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Cost-effectiveness and acceptability study of the Unified Protocol for the treatment of emotional disorders in brief groups in primary care services of the Spanish National Health System: a study protocol

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Abstract

Background Emotional disorders are the most prevalent mental health conditions worldwide. In Spain, the limited availability of mental health professionals has led to long waiting lists, contributing to the saturation of the Spanish National Health System (SNHS). This study protocol aims to evaluate the cost-effectiveness and acceptability of the Unified Protocol delivered in group format, using two brief versions (5 and 8 sessions), through a randomized controlled trial in Primary Care centers across Spain. The study also aims to identify patient profiles responding better to each condition.

Method Participants diagnosed with emotional disorders will be randomly assigned (1:1 ratio) to the 5- or 8-session Unified Protocol condition. Randomization will be stratified by severity of anxiety and depressive symptoms. A minimum of 180 participants will be recruited. Assessments will be conducted up to the 6-month follow-up. Data will be analyzed using descriptive statistics, Pearson's *r* correlations, multiple linear regressions, *t*-tests, repeated measures ANOVA, hierarchical models, cross lagged panel models and effect size calculations (Cohen's *d*). The results of this study will explore the cost-effectiveness, and acceptability of the two brief Unified Protocol formats, as well as identify patient profiles that benefit most from each version.

Discussion Findings could improve access to evidence-based care, reduce waiting lists and identify patient profiles to guide personalized, efficient interventions while optimizing SNHS resources.

Trial registration Clinical Trial Number (NCT06547450||https://clinicaltrials.gov/study/NCT06547450) with the Clinical Trial Registry (7th August 2024).

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Keywords Brief Group Interventions, Unified Protocol, Emotional Disorders, Primary Care, Transdiagnostic, Study Protocol

Background

Mental disorders are among the top 10 causes of health loss worldwide according to the Institute for Health Metrics and Evaluation (IHME) [1]. Specifically, depressive, anxiety and related disorders (e.g., obsessive-compulsive, trauma, somatic), also known as Emotional Disorders (EDs) [2], are the most prevalent mental health disorders worldwide and also among different age groups [3].

In the case of Spain, about 5 million people suffered from at least one ED in 2020, representing 12.69% of the population [4]. During 2022, the most common mental health problems in the country were anxiety disorders, sleep disorders and depressive disorders. The prevalence of these disorders shows an increasing trend since 2016; specifically, they have increased by 105%, 59% and 20%, respectively. The rates recorded for these disorders in 2022 were: 106.5 cases per 1,000 population for anxiety disorders, 81.6 per 1,000 for sleep disorders and 47.8 per 1,000 for depressive disorders [5].

On the other hand, the high prevalence of EDs is reflected in their high incidence in Primary Care (PC), where we find that anxiety disorders have a prevalence of 126.9 cases per 1,000 inhabitants, while depression affects 46.8 cases per 1,000 inhabitants [6]. Finally, these disorders represent a cost of 4.2% of Spain's Gross Domestic Product (GDP) [7]. As a result of their high prevalence and associated costs, EDs have become a general health problem.

A study conducted by the World Health Organization (WHO) highlights the need for investment in mental health services in PC, as this represents a fundamental change towards achieving accessible, comprehensive and person-centered care. Despite being a good theoretical approach, in practice we encountered various difficulties, such as lack of resources, infrastructure and professionals' recruitment [8]. Regarding human resources, the ratio of psychology professionals in Spain is 5.58 per 100,000 inhabitants, well below the recommended minimum of 12 psychologists per 100,000 inhabitants [9]. In the Spanish National Health System (SNHS), each psychology professional cares for approximately 330 patients per year (about 9 patients per day), exceeding international recommendations, which estimate 86 patients per professional per year [10].

The high burden of care, mostly of people with EDs, contributes to delays in care, leads to long waiting lists and limits the time spent in each appointment [11]. In specialized care, waiting lists for a first psychology session average 4 months for ordinary cases, and 1 month for preferential cases [10] and the average time between sessions is 1.8 months [12]. This hinders an adequate evaluation and the implementation of evidence-based treatments, which should be applied in 8 sessions (depending on the disorder) and on a weekly basis [13, 14].

