

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

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/05/2009	<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

### Contact name

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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)

### **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**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration