham et al., 2010; Grimshaw et al., 2012). Specifically, the implementation of blended therapy combining face-to-face and Internet-delivered interventions is still limited. The use of blended therapy may depend on its

clinical effectiveness, but also on its acceptance by patients undergoing the treatment. In this regard, knowledge about barriers and facilitators in the implementation of a blended therapy from the patients' perspective seems to be essential. A qualitative approach (focus group) will be followed to explore this aspect.

In summary, this feasibility study presents a user-centered blended group intervention for the treatment of emotional disorders. To the best of our knowledge, this is the first study to investigate the feasibility of a blended group transdiagnostic treatment in patients with emotional disorders.

We are aware that this study has limitations. On the one hand, the trial has no control group, and so no conclusions can be drawn about the clinical efficacy of the intervention. The selection of an adequate control group (e.g., advantages and disadvantages of different types of control group) will be carefully considered when planning the future RCT. However, the aim of this study is to gain insight into the implementation value of a transdiagnostic group blended treatment, rather than its clinical effectiveness. On the other hand, because face-to-face sessions take place once every 3 weeks, some patients' use of the online platform might be lower than expected. To mitigate this, we developed a support protocol that includes automatized emails and text messages (e.g., with reminders about the importance of doing the homework tasks, practicing the different strategies, and so on).

The results of this study will provide data on the acceptability and feasibility of a transdiagnostic blended treatment for patients with emotional disorders. Furthermore, it will facilitate knowledge acquisition and open up new forms of patient-to-patient or patient-to-therapist communication. This will provide valuable data about the way patients use the program modules, the frequency and duration with which they enter them, the opinion about each of them, and the adherence to the program. This study may help to consider the utility of feasibility studies in practice, with the aim of better understanding the way an intervention works and facilitating ongoing adaptation of the treatment and assessment design in preparation for a randomized controlled trial of a blended transdiagnostic group treatment for emotional disorders.

Ethics approval and consent to participate

The study follows the guidelines of the Declaration Helsinki and existing guidelines in Spain and the European Union for the protection of patients in clinical trials. All participants interested in participating signed an informed consent form. The study has been approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain).

Consent for publication

"Not applicable" in this section.

Availability of data and material

It is not possible to share the data because the study is in progress. We are now at the stage of data recruitment.

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CRediT authorship contribution statement

AD-G drafted the manuscript. AD-G, in collaboration with AG-R, AG-P, and CB designed the study. IF-F, CT, and DC participated in each of its phases. AG-P and CB participated in the review and revision of the manuscript. All the authors have approved the final manuscript to be published.

Authors' information

AD-G holds a PhD in Clinical Psychology at Universitat Jaume I in the Department of Basic and Clinical Psychology, and Psychobiology, granted by Ministry of Economy and Competitiveness. AD-G is also PhD Assistant Professor at the Department of Psychology and Sociology (Universidad de Zaragoza) and member of LabPsiTec (Laboratory of Psychology and Technology) (www.labpsitec.com) at Universitat Jaume I. AG-R is PhD Assistant Professor at the Department of Psychology and Sociology (Universidad de Zaragoza) and IF-F and CT are PhD student in Clinical Psychology at LabPsiTec. DC holds a PhD in Clinical Psychology and she is PhD Assistant Professor at Universidad de Valencia, Spain, in the Department of Personality, Evaluation and Psychological Treatments, and she is member of LabPsiTec. AG-P is Full Professor of Clinical Psychology in the Department of Basic and Clinical Psychology, and Psychobiology. AG-P is also director of LabPsiTec. CB is professor emeritus at Universitat Jaume I in the Department of Basic and Clinical Psychology, and Psychobiology.

Declaration of competing interest

The authors declare that they have no competing interests.

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