In view of this situation, it has been proposed to increase the number of clinical psychologist positions in the SNHS, especially in PC. Autonomous communities such as Catalonia, Madrid, Valencia, Balearic Islands, Asturias, Galicia, La Rioja, Region of Murcia, Andalusia, Cantabria, Navarra, Canary Islands, Ceuta and Melilla are adopting this measure to address the problem [15]. The incorporation of psychology services into PC will help to improve the intervention's efficiency through an appropriate assessment, intervention and referral, for example, determining which cases do not require psychological treatment, conducting brief psychological interventions to those individuals with mild to moderate emotional symptoms, and referring more severe cases to specialized mental health services and specialized units (i.e., personality disorders unit or eating disorders unit).

Another alternative that has emerged to mitigate the high demand for care is the use of group psychological interventions, a cost-effective format for systems with limited resources, as in the case of the SNHS [16]. In relation to this, the transdiagnostic approach has also led to the design of different psychological interventions for EDs that have been tested in the context of the SNHS with promising results. In this context, a systematic review and meta-analysis conducted by Corpas et al. [17], which examined the effectiveness of brief transdiagnostic interventions for EDs in PC settings in 11 countries (United Kingdom, Australia, China, Zimbabwe, Pakistan, Germany, Taiwan, India, and Sweden), found no significant differences in effect size at the end of the intervention between psychological interventions and the combination of these with pharmacological treatment. Furthermore, the findings suggest that brief interventions, consisting of approximately six sessions, may be sufficient to produce a clinically meaningful change in individuals with EDs.

One transdiagnostic psychological intervention is the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP), a cognitive-behavioral intervention developed by Dr. Barlow's team. It aims to target the transdiagnostic mechanisms associated with the etiology and maintenance of EDs through training in 5 emotional regulation skills: Nonjudgmental Mindfulness, Cognitive Flexibility, Oppositional Behaviors, Interoceptive Exposure and Emotional Exposure. These five skills

are included within the 8 modules of the UP: (1) Motivation for change; (2) Emotional psychoeducation; (3) Training in emotional awareness; (4) Cognitive restructuring; (5) Correct avoidant behaviors; (6) Increase tolerance to physical sensations; (7) Emotional exposure and (8) Relapse prevention [18].

So far, we know that the UP is an evidence-based and versatile intervention, which has allowed its adaptation to different contexts, as well as the duration and number of sessions [19]. One of the characteristics of these adaptations is that they always maintain the 5 emotional regulation skills trained in the UP. Its efficacy is supported by multiple reviews and meta-analyses [20–22]. In the Spanish context, a 12-session group format was implemented in specialized mental health care services [12], where UP group intervention was statistically noninferior to treatment as usual (TAU), both conditions showing significant improvements over time. At 15 months, effect sizes favored UP, which also showed higher treatment retention, better outcomes in diagnostic criteria and comorbidity, and greater participant satisfaction. Another outcome derived from this study was that, although the UP applied in group format involved a higher initial cost, it proved its cost-effectiveness in the long term compared to individual face-to-face treatment [12]. These findings highlighted that a group-based transdiagnostic intervention can effectively reach a larger population in less time and at a lower cost, while maintaining therapeutic efficacy.

Given all this, there is an interest in finding out the number of sessions that are necessary for a person with ED to recover. This idea is consistent with the "stepped-care" movement, a staged approach to mental health service delivery, which offers the most effective intervention with the fewest resources, increasing intensity if necessary [23]. Stepped-care models are evidence-based and have proven to be cost-effective alternatives to conventional mental health care, achieving greater efficiency in health services (reductions in waiting lists and greater access to evidence-based treatment) [24, 25].

Regarding the application of the UP in PC, we found the study by Corpas et al. [26] which included 105 participants with a diagnosis of ED. In this study they compared the UP in brief group format with TAU. The transdiagnostic intervention condition consisted of the UP adapted to a brief format of 8 sessions delivered over 8 weeks. The TAU consisted of pharmacological treatment. The results showed that the brief group UP condition was more effective than TAU in reducing clinical symptoms of EDs, as well as in modifying cognitive processes and emotional regulation strategies.

