

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

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| Submission date 23/12/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 14/02/2008 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 17/03/2014 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Abridged somatization disorder

Interventions

The participants will be randomly 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(s)

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

Key secondary outcome(s)

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]

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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)

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

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 |