

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

<b>Submission date</b> 02/05/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/06/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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 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  
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### **Study website**

<http://www.desordenesemocionales.es/>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Antonio Cano-Vindel

### **Contact details**

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Public

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## **Additional identifiers**

**EudraCT/CTIS number**

2013-001955-11

**IRAS number****ClinicalTrials.gov number****Secondary identifying numbers**

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 Committee 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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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.

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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)

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## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

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  $\geq 10$ ), 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  $\geq 10$ ), 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  $\geq 5$ ), 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  $\geq 8$ ) 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  $\geq 10$ ), 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  $\geq 6$ ) 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 [IACATA], 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  $\geq 10$ )], 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  $\geq 10$ ), 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  $\geq 5$ ), 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  $\geq 8$ ), including the first 4 items (Wittkamp, 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.

### **Secondary outcome measures**

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 (IACATA-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.

### **Overall study start date**

30/06/2013

### **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

1126 eligible patients. 563 participants will be randomly assigned to each group.

**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 Psicología

Madrid

Spain

28230

**Sponsor information**



**Organisation**

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

**Sponsor details**

Psicofundación. Fundación Española para Promoción, Desarrollo Científico y Profesional de la Psicología  
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**Sponsor type**

Other

**Website**

<http://www.psicofundacion.es/>

**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****Publication and dissemination plan**

As of March 2020, a manuscript of the major results primary (symptoms) and secondary outcomes and long-term has been prepared for publication. (added 19/03/2020)

**Intention to publish date**

15/12/2020

# 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?
<a href="#">Protocol article</a>	protocol	23/12/2016		Yes	No
<a href="#">Results article</a>	results	08/02/2021	09/02/2021	Yes	No
<a href="#">Results article</a>		06/06/2025	18/06/2025	Yes	No