ISRCTN58437086 https://doi.org/10.1186/ISRCTN58437086

A pilot project to treat emotional disorders in Primary Care with evidence-based psychological techniques: a randomized controlled trial

Submission date
02/05/2013

Recruitment status
No longer recruiting

Registration date
20/05/2013

Overall study status
Completed

Last Edited
18/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

The strong demand for primary care (PC) services in Spain exceeds the existing resources. Part of this demand is due to the increasing number of anxiety, depression and somatisation disorders that affect the general population. These disorders, commonly known as emotional disorders, are very common in Spanish PC settings, are poorly detected by the physician, rarely receive adequate treatment [if they receive treatment it is mostly pharmacological (treatment with medicinal drugs) instead of psychological treatment], they generate a highly frequent use of PC services, a greater burden than physical diseases and tend to become chronic without treatment. Other countries have successfully put psychological techniques in PC into practice (in the UK, for example, the programme known as Improving Access to Psychological Therapies has obtained very positive results) in order to correctly diagnose and treat emotional disorders. The results obtained in terms of symptoms, quality of life, diagnosis, etc., have been better than the usual treatment that is offered, with no side effects, fewer relapses, and lower costs in the long term. The aim of this study is to test how well a psychological treatment programme for anxiety, depression and somatisation disorders works in PC and to compare the results obtained after seven 90-minute group sessions of a transdiagnostic cognitive behavioral therapy (TD-GCBT) (approximately every to two to four weeks) with the usual treatment offered in Spanish PC services. The group sessions will be made up of one clinical psychologist and about eight participants.

Who can participate?

About 1130 adults, regardless of their age and sex, with an anxiety, depression and/or somatisation disorder (diagnosed with a simple and short questionnaire) will participate in this study. Participation will be voluntary and confidentiality will be guaranteed.

What does the study involve?

Half of the participants in the study will be randomly assigned to receive their usual care and the other half will receive psychological treatment, within the same healthcare centre. Neither the health professional nor the patient will know which treatment will be applied. Psychological assessments will be carried out before and after receiving treatment. The following variables

will be assessed: clinical symptoms (anxiety, depression, somatisations), levels of adjustment (work, family, social), quality of life (physical, psychological, social, environmental), emotional and thoughts (worries, beliefs, coping strategies, negative thoughts, etc.), treatment satisfaction, frequent use of services, and psychoactive drug use. After receiving either the usual or the psychological treatment, participants will be followed up at 3, 6 and 12 months.

What are the possible benefits and risks of participating?
The aim of this study will be to maximize benefits and reduce potential harms. Participation will pose no risks different from the typically present when receiving usual treatment.

When is the study starting and how long is it expected to run for?
It will be carried out in 11 primary care centres in Madrid, Valencia, Albacete, Mallorca, Murcia, Vizcaya and Melilla, and may be extended to other centres and cities.

When is the study starting and how long is it expected to run for?
It is expected to start in June 2013 and finish by the end of 2014. The study will be open to participants until recruitment is completed.

Who is funding the study?
Psicofundación (Spanish Foundation for the Promotion, Scientific and Professional Development of Psychology) and the Spanish Ministry of Economy and Competitiveness.

Who is the main contact?
Dr. Antonio Cano-Vindel
canovindel@psi.ucm.es

Contact information

Type(s)
Scientific

Contact name
Prof Antonio Cano-Vindel

Contact details
Facultad de Psicologia
Departamento de Psicologia Basica II (Procesos Cognitivos)
buzon 23
Universidad Complutense de Madrid
Madrid
Spain
28230
+34 (0) 60 770 57 40
canovindel@psi.ucm.es

Type(s)
Public

Contact name
Prof Roger Muñoz Navarro

ORCID ID
https://orcid.org/0000-0002-7064-3699

Contact details
Department of Psychology and Sociology
Faculty of Social and Human Sciences
University of Zaragoza
Teruel
Spain
44003
+34 978618101
rogermnavarro@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
2013-001955-11

Protocol serial number
AP105162012

Study information

Scientific Title
Transdiagnostic Cognitive Behavioral Therapy Versus Treatment as Usual in Adult Patients With Emotional Disorders in the Primary Care Setting. The PsicAP Randomized Controlled Trial

