ISRCTN57684245 https://doi.org/10.1186/ISRCTN57684245

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

Submission date
03/02/2005

Registration date
04/04/2005

Last Edited
04/10/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ulrich T Egle

Contact details
Untere zahlbacher 8
Mainz
Germany
D-55131
+49 (0)6131 177381
egle@psychosomatik.klinik.uni-mainz.de

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 supervisioned 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
Mainz
Germany
D-55131

Sponsor information

Organisation
German Research Foundation (Deutsche Forschungsgemeinschaft)

Sponsor details
Kennedyallee 40
Bonn
Germany
D53175
+49 (0)228 8851
postmaster@dfg.de

Sponsor type
Research organisation

ROR
https://ror.org/018mejw64

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