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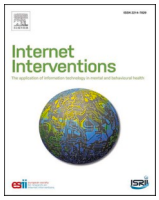

Enhancing Internet-based psychotherapy for adults with emotional disorders using ecological momentary assessments and interventions: Study protocol of a feasibility trial with "My EMI, Emotional Well-being" app

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ABSTRACT

Introduction: Emotional disorders are the most frequent mental health problems globally. To ensure the dissemination of psychological treatments for these conditions, novel forms of delivery (e.g., Internet or mobile apps) and more scalable forms of psychotherapy (e.g., transdiagnostic interventions) have become increasingly popular. Research, however, shows that a significant number of patients, around 40 % according to some studies, do not respond to the interventions as expected (i.e., not-on-track patients). Ecological momentary assessments (EMAs) and ecological momentary interventions (EMIs) could simplify tailoring treatments to the patients' progress and rapidly respond to undesired outcomes during psychotherapy. Therefore, these would facilitate measurement-based care with little therapist involvement. This study aims to explore the feasibility of an app-based system called *My EMI, Emotional Well-being* for people with emotional disorders. According to daily EMAs, the app will provide personalized EMIs while participants receive a self-applied online transdiagnostic treatment. The app will be used as an add-tool to the online intervention to address emotion dysregulation, foster adherence, and reinforce contents. The current study describes the study protocol for this trial.

Method and analysis: A single-group, open trial design will be used. Participants will be 30 adults suffering from emotional disorders. Primary outcomes will be app usability, acceptability, and response rates. Secondary outcomes will be either evaluated in Qualtrics at pre-treatment, post-treatment, and 3-month follow-up (depression and anxiety severity, and transdiagnostic dimensions of emotional disorders) or daily throughout the study with the app (EMAs of mood and five transdiagnostic mechanisms of therapeutic change). EMIs will consist of brief, evidence-based transdiagnostic CBT digital content (images, infographics, or videos) delivered just-in-time. Only if problems persist, short phone calls or episodic videocalls will be conducted. The Ethics Committee of the Jaume I University approved the study and all its procedures (CD/111/2021) in December 2021.

Discussion: Identifying personalized and scalable interventions is paramount to improve mental health care, especially its accessibility, and to reduce the psychological distress of people with mental health problems. Feasibility data of the app (EMA and EMI system) supported by a self-applied online transdiagnostic intervention will be important to explore whether this modern approach is a real option to move forward personalized psychological interventions for persons with emotional disorders.

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1. Introduction

According to transdiagnostic definitions, people with emotional disorders, which generally include anxiety and depressive disorders, are characterized by a) experiencing frequent and intense negative emotions, b) having an aversive reaction to the emotional experience (feeling out of control and a negative appraisal of the emotion), and c) trying to escape or avoid this emotional experience (Barlow et al., 2016; Bullis et al., 2019). Emotional disorders are alarmingly frequent worldwide. Epidemiologic studies before the pandemic (i.e., mostly from 2016) pointed to global estimates of approximately 3.6 % for depression and 5 % for anxiety (Bueno-Notivol et al., 2021; World Health Organization, 2021, 2017). In Spain, the numbers were generally similar both for anxiety disorders (5.2 %) and depression (4.1 %) (Vieta et al., 2021; World Health Organization, 2017). As a consequence of these high prevalence rates, emotional disorders have traditionally lead to considerable direct and indirect economic losses for countries (US$ 1 trillion per year of the global economy) (World Health Organization, 2019), and have resulted in preoccupying global burden in terms of quality of life and overall impaired functioning (Doran and Kinchin, 2019). In addition, the COVID-19 pandemic not only has boosted the incidence of mental disorders in healthy people, but also has exacerbated emotional problems in vulnerable populations. As a result, the prevalence of emotional disorders has increased by at least 25 % and affect up to 25 % of the population globally (Bueno-Notivol et al., 2021; Santomauro et al., 2021; Sher, 2020; World Health Organization, 2022).

In addition, research also indicates that only one in four people with emotional disorders are estimated to receive psychotherapy and, in many cases, these interventions are not evidence-based (Harvey and Gumport, 2015). Particularly in Spain, public resources allocated to mental care are clearly insufficient (Hazo et al., 2017), which is reflected in long waiting lists and lack of therapists - 6 therapists for every 100 thousand inhabitants, while the average in European countries is 18 (Duro Martínez, 2021).

Encouragingly, in recent years, innovations and extensions of cognitive behavioral therapy (CBT) have been developed to address the aforementioned limitations in existing resources for mental health care and, ultimately, facilitate the dissemination of psychotherapy (Hofmann and Asmundson, 2017). Specifically, the development of novel forms of delivery of psychotherapy, particularly Internet-delivered CBT (iCBT) and mobile applications (apps), and the emergence of transdiagnostic interventions have received increasing attention in the literature (Norton, 2022). iCBT has emerged in recent years as an effective alternative to face-to-face psychotherapy to reduce costs, save therapists' and patients' time, bring psychological treatments closer to the population, disseminate interventions easily, and to positively impact the treatment cost-effectiveness ratio (Andrews et al., 2018; Massoudi et al., 2019; Richards et al., 2020). Additionally, the development of mobile apps presents a unique opportunity to improve the delivery of psychological assessments and interventions in the person's natural context (Colombo et al., 2018).

Another innovation to CBT that could maximize the dissemination of psychological treatments is the transdiagnostic approach to emotional disorders (Leonardo et al., 2021; Newby et al., 2015). The transdiagnostic approach has emerged as an arguably cost-effective alternative to treat persons with all sorts of emotional disorders simultaneously, thus making treatments more scalable. While several transdiagnostic psychological interventions exist, the Unified Protocol (UP), an extension of CBT that aims to regulate emotions in a more adaptive way through different core treatment modules, has been recently developed and successfully implemented for the treatment of emotional disorders cross-culturally (Leonardo et al., 2021; Osma et al., 2018; Sakiris and Berle, 2019). So far, the UP has obtained promising effects not only when delivered onsite (Sakiris and Berle, 2019), but also online (González-Robles et al., 2020; Sandín et al., 2020; Schaeuffele et al., 2022), which makes it an excellent psychological option to reach a large number of persons with emotional disorders with a single treatment protocol.

Even though there is evidence that both disorder-specific and transdiagnostic forms of CBT work in different forms of delivery (e.g., online and onsite), research has also revealed that psychological treatments only tend to work on average. In fact, around 40 % of the patients do not improve or only partially respond to the interventions as expected (Andersson et al., 2019; Cuijpers et al., 2019). As pointed out by Professor Sir Grimley Evans in the 90s, while "healthcare managers and trialists may be happy for treatments to work on average; patients expect their doctors to do better than that" (Evans, 1995, p. 462). For this reason, in the past decades and increasingly in the past years, there has been an expanding concern in understanding the reasons why an intervention works for some patients, but not for others (i.e., not-on-track patients) (Hofmann and Hayes, 2019).

A possible explanation for the limited effectiveness of psychotherapy may lie in the structure of both face-to-face and Internet-based treatments. Traditionally, randomized controlled trials using psychotherapy have utilized pre-established and rigid treatments based on a number of pre-determined modules that patients must complete in a linear manner and a very limited number of assessment points, generally a pre-treatment, a post-treatment, and a few follow-ups (Graham et al., 2020; McCloud et al., 2020; Stolz et al., 2018). This clearly ignores patients' needs and evolution during treatment, which might ultimately negatively impact treatment acceptability (patient's satisfaction), adherence (dropout rates and amount of completed practice, which are often a problem in iCBT), and the effectiveness of interventions due to poor personalization (Kok et al., 2014; Milosevic et al., 2015; Stumpp and Sauer-Zavala, 2021). Additional reasons for personalization include heterogeneity and individual differences between patients and changes occurring within each patient during psychotherapy (Zilcha-Mano, 2020). Therefore, providing the same intervention to all patients irrespective of their specific needs and characteristics does not appear to be a sensible practice (Cook et al., 2017; Hofmann and Hayes, 2019). For that reason, providing personalized and adapted just-in-time psychological interventions only when the patient is in need or willing to receive support is paramount to promote engagement and adherence in psychotherapy (Nahum-Shani et al., 2018).Consistent with the previous lines, some authors now suggest a shift toward a model of flexibility in fidelity in manualized treatments (Cook et al., 2017; Păsărelu et al., 2017). Measurement-Based Care (MBC), which consists of routine patient monitoring, periodic feedback to the therapist (or both therapist and patient), and adaptation of the intervention according to such feedback, appears to be a feasible option to personalize and adapt the treatments to the patients' needs during psychotherapy (Gual-Montolio et al., 2020; Stumpp and Sauer-Zavala, 2021; Zilcha-Mano, 2020). Recurrent patient monitoring is now easier than ever with the rapid growth of technologies in our society and the availability of smartphones and mobile apps (Alanzi, 2021). Apps can be used as support tools for the ecological momentary assessment (EMA) of several psychological variables (i.e., outcome variables and mechanisms of change) altogether at the patient's own pace without the need to travel to the clinic or laboratory, and the information can be sent to the clinicians in real time to make rapid adaptations to the intervention (Suso-Ribera et al., 2020).

Adaptation of the treatment to the patients feedback and specific needs is also easier thanks to the recent development of brief, just-in-time interventions, which are based on mechanisms of change that contribute to psychological distress (Nahum-Shani et al., 2018; Walton and Wilson, 2018). These interventions can now be rapidly delivered using apps in the form of ecological momentary interventions (EMIs) (Colombo et al., 2018) that occur in response to pre-set clinical alarms (McDevitt-Murphy et al., 2018; Nahum-Shani et al., 2018) and can serve as timely-relevant therapeutic recommendations or instructions when critical problems arise (Castilla et al., 2022). In particular, this technology-supported approach to care might be an especially relevant

option for not-on-track patients (Gual-Montolio et al., 2020).

The use of MBC enhanced by EMAs and EMIs would facilitate this model shift in psychotherapy that could be used as a complement to existing psychological therapies or as an independent intervention in real time when needed (Goldberg et al., 2018). They can also be used to monitor and encourage participants to actively perform tasks, which can be a very important approach to improve not only effectiveness, but also something as crucial as adherence in self-applied treatments through the Internet (Boswell et al., 2022).

1.1. Objectives

The current study aims to explore the feasibility of an app-based system called *My EMI, Emotional Well-Being*, a recently developed app that will provide personalized EMIs according to the patients' daily assessment observed in the app with the EMAs (Castilla et al., 2022). The app will complement a self-applied online transdiagnostic treatment for people with emotional disorders that has shown to be effective in past research (González-Robles et al., 2020).

The EMA + EMI app developed for the present study has great potential to further enhance online psychotherapy by making these treatments even more personalized and, therefore, potentially more effective. Thanks to the EMA + EMI system, the app will facilitate the provision of the optimal amount of support to the patient at the right time according to their moment-to-moment needs and context (Bernstein et al., 2022; Nahum-Shani et al., 2018). For example, with our app, patients will be assessed daily in their real-life context (e.g., EMA) so that, if a critical situation is experienced (e.g., exacerbation of distress that cannot be controlled with current psychological resources), an EMI based on a just-in-time intervention will be provided in the same app. This just-in-time EMI content will be aligned with the content of the alarm reported (i.e., personalization) and will be provided immediately after the patient reports the event. In doing so, treatments will be based on patient evolution and needs (MBC) as opposed to a pre-established, rigid protocol only.

The objectives of this feasibility study are: 1) to test whether the app is appraised as simple to use, useful, and acceptable by patients (app usability, acceptability, and satisfaction), 2) to test the number of completed assessments and transdiagnostic content (adherence to the app and treatment compliance), and 3) to test the feasibility of support calls and videoconferences made by therapists. As a secondary goal, we will investigate the effectiveness of the app by exploring whether changes in outcome variables and mechanisms of change (i.e., anxiety, depression, and emotion regulation) occur at an individual level after the using the app. These variables are recognized as the key transdiagnostic mechanisms of change across CBT treatments (Schaeuffele et al., 2022).

We anticipate that the implementation of the app *My EMI, Emotional Well-Being* will be feasible in terms of usability, acceptability, satisfaction, compliance, retention rates, and adherence. We also expect to see changes in the mood status and emotion regulation outcomes in at least half of the participants, in line with past research (Parker et al., 2014; Petersen-Brown et al., 2012). The study results in relation to changes in mood and emotional regulation will also be compared with past research using the self-applied online transdiagnostic treatment only (González-Robles et al., 2020) to obtain some insights regarding the potential efficacy boosting contribution of adding an EMI to the online intervention.

The design of a future clinical trial will be optimized according to the results of the present investigation. The current article describes the study protocol of this trial.

2. Methods

2.1. Study design

The current study describes the study protocol of a feasibility trial with a single-group, open-trial design. This study was previously registered at Clinicaltrials.gov (NCT05109780) on November 2021, with the last update posted on September 2022. We will follow the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) (see Additional file 1) (Chan et al., 2013).

2.2. Participants and recruitment

The participants will be recruited using several strategies. On the one hand, this treatment will be offered to people who seek psychological therapy at the Psychological Assistance Service of the Jaume I University of Castellon (Spain). On the other hand, participants will also be recruited through social media platforms (WhatsApp, Instagram, Facebook, and Linkedin) and using poster advertisements placed in community spaces at the Jaume I University.

It has been suggested that 30 participants are sufficient in this type of work to obtain enough feasibility data of new forms of treatment, such as adherence, acceptance, satisfaction with the app, and platform usage (Lancaster et al., 2004). We plan to start recruiting participants by February 2023. This recruitment will end when we have the 30 participants needed for the study, which we expect to happen by June 2023.

2.3. Eligibility criteria

Participants will have to meet the following inclusion criteria: (1) age $\geq$18 years; (2) showing problematic levels (see Measures section for a broader explanation) in at least one of the 9 transdiagnostic dimensions of the *Multidimensional Emotional Disorders Inventory* (MEDI; Osma et al., 2021; Rosellini and Brown, 2019) or having moderate-to-severe anxiety (scores $\geq$8) or depressive symptoms (scores $\geq$5) in the *Overall Anxiety Severity and Impairment Scale* (OASIS) and the *Overall Depression Severity and Impairment Scale* (ODSIS) (González-Robles et al., 2018; Mira et al., 2019); (3) having the ability to read and understand Spanish; (4) having a computer and a mobile phone Internet access; and (5) signing the online informed consent.

Participants will be excluded if: (1) they have a severe mental health condition, substance abuse problem, or high suicide risk (DSM-5 diagnostic criteria); (2) they are receiving psychological treatment for the same emotional problem targeted by our study; or (3) they experience changes and/or increases in pharmacological treatment during the study (stable medication will be accepted). Patients with severe mental health problems or high suicide risk will be excluded, as this might not be the appropriate treatment for these patients. To evaluate this, our team developed an ad hoc questionnaire (see Additional file 2) with current DSM-5 diagnostic criteria for severe mental disorders like bipolar disorder, substance abuse, or schizophrenia, as well as to detect active suicide risk. Treatment recommendations (i.e., other potential clinics) will be made in the eligibility assessment procedure for patients who present any of these severe mental health problems.

In this study, we will move from categorical to dimensional eligibility criteria (Brown and Barlow, 2009). Thus, there will be no need for a categorical disorder if the severity of the affected transdiagnostic dimensions or the severity of symptomatology is sufficiently impairing and long-lasting according to the three well-established transdiagnostic measures presented, which are aligned with the transdiagnostic definition of emotional disorders (Barlow et al., 2016; Bullis et al., 2019). The study flowchart appears in Fig. 1.

2.4. Procedure

Individuals interested in participating will have to complete an online questionnaire via Qualtrics, a web-based survey tool. The questionnaire will contain the personal data protection clause, the study information sheet (see Additional file 3), and the written informed consent (see Additional file 4). Once, they sign the online informed consent, participants will have to respond to an online eligibility

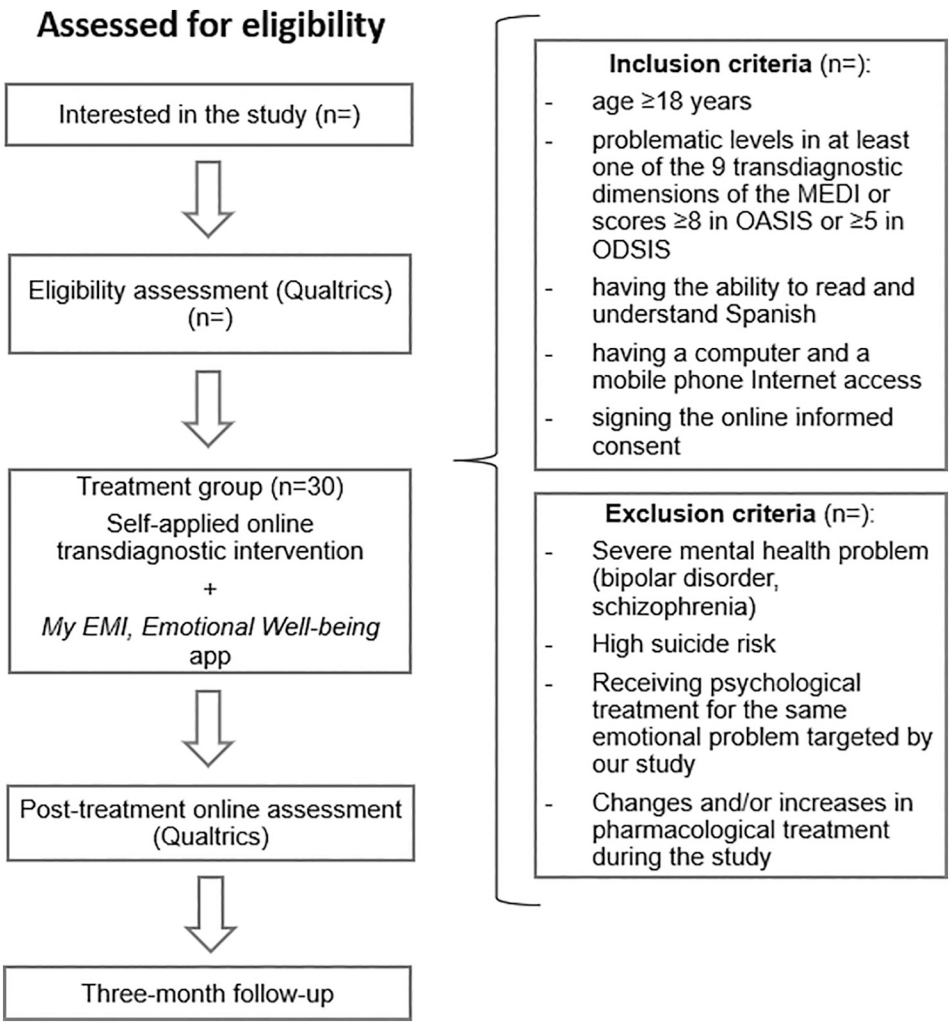

Fig. 1. Flowchart of participants.

evaluation via Qualtrics. The measures used for eligibility will be the MEDI (Osma et al., 2021; Rosellini and Brown, 2019), OASIS and ODSIS (González-Robles et al., 2018; Mira et al., 2019), and an ad hoc questionnaire with DSM-5 diagnostic criteria questions for severe mental disorders and active suicide risk (see Additional file 2).

If a participant does not meet the eligibility criteria at the end of this first evaluation, they will receive automatic feedback informing about their outcome. We will provide these individuals with the contact information of other psychological services they can refer to. Participants who meet the eligibility criteria will receive a unique anonymous alphanumeric code after completing the first assessment. Then, they will be linked to a separate online evaluation form where they will be asked to provide their identifying information (name and surname, phone number, and email), which will be used to identify their clinical records for confidentiality and safety reasons. All the individuals who meet the inclusion criteria and agree to participate will also be asked to download and use the *My EMI, Emotional Well-Being* app daily during the whole study (Castilla et al., 2022), and will be granted access to the self-applied online psychological transdiagnostic intervention that has been tested in past research (González-Robles et al., 2020). The Qualtrics evaluation will be administered again at the end of the treatment to evaluate whether changes occurred at the individual level in the secondary outcomes of the study.

2.5. Measures

Baseline (eligibility), post-treatment, and follow-up evaluations will be conducted online with Qualtrics. Daily assessments (EMAs) will be conducted with the app. Table 1 represents the SPIRIT figure, providing an overview of time points, interventions, and assessments (Chan et al., 2013).

2.5.1. Demographics

The sociodemographic information will be collected with Qualtrics at the end of the enrolment process if eligibility criteria are met. This information will include sex, gender, age, marital status, educational level, job status, place of residence, and country of birth.

2.5.2. Primary outcomes

2.5.2.1. App usability and acceptability. Acceptance and perceived usability of the app-system will be assessed with the System Usability Scale (SUS; Brooke, 1996; Sevilla-Gonzalez et al., 2020) by patients one week after app use through the app. The SUS is a 10-item scale that examines the perceived usability of a technological tool, that is, the perception that the app is simple to use and useful. The SUS has an acceptable reliability (Cronbach's alpha of 0.91) (Lewis, 2018). Responses are measured using a 5-point Likert scale (0 = "strongly disagree" to 4 = "strongly agree"). Additionally, acceptability of the app will be evaluated by the Usability and Acceptability Questionnaire (CUA-Brief),

Table 1
Schedule of enrolment, interventions, and assessments.

	STUDY PERIOD				
	Enrolment	Pre-allocation	Intervention	Post-allocation	
TIMEPOINT	$-t_1$	t_0 (baseline)	t_1	t_2 (post-treatment)	t_3 (follow-up)
ENROLMENT:					
Informed consent	X				
ALLOCATION:					
MEDI	X			X	X
OASIS	X			X	X
ODSIS	X			X	X
INTERVENTIONS:					
Self-applied online intervention		←	—	→	
My EMI, Emotional Well-being app		←	—	→	
Construct EMAs:					
Anxiety		←	—	→	
Sadness		←	—	→	
Anger		←	—	→	
Happiness		←	—	→	
Activity level		←	—	→	
Mechanisms of change EMAs:					
Understanding of emotions		←	—	→	
Mindfulness		←	—	→	
Cognitive flexibility		←	—	→	
Tolerance to physical sensations		←	—	→	
Situational exposure		←	—	→	
Other parameters:					
Demographics	X				
SUS				X	
CUA-Brief				X	
Adherence to the app and treatment				X	
Feasibility of support calls and videoconferences				X	

EMA, Ecological Momentary Assessment; MEDI, Multidimensional Emotional Disorders Inventory; OASIS, Overall Anxiety Severity and Impairment Scale; ODSIS, Overall Depression Severity and Impairment Scale; SUS, System Usability Scale; t1, baseline; t2, immediately after the intervention; t3, 3 months follow-up; CUA-Brief, Usability and Acceptability Questionnaire.

which contains 7 items that assess the participant's opinion about an app (Castilla et al., 2016). This measure has been used in previous studies and its Cronbach alpha was excellent (0.94). Responses in the CUA-Brief are rated using a 5-point Likert scale (0 = "Totally disagree" to 4 = "totally agree").

2.5.2.2. Satisfaction with the app and app-associated burden. These will be evaluated at the post-treatment through the app with a series of app-related items developed by our team and used in previous works using technology (Suso-Ribera et al., 2018a). Example items are "To what extent are you satisfied with the app?" and "To what extent would you recommend the app?"

2.5.2.3. Adherence to the app and to the treatment (i.e., attrition and dropout percentages). Response rates to the app will be calculated at the post-treatment by dividing the number of the completed assessments in the app by the number of planned evaluations (percentage of daily assessments completed from the assessments prompted). Additional data will be passively collected from the online treatment platform and the app, such as the number of modules and tasks completed in the online intervention and the content reviewed in the app.

2.5.2.4. Feasibility of the support calls and videoconferences. The number of support calls and videoconferences made will be recorded as a function of the alarms received, the response rate by patients to this supportive care, and their duration.

2.5.3. Secondary outcomes

2.5.3.1. Pre-to-post-to-follow-up variables. In addition to the feasibility measures, secondary outcomes will also include changes in the severity of depression and anxiety, as well as changes in the transdiagnostic mechanisms of change of emotional disorders, which will be assessed at baseline, at the post-treatment, and at the three-month follow-up via Qualtrics.

1. *Overall Anxiety Severity and Impairment Scale* (OASIS; González-Robles et al., 2018; Norman et al., 2006). It consists of 5 online questions that measure the severity and interference of anxiety during the previous week. The total scale score ranges from 0 to 20. Items are rated on a 5-point Likert scale ranging from 0 to 4. The Spanish validation has shown excellent internal consistency estimates ($\alpha = 0.86$) in patients with emotional disorders (González-Robles et al., 2018). A cut-off point of 8 for the online OASIS was found to be the best rate for a Spanish sample of people diagnosed with emotional disorders (González-Robles et al., 2018).
2. *Overall Depression Severity and Impairment Scale* (ODSIS; Bentley et al., 2014; Mira et al., 2019). It consists of 5 questions that measure the severity and interference of depression. Again, the total scale score ranges from 0 to 20. Items are rated on a 5-point Likert scale ranging from 0 to 4. The Spanish validation has shown excellent internal consistency estimates ($\alpha = 0.93$) in patients with emotional disorders (Mira et al., 2019). A cut-off point of 5 for the online ODSIS was found to be the optimal rate for a Spanish sample of people diagnosed with emotional disorders (Mira et al., 2019).
3. *Multidimensional Emotional Disorders Inventory* (MEDI; Osma et al., 2021; Rosellini and Brown, 2019). The MEDI has 49 questions grouped in 9 dimensions: Neurotic Temperament (NT), Positive Temperament (PT), Depressed Mood (DM), Autonomic Activation (AA), Avoidance (AVD), Somatic Anxiety (SOM), Social Anxiety (SOC), Intrusive Cognitions (IC), and traumatic Re-experimentation (TRM) dimension (Osma et al., 2021). The Spanish validation of the MEDI has shown excellent reliability indices as estimated with the internal consistency of the nine factors (Cronbach's alphas between 0.74 and 92) (Osma et al., 2021). Items are rated on an 8-point Likert scale ranging from 0 to 8. Based on the Spanish validation of the MEDI and the consequent normative scores (Osma et al., 2021), we selected the percentile above 75 as the cut-off point for all dimensions of the MEDI (e.g., NT dimension above 25), except for the PT dimension. Because the PT is the only positively worded dimension in the MEDI, we used the lowest percentile of 25 as cut-off.

