Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	Netherlands Trial Register
Last refreshed on:	30 May 2022
Main ID:	NTR7356
Date of registration:	13/07/2018
Prospective Registration:	Yes
Primary sponsor:	VU University Medical Center
Public title:	Psychosomatic therapy for patients with medically unexplained symptoms
Scientific title:	Cost-effectiveness of psychosomatic therapy for patients frequently attending primary care with medically unexplained symptoms
Date of first enrolment:	01/09/2018
Target sample size:	158
Recruitment status:	Pending
URL:	https://trialregister.nl/trial/7157
Study type:	Interventional
Study design:	Randomized: No, Masking: None, Control: Active, Group: undefined, Type: 2 or more arms, randomized
Phase:	

Countries of recruitment

The Netherlands

Contacts

Name:	Margreet Wortman	**Name:**	Margreet Wortman
Address:		**Address:**	
Telephone:		**Telephone:**	
Email:	m.wortman@vumc.nl	**Email:**	m.wortman@vumc.nl
Affiliation:		**Affiliation:**	

Key inclusion & exclusion 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 >/= 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.

Age minimum:
Age maximum:
Gender:

Health Condition(s) or Problem(s) studied

Medically unexplained symptoms (MUS) Somatisch onvoldoende verklaarde lichamelijke klachten (SOLK)

Intervention(s)

Patients randomized to the intervention group will be invited to attend 6 to12 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)

Primary Outcome(s)

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(s)

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.

Secondary ID(s)

Source(s) of Monetary Support

ZonMW, the Netherlands Organization for Health research and innovation.

Secondary Sponsor(s)

Ethics review

Status:
Approval date:
Contact:

Results

Results available:	
Date Posted:	
Date Completed:	
URL:	