

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	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/05/2009	Condition category 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

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

Intentional

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

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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