Cost-effectiveness of psychosomatic therapy for patients frequently attending primary care with medically unexplained symptoms

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In order to guarantee optimal health care for patients who frequently attend with MUS in primary care, we want to study the cost-effectiveness of psychosomatic therapy. An effective and acceptable treatment is urgently needed because (1) these...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49180

Source
ToetsingOnline

Brief title
CORPUS trial

Condition

- Other condition

Synonym
Medically Unexplained Symptoms (MUS)

Health condition

onvoldoende verklaarde lichamelijke klachten

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Promotiebeurs voor leraren voor de loonkosten van de onderzoeker en ZonMw Doelmatigheid.,Stichting Stoffels-Hornstra

Intervention

Keyword: cost-effectiveness, Medically unexplained symptoms (MUS), primary health care, psychosomatic therapy

Outcome measures

Primary outcome

Primary outcome measure:

In order to estimate likely treatment effects we will measure patients* level

of specific functioning and disability measured with

the patient-specific functional scale (PSFS). The PSFS is a self-reported

thoroughly validated measurement instrument for up

to three individual activity limitations rated on a 11-point numeric rating

scale ranging 0-10 (0 represents not a problem at all

and 10 impossible).

Secondary outcome

Secondary outcome measures:

- Perceived symptom severity measured on a Visual Analogue Scale (VAS) (range

0-10; 10 represents most severe

symptoms).

- Patients* self-rated symptoms of distress, depression, anxiety and

somatization measured on Four Dimensional Symptom

Questionnaire (4DSQ). 4DSQ subscales distress and somatisation scores range from 0 to 32 (low: 0-10; moderate: 11-20; high: 21-32), subscale anxiety scores range from 0 to 24 (low: 0-7; moderate: 8-12; high: 13-24) and subscale depression scores range from 0 to 12 (low: 0-2; moderate: 3-5; high: 6-12), so higher scores represent worse health.

- Physical and mental health status and quality of life are measured with the Short Form Health Survey-36 items (SF-36). SF-36 scores range from 0 to 100, where higher scores correspond to better health. From the SF-36 scores the mental component summary (MCS) and the physical component summary (PCS) will be calculated.

- Health anxiety and illness behaviour are measured with the Illness Attitude Scale (IAS) on a five point Likert-scale (ranging from 0 (never) to 4 (most of the time)).

-Illness beliefs are measured with the IPQ-K on a 11-point NRS, ranging 0 (not at all) to 10 (very much)

- Patient perceived recovery and satisfaction with the psychosomatic therapy are measured with the Global Perceived Effect scale (GPE) on a seven point Likert scale (from completely recovered to worse than ever).

- Health care costs, medical consumption and work limitations will be measured by the Medical Consumption Questionnaire (iMCQ) and work limitations by the Productivity Cost Questionnaire (iPCQ).

Baseline characteristics age, gender, marital status, social economic status

(employment and level of education), source of

income, working hours, intensity and duration of MUS, expectations about the

prognosis of complaints and expectations about

the effect of the treatment will be included in the first questionnaire. The GP

will be asked for the total number of consultations

and referrals of the patient in the year after the psychosomatic therapy.

Study description

Background summary

In primary care one-tenth of the attenders account for between 30% and 50% of consultations. Compared to *normal* attenders, these frequent attenders (FAs) generate five times as many prescriptions and hospital contacts and they incur up to five times the health care costs over the preceding 10 years. However, they still have lower quality of life. FAs often seek medical care with somatic symptoms not explained by physical disease (i.e. medically unexplained symptoms (MUS)). These symptoms are often accompanied by psychological, psychiatric, social(-economic) problems or stressful life events. Verhaak indicated that 2,5% of the patients attending primary care can be classified as persisting MUS. These patients are at risk for false-positive diagnostic tests and potentially harmful additional testing and treatment procedures. Medically Unexplained Symptoms (MUS) have been defined as symptoms of which the origins remain unclear to a medical doctor after adequate history taking, physical examination and careful consideration of the psychosocial context. These symptoms are common in primary and secondary care and associated with enormous societal costs. Patients with MUS generate costs for the use of healthcare services of 3123 EUR per patient per year. When work-related costs are taken into account (absence from work, lower on-the-job productivity and paid substitution of domestic tasks) the total costs are enlarged to 6815 EUR per patient per year.
Recently, a Cochrane Review assessed the effects of non-pharmacological interventions for MUS. This review concludes that when all psychological therapies included in the review were combined they seem to be superior to usual care or waiting list in terms of reduction of symptom severity. However, effect sizes were small and as only CBT has been adequately studied as single treatment the review only allow tentative conclusions for daily practice. Furthermore, most patients do not accept CBT as treatment for their MUS. The authors of the review state that the number of studies investigating various

treatment modalities (other than CBT) needs to be increased and that this is especially relevant for studies concerning physical therapies.
Psychosomatic therapy is such a physical (multi-component) treatment. This therapy is 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. Recently we performed a pilot randomized trial comparing psychosomatic therapy with usual care in order to study feasibility and treatment effects. Trial retention as well as acceptability of the intervention was good, as 86% of the included patients completed the trial and 81% of the patients were (very) satisfied with the intervention. At 12 month follow-up patients who received psychosomatic therapy showed significant and clinically relevant improvements with regard to perceived symptom severity (adjusted mean difference -2.0, 95%CI:-3.6 to -0.3), symptoms of somatisation (adjusted mean difference -4.4, 95%CI: -7.5 to -1.4) and symptoms of hyperventilation (adjusted mean difference -5.7, 95%CI: -10.5 to -0.8). Aspects of approaches incorporated in psychosomatic therapy have been shown effective in several studies. A combination of cognitive behavioural intervention or education and exercise was found to reduce pain and fatigue and to increase physical functioning and quality of life in patients with MUS. Mindfulness has shown to improve mental functioning in patients with MUS. An observational before and after cohort study by the Dutch psychosomatic therapists association in 119 patients with MUS demonstrated that patients improve significantly after psychosomatic therapy (in comparison with baseline scores) on self-rated symptom severity, symptoms of distress, quality of life, level of functioning, sick leave and use of medication.

Given the problems GPs are facing when patients with MUS consult them, the risk of unnecessary medical interventions, the limited prospects for improvement, and the lack of a therapy acceptable for many patients, a cost-effective approach in primary care is urgently needed.

Study objective

In order to guarantee optimal health care for patients who frequently attend with MUS in primary care, we want to study the cost-effectiveness of psychosomatic therapy. An effective and acceptable treatment is urgently needed because (1) these patients are functionally impaired in the absence of an effective treatment, (2) the proportion of patients who frequently attend appears to be increasing, and (3) patients are a burden for the health care system since they generate high, often unnecessary, health care costs.

Aim of the study:
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. In addition to the quantitative effectiveness study, we perform a process evaluation to: a) identify which modules are actually deployed; b) identify the most effective elements of psychosomatic therapy and c) understand which patients can benefit from this approach. In a qualitative project we will examine the experiences of patients as part of study section b) and c).

Study design

The study consists of two phases

Part 1;
Effect and economic evaluation:
We will perform a randomized cost-effectiveness trial in primary care. Patients (n=158) 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.
The participants will be randomized by a research assistant directly after receiving the written informed consent. The research assistant will be unaware of the health status of the participant and will use a computer-generated permuted block randomization table.

Part 2;
Process evaluation:
We will perform a quantitative and qualitative (sub)study with both therapists and patients; questionnaires for therapists and interviews with therapists and participating patients in the interventiongroup.

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Intervention

Intervention:
Patients randomised to the intervention group will be invited to attend 6 to 12 sessions 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 Dutch psychosomatic therapists. These healthcare providers 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 was developed from the broad 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 is a multi-component, a 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.
The intervention, psychosomatic therapy, implies that patients* symptoms, illness beliefs, anxiety, concerns, illness behaviour and social environment are addressed. It is a tailor-made treatment for the symptoms and 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, fitting within the recommendations of the recent Cochrane review on non-pharmacological interventions of somatoform disorders and MUS.
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. This will result in empowerment of the patients to regain control over their own health.

Usual care / comparison:
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. It advocates GPs to focus on the exploration of the symptoms, and related cognitions, emotions and behaviour, and apply psychoeducation, monitoring, and when necessary refer for physical therapy, mental health nurse-practitioners or cognitive behavioural therapy (CBG). GPs don*t use these additional referral options very often as patients resist *psychological* treatments for their physical symptoms.

Study burden and risks

Questionnaires will be administered at baseline, at 4 and 12 months. These questionnaires consist in total of 166 items and will take patients approximately one hour to complete.
The patients in the interventiongroup will get 6 to 12 sessions psychosomatic therapy, each of 45 minutes, delivered by a specialized exercise or physical therapist.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The target population included primary care patients aged 18 and over who frequently, twice or more in the recent period, consult their GP for MUS. Patients 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 and age above 80 years.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2019
Enrollment:	158
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL59267.029.18