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From research to clinical practice: Implementation of an Internet-based transdiagnostic treatment program for emotional disorders in primary care

Submission date
31/10/2025

Recruitment status
Recruiting

Registration date
26/11/2025

Overall study status
Ongoing

Last Edited
25/11/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The World Health Organization (WHO) defines mental health as a state where every individual realizes their potential, can cope with life's stresses, can work productively, and can contribute to their community. Unfortunately, many people do not achieve or maintain this state of well-being. When this happens, it often manifests as a mental disorder, with depressive and anxiety disorders being the most common. In Spain, around 6% of the population experience these conditions, which can seriously affect people’s personal, social, and work lives. The COVID-19 pandemic has also increased awareness of mental health and the need for accessible and effective treatments.

Although effective psychological and drug treatments exist, only a small percentage of people actually receive adequate care. For example, a recent study found that only 23% of people with depression in high-income countries and 3% in middle-income countries receive sufficient treatment. This shows that mental health is not only a health issue but also a social and ethical challenge.

Possible solutions include increasing the number of mental health professionals and organizing services more efficiently, from prevention to specialized care. In this regard, one possible solution is to use online psychological treatments, which research has shown to be as effective as face-to-face therapy for people with moderate depression and anxiety disorders.

The main objective of this project is to optimize mental health services by incorporating an online treatment program to increase citizens' access to effective psychological treatments. Specifically, the study aims to test how effective and cost-efficient the "UJI online transdiagnostic protocol" is compared to the usual treatment patients receive. It also aims to explore how acceptable and practical it is for both patients and professionals, and what barriers or facilitators exist for successfully integrating the "UJI online transdiagnostic protocol" into mental health services.

If successful, this project could make psychological treatment more accessible, helping people receive care earlier and more conveniently, and allowing professionals to focus face-to-face resources on those with more severe conditions.

Who can participate?
Participants will be adult patients (age range ≥18 years) of both sexes from the two mental health centers managed by Mutua Terrassa. They can only participate if they have a clinical diagnosis of a depressive, anxiety, obsessive-compulsive or adjustment disorder. Healthy volunteers and people with severe mental health conditions that require intensive or specialized treatment will not take part in this study

What does the study involve?
The study is a clinical trial that will compare the effectiveness and costs of:
1. The online intervention: Participants will receive the "UJI online transdiagnostic protocol", an interactive, web-based psychological treatment. This is a program developed and validated by the Universitat Jaume I (UJI) that uses a transdiagnostic approach (meaning it addresses common symptoms shared by different disorders like depression and anxiety). The aim of the program is to help people learn skills to manage depression and anxiety symptoms by focusing on emotions, thoughts, and behaviors that are common across different mental health problems. The program is structured into several modules and includes exercises and feedback from professionals.
2. Treatment As Usual (TAU): Participants will receive the standard treatment offered at Mutua Terrassa, which may include face-to-face therapy, medication, or other types of support, depending on the patient's needs.
Not all participants will receive the same treatment; they will be randomly assigned to one of the two comparison groups.
Throughout the study, researchers will measure:
• The effectiveness of the treatments (measuring the reduction of depression and anxiety symptoms in the short and long term).
• The costs involved (economic efficiency).
• The opinions and satisfaction of both patients and mental health professionals regarding the implementation of the online program.
• An analysis of the barriers and facilitators (what helps and what hinders) the sustained incorporation of the online program into the services.

What are the possible benefits and risks of participating?
Possible Benefits:
• Access to an Evidence-Based Treatment: Participants assigned to the online treatment group will receive a program that has been rigorously validated in clinical trials and shown to be effective for depression and anxiety. This format may also be more flexible and easier to integrate into their daily lives.
• Symptom Improvement: All participants have the chance to experience a significant improvement in their depression and/or anxiety symptoms, regardless of the treatment group they are assigned to.
• Contributing to Better Healthcare: By participating, individuals will help determine the usefulness and sustainability of an affordable and scalable treatment alternative. Positive results could lead to the widespread adoption of this program, significantly improving mental health care access for many others in the future.
Possible Risks:
• Risk of Not Receiving the New Treatment: Participants assigned to the TAU group will not directly benefit from the new online alternative. However, they will receive the standard care already available at the center and will be given access to the online treatment at the end of the study.
• Potential Emotional Discomfort: As with any form of psychological therapy, the process (both online and face-to-face) involves confronting difficult thoughts and emotions, which may

temporarily cause some emotional distress or discomfort.
• Technology Reliance: For the online treatment group, participation requires access to and comfort using mobile technology and a reliable internet connection.

Where is the study run from?
The study is a collaborative effort between the Universitat Jaume I (UJI) and Mutua Terrassa, which is implementing the program within its two mental health centres serving over 200,000 inhabitants.

When is the study starting and how long is it expected to run for?
Recruitment is expected to start at the end of 2026 and the study will run until 2029. This period includes participant recruitment, delivery of the treatment, and follow-up assessments to measure both short-term and long-term effects.

Who is funding the study?
The study has no specific external grant. It is supported by Universitat Jaume I and Mútua Terrassa, and by a predoctoral fellowship from the Spanish Ministry of Science, Innovation and Universities (FPU24/03470).

Who is the main contact?
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Additional identifiers

Protocol serial number
PTon-Terrassa

Study information

Scientific Title
Implementation and cost-effectiveness of a transdiagnostic Internet-based intervention for emotional disorders within a community care system: a hybrid effectiveness-implementation type I randomised controlled trial

Acronym
TREAT-ED

Study objectives
Current study objectives as of 25/11/2026:
1. The online treatment will show an evolution of depressive and anxiety symptoms equivalent to that of treatment as usual (TAU) from post-treatment to the 12-month follow-up, as well as comparable outcomes in affect and quality of life.
2. The online treatment will be cost-effective compared with TAU, reducing direct and indirect costs.
3. The online treatment will receive positive scores in implementation measures assessed by patients and professionals (acceptability, appropriateness, feasibility, adoption) and in platform usage data.
4. The implementation strategy (training and monitoring of professionals) will be described in terms of changes in professionals' attitudes towards evidence-based and online treatments; it is not formally tested, in line with a hybrid type I design.

Previous study objectives:
1. The implementation strategy (training protocol) will be assessed by professionals as a valid strategy for implementing the online treatment, increasing scores on adoption measures (attitudes toward evidence-based treatments and online treatments) after receiving training and at the end of their participation in the empirical study.
2. The online treatment will be equally effective as the treatment as usual (TAU) in the short term (post-test) and long term (3, 6, 9, and 12-month follow-ups): reduction in depressive symptoms, anxiety, and negative affect, and increase in positive affect and quality of life in the post-test, with maintenance of gains in the follow-ups.
3. The online treatment will be cost-effective. Compared to the treatment as usual, the application of online treatment will result in a significant reduction in direct and indirect costs, as well as in professional time, and a faster return of patients from specialized care to primary

care.
4. The online treatment will receive positive scores in implementation measures assessed by patients and professionals (scales, interviews, and focus groups) and obtained through analysis of data on the use of the technological platform (program entries and module completion): acceptability, adequacy, feasibility, adoption, barriers, and facilitators.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 27/05/2025, Fundació Assistencial Mútua Terrassa Comité Ètic D'investigació Amb Medicaments (Pl/ Doctor Robert, 5, planta -1, Terrassa, 08221, Spain; +34 937365050; ceim@mutuaterrassa.cat), ref: P/25-083

2. Approved 27/05/2026, Fundació Assistencial Mútua Terrassa Comité Ètic D'investigació Amb Medicaments (Pl/ Doctor Robert, 5, planta -1, Terrassa, 08221, Spain; +34 937365050; ceim@mutuaterrassa.cat), ref: P/25-083

Primary study design
Interventional

Study design
Hybrid effectiveness-implementation type I, two-arm, parallel-group, non-blinded randomized controlled trial conducted in two centres

Study type(s)
Efficacy, Treatment, Other

Health condition(s) or problem(s) studied
Treatment of emotional disorders: depressive disorders, anxiety disorders, obsessive-compulsive disorder and adjustment disorder

Interventions
Current interventions as of 25/11/2026:
Arm 1: Experimental - UJI online transdiagnostic protocol. This protocol, based on the transdiagnostic perspective, offers the possibility of applying a single psychological treatment for different emotional disorders by proposing that these disorders share a common vulnerability which, associated with certain stress factors, gives rise to different manifestations of this vulnerability (depression and various anxiety disorders). This protocol consists of a set of techniques that have proven effective in improving the lives of people with emotional disorders and is designed to be applied via the Internet. Its objective is to teach strategies that improve the ability to regulate emotions in a more adaptive way. It includes the following core therapeutic components, aimed primarily at regulating negative affect: a) emotional awareness focused on the present moment and acceptance, b) cognitive flexibility, c) emotional and behavioral avoidance, and d) exposure to emotional experiences (interoceptive and situational). In addition, the protocol also includes traditional evidence-based components for the treatment of emotional disorders, such as psychoeducation, motivation for change, and relapse prevention. Finally, it also includes a specific component for regulating positive affect, with the aim of promoting psychological strengths and improving well-being. The protocol has 16 modules (one

per week recommended, with no maximum access period) and is delivered through the patient app of Mútua Terrassa (Campus Pacient), with brief weekly support telephone calls from the treating professional.

Arm 2: Active Comparator - Treatment As Usual (TAU). TAU may include pharmacological treatment(antidepressants and/or anxiolytics), psychological treatments (case management, group therapy, empathic listening, and counseling and advice), mental health nursing follow-up with psychosocial interventions, or a combination thereof. Participants in either arm who receive another psychological treatment outside the study protocol during the treatment period will be excluded. Pharmacological treatment and other co-interventions are allowed and recorded in both arms. The specific treatment received by each patient will be recorded. After the study, TAU participants will be given access to the online treatment.

Recruitment of 172 participants (up to 200): Mental health professionals from Mutua Terrassa will be responsible for recruiting participants among patients referred by primary care providers who meet the study's inclusion criteria. Professionals will identify potential participants and present the study's characteristics with the help of a description study sheet, ensuring that any questions are addressed and that participants fully understand the study procedures. Those who agree to participate voluntarily will sign an informed consent form. Subsequently, professionals will conduct a detailed assessment to verify compliance with the inclusion criteria. After informed consent, the professional registers the participant in REDCap, where the randomisation module allocates the participant 1:1 to one of the two conditions (permuted blocks of 4, stratified by main diagnosis).

Previous interventions:
Arm 1: Experimental - UJI online transdiagnostic protocol. This protocol, based on the transdiagnostic perspective, offers the possibility of applying a single psychological treatment for different emotional disorders by proposing that these disorders share a common vulnerability which, associated with certain stress factors, gives rise to different manifestations of this vulnerability (depression and various anxiety disorders). This protocol consists of a set of techniques that have proven effective in improving the lives of people with emotional disorders and is designed to be applied via the Internet. Its objective is to teach strategies that improve the ability to regulate emotions in a more adaptive way. It includes the following core therapeutic components, aimed primarily at regulating negative affect: a) emotional awareness focused on the present moment and acceptance, b) cognitive flexibility, c) emotional and behavioral avoidance, and d) exposure to emotional experiences (interoceptive and situational). In addition, the protocol also includes traditional evidence-based components for the treatment of emotional disorders, such as psychoeducation, motivation for change, and relapse prevention. Finally, it also includes a specific component for regulating positive affect, with the aim of promoting psychological strengths and improving well-being.

Arm 2: Active Comparator - Treatment As Usual (TAU). TAU may include pharmacological treatment(antidepressants and/or anxiolytics), psychological treatments (case management, group therapy, empathic listening, and counseling and advice), mental health nursing follow-up with psychosocial interventions, or a combination thereof. Participants in TAU and receiving treatment outside the center will be excluded from the study. The specific treatment received by each patient will be recorded. After the study, TAU participants will be given access to the online treatment.

Recruitment of 200 participants: Mental health professionals from Mutua Terrassa will be responsible for recruiting participants among patients referred by primary care providers who meet the study's inclusion criteria. Professionals will identify potential participants and present

the study's characteristics with the help of a description study sheet, ensuring that any questions are addressed and that participants fully understand the study procedures. Those who agree to participate voluntarily will sign an informed consent form. Subsequently, professionals will conduct a detailed assessment to verify compliance with the inclusion criteria and will notify a researcher, who will perform the random allocation of participants to study conditions using dedicated software. The assignment results will then be communicated to the participating professionals.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcomes as of 25/11/2026:
1. Depression severity and impairment measured using the Spanish version of the Overall Depression Severity and Impairment Scale (ODSIS) at end of intervention and 3-, 6-, 9- and 12-month follow-ups, adjusted for baseline score
2. Anxiety severity and impairment measured using the Spanish version of the Overall Anxiety Severity and Impairment Scale (OASIS) at end of intervention and 3-, 6-, 9- and 12-month follow-ups, adjusted for baseline score

Previous primary outcomes:
1. Depression severity and impairment is measured using the Spanish version of the Overall Depression Severity and Impairment Scale (ODSIS) at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months
2. Anxiety severity and impairment is measured using the Spanish version of the Overall Anxiety Severity and Impairment Scale (OASIS) at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months
3. Positive and negative affect is measured using the Spanish version of the Positive and Negative Affect Scale (PANAS) at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months
4. Health-related quality of life is measured using the Spanish version of the EuroQol-5D-5L at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months

Key secondary outcome(s)
Current secondary outcomes as of 25/11/2026:
Effectiveness:
1. Positive and negative affect measured using the Positive and Negative Affect Schedule (PANAS) at baseline, end of intervention and 3-, 6-, 9- and 12-month follow-ups
2. Health-related quality of life measured using the EuroQol-5D-5L at baseline, end of intervention and 3-, 6-, 9- and 12-month follow-ups
3. Proportion of participants with clinically significant improvement (below the clinical cut-off on both ODSIS and OASIS; Reliable Change Index) at end of intervention and follow-ups

Implementation outcomes:
4. Feasibility measured using the Feasibility of Intervention Measure (FIM): patients in the online arm at end of intervention; professionals at pre-study, post-study and 3- and 12-month follow-ups; and passive platform data (module completion, dropout, frequency of use)
5. Acceptability measured using the Acceptability of Intervention Measure (AIM) (same time points as FIM), the System Usability Scale (SUS) at the end of the online treatment, and the Client Satisfaction Questionnaire adapted to Internet-based interventions (CSQ-I) at end of intervention in both arms

6. Appropriateness measured using the Intervention Appropriateness Measure (IAM): patients in the online arm at end of intervention; professionals at pre-study, post-study and 3- and 12-month follow-ups; and passive platform data (module completion, dropout, frequency of use)
7. Adoption measured using the Evidence-Based Practice Attitude Scale (EBPAS-15) and the Attitudes towards Psychological Online Interventions questionnaire (APOI) in professionals before and after training, at pre-study, post-study and 3- and 12-month follow-ups; APOI in patients at all time points; proportion of professionals who enrol at least one participant
8. Contextual determinants measured using the Organizational Readiness for Implementing Change (ORIC) scale and the Pragmatic Context Assessment Tool (pCAT) at pre-study, post-study and 3- and 12-month follow-ups, and qualitatively using semi-structured interviews and focus groups with patients and professionals

Cost-effectiveness:
9. Direct healthcare and social service costs measured using the TiC-P Adults questionnaire at baseline, end of intervention and 3-, 6-, 9- and 12-month follow-ups
10. Indirect costs due to lost work productivity measured using the Productivity Costs Questionnaire (iPCQ) at baseline, end of intervention and 3-, 6-, 9- and 12-month follow-ups

Exploratory:
11. Sensitivity to punishment and sensitivity to reward measured using the Sensitivity to Punishment and Sensitivity to Reward Questionnaire (SPSRQ-20) at baseline (moderator of treatment response)

Previous secondary outcomes:
Implementation outcomes:
1. Feasibility is measured using the Feasibility of Intervention Measure (FIM) and passive platform data including module completion, dropout, and frequency of use at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months
2. Acceptability is measured using the System Usability Scale (SUS), Acceptability of Intervention Measure (AIM), and the Client Satisfaction Questionnaire adapted to Internet-Based interventions (CSQ-I) at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months
3. Appropriateness is measured using the Intervention Appropriateness Measure (IAM) at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months
4. Adoption is measured using the Evidence-Based Practice Attitude Scale (EBPAS-50) and the Attitudes towards Psychological Online Intervention (APOI) at baseline, end of intervention, and follow-up at 3, 6, 9, and 12 months
5. Barriers and facilitators are measured quantitatively using the Pragmatic Context Assessment Tool (pCAT) and qualitatively using semi-structured interviews and focus groups following Consensual Qualitative Research (CQR) guidelines at end of intervention and follow-up at 3, 6, 9, and 12 months

Cost-effectiveness:
6. Direct healthcare and social service costs are measured using the TiC-P Adults questionnaire at end of intervention and follow-up at 3, 6, 9, and 12 months
7. Indirect costs due to lost work productivity are measured using the Productivity Costs Questionnaire (iPCQ) at end of intervention and follow-up at 3, 6, 9, and 12 months

Completion date
01/07/2029

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/11/2026:
Patients:
1. Over 18 years of age
2. Meet the ICD-10 diagnostic criteria for one of the following: depressive episode or recurrent depressive disorder, dysthymia, agoraphobia, social phobia, panic disorder, generalized anxiety disorder, obsessive-compulsive disorder, adjustment disorder, or unspecified mood or anxiety disorder
3. Understand and read Spanish or Catalan
4. Have regular access to the Internet and an email address that they check regularly
5. Give informed consent

Mental Health Professionals:
1. They work at centers participating in the study
2. They agree to participate in the study
3. They sign an informed consent form

Previous inclusion criteria:
Patients:
1. Over 18 years of age
2. Meet the diagnostic criteria for an anxiety or depressive disorder according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5)
3. Understand and read Spanish or Catalan
4. Have access to the Internet and an email address
5. Give informed consent

Mental Health Professionals:
1. They work at centers participating in the study
2. They agree to participate in the study
3. They sign an informed consent form

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 25/11/2026:
Patients:
1. Diagnosis of schizophrenia, bipolar disorder, or alcohol or substance dependence
2. High risk of suicide
3. Presence of a medical condition that prevents psychological treatment
4. Receiving other psychological treatment (other than TAU or the online program) during the study

Previous exclusion criteria:
Patients:
1. Diagnosis of schizophrenia, bipolar disorder, or alcohol or substance dependence
2. High risk of suicide
3. Presence of a medical condition that prevents psychological treatment
4. Receiving other psychological treatment (other than TAU or the online program) during the study
5. For participants in the online treatment condition with pharmacological treatment, this must be stabilized (doses cannot be changed or increased during the study, only reduced)

Date of first enrolment
18/11/2026

Date of final enrolment
15/01/2028

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari Mutua Terrassa
Plaça del Doctor Robert, 5
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Spain
08221

Study participating centre
Laboratorio de Psicología y Tecnología (LABPSITEC)
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Study participating centre
Mútua Terrassa Adult Mental Health Outpatient Service, Rambla and Sant Cugat del Vallès centres and others
Spain

Sponsor information

Organisation
Laboratorio de Psicología y Tecnología (LABPSITEC)

Organisation
Hospital Universitari Mutua Terrassa

Funder(s)

Funder type
Other

Funder Name
Ministerio de Ciencia, Innovación y Universidades

Alternative Name(s)
Ministry of Science, Innovation and Universities, MCIU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 25/11/2026:
The anonymised datasets generated during the study will be made available in the Open Science Framework repository upon publication of the main results.

Previous IPD sharing plan:
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (Open Science Framework).

IPD sharing plan summary

Stored in publicly available repository