

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

☐ Prospectively registered

☐ Protocol

Registration date
14/02/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
17/03/2014

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Javier Garcia Campayo

Contact details

Hospital Miguel Servet

Avda Isabel la Catolica 1-3

Zaragoza

Spain

50.009

+34 976 253621; +34 686 673302

jgarcamp@arrakis.es

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 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 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

Ctra. Majadahonda - Pozuelo

Km 2 28220 - Majadahonda

Madrid

Spain

28220

+34 91 5097900

director.cnsa@isciii.es

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 |