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

Submission date	Recruitment status	[X] Prospectively registered
18/06/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/08/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/12/2020	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 werent 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

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 contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
15/09/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Sample size adjusted for design effect = 296 (148 in each arm)

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)

Sponsor details
General Sub-Department for the Evaluation and Promotion of Research
(Subdirección General Evaluación y Fomento de la Investigación)
Monforte de Lemos, 5
Madrid
Spain
28029

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/12/2011	29/12/2020	Yes	No