Along the same lines, our research group adapted the UP into brief formats of 5 and 8 sessions, which were implemented in a pilot study conducted in PC settings with a total of 43 participants. This investigation compared two conditions of the UP: a 5-session group format focusing on the five core emotional regulation skills, and an 8-session group format in which each session targeted a different module of the original manual [18]. The results showed statistically significant improvements in anxiety and depression symptoms, emotion regulation, quality of life, and transdiagnostic variables in both conditions. Moreover, no statistically significant differences were found between the two formats [27].

Based on existing research and the results of the pilot study, the primary aim of this study is to conduct a multicenter randomized clinical trial applying the UP in a group format delivered in 5 and 8 sessions in PC. This trial will assess the cost-effectiveness and acceptability of two transdiagnostic group interventions based on the UP, and will also include secondary analyses to identify patient profiles that benefit the most from the intervention.

Method

Study design

This study will be a randomized, multicenter, controlled trial with a parallel-group design, conducted in PC centers within the SNHS. There will be two active intervention conditions. The UP [18] will be delivered in group format, with either 5 or 8 sessions, to individuals diagnosed with EDs.

Participants

The sample will consist of adults diagnosed with an ED presenting with mild to moderate symptomatology, receiving care at PC centers in various regions of Spain.

Inclusion criteria for this study will be as follows: (1) Have at least one ED diagnosis (anxiety, depressive, obsessive-compulsive, trauma and somatic disorders) through the ADIS-5 interview [28]; (2) present a severity score between 0 and 5 (mild-moderate) in the diagnoses in the "Clinical Severity Rating" (CSR) of the ADIS-5 [28]; (3) be able to attend all assessment and treatment sessions and sign the informed consent; (4) if taking any medication, they will be asked to maintain the dosage for the duration of the study, unless there is a medical contraindication.

On the other hand, the exclusion criteria are as follows: (1) Absence of clinical diagnosis; (2) having a diagnosis of ED with a diagnostic severity score above 5 on the ADIS-5 CSR [28] (severe) or a clinical condition requiring specialized mental health intervention, such as the presence of severe mental disorder (e.g., personality disorder, bipolar disorders or schizophrenia), suicide risk at the time of assessment, or substance use in the past 3 months; (3) having received 8 or more sessions of Cognitive Behavioral Therapy (during the past 5 years) with

cognitive flexibility or exposure techniques; (4) currently receiving psychological treatment.

Procedure

The study procedure can be seen in Fig. 1. First, the sample will be recruited through PC centers collaborating in the study, specifically within their Psychology Programs. Patients will be referred by their family physician to the psychologists of the corresponding Psychology Program. During the initial consultation, these psychologists will inform patients about the possibility of participating in the study. Those who agree to participate will be evaluated to determine whether they meet the inclusion and exclusion criteria, and will undergo assessment by psychologists using the Anxiety Disorders Interview Schedule for DSM-5 (ADIS-5) [28] and the ADIS-5 Clinician Severity Rating (CSR) [28]. The CSR rates the severity of clinical diagnoses on a 9-point scale (0: not at all; 1–2: mildly disturbing and disabling; 3–5: clearly disturbing and disabling; 6–7: markedly disturbing and disabling; 8: very disturbing and disabling). Participants presenting with severe mental disorders or CSR scores above 5 will be referred to specialized mental health services.

Participants who meet the inclusion criteria and provide informed consent will complete the assessment battery through the online platform Qualtrics (http://www.qualtrics.com/es). In cases where internet access is not available, assessments will be administered in paper format. Participants will be randomly assigned to one of the two conditions in a 1:1 ratio, using stratified randomization based on the severity of anxiety and depressive symptoms, as measured by the Overall Depression Severity and Impairment Scale (ODSIS) [29, 30] and the Overall Anxiety Severity and Impairment Scale (OASIS) [30, 31], in order to ensure comparability between groups in terms of symptom severity. Single blinding will be implemented, with data analysts blinded to group allocation. Randomization will be performed using the "*randomizer*" software (https://www.randomizer.org/) to assign partic ipants to one of the treatment conditions: the 8-session group UP condition or the 5-session group UP condition. Participants can drop out from the study at any time on request.

