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Evaluation of a randomised-controlled cognitive-behavioural individual therapy for patients with somatoform disorders

Submission date	Recruitment status	[ ] Prospectively registered
29/03/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/05/2017	Mental and Behavioural Disorders	

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
N/A

Study information

Scientific Title

Evaluation of a randomised-controlled cognitive-behavioural individual therapy for patients with somatoform disorders

Acronym
SOMA

Study objectives
To determine whether a new Cognitive-Behavioural Therapy (CBT) multicomponent manual for individual therapy for somatoform disorders is effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission of the German Society of Psychology, 29/10/2006, ref: WH 28092006DGPS

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Somatoform disorder

Interventions
All outpatients receive cognitive behavioural therapy for 5 months. The patients are referred by their general practitioners. After randomised assignment, the intervention group receives 20 sessions (50 minutes per session) of cognitive behavioural individual psychotherapy. The subjects randomised into the waiting list control group must wait for 5 months before starting with the same intervention. The treatment consists of modules and focuses on explanatory illness model, stressors and coping with stress, the effect of attention versus distraction on bodily complaints or dysfunctions, relaxation training, cognition and beliefs about unexplained bodily symptoms and illness behaviour.

The primary and secondary outcomes will be measured at:
1. First contact with the patient (after referral)
2. Beginning of therapy (after session no. 1)
3. End of therapy (after session no. 20)
4. 6-month follow-up
5. 12-month follow-up

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Severity and distress related to the somatoform symptoms as indicated on Somatoform Disorders Screening Instrument - 7 days (SOMS-7) measured at first contact with the patient (after referral), beginning of therapy (after session no. 1), end of therapy (after session no. 20), 6-month follow-up and 12-month follow-up

Key secondary outcome(s))
1. Self-reported psychological symptoms, measured using the Brief Symptom Inventory (BSI)
2. Depressive symptoms, measured using the Beck Depression Inventory (BDI)
3. Functional limitations, measured using the Short Form-36 Health Survey (SF-36)
4. General life satisfaction, measured using "Questions on Life Satisfaction" (FLZ-M)

Measured at first contact with the patient (after referral), beginning of therapy (after session no. 1), end of therapy (after session no. 20), 6-month follow-up and 12-month follow-up

Completion date
30/03/2008

Eligibility

Key inclusion criteria
1. The presence of a somatoform disorder (Somatic Symptom Inventory [SSI] 3 - patients with at least three current Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition [DSM IV] somatoform symptoms)
2. The somatoform disorder is the main treatment issue (co-morbidities are allowed)
3. Indication for individual therapy
4. Age 18-65
5. Written informed consent

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. Age: under 18, over 65 years
2. Ongoing psychological treatment

3. Treatment in a psychiatric hospital during the last 5 years
4. Acute psychotic or manic symptoms
5. Substance dependency
6. Severe depression, suicidal thoughts or behaviours
7. Post Traumatic Stress Disorder (PTSD) and personality disorder (clusters A & B)
8. Dementia or neurodegenerative disorders
9. Unable to understand German language
10. Request of early retirement because of somatoform disorder

Date of first enrolment
01/01/2007

Date of final enrolment
30/03/2008

Locations

Countries of recruitment
Germany

Study participating centre
Psychological Institute University of Mainz
Mainz
Germany
55099

Sponsor information

Organisation
Psychological Institute, University of Mainz (Germany)

ROR
https://ror.org/023b0x485

Funder(s)

Funder type
University/education

Funder Name
Johannes Gutenberg-Universität Mainz

Alternative Name(s)
Johannes Gutenberg University of Mainz, University of Mainz, Johannes Gutenberg University Mainz, JGU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

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	25/05/2017		Yes	No