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Psychosomatic Intervention for Patients with Multisomatoform Disorder in Different Somatic Specialities

Submission date	Recruitment status
28/11/2005	No longer recruiting
Registration date	**Overall study status**
05/01/2006	Completed
Last Edited	**Condition category**
17/04/2012	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

Study website
http://www.piso-studie.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1359/05

Study information

Scientific Title

Acronym
PISO

Study objectives
Patients with medically unexplained physical symptoms are 'high utilizers' of the health care system with high psychiatric co-morbidity and severe impairments in quality of life (QoL). There is preliminary evidence that psycho-dynamic-interpersonal therapy (PIT) is beneficial as it reduces the intensity of physical symptoms and increases quality of life. The trial interventions so far lacked generalizability over a larger clinical spectrum of disabling somatoform symptoms. We developed a multi-centre two-arm randomized controlled trial with a primary end point and follow-up after one year. PISO has two new aspects:
1. PISO uses a diagnostic category that is independent of the type of currently dominant symptom and therefore serves as a common point of reference
2. PISO uses a manualized psychotherapeutic intervention that is adapted to the specific lead symptom in the beginning, but later on emphasizes more general aspects of experiencing 'unexplained' physical symptoms across single functional syndromes and somatic specialities
In the trial, we test a bio-psycho-social model of change including psychobiological parameters like heart rate variability and prefrontal/limbic neural activations. If the intervention tested in PISO proves to be efficacious as compared to enhanced medical care it will be useful as an economic and versatile tool that is applicable in cooperation with psychosomatic medicine across a range of somatic specialities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
05/08/2005, project number 1359/05

Study design
Multi-centre two-arm randomized controlled trial with major end point at 1-year follow-up, the guidelines of Good Clinical Practice (GCP) will be followed, reporting will follow the CONSORT rules.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Not specified

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
Multisomatoform Disorder

Interventions
Psycho-dynamic-interpersonal therapy (PIT) as a special form of psychosomatic therapy will be compared to enhanced medical care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
SF-36 Physical Component Summary (PCS): In patients with multi-somatoform disorder, symptom-related incapacity is best captured with the PCS. The German version of the SF-36 health survey short form has been validated and is sensitive to change, the assumed effect size of 0.50 is clinically relevant.

Secondary outcome measures
1. IPQ, Brief Form: The brief form of the 'Illness Perception Questionnaire' (BIPQ, Broadbent et al. in submission) provides a quantitative measure of the components of illness representations that has been shown in treatment trials to be sensitive to change. The German version was developed and validated by Gaab (unpublished manuscript).
2. PHQ-D: The 'Patient Health Questionnaire', German version (PHQ-D) is a brief self-report measure for anxiety, depression and other mental disorders. Criterion validity was established with respect to diagnostic gold standards and the PHQ has proven to be a responsive and reliable measure of depression treatment outcome (Löwe et al. 2004).
3. SOMS-7: Seven-day version of the 'Screening for Somatoform Symptoms'. A 53-item instrument for the evaluation of treatment effects in somatoform disorders, covering all somatic symptoms occurring in somatization disorder, according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) and International Statistical Classification of Diseases and Related Health Problems - tenth revision (ICD-10) (Rief and Hiller 2003).
4. Whiteley-Index-7: The seven-item version of the Whiteley Index, an established hypochondriasis scale first described by Pilowsky, was developed and validated by Christensen et al. (2003) specifically to assess treatment effects.
5. LEAS: The 'Levels of Emotional Awareness Scale' (Lane and Schwartz 1987, German version: Subic-Wrana et al. 2002) is a projective text based measure that assesses the capacity to describe own emotional experience and the one assumed in others. It will be used as a predictor variable conceptually related to the theory of change assumed for the treatment intervention.

6. Heart rate variability (HRV): HRV measurement and analysis equipment will be present at each centre. Time-domain (RMSSD) and frequency domain (HF-HRV) analysis will be performed during a stress test with the emotional stroop paradigm.

Overall study start date
01/01/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Patients screened positive and diagnosed in a structured interview in different somatic specialities with a diagnosis of pain-predominant multi-somatoform disorder and a quality of life (QoL) of 1 standard deviation below population norm in the SF-36
2. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
176

Key exclusion criteria
1. Age younger than 18 years
2. Insufficient German language ability
3. Insufficient cognitive abilities (Mini Mental State <24)
4. Severe and chronic somatic disease
5. Severe co-morbid mental disorder causing major impairment of social functioning

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Germany

Study participating centre
Dept. of Psychosomatics
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Sponsor information

Organisation
Munich Technical University (Germany)

Sponsor details
University Hospital 'Rechts der Isar'
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Sponsor type
University/education

Website
http://www.med.tu-muenchen.de

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
Not defined

Funder Name
Sponsor Code: 1359/05

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft [DFG])/German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF])
Code: He 3200/4-1; 60665-02-2/167/04

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		01/06/1999		Yes	No
Abstract results		01/04/2003		No	No
Results article	results	01/01/2012		Yes	No