

# Effectiveness of an implementation strategy of Clinical Practice Guideline for patients with anxiety disorders in Primary Care

|                                        |                                                               |                                                              |
|----------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------|
| <b>Submission date</b><br>18/06/2010   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered |
|                                        |                                                               | <input checked="" type="checkbox"/> Protocol                 |
| <b>Registration date</b><br>04/08/2010 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan           |
|                                        |                                                               | <input type="checkbox"/> Results                             |
| <b>Last Edited</b><br>29/12/2020       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data         |
|                                        |                                                               | <input type="checkbox"/> Record updated in last year         |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mrs M Eugenia Tello

### Contact details

Avda. de los Pinos, 30.  
Leganés  
Spain  
28914

## Additional identifiers

### Protocol serial number

PI09/90304

## Study information

### Scientific Title

Cluster randomized trial for evaluate the effectiveness of an implementation strategy of a clinical practice guideline for patients with anxiety disorders

### Acronym

GRITA

### **Study objectives**

The percentage of patients with a decrease of 2 or more points in the Goldberg Anxiety Scale after 6 months, will be 20% higher in those that were involved in the focused organisational strategy over those that weren't involved in it.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Committee of Ethical Investigation of the 9th Madrid Health Area approved on the 29th of April 2010

### **Study design**

Multicentre cluster randomised 2 arm open label controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Generalised anxiety disorder, panic disorder and panic attacks

### **Interventions**

1. Control group:

- 1.1. The Clinical Practice Guideline (CPG) will be included on the official working place website
- 1.2. The CPG will be presented in a formative session of 2 hours of length to which will be invited to assist 1 or 2 members of each one of the 22 Health Centres involved in the study

2. Intervention group:

- 2.1. They will also receive an special formative session of 2 hours of length focused on the professionals with the protocol of intervention
- 2.2. They will receive special educational material as information sheets for patients, quick guides, etc.
- 2.3. A local opinion leader will be chosen on each team as the responsible person for the CPG
- 2.4. A defined system for reminding, audit and feedback will be developed to give back information about the intermediate results of the study at 3 and 6 months of the beginning.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Variation of 2 or more points in the Goldberg Anxiety Scale
2. Evaluative criteria
  - 2.1. 4 or more affirmative responses in the Anxiety subscale

2.2. 2 or more affirmative responses in the Depression subscale

Outcomes will be measured at baseline, 6 and 12 months.

**Key secondary outcome(s))**

1. Compliance with the Guideline recommendations on treatment

2. Information and referrals to Mental Health Services

Outcomes will be measured at baseline, 6 and 12 months in data collecting notebooks

**Completion date**

15/09/2012

## **Eligibility**

**Key inclusion criteria**

1. Patients older than 18

2. Diagnosed as generalised anxiety disorder, panic disorder and panic attacks by Diagnostic and Statistical Manual of Mental Disorders 4th edition (text revision) (DSM-IV-TR)

3. Signed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Subjects that have been diagnosed of one of the following types of anxiety:

1.1. Post-traumatic stress disorders

1.2. Acute stress disorders

1.3. drug-related anxiety disorders

1.4. Anxiety disorders due to a medical or a mental illness

2. Subjects not able to read or understand Spanish language

3. Subjects that will not stay living on the Health Area in the next year after their inclusion on the study

4. Institutionalised or immobilised patients

**Date of first enrolment**

15/09/2010

**Date of final enrolment**

15/09/2012

# Locations

## Countries of recruitment

Spain

## Study participating centre

Avda. de los Pinos, 30.

Leganés

Spain

28914

# Sponsor information

## Organisation

Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)

## ROR

<https://ror.org/00ca2c886>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) - Spanish Ministry of Health  
Supporting Investigation Department (ref: PI09/90304)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 01/12/2011   | 29/12/2020 | Yes            | No              |