2.5.3.2. EMAs. The EMAs included in *My EMI, Emotional Well-being* app will allow the daily monitoring of both outcome variables (i.e., anxiety, sadness, anger, happiness, activity level) and mechanisms of change according to the UP (i.e., understanding the role of emotions, mindfulness, cognitive flexibility, tolerance to unpleasant emotions and physical sensations, and situational exposure). These core components are considered the fundamental skills needed to reduce emotional dysregulation according to the UP (Sauer-Zavala et al., 2021).

Constructs in the app will be evaluated using a single item, which is a frequent practice in EMA research to facilitate adherence and reduce burden of daily assessment (García-Palacios et al., 2014). Items from the outcome variables (items from 1 to 5; see Appendix A) have been previously validated by our group (Colombo et al., 2018; Suso-Ribera et al., 2018a). Items from the mechanisms of change (items from 6 to 10; see Appendix A) have been adapted ad hoc for this investigation. Similar to past research (Suso-Ribera et al., 2018a), a panel of experts from our group extracted and adapted two items (directly and inversely worded items) to avoid acquiescence and to represent each mechanism from well-established measures (Sauer-Zavala et al., 2021; Schaeuffele et al., 2022). These measures were the Difficulties in Emotion Regulation Scale – Awareness Subscale (DERS-A) for understanding of emotions (Kaufman et al., 2016), the Southampton Mindfulness Questionnaire (SMQ) for mindfulness (Chadwick et al., 2008), the Cognitive Flexibility Inventory (CFI) for cognitive flexibility (Dennis and Vander Wal, 2010), the Anxiety Sensitivity Index (ASI) for interoceptive exposure (Reiss et al., 1986), and the Multidimensional Experiential Avoidance Questionnaire – Behavioral Avoidance subscale (MEAQ-BA) for behavioral avoidance (Gámez et al., 2011).

As in past similar research, the criteria to select an item was based on content validity (representativeness), length (short-items are preferred), and factor loading (Suso-Ribera et al., 2018a). Then, experts discussed whether the selected items needed modification for readability reasons. The final set of items can be found in Appendix A. Finally, response options were homogenized to a 0–10 Likert type scale to facilitate the use of the app (García-Palacios et al., 2014; Suso-Ribera et al., 2018b). Cut-off scores of mild to severe symptomatology were established based on past research (0–4 for mild, 5–6 for moderate, and 7–10 for severe) (Castilla et al., 2022).

The daily assessments with the app will be conducted in the afternoon (at 7:00 pm) based on clinical experience, item content, which refers to daily performance and has to be evaluated at the end of the day, and past similar research by our group which included patient advise to facilitate adherence in EMA (Suso-Ribera et al., 2018a). A notification will be sent using a push system and the participants will have 2 h to respond to the items. If a participant does not reply to the prompt in the first hour, a second reminder will be sent to facilitate adherence. If the participant does not reply after the second reminder, this will be considered a missing evaluation to avoid compromising the ecological nature of the assessments. However, following the just-in-time approach of EMAs and EMIs, the participants will be able to answer to these questions on demand at any moment (Nahum-Shani et al., 2018).

2.5.3.2.1. My EMI, Emotional Well-being app. My EMI, Emotional Well-being is a recently developed app that allows EMAs and EMIs (Castilla et al., 2022) (Fig. 2).

In the app, the participants will report their status daily ten days before the beginning of the treatment (baseline or A phase) to obtain a reliable measure of their baseline status and during the whole duration of the intervention (18 weeks). According to the results of daily EMAs in the app during the treatment phase, the system will offer personalized adaptations of the treatment (MBC) to the participant in the form of EMIs. In addition, all the EMIs received will be available in the *Revise* section of the app, which will be available for repeated visualization at the patient's will. The app is available for free download from Google Play store in Android, which is the operating system used by >80 % of users in Spain (Sava, 2022).

For the EMIs, clinical alarms are set in the app according to the severity and frequency of participants' daily responses of EMAs. These clinical alarms for the clinical outcomes and the mechanisms of change were established after consensus with experts in clinical psychology and emotional disorders, as in previous research (Suso-Ribera et al., 2020). Artificial intelligence (AI) algorithm has been created so that the clinical alarms that result in EMIs occur in the presence of severe symptomatology (cut-off scores from 7 to 10 in the EMA items, which can be found in the Appendix). Particularly, the algorithm is established so that the alarms will be triggered after five days of experiencing the severe symptomatology, as recommended in past research to avoid false positives (Kratochwill et al., 2010).

When a participant reaches the specific score and frequency for one or more constructs described in the previous section, an alarm will be activated and an EMI with multimedia objects of increasing intensity will be delivered to the patient within the app according to the score and

Fig. 2. My EMI, Emotional Well-being app.

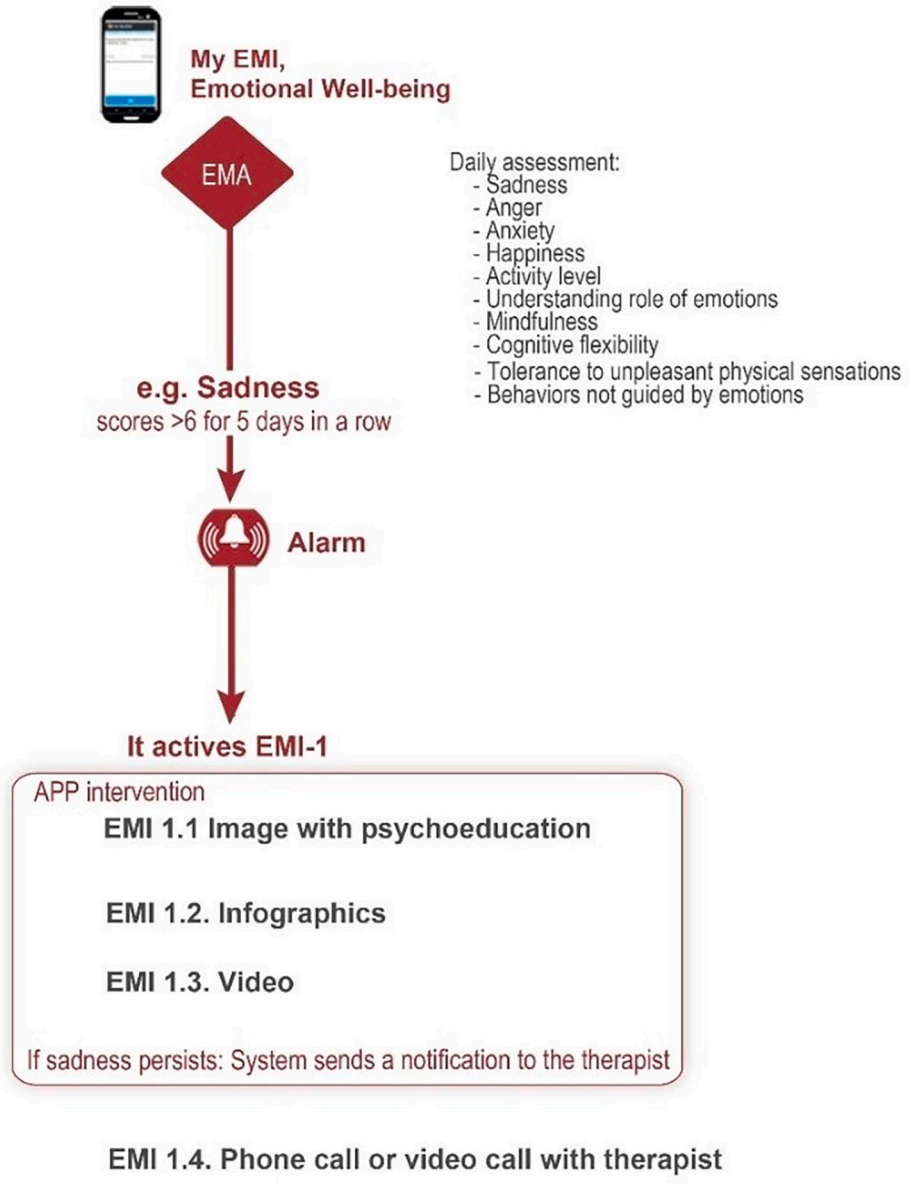

Fig. 3. Example of EMI flow app for sadness construct.

the problematic construct. Thus, the EMIs will be provided according to the patient needs in these outcome variables and mechanisms of change immediately after the daily assessment is completed by the patient if an alarm is received (i.e., EMI). Patients will not know in advance the algorithm for the alarms, so that they will not know how to force an alarm.

EMIs will consist of different evidence-based just-in-time transdiagnostic CBT interventions that aim to address emotion dysregulation. These EMIs will first consist of automatic, supportive digital content (images, infographics, or videos). However, if a problem persists after these low-intensity EMIs, the system will send a notification to the therapist and then, short phone calls or episodic videocalls will be performed (see Fig. 3) (Delgadillo et al., 2022). In this case, the EMI will also notify the patient of this prospective therapist intervention. The content of the EMIs has been created by a team of psychologists based on previous research (see Appendix B to observe the EMIs that correspond to each construct assessed) (Castilla et al., 2022). Some examples of EMIs include sending a behavioral activation protocol if inactivity is reported, sharing a short video with educational content on emotion regulation if emotion regulation problems are observed, or proposing a brief relaxation technique via audio if anxiety is very severe.

Additional alarms have been set to detect poor adherence to the app evaluations and to the online intervention. Regarding app use, 2 consecutive days with missing data will lead to a message to the patient to encourage adherence. If the problem persists for a week, an email will be sent to the therapist, who will call the patient to encourage app use. In addition, if the patient does not use the online self-applied treatment during 2 weeks, therapists will receive an alarm by email and will call them to encourage compliance with the online treatment.

2.6. Therapist support

As noted earlier, therapist support will only occur if alarms persist after low-intensity interventions (i.e., EMIs) or in case of poor adherence to the app and/or to the online intervention, as described in the previous section. In total, two therapists will oversee patient support. Both therapists are qualified clinicians with expertise in the treatment of emotional disorders using transdiagnostic protocols. Supervisions will occur bi-weekly with another expert clinician with an ample experience in evidence-based CBT.

2.7. Online intervention

The online self-applied transdiagnostic intervention consists of 12 modules adapted from the UP (Barlow et al., 2017) to a multimedia web platform "Psychology and Technology" designed by our research group (https://psicologiaytecnologia.labpsitec.es). A more detailed description of the treatment has been published elsewhere (Díaz-García et al., 2017; González-Robles et al., 2020). The objective of this online intervention is to improve the core emotional regulation strategies of the UP, that is, understanding the role of emotions, mindfulness, cognitive flexibility, acceptance and tolerance to unpleasant emotional experiences and physical sensations associated with certain emotions, and the adoption of value-driven as opposed to emotion-driven behaviors to move toward a meaningful life (Barlow et al., 2017; Sauer-Zavala et al., 2021). Participants will be asked to complete one module per week, so that they can finish the treatment in 12 weeks. Consistent with past research, because users may require more time to complete some of the modules due to unexpected events during the course of the treatment, the modules will be available during 18 weeks. The intervention contains different multimedia elements: texts, videos, photos, interactive exercises, and downloadable pdfs. Participants will be able to access the online platform at any time to review the content, to do the homework tasks, to see the calendar where the session record appears, and to view their progress.

If the patient finishes the last module of the self-applied online intervention and the post-treatment evaluation shows levels below the cut-offs in the MEDI, the OASIS and the ODSIS, the patient will be discharged. Conversely, the patients that continue to present severe symptomatology may choose to receive a more intensive treatment. This will be offered either at our clinic (face-to-face or videoconference format) or at other clinics at the preference of the patient.

3. Data analysis plan

Primary outcomes will be analyzed using descriptive methods (frequencies, means, and standard deviations).

For our secondary goal, we will calculate the Nonoverlap of All Pairs (NAP) for outcomes evaluated daily in the app. In doing so, we will calculate the percentage of data overlap between the two phases of the study (baseline-to-treatment). The NAP will show the percentage of improvement or deterioration with a score from 0 (lower treatment effectiveness) to 100 (higher treatment effectiveness) (Parker et al., 2014; Petersen-Brown et al., 2012). The Single Case research website (http://www.singlecaseresearch.org/calculators/nap) will be used to calculate the NAP index of each item of the app for each participant of the study. In general, NAP scores lower than 50 % correspond to deterioration, NAP scores from 50 % to 68 % would reflect mild-to-moderate intervention effects, NAP scores between 69 % and 96 % should be interpreted as moderate-to-large effects, and scores over 96 % would correspond to very large treatment effects (Parker and Vannest, 2009). In addition, an individual measure of pre-to-post-to-follow-up analysis of percentage of change will be calculated for each of the 30 participants for each of the 11 psychological dimensions evaluated with Qualtrics (i.e., nine from the MEDI, one from the OASIS, and one from the ODSIS). This will be done to obtain a measure of individual change given the nature of the study and the consequent sample size and lack of control group. This analytical approach is an index that has emerged as a less arbitrary alternative and more sensitive to initial levels of severity than the classic analysis of reliable change index (Hiller et al., 2012).

All analyses will be conducted with SPSS version 26 (IBM Corp, 2019), except for the NAP analyses, which will be conducted with an online tool designed for this purpose (Vannest et al., 2016). Data and analysis code will be shared by the corresponding author upon reasonable request for replication purposes.

4. Ethics and dissemination

The Ethics Committee of the Jaume I University approved the study and all its procedures (CD/111/2021). Modifications, if necessary, will be sent to the aforementioned ethical committee. This study was previously registered in Clinicaltrials.gov (NCT05109780) on November 2021. To present the protocol of the present study, we follow a Standard Protocol Items Recommendations for Interventional Trial (SPIRIT) (see Additional file 1) (Chan et al., 2013; Lancaster and Thabane, 2019; Thabane and Lancaster, 2019).

Informed consent will be obtained from the participants before they are assigned to the treatment group. They will be previously informed of the objectives and characteristics of the study. The data will be treated anonymously and will only be used for the purposes of the study. The ethical standard of the relevant national and institutional committees on human experimentation and the Helsinki Declaration will be complied by all procedures of the present study (World Medical Association (WMA), 2013). Qualtrics responses and evaluations in the app will be completely anonymous. Data collection and storage will be guaranteed in accordance with the provisions of Spanish Organic Law 3/2018, of December 5, on the Protection of Personal Data (LOPD) and guarantee of digital rights, which adapts the Spanish legislation to the General Data Protection Regulation of the European Union (GDPR) on the protection of personal data and on the free movement of such data.

When authorized by the patient in the informed consent form, the external researcher responsible for the study (J.B.L) will have access to their personal information (i.e., email, phone number, name and

surnames) to contact eligible participants.

Adverse events or negative effects will be monitoring thanks to EMA and the corresponding alarms that lead to EMIs (e.g., increased or persistent depression or treatment abandonment as indicated by lack of response to the daily app).

5. Discussion

This paper describes the protocol of a study that aims to explore the feasibility of an app-based system called *My EMI, Emotional Well-being* (Castilla et al., 2022) that will provide personalized EMIs according to patients' evolution observed with EMAs. This EMA + EMI system will complement a self-applied online transdiagnostic treatment that has been already tested in people with emotional disorders (González-Robles et al., 2020).

Emotional disorders have a significant impact on the patients' quality of life and overall functioning (Moreno et al., 2020; World Health Organization, 2019). Encouragingly, evidence-based interventions for people with emotional disorders have demonstrated their efficacy in numerous studies (Andersson, 2016; Karyotaki et al., 2018). While extensions and innovations of CBT, such as transdiagnostic interventions and online formats are helping in the dissemination of psychotherapy for emotional disorders (Osma et al., 2018), a large number of patients (i.e., not-on-track patients) do not respond to the interventions as expected (Cuijpers et al., 2019; Kazdin, 2007). The morphology of internet-based treatments, which are characterized by having pre-established modules that patients must complete in a linear manner, clearly ignoring patients' needs and evolution during treatment, might partly explain the limited efficacy of iCBT.

Personalized interventions using information and communication technologies, such as apps, are likely to hold the key to tackle this global challenge of treating emotional disorders (Holmes et al., 2020). In particular, EMAs and EMIs could facilitate tailoring treatments to patients' progress during psychotherapy, which is known as measurement-based care (Ebert et al., 2013; Gual-Montolio et al., 2020). In this study, the potential contribution of EMAs and EMIs to the effectiveness of psychotherapy will be investigated by comparing our results with those of previous research using the online transdiagnostic intervention only (González-Robles et al., 2020).

This new approach is expected to facilitate the dissemination and reach of psychological therapies for people with emotional disorders, thus reducing the time of suffering of many patients and improving the sustainability of public health systems. In addition, the self-applied online intervention together with the app will allow a large administration of this psychological intervention for people with limited mobility, access to mental care, and limited resources. If positive results were found in our study, the app could potentially be useful to improve adherence to self-applied online interventions, to reduce clinical symptomatology, and to address transdiagnostic mechanisms of change more effectively. Moreover, daily EMAs will allow to provide the most appropriate psychological EMIs for each clinical alarm detected according to the patient's evolution during therapy, a procedure called stratified care (Delgadillo et al., 2022; Foster et al., 2013). Unlike a stepped care model, where low-intensity guided self-help interventions are sequentially followed by high-intensity psychotherapy, in stratified care models, the intensity of treatment for patients, either low or high-intensity, is matched to the level of complexity according to their assessment (Delgadillo et al., 2022). This app greatly facilitates EMAs and, therefore, allows psychologists to react in real-time or close-in-time when a problem is detected and facilitates the adaptation of treatments to the evolution of patients during therapy and according to their needs at a given time.

Previous studies have shown that several apps for people with different mental health problems can improve their symptomatology (Balaskas et al., 2021; Castilla et al., 2022). However, this is the first study to evaluate the feasibility of an EMA + EMI app together with a self-applied online intervention for people with emotional disorders.

We expect that this study protocol will inspire other researchers and provide a basis for a future randomized clinical trial.

5.1. Limitations

The present study has some limitations. Regarding the study design, there is no control group in our study. Therefore, establishing differences between groups will not be possible, and exploring the potential effectiveness of the study in terms of within-group changes (from baseline to post-intervention and follow-up) will be interpreted with caution. This clearly impacts on the study's ability to produce reliable findings. An additional shortcoming is that the small number of participants investigated may difficult generalization of our results. Regarding the inclusion criteria, our sample is limited to people with access to a computer and a mobile app. Therefore, people without these technologies will be excluded from the study, which limits the generalizability and reach of the study.

6. Conclusion

This study aims to investigate the feasibility data of *My EMI, Emotional Well-being* app (EMA and EMI system) together with a self-applied online transdiagnostic intervention for population with emotional disorders. We believe that, through this study, we can determine if this modern approach is a real option to move forward personalized psychological interventions for persons with emotional disorders.

Ethics approval

The Ethics Committee of the Jaume I University approved the study and all its procedures (CD/111/2021). 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.

Consent for publication

Not applicable.

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CRediT authorship contribution statement

Background, P.G.-M., C.S.-R. and J.B.-L.; Methodology, P.G.-M., C.S.-R., D.C., and J.B.-L.; software, I.Z. and D.C.; writing—original draft preparation, P.G.-M., C.S.-R. and J.B.-L.; writing—review and editing, P.G.-M., C.S.-R., D.C., A.G.-P. and J.B.-L. All authors read and approved the final manuscript.

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.

Availability of data and material

Data availability is not applicable to this article as no new data were created or analyzed in this study.

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Appendix A. Items and pre-specified clinical alarms detected by the in the app

Construct	Origin	Question	Response scale	Clinical alarm
1. Sadness	(Suso-Ribera et al., 2020, 2018a)	Please indicate the intensity of your CURRENT SADNESS	0 = no sadness 10 = extremely sad	≥7 for 5 days in a row
2. Anxiety		Please indicate the intensity of your CURRENT ANXIETY	0 = no anxious 10 = extremely anxious	≥7 for 5 days in a row
3. Anger		Please indicate the intensity of your CURRENT ANGER	0 = no anger 10 = extremely anger	≥7 for 5 days in a row
4. Happiness		Please indicate the intensity of your CURRENT HAPPINESS	0 = no happiness 10 = extremely happy	≤3 for 5 days in a row
5. Activity level		To what extent have you been active TODAY?	0 = nothing at all 10 = totally active	≤3 for 5 days in a row
6. Understanding the role of emotions	(Kaufman et al., 2016)	Direct: TODAY, I knew exactly how I was feeling Inverse: TODAY, I had no idea how I was really feeling	0 = not at all 10 = completely agree	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)
7. Mindfulness	(Chadwick et al., 2008)	Direct: TODAY, when I experienced distressing thoughts and images, I just noticed them and let them go Inverse: TODAY, when I experienced distressing thoughts and images, they took over my mind for quite a while afterwards	0 = not at all 10 = completely agree	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)
8. Cognitive flexibility	(Dennis and Vander Wal, 2010)	Direct: TODAY, when in difficult situations, I was able to appraise and interpret my problems in different ways Inverse: TODAY, when in difficult situations, I had difficulties in looking at a situation from different viewpoints	0 = not at all 10 = completely agree	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)
9. Tolerance to unpleasant physical sensations	(Reiss et al., 1986)	Direct: TODAY, unusual body sensations scared me Indirect: TODAY, it did not scare me when I experienced body sensations	0 = not at all 10 = completely agree	≥7 for 5 days in a row (direct) - ≤3 for 5 days in a row (indirect)
10. Behaviors not guided by emotion	(Gámez et al., 2011)	Direct: TODAY, when working on something important, I did not quit even if things got difficult Indirect: TODAY, I went out of my way to avoid uncomfortable situations	0 = not at all 10 = completely agree	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)

Appendix B. EMIs corresponding to each construct assessed

Item	Construct assessed	EMIs will be offered when item scores	EMI
1	Sadness	≥7 for 5 days in a row	• Image with psychoeducation of the function of emotions; image of the 2 climbers (therapist and patient) metaphor • Infographics to check the facts and observe the function of the emotion • Video about behavioral activation based on goals and values; mindfulness in a joyful environment • Phone call or videocall to talk about the situation that triggered the emotion
2	Anger	≥7 for 5 days in a row	• Image with psychoeducation about the function of emotions; heater metaphor; ice metaphor; 2 climbers (therapist and patient) metaphor • Infographics to check the facts and observe the function of the emotion; STOP exercise; problem solving • Video with tools to reduce the intensity of anger; mindfulness in a joyful environment; relaxation video (progressive muscle relaxation) • Phone call or videocall talking about the situation that triggered the emotion
3	Anxiety	≥7 for 5 days in a row	• Image with psychoeducation of the function of emotions; image of the 2 climbers (therapist and patient) metaphor • Infographics to check the facts and observe the function of the emotion • Video of a relaxation breathing technique or progressive muscle relaxation; mindfulness in a relaxing environment; video with a conversation with anxiety. • Phone call or videocall to talk about the situation that triggered the emotion
4	Happiness	≤3 for 5 days in a row	• Image with psychoeducation of the function of emotions • Infographics to observe the function of the emotion • Video to enhance savoring • Phone call or videocall to talk about the situation that triggered the emotion
5	Activity level	≤3 for 5 days in a row	• Image with psychoeducation about the relationship between activity and emotional well-being; image of the 2 climbers (therapist and patient) metaphor • Infographics with steps for behavioral activation based on values and goals

(*continued on next page*)

(*continued*)

Item	Construct assessed	EMIs will be offered when item scores	EMI
6	Understanding the role of emotions	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)	• Video of mindfulness while walking; mindfulness with 5 senses • Phone call: motivational interviewing or videocall • Image of the adaptive function of emotions • Infographics with the 3 component model of emotions; examples of the 3 components of emotions • Video of "What is an Emotion?" and "Identifying emotions"
7	Mindfulness	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)	• Phone call or videocall • Image of acceptance of emotional experiences; Image of a sky (mind) and clouds (thoughts), waves of the sea • Infographics of the guardian at the palace gate; resignation vs. acceptance • Videos of mindfulness exercises (5 senses, instrument, "how" and "what" skills)
8	Cognitive flexibility	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)	• Phone call or videocall • Image of the mind as a filter of attention; glasses; wheat spike • Infographics with thought traps; functional analysis; 3 components of emotional experiences • Video about thinking about a different interpretation
9	Tolerance to unpleasant physical sensations	≥7 for 5 days in a row (direct) - ≤3 for 5 days in a row (indirect)	• Phone call or videocall • Image with psychoeducation of physical sensations • Infographics about an explanation of physical sensations • Video of mindfulness exercises (body scan)
10	Behaviors not guided by emotion	≤3 for 5 days in a row (direct) - ≥7 for 5 days in a row (indirect)	• Phone call or videocall • Image of emotional avoidance strategies; adaptive behaviors not guided by emotions • Infographics of the 3 types of avoidance strategies; opposite action • Video of opposite action • Phone call or videocall

Appendix C. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.invent.2023.100601.

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