

# Psychosomatic therapy for patients with medically unexplained symptoms

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27191

### Source

Nationaal Trial Register

### Brief title

CORPUS

### Health condition

Medically unexplained symptoms (MUS)

Somatisch onvoldoende verklaarde lichamelijke klachten (SOLK)

## Sponsors and support

**Primary sponsor:** VU University Medical Center

**Source(s) of monetary or material Support:** ZonMW, the Netherlands Organization for Health research and innovation.

## Intervention

## Outcome measures

### Primary outcome

The primary clinical outcome is patients' level of specific functioning and disability measured with the patient-specific functional scale (PSFS).

The primary outcome measure for the economic evaluation is quality of life assessed by the SF-6D, which will be derived from the SF-36. Health care costs, medical consumption and work limitations will be assessed with the Medical Consumption Questionnaire (iMCQ) and work limitations with the Productivity Cost Questionnaire (iPCQ).

## **Secondary outcome**

Perceived symptom severity (NRS); Self-rated symptoms of distress, depression, anxiety and somatization (4DSQ); Physical and mental health status and quality of life (SF-36); Health anxiety, illness behaviour and illness beliefs (resp. IAS and IPQ-K); Patients' perceived recovery and satisfaction with the psychosomatic therapy (GPE); number of GP consults.

# **Study description**

## **Background summary**

Medically unexplained symptoms are common in primary and secondary care and associated with large societal costs, including both health care costs and costs of lost productivity. Patients have lower quality of life. Furthermore, these patients are often dissatisfied with the medical care they receive. Psychosomatic therapy is a physical (multi-component) treatment administered by physical and exercise therapists with special interest in MUS. It is a stepped-care and tailor-made approach in which (psycho)education, relaxation therapy, mindfulness, cognitive behavioural therapeutic interventions and activating exercise therapy are key elements.

We will evaluate the effects and costs of psychosomatic therapy in primary care for patients who frequently attend the GP for MUS in improving symptoms and daily functioning and disability, while reducing consultation frequency and referrals to secondary care.

The study consists of two parts. Part 1; Effect and economic evaluation: We will perform a randomized cost-effectiveness trial in primary care. Patients will be randomized into intervention (psychosomatic therapy in addition to usual care) or control condition (usual care alone). All patients will be followed for one year and will be asked to complete questionnaires at baseline and at 4 and 12 months follow-up. Part 2; Process evaluation: We will perform a quantitative and qualitative (sub)study with both therapists and patients; questionnaires for participating therapists and semi-structured interviews with participating patients in the intervention group.

We expect that psychosomatic therapy for patients frequently attending primary care with medically unexplained symptoms improves daily functioning, decreases severity of the

symptoms and the care consumption, while lowering costs.

## **Study objective**

We expect that psychosomatic therapy for patients frequently attending primary care with medically unexplained symptoms improves daily functioning, decreases severity of the complaints symptoms and the care consumption, while lowering costs.

## **Study design**

Baseline, at 4 and 12 months

## **Intervention**

Patients randomized to the intervention group will be invited to attend 6 to 12 sessions, depending on the severity of the complaints, of tailor-made psychosomatic therapy, lasting 45 minutes each. These sessions are additional to the usual care for patients with MUS provided by their GP and other healthcare professionals.

Psychosomatic therapy is administered by psychosomatic therapists. These are physical and exercise therapists with special interests in MUS, respectively from the Dutch Association for Psychosomatics in Physical Therapy (NFP) and the Dutch Association for Exercise Therapists (VvOCM). Psychosomatic therapy has been developed using the well-known concept of the biopsychosocial model in which illness is viewed as a result of interacting mechanisms at the biomedical, interpersonal and environmental levels. Psychosomatic therapy implies that patients' symptoms, illness beliefs, anxiety, concerns, illness behaviour and social environment are addressed.

It is a multi-component, stepped-care and tailor-made approach and includes the following modules: (1) psycho-education, (2) relaxation therapy and mindfulness, (3) cognitive behavioural approaches and (4) activating therapy. Psychosomatic therapy is captured in a treatment protocol which allows the therapists to change the intensity, frequency and order of the four modules in order to deliver a tailor-made approach. In the psychosomatic therapy sessions the therapist together with the patient explores and treats somatic symptoms by integrating the physical, cognitive, emotional, behavioural and social dimensions of the symptoms presented. During the therapy, underlying beliefs and psychosocial factors which influence the perceived somatic symptoms, are identified in order to give patients (experienced) insight in the interaction of these factors with the somatic symptoms. The aim of the intervention is empowerment of the patients to regain control over their own health.

Patients in the control group will receive usual care provided by the GP and other health care professionals. The usual care for patients with MUS has been described in the guideline on the management of MUS of the Dutch College of General Practitioners.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

The target population includes primary care patients aged 18-80 years who frequently, i.e. twice or more in the last 3 months, consult their GP for MUS. Patients should have a PHQ-15 score of  $\geq 5$ .

### Exclusion criteria

Exclusion criteria are receiving palliative care, having a severe psychiatric disorder (i.e. psychosis-related disorders, dementia and bipolar disorder), mental retardation, visual impairment, illiteracy, insufficient understanding of the Dutch language.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	158
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	13-07-2018
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL7157
NTR-old	NTR7356
Other	843001802 : ZonMW projectnummer

## Study results