Supplementary material. Patient Informed Consent

PATIENT INFORMED CONSENT

PROJECT TITLE: Study of the implementation, efficacy and cost-effectiveness of the Unified Protocol in hybrid format for the transdiagnostic treatment of emotional disorders in the Spanish NHS (PI20/00697)

PRINCIPAL INVESTIGATOR: <<name and surname of the principal investigator>>

Centre/Hospital: <<name of the Mental Health Centre>>

FUNDING ENTITY: Study funded by the Ministry of Science and Innovation, Instituto de Salud Carlos III for Health Research Projects of the 2020 call of the Strategic Action in Health 2017-2020 (code PI20/00697).

GENERAL DESCRIPTION: We are writing to inform you about a research study in which you are invited to participate and which has been approved by the <<name of the Drug Research Ethics Committee of the Hospital>>. Considering that you suffer from an Emotional Disorder (mood or anxiety disorder), we are asking for your consent to participate in a study about which we inform you below. Before deciding whether or not you want to participate, please read this document carefully, which includes information about this project. You can ask any questions you may have and ask for clarification on any aspect of the study.

PURPOSE OF THE STUDY: We are contacting you to request your collaboration in the research project entitled: "Study of implementation, efficacy and cost-effectiveness of the Unified Protocol in hybrid format for the transdiagnostic treatment of emotional disorders in the Spanish NHS". Our objective with this research is to analyse the efficacy and cost-effectiveness of a transdiagnostic psychological treatment applied in a hybrid format (face-to-face treatment + mobile App), with the aim of providing a resource that allows working and training skills in the period between face-to-face appointments. To do this, a randomly selected group of users of a Mental Health Unit will receive the usual psychological treatment at the centre, and another group will receive the treatment in hybrid format (face-to-face treatment + mobile App).

EXPLANATION OF THE STUDY: Through a randomisation system, participants will be assigned to one or other of the following treatment modalities:

- Usual psychological treatment modality of the centre (individual and face-to-face format).
- Hybrid treatment modality (individual and face-to-face treatment + mobile App).

Study activities - Usual psychological treatment condition of the centre

The following is the procedure and activities that you will carry out in this treatment modality:

1. An initial psychological assessment will be carried out (by means of structured diagnostic clinical interview). The results of the assessment will be part of a database of participants. The estimated duration is between 20-30 minutes.

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2. Pre-intervention assessment: Before starting the psychological intervention, you will have to complete the full assessment protocol. This consists of a series of questionnaires and is estimated to take between 30-45 minutes to complete.
3. Usual treatment: Psychological intervention following the usual treatment used in your health centre. You will have a psychologist assigned to you from your Mental Health Centre, who will be in charge of making individual appointments and offering you the psychological treatment he/she considers appropriate according to your psychological needs.
4. Follow-up evaluations at 3, 6 and 12 months after starting the intervention: the complete evaluation protocol will be administered again during the follow-ups that will take place at 3, 6 and 12 months after starting the psychological intervention (estimated duration to fill them in is between 30-45 minutes).

Study activities - Hybrid treatment condition (individual and face-to-face treatment + mobile App).

Below, we present the procedure and activities that you will carry out in the event that you agree to participate in this project and are assigned through the randomisation system to the hybrid treatment condition (face-to-face treatment + mobile App):

5. An initial psychological assessment (by means of a structured clinical diagnostic interview) will be carried out. The results of the assessment will be part of a database of participants. The estimated duration is between 20-30 minutes.
6. Pre-intervention assessment: Before starting the psychological intervention, you will complete the full assessment protocol consisting of a series of questionnaires, estimated to take between 30-45 minutes to complete.
7. Psychological Treatment based on the Unified Protocol + App: Transdiagnostic cognitive-behavioural treatment applied in a hybrid format (face-to-face treatment + App). To ensure that all participants receive the same intervention, therapists will use the Unified Protocol Manual (Barlow et al., 2018a). This Protocol consists of 8 treatment modules (Table 2). The duration and frequency of individual sessions will be determined by the clinical psychologist according to their availability and schedule. The treatment modules content is shown in Table 2.