Each group will consist of 6 to 8 participants. Throughout the intervention, participants will receive a summary of each session's content, along with self-monitoring forms and between-session exercises derived from the second edition of the UP Manual [18]. In both conditions, sessions will be delivered in a group format, with a therapist and co-therapist, with each session lasting two hours and having a weekly frequency throughout the treatment phase.

Outcome assessments will be conducted at the following time points: pre-treatment, post-treatment, and at 1-month, 3-month, and 6-month follow-ups. Brief assessment instruments will be prioritized in order to minimize participant burden. Finally, ODSIS [29, 30] and OASIS [30, 31] will be used as monitoring tools from session to session.

Additionally, after the second treatment session, participants will receive a phone call from research team members who are not involved in the therapeutic process. The purpose of this contact is to enhance treatment adherence and to assess participants' motivation and expectations regarding the intervention (ECQ) [32], as well as to administer the Group Climate Questionnaire (GCQ) [33, 34] and the Working Alliance Inventory (WAI-S) [35, 36].

Therapists and co-therapist will be previously trained in UP and will also complete a 5-hour training session focused on the UP adaptations for PC settings, followed by weekly clinical supervision sessions provided by a UP expert certified to UP level 3 (Becoming a UP trainer). Once they have implemented the intervention in 5 or 8 sessions, they will be given access to the Qualtrics platform to complete the Barriers to Implementation Questionnaire [37, 38] and an acceptability questionnaire (see "Evaluation Instruments" section), in addition to the post-treatment.

Finally, this study was approved by the ethics committees of the collaborating centers. This study has been previously registered with clinicaltrials.gov (registration number NCT06547450) on August 7, 2024. Participant recruitment will be initiated in February 2026, with completion of the required recruitment for the project expected by September 2027.

Measures

The evaluation battery includes the following instruments which will be administered at the different assessment points, as shown in Table 1.

Intervention

The UP is a cognitive-behavioral psychological intervention [18]. This intervention is designed to address the transdiagnostic mechanisms associated with the etiology and maintenance of EDs (e.g., neuroticism, lack of mindfulness, avoidance, anxiety sensitivity, among others) through training in five emotional regulation skills, which can be seen in Table 2. Additionally, problem-solving content has been incorporated into the cognitive flexibility module.

All sessions will follow the same structure. At the beginning of each session, ODSIS and OASIS will be administered in order to conduct a weekly assessment of anxiety and depressions symptoms. Subsequently, exercises from the previous week will be reviewed, and true/false questions will be completed by the participants, as outlined in the original treatment manual [18], to ensure that

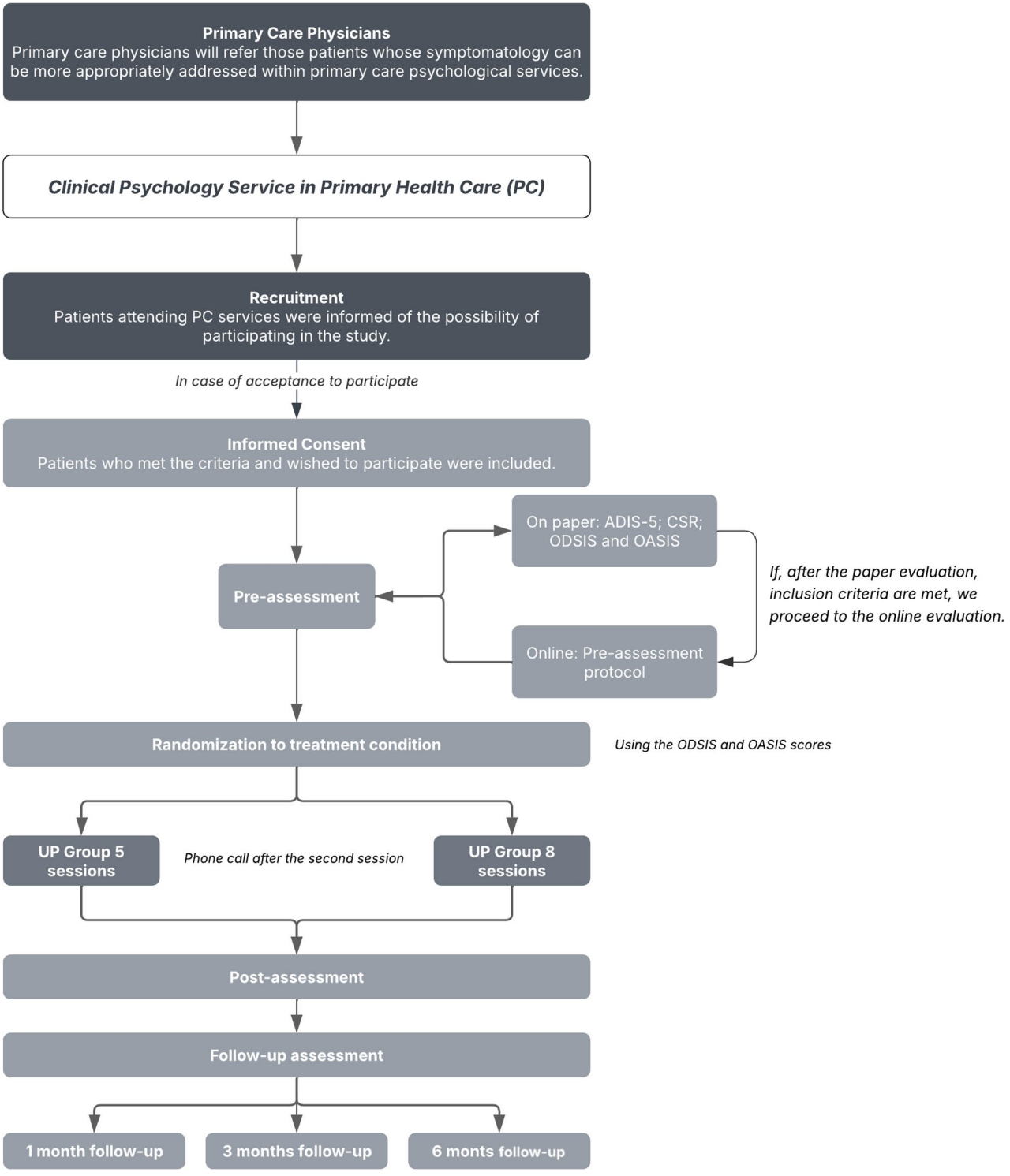

Fig. 1 Flow chart of participants and procedures

they have understood the main concepts of the session. Any doubts that may arise will be addressed afterward. Following this, new session content will be introduced, and in-session exercises will be implemented to promote the acquisition and practice of the corresponding skills. Finally, participants will be assigned between-session practice tasks designed to consolidate the material covered and facilitate the application of skills in their daily lives and will receive a manual containing the session's main information, exercises, and corresponding records.

Table 1 Summary of variables, instruments, and assessment time points in the study

			Assessment points			
	Variable / Construct	**Instrument**	***PRE-T***	***T***	***POST-T***	***Follow-Ups***
Diagnostic Interview	Clinical Diagnosis	Anxiety and Related Disorders Interview Schedule for DSM-5 (ADIS-5) [28]	X		X	
	Clinician-rated severity level	ADIS-5 Clinical Severity Rating (CSR) [28]	X		X	
Primary outcomes	Depression symptoms and interference	Overall Depression Severity and Impairment Scale (ODSIS) [29, 30]	X	X	X	X
		Patient Health Questionnaire-9 (PHQ-9) [39, 40]	X		X	X
	Anxiety symptoms and interference	Overall Anxiety Severity and Impairment Scale (OASIS) [30, 31]	X	X	X	X
		Generalized Anxiety Disorder-7 (GAD-7) [41, 42]	X		X	X
	Quality of life	The World Health Organization-Five Well-Being Index (WHO-5) [43]	X		X	X
	Difficulties in emotion regulation	Difficulties in Emotion Regulation Scale (DERS) [44, 45]	X		X	X
Secondary outcomes	Social and Occupational Functioning	Work and Social Adjustment Scale (WSAS) [46, 47]	X		X	X
	Transdiagnostic dimensions and mechanisms in ED	The Multidimensional Emotional Disorder Inventory (MEDI) [48, 49]	X		X	X
	Maladjustment	Maladjustment Scale (MI) [50, 51]	X		X	X
	Therapeutic alliance	Working Alliance Inventory-Short (WAI-S) [35, 36]		X		
	Treatment expectations	Credibility/Expectancy Questionnaire (ECQ) [32]		X		
	Group cohesion	Group Climate Questionnaire (GCQ-S) [33, 34]		X		
	Use of health and social services	Client Service Receipt Inventory (CSRI) [52]			X	
	Treatment satisfaction	Treatment Satisfaction Questionnaire (STQ); Adaptation of Client Satisfaction Questionnaire (CSQ-8) [53]			X	
Therapist-Reported Variables	Implementation barriers	Barriers to Implementation Inventory [37, 38]			X	
	Treatment acceptability	Ad hoc			X	

PRE-T Pre-treatment, *T* Treatment, *POST-T* Post-treatment, *Follow-Ups* 1-month, 3-month, and 6-month follow-ups

Table 2 Structure and content of the 8-session and 5-session UP conditions

8-session UP condition	**5-session UP condition**
Session 1. Setting goals and maintaining motivation (module 1)	Session 1. Understanding emotions (module 2)
Session 2. Understanding emotions (module 2)	Session 2. *Mindful emotion awareness* (module 3)
Session 3. *Mindful emotion awareness* (module 3)	Session 3. *Cognitive flexibility* (and problem solving) (module 4)
Session 4. *Cognitive flexibility* (and problem solving) (module 4)	Session 4. *Countering emotional behaviors* (module 5)
Session 5. *Countering emotional behaviors* (module 5)	Session 5. *Interoceptive* and *emotional exposure* (module 6 and 7)
Session 6. *Understanding and confronting physical sensations* (module 6)	Follow-ups: Recognizing Accomplishments and Looking to the Future (module 8)
Session 7. *Emotion Exposures* (module 7)	
Session 8. *Emotion Exposures* (module 7) - II	
Follow-ups: Recognizing Accomplishments and Looking to the Future (module 8)	

In italics the main emotional regulation skills of the UP treatment

Power analysis

Sample size calculation was performed using G*Power software [54]. A total sample size of 153 participants was obtained with a power of 95% and an alpha coefficient of 0.05 and a conservative effect size of 0.25. Considering a dropout rate of 15%, we plan to recruit at least 180 participants ($n = 90$ for each condition). This sample size coincides with that established by the design guidelines for this type of study [55], and with other studies carried out with a similar objective [56, 57].

Statistical analysis

Data will be analyzed through descriptive statistics, Pearson's r correlations, multiple linear regressions, t-tests, repeated measures ANOVA, and hierarchical models using the lm4 package (version lme4_1.1–13) [58] for the R statistical software (version 4.1.0) [59] and SPSS v25.0 [60]. Models will follow the structure: [Dependent Variable ~ Time × Experimental Group + (1|Participant) + (1|Center)]. Additionally, cross-lagged panel model will be conducted using the *lavaan* package (version 0.6–13) [61] to examine potential mediation or moderation effects among participants' variables. Effect sizes (Cohen's d) [62] will also be calculated to assess the

magnitude of change in the study variables [small: $d \approx 0.2$; medium: $d \approx 0.5$; large: $d \approx 0.8$]. Finally, a cost-effectiveness analysis will be conducted using Quality-Adjusted Life Years (QALYs) [63], and qualitative analyses will be performed to assess intervention acceptability and satisfaction, using the MAXQDA software [64]. All participants' data will be included in the intention-to-treat analyses.

Discussion

The randomized controlled trial design described in this study protocol, which compares the group-based UP delivered in 5 versus 8 sessions, aims to provide evidence on the minimum number of sessions required to achieve clinically significant outcomes within the PC settings in the SNHS. If the pilot study results [27] were to be replicated in a larger sample within a randomized controlled trial framework, the clinical implications would be substantial. Specifically, implementing the UP in 5 or 8 sessions in PC settings could maximize access to evidence-based treatments for mild to moderate cases, delivered in the recommended number of sessions [13, 14] and at weekly intervals over a time period of 1.5 or 2 months, thereby helping to reduce the duration of emotional distress. This would reduce waiting lists [11] and alleviate the workload of healthcare professionals [10] without compromising clinical effectiveness. Therefore, the findings from this study, which will be disseminated through specific publications in scientific journals, will represent a meaningful advance in scientific knowledge in the field of mental health care, particularly regarding EDs, and will support the transferability of this intervention to routine clinical practice in PC services.

Additionally, this study seeks to provide further information about the feasibility and acceptability of the UP in its natural implementation context, Spanish PC services. It is important to demonstrate that it is possible to use it in PC services by psychologists working in these services (viability) and that both group participants and therapists consider its use beneficial (acceptability). Demonstrating feasibility and acceptability is critical to support large-scale implementation in public healthcare services and contributes to improving their quality and facilitates treatment commitment and adherence [65].

Although brief and intensive UP treatments have shown overall efficacy, it is plausible that certain patient profiles may not benefit equally from such condensed interventions. Identifying the main characteristics of individuals who respond better or worse to the 5- versus 8-session formats could contribute to the personalization of psychological treatments and promote adherence to these brief interventions, which maintain high efficacy in line with the stepped-care approach [23]. This knowledge will inform recommendations about the optimal treatment "dose" for different patient profiles and guide decisions about who may require more extended or alternative interventions, or adaptations such as including specific treatment components (e.g., social skills training) [66, 67].

Moreover, the availability of brief yet effective group psychological treatments could help reduce costs for the SNHS [11]. In recent studies conducted in PC, patients attended an average of four sessions before been discharged. One year after treatment, psychotropic medication prescriptions were reduced by half, and only 20% of users who were not referred to a higher level of care (i.e., those with greater severity) requested additional psychological support [68]. Moreover, receiving effective interventions within a few sessions has been shown to improve patients' psychological adjustment and reduce the risk of chronicity of psychopathology [69] which indirectly has an impact on the costs of the SNHS.

In conclusion, if the interventions prove to be efficacious, feasible, cost-effective, and acceptable for individuals with mild to moderate emotional symptoms in PC, it could be incorporated into mental health services and clinical guidelines as a structured, evidence-based intervention. The findings will also guide recommendations regarding the optimal number of sessions for different patient profiles, supporting personalized and sustainable mental healthcare delivery for the SNHS.

Abbreviations

IHME	Institute for Health Metrics and Evaluation
EDs	Emotional Disorders
WHO	World Health Organization
PC	Primary Care
GDP	Gross Domestic Product
SNHS	Spanish National Health System
UP	Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders
TAU	Treatment as usual

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-026-03347-w.

Supplementary Material 1.

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Authors' contributions

JO conceptualized the research. MSA, IPR, AFJ, MNH and OP advised and contributed to the study design. MSA and OP developed the statistical analysis plan. JO, MSA, IPR, AFJ, MNH and OP jointly developed the study protocol. The project was administrated by JO. MSA, IPR and OP wrote the original draft of the manuscript, which was reviewed by JO, MSA, IPR, AFJ, MNH and OP. All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study will be performed in line with the principles of the Declaration of Helsinki. The study was approved by the ethics and research committee of the Hospital Universitario de la Plana (02/2025), Hospital Comarcal de Vinaròs (PI_25/001), Hospital General Universitario de Castelló (REV-AGO-03-25), CEIm Área de Salud de Zamora (711), CEIm de Atención Primaria del Área IV de Asturias (2025.510), IDIAP Jordi Gol (25/115-P), and the CEIm de las Áreas de Salud de Valladolid (Hospital Universitario Río Hortega; acta nº 1 de 2026, 21/01/2026). Approval will be granted by the Ethics Committee of all collaborating centers.
All participants will consent to participate and will sign the informed consent form.
All changes to this original study protocol (current protocol version; 24th October 2025) will be communicated to the aforementioned Ethics Committee for their approval and will be shown in clinicaltrials.gov.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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