Acronym
ED, PC

Study objectives
Current study hypothesis as of 19/03/2020:
Our general hypothesis is that the psychological treatment (TD-GCBT) will be more effective and efficient than usual treatment in primary care and that the gains will be maintained at follow-up. The working hypotheses are that if: (a) an evidence-based cognitive-behavioural treatment protocol, transdiagnostic, in group format, is applied considering that EDs are associated with stress, negative emotions, lack of valid information and coping skills, cognitive errors, emotion regulation deficits, and emotional learning through direct conditioning; (b) bearing in mind that this cognitive-emotional process is reversible; (c) the protocol comprises the most efficient cognitive-behavioural techniques that include the following principles: psychoeducation and cognitive restructuring, relaxation techniques for reducing anxiety, and behavioural skills training; and (d) we apply this psychological intervention protocol to the experimental group; then, we expect this group to obtain better results in the dependent variables under study than the control group that will receive treatment-as-usual, at post-treatment and follow-up (3, 6 and 12 months).

Previous study hypothesis:
Our general hypothesis is that the psychological (cognitive behavioural) treatment will be more effective and efficient than usual treatment in primary care and that the gains will be maintained at follow-up. The working hypotheses are that if: (a) an evidence-based cognitive-

behavioural treatment protocol is applied considering that EDs are associated with stress, negative emotions, lack of valid information and coping skills, cognitive errors, emotion regulation deficits, and emotional learning through direct conditioning; (b) bearing in mind that this cognitive-emotional process is reversible; (c) the protocol comprises the most efficient cognitive-behavioural techniques that include the following principles: psychoeducation and cognitive restructuring, relaxation techniques for reducing anxiety, and behavioural skills training; and (d) we apply this psychological intervention protocol to the experimental group; then, we expect this group to obtain better results in the dependent variables under study than the control group that will receive treatment-as-usual, at post-treatment and follow-up (3, 6 and 12 months).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité Ético de Investigación corporativo de Atención Primaria de la Comunitat Valenciana (Ethics Comittee of Corporative Research in Primary Care in Valencian Department), 14/11/2013, Number: Versión 3, salud 2; fecha 21/02/2013

Study design
Multicentre longitudinal randomised controlled trial with two parallel arms

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Emotional disorders

Interventions
Current interventions as of 19/03/2020:
Experimental group: seven 90-minute group sessions of evidence-based psychological techniques, with a transdiagnostic group cognitive behavioural treatment (TD-GCBT). The manualized protocol will include the following training: psychoeducation (on emotions and emotional disorders) and cognitive bias modification, progressive muscle relaxation, breathing skills, imagination and suggestion of relaxing images, behavioural and social skills, exposure to emotional situations and relapse prevention.

Control group: treatment as usual (basically pharmacological, including muscle relaxants, pain relievers, anti-anxiety and antidepressant medication)

Joint/secondary sponsor details:
Ministerio de Economía y Competitividad, Gobierno de España.
https://sede.micinn.gob.es/csv/
Subdirección General de Proyectos de Investigación
Calle Albacete, 5.
Tel: +34 916037770
E-mail: sgpi.secretaria@mineco.es

Previous interventions:
Experimental group: seven 90-minute group sessions of cognitive behavioural treatment (evidence-based psychological techniques). The manualized protocol will include the following training: psychoeducation (on emotions and emotional disorders) and cognitive bias modification, progressive muscle relaxation, breathing skills, imagination and suggestion of relaxing images, behavioural and social skills, exposure to emotional situations and relapse prevention.

Control group: treatment as usual (basically pharmacological, including muscle relaxants, pain relievers, anti-anxiety and antidepressant medication)

Joint/secondary sponsor details:
Ministerio de Economía y Competitividad, Gobierno de España.
https://sede.micinn.gob.es/csv/
Subdirección General de Proyectos de Investigación
Calle Albacete, 5.
Tel: +34 916037770
E-mail: sgpi.secretaria@mineco.es

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measure as of 19/03/2020:
All of the following measures will be assessed at the completion of the 7 session program and at 3, 6, and 12 months follow-up
1. Self-reported emotional symptoms (total anxiety, depression, and somatic scores):
a. Total symptoms measured by the Patient Health Questionnaire (PHQ; Spitzer, Kroenke, & Williams, 1999)
b. Anxiety symptoms measured using GAD-7 (anxiety symptom severity >= 10), with seven items, each of which is scored 0 to 3, providing a 0 to 21 severity score (Spitzer, Kroenke, Williams, & Lowe, 2006)
c. Depression symptoms measured using PHQ-9 (depression >= 10), with nine items, each of which is scored 0 to 3, providing a 0 to 27 severity score (Kroenke, Spitzer, & Williams, 2001)
d. Somatic symptoms measured using PHQ-15 (somatic symptom severity >= 5), with 15 items, each of which is scored 0 to 2, providing a 0 to 30 severity score (van Ravesteijn et al., 2009)
2. Percentage of cases with probable emotional disorder according to DSM-IV diagnostic criteria, using the PHQ subscales (Spitzer, Kroenke, & Williams, 1999):
a. Generalized Anxiety Disorder measured using GAD-7 (diagnostic algorithm >= 8) where a score of at least 2 on the first question, plus three more items is given (Spitzer, Kroenke, Williams, & Lowe, 2006)
b. Major Depression Disorder measured using PHQ-9 (diagnostic algorithm >= 10), where at least one of the two first items is rated with a 2 (more than half of the days) or a 3 (most days) and four of the remaining items are also rated with a score of 2 or 3 (with the exception of item 9, in which a rating of 1 is sufficient for diagnosis) (Kroenke, Spitzer, & Williams, 2001)
c. Somatization Disorder measured using PHQ-15 (diagnostic algorithm >= 6) where 2 points are scored on at least five of the first 13 symptoms (van Ravesteijn et al., 2009)
d. Panic Disorder measured using PHQ-PD (diagnostic algorithm = modified) where an

affirmative response is given to the first screening item, to one of the three items on the next scale, and to four or more items of the somatic symptoms (Muñoz-Navarro et al., 2017)

Previous primary outcome measure:
When comparing the pre- and post-treatment measures, the experimental group but not the control group will show a decrease in the following measures:
1. Self-reported emotional symptoms (total anxiety, depression, and somatic scores as measured by the Patient Health Questionnaire (PHQ); Spitzer, Kroenke, & Williams, 1999)
2. Associated cognitive-emotional factors, such as ruminations (measured using the 5-item Brooding Subscale of the Ruminative Response Scale (RRS) with response options from 1 (never) to 4 (always); Nolen-Hoeksema & Morrow, 1991)
3. Pathological worry (using 8 items from the Penn State Worry Questionnaire (PSWQ) with response options from 1 (not at all typical) to 5 (very typical); Meyer, Miller, Metzger & Borkovec, 1990)
4. Attentional and interpretive biases (using 5 items from the Inventory of Cognitive Activity in Anxiety Disorders [IACTA], with response options from 0 [almost never] to 4 [almost always]; Cano-Vindel & Miguel-Tobal, 2004)
6. Emotion regulation (using the 10-item Emotion Regulation Questionnaire (ERQ) with response options from 1 (totally disagree) to 7 (totally agree); Gross & John, 2003)
7. Negative metacognitions (using the 6-item Negative Metacognitions Subscale of the Metacognitions Questionnaire [MCQ-30], with response options from 1 [totally disagree] to 4 [totally agree] Wells & Cartwright-Hatton, 2004)
8. Percentage of cases with probable ED according to DSM-IV diagnostic criteria [using the PHQ subscales: GAD-7 (anxiety symptom severity >= 10)], with seven items, each of which is scored 0 to 3, providing a 0 to 21 severity score (Spitzer, Kroenke, Williams, & Lowe, 2006); PHQ-9 (depression >= 10), with nine items, each of which is scored 0 to 3, providing a 0 to 27 severity score (Kroenke, Spitzer, & Williams, 2001); PHQ-15 (somatic symptom severity >= 5), with 15 items, each of which is scored 0 to 2, providing a 0 to 30 severity score (van Ravesteijn et al., 2009), PHQ-PD (panic disorder >= 8), including the first 4 items (Wittkampf, Baas, van Weert, Lucassen, & Schene, 2011)
9. Their levels of work, family and social impairment (using the Sheehan Disability Scale (SDS) which is a 10-point visual analog scale that uses spatiovisual, numeric and verbal descriptive anchors simultaneously; Sheehan, Harnett-Sheehan, & Raj, 1996)
10. An increase in physical, psychological, social, and environmental quality of life (as measured by the different WHOQOL-BREF scales, which includes four types of 5-point Likert interval scales that inquire how much, how completely, how often, how good or how satisfied the respondent felt in the last 2 weeks; Rocha, Power, Bushnell, & Fleck, 2012)
These gains will be maintained at 3, 6, and 12 months follow-up. In addition, the experimental group will report higher treatment satisfaction than the control group.