Table 2. Treatment modules and content

Module 1	Setting Goals & Maintaining Motivation
Module 2	Understanding your emotions
Module 3	Mindful Emotion Awareness
Module 4	Cognitive flexibility
Module 5	Countering Emotional Behaviors
Module 6	Facing Physical Sensations
Module 7	Emotion exposures

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Module 8	Moving UP from here

8. Follow-up assessments at 3, 6 and 12 months after starting the intervention: the complete assessment protocol will be administered again during the follow-ups that will take place 3, 6 and 12 months after starting the psychological intervention (estimated time to complete them is between 30-45 minutes).

RISKS AND DISCOMFORTS OF PARTICIPATING IN THE STUDY

Both treatment modalities have demonstrated their efficacy and the benefit to be obtained with this study is to improve the efficiency of psychological treatments for the treatment of people with emotional disorders. In addition, there are no risks associated with participation in this research.

BENEFIT AND MEDICAL CARE

It is likely that you will not receive any personal benefit from your participation in this study. However, the data collected in this study may lead to increased knowledge about emotional disorders.

VOLUNTARY PARTICIPATION

Your participation in this study is completely voluntary: If you decide not to participate, you will receive all the medical care you may need and your relationship with the medical team caring for you will not be affected.

DATA PROCESSING AND CONFIDENTIALITY

Your consent is requested for the use of your data for the development of this project. Both personal data (age, sex, race) and health data will be collected using a coding procedure. Only your therapist and the main researcher at the centre, will be able to relate this data to you, being responsible for keeping all data you provide. The information will be processed during the analysis of the results obtained and will appear in the final reports. In no case will it be possible to identify you, guaranteeing the confidentiality of the information obtained, in compliance with current legislation.

The study complies with the provisions of Organic Law 3/2018, of 5 December, on the protection of personal data and the guarantee of digital rights, which repeals Organic Law 15/1999, of 5 December, on the protection of personal data. Also complies with the European Parliament Regulation 2016/679 of personal data protection, the Helsinki Declaration (Seul, 2008) and the Biomedic Research Law 14/2007.

Personal data will be processed by <<name and surname of the principal investigator>>. No data will be passed on to third parties, unless legally obliged to do so. You will be informed that you have the right to access, rectify, delete, limit or oppose the processing of your data.

Access to your identified personal information will be restricted to the study doctor/collaborators, health authorities (Spanish Agency of Medicines and Health Products, foreign health authorities), the Research Ethics Committee and personnel authorised by the sponsor (study monitors, auditors), when required to check the study data and procedures, but always maintaining their confidentiality in accordance with current legislation.

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The data will be collected in a research file under the responsibility of the institution and will be processed in the framework of its participation in this study.

The promoter will adopt the appropriate measures to guarantee the protection of your privacy and will not allow your data to be cross-referenced with other databases that could allow you to be identified.

In accordance with data protection legislation, you may exercise your rights of access, modification, objection and deletion of data by contacting your psychologist.

REVOCATION OF CONSENT

You may revoke your participation at any time without explanation. In this case, no new data will be collected after you leave the study.

If you have any questions you can ask your psychologist now or later, even after the study has begun. If you wish to ask questions later, you can contact the person in charge of the research: blind note

Thank you very much for your attention.

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INFORMED CONSENT FORM

PROJECT TITLE: Study of the implementation, efficacy and cost-effectiveness of the Unified Protocol in hybrid format for the transdiagnostic treatment of emotional disorders in the Spanish NHS (PI20/00697)

PRINCIPAL INVESTIGATOR: <<name and surname of the principal investigator>>

Centre/Hospital: <<name of the Mental Health Centre>>

FUNDING ENTITY: Study funded by the Ministry of Science and Innovation, Instituto de Salud Carlos III for Health Research Projects of the 2020 call of the Strategic Action in Health 2017-2020 (code PI20/00697).

I, <<name and surname of the participant>>

□ I have read the information sheet I have been given about the study.

□ I have been able to ask questions about the study.

□ I have received sufficient information about the study.

□ I have spoken to <<name and surname of the Psychologist>>.

□ I understand that my participation is voluntary.

□ I understand that I can withdraw from the study:

- Whenever I want.
- Without having to explain myself.
- Without affecting my medical care.

I will receive a signed and dated copy of this informed consent document.

I freely give my agreement to participate in the study.

Signature of the legal representative, family member or de facto related person	Signature of the researcher/Psychologists

Date:

I wish to be informed of information derived from the research that may be relevant to my health:

☐ YES

☐ NO