

# A randomised comparison of out patient psychodynamic versus cognitive behavioural group psychotherapy in patients with somatoform pain

<b>Submission date</b> 03/02/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/04/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/10/2007	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

MASOPA

## Study objectives

Somatoform disorder with pain as a leading complaint (International Statistical Classification of Diseases and Related Health Problems - tenth revision [ICD10]: F45).

The study was designed to compare efficacy of psychodynamic and cognitive behavioural group psychotherapy in patients with somatoform pain. Therefore, a total of 150 patients are randomised to one of either therapies. Both therapies are manualized and supervised by video. Patients living more than one hour driving distance to the university hospital who cannot take part in out patient therapy serve as controls by receiving care as usual.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Somatoform pain

## Interventions

Patients receive out patient psychotherapy for 6 months. They were randomised into psychodynamic versus cognitive behavioural therapy. Therapy was manualized. Sessions took place twice a week and once a week respectively. The total amount of therapy was 3600 minutes

in psychodynamic and 2750-3000 minutes cognitive behavioural therapy. Groups consist of 8-10 patients starting therapy together, they were closed for further participants.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Pain intensity and pain disability. Due to the chronic condition, a one year follow-up will service as the primary outcome.

**Secondary outcome measures**

Pain intensity and pain disability.

**Overall study start date**

01/01/2000

**Completion date**

30/11/2005

**Eligibility****Key inclusion criteria**

Patients were included if they had persistent pain (>6 months) without an adequate physical explanation after a broad multidisciplinary check and if they could understand German.

Patients were referred by their general practitioners or specialists in or outside the university hospital. A total of 150 patients will be randomised to one of either therapies, patients living more than one hour driving distance to the university hospital cannot take part in out patient therapy and will serve as controls by receiving treatment as usual (n = 70). Due to the chronic condition, a one year follow-up will serve as primary outcome. A two year follow-up is intended.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

150

**Key exclusion criteria**

Age <18 or >65, psychosis, severe substance dependency, missing understanding of German language, and a request to retire because of disease.

**Date of first enrolment**

01/01/2000

**Date of final enrolment**

30/11/2005

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

Untere Zahlbacher 8

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## **Sponsor information**

**Organisation**

German Research Foundation (Deutsche Forschungsgemeinschaft)

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**Sponsor type**

Research organisation

**ROR**

<https://ror.org/018meiw64>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

## 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