Key secondary outcome(s))

Current secondary outcome measures as of 19/03/2020:
All of the following measures will be assessed at the completion of the 7 session program and at 3, 6, and 12 months follow-up
1. Levels of work, family and social impairment measured using the Sheehan Disability Scale (SDS) which is a 10-point visual analog scale that uses spatiovisual, numeric and verbal descriptive anchors simultaneously (Sheehan, Harnett-Sheehan, & Raj, 1996)
2. Increase in physical, psychological, social, and environmental quality of life measured by the different World Health Organization Quality of Life Instruments (WHOQOL-BREF) scales, which includes four types of 5-point Likert interval scales that inquire: how much; how completely; how often; how good; or how satisfied the respondent felt in the last 2 weeks (Rocha, Power,

Bushnell, & Fleck, 2012).
3. Associated cognitive-emotional factors, such as:
a. Ruminations measured using the 5-item Brooding Subscale of the Ruminative Response Scale (RRS) with response options from 1 (never) to 4 (always) (Nolen-Hoeksema & Morrow, 1991)
b. Pathological worry measured using 8 items from the Penn State Worry Questionnaire-Abbreviated (PSWQ-A) with response options from 1 (not at all typical) to 5 (very typical) (Meyer, Miller, Metzger & Borkovec, 1990)
c. Attentional and interpretive biases measured using 5 items from the Inventory of Cognitive Activity in Anxiety Disorders for panic disorders (IACTA-PD), with response options from 0 (almost never) to 4 (almost always) (Cano-Vindel & Miguel-Tobal, 2004)
d. Emotion regulation measured using the 10-item Emotion Regulation Questionnaire (ERQ) with response options from 1 (totally disagree) to 7 (totally agree) (Gross & John, 2003)
e. Negative metacognitions measured using the 6-item Negative Metacognitions Subscale of the Metacognitions Questionnaire (MCQ-30), with response options from 1 (totally disagree) to 4 (totally agree) (Wells & Cartwright-Hatton, 2004)
4. Cost-effectiveness and cost-utility measures determined from information obtained from patient self-reports and the objective data collected by the healthcare information systems at the different centres
5. Treatment Satisfaction determined by patient self-reports

Previous secondary outcome measures:
The experimental group but not the control group will have reduced the frequency of PC visits and psychoactive drug use (as well as other healthcare costs) at post-treatment and 6-month follow-up. This will result in better, more cost-effective services than the ones offered to the control group with usual care. This information will be obtained from patients self-reports and the objective data collected by the healthcare information systems at the different centres.

Completion date
31/07/2019

Eligibility

Key inclusion criteria
Any adult patient seeking treatment, regardless of his/her age and sex, with a probable anxiety, mood and/or somatisation disorder (diagnosed with the Patient Health Questionnaire) will be offered to participate in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1061

Key exclusion criteria
1. Patients with severe mental disorders will be excluded (e.g., bipolar disorder, personality disorder)
2. A history of frequent or recent suicide attempt(s)
3. High level of disability

Date of first enrolment
30/06/2013

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Spain

Study participating centre
Facultad de Psicologia
Madrid
Spain
28230

Sponsor information

Organisation
Spanish Foundation for the Promotion and Development of Scientific and Professional Psychology (Spain)

Funder(s)

Funder type
Government

Funder Name
Psicofundación. Fundación Española para Promoción, Desarrollo Científico y Profesional de la Psicología (Spain), ref: AP105162012

Funder Name

Ministry of Science and Innovation, Government of Spain (Ministerio de Economía y Competitividad, Gobierno de España) (Spain), ref: PSI2012-36589

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/02/2021	09/02/2021	Yes	No
Results article		06/06/2025	18/06/2025	Yes	No
Protocol article	protocol	23/12/2016		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes