

Psychosomatic Intervention for Patients with Multisomatiform Disorder in Different Somatic Specialities

Submission date 28/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/04/2012	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
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multisomatiform 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Munich

Germany

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Sponsor information**Organisation**

Munich Technical University (Germany)

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

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
Results article	results	01/01/2012		Yes	No
Abstract results		01/04/2003		No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes