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Medically unexplained physical symptoms in primary care: a controlled study on the effectiveness of cognitive-behavioural treatment by the general practitioner

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
15/05/2009

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR148; 940-38-013

Study information

Scientific Title

Acronym
SOUL

Study objectives
A cognitive-behavioural intervention provided by the GP will be more effective in reducing somatic symptoms and functional impairment in medically unexplained physical symptoms than care as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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

Interventions
Care as usual plus an additional five sessions of 45 minutes of cognitive-behavioural therapy with their general practitioner compared with care as usual.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. Severity of the main physical symptom as indicated on a VAS and the self-rated improvement of symptoms at 6 and 12 months follow-up
2. Recovery was defined as a decrease of at least 30% on the VAS for the severity of the main physical symptom

Secondary outcome measures
1. Self-reported physical symptoms (PSC)
2. Anxiety and depressive symptoms (HADS)
3. Functional limitations (SF-36)
4. Health anxiety and behaviour (IAS)
5. Health care utilisation

Overall study start date
01/04/2000

Completion date
01/06/2004

Eligibility

Key inclusion criteria
1. The presence of a somatoform disorder
2. A minimum score of 5 for the main unexplained physical symptom on a Visual Analogue Scale (VAS - range 0 - 10)
3. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
65

Key exclusion criteria
1. Unable to participate in treatment due to handicaps such as deafness, aphasia or cognitive impairment
2. Ongoing psychological treatment
3. Serious somatic disease
4. Serious psychiatric disorder such as psychosis, substance abuse, post-traumatic stress disorder or severe personality disorder

Date of first enrolment

01/04/2000

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Public Health and Primary Care.
Leiden
Netherlands
2301 CB

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

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