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Cognitive Behaviour Therapy for Abridged Somatization Disorder (Somatic Symptom Index [SSI] 4,6) patients in primary care

Submission date
23/12/2007

Recruitment status
No longer recruiting

Registration date
14/02/2008

Overall study status
Completed

Last Edited
17/03/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
04/1993

Study information

Scientific Title

Acronym
CBTASD

Study objectives
Patients randomized to cognitive behavioural therapy significantly improve in measures related to quality of life, somatic symptoms, psychopathology and health services use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Aragon Ethics Review Board, approved in June 2005 (ref: 05/24)

Study design
Multi-centre randomized 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Abridged somatization disorder

Interventions
The participants will be randomely allocated to the intervention and control groups in equal numbers.

Intervention group: A manualised intervention program of cognitive behaviour therapy (10 sessions) for somatoform disorders according to Escobar (Arch Intern Med 2006; 166: 1512-18; http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=16864762)

Control group: Usual care plus "Smith's norms." The general practitioners receive a short letter on recommendations (widely accepted and obtained from evidence-based medicine) to manage patients with somatoform disorders.

Duration of interventions: 3 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Severity of Clinical Global Impression scale at baseline, 3 and 6 months and 1-year follow-up

Secondary outcome measures
The following will be assessed at baseline, 3 and 6 months and 1-year follow-up:
1. Quality of life: 36-item Short Form health survey (SF-36)
2. Hamilton Depression Scale
3. Hamilton Anxiety Scale
4. Screening for Somatoform Symptoms [SOMS]

Overall study start date
15/01/2008

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. Fluent in Spanish language
3. Diagnosis of Abridged Somatization Disorder (SSI 4,6) according to Escobar's criteria
4. Stable pharmacological treatment during last month and the expectation to maintain it during the next three months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex

Both

Target number of participants
140 patients

Key exclusion criteria
1. Primary diagnosis of a psychiatric disorder different from somatization disorder
2. Severe personality disorder that interferes with adequate completion of the intervention program
3. Impossible to attend the intervention therapy
4. Refusal to participate

Date of first enrolment
15/01/2008

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Miguel Servet
Zaragoza
Spain
50.009

Sponsor information

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.isciii.es

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Carlos III Institute of Health (Madrid), Funding for Health Research for Social Security (Instituto de Salud Carlos III, Fondo de Investigaciones Sanitarias de la Seguridad Social) (Spain)

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?
Results article	results	01/07/2013		Yes	No