Reducing Worry in Patients with Medically Unexplained Symptoms: A Feasibility Study

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The primary goal of this study is to assess the feasibility and acceptability of the worry reduction intervention among MUS-patients and GPs as implemented in primary care. A second important goal of this study is to assess the feasibility of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42750

Source
ToetsingOnline

Brief title
WorRI in MUS

Condition

- Other condition

Synonym
medically unexplained symptoms; unexplained physical symptoms

Health condition

onverklaarde lichamelijke klachten

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Feasibility study, Medically unexplained symptoms, Primary Care, Worry reduction intervention

Outcome measures

Primary outcome

Our primary outcome measure is the feasibility and acceptability of the WRI, measured primarily with in-depth interviews for which four GPs and approximately ten MUS-patients will be invited to talk about their experiences with the intervention. Additionally, patient satisfaction with the intervention, measured with a Likert-scale, ranging from 0 (not satisfied at all) to 5 (very satisfied), percentage of patient withdrawal and feasibility and ease with which general practitioners were able to include patients in the study, measured with a Visual Analogue Scale ranging from 0 (not easy at all) to 10 (very easy), will be assessed.

Secondary outcome

Secundary outcome measures are: somatization, distress, depression and anxiety as measured by the Vier-Dimensionele Klachtenlijst, perceived symptom severity as measured with a Visual Analogue Scale ranging from 0 (no symptoms) to 10 (very severe symptoms), spirituality as measured with two scales (trust and acceptance) of the Spiritual Attitude and Involvement List, worry frequency, worry duration, affect and success of postponement will be measured with the experience sampling method, using an application on a smartpone which will send

8 prompts per day to the participants, and lastly, repetitive negative thinking

will be measured with the Perseverative Thinking Questionnaire.

Study description

Background summary

Somatic complaints (SC), such as headaches, gastrointestinal problems, fatigue and back pain, are the second most reported health problems in primary healthcare in the Netherlands. One in five patients presenting with such SCs in primary care, has Medically Unexplained Symptoms (MUS). MUS are symptoms without a clear medical, organic cause. MUS are often vague, consequently, medical professionals cannot adequately help people presenting with these symptoms, which often results in unnecessary, unproductive referrals and medical procedures. Consequently, MUS are not only responsible for high health care costs, but also for economical costs in the form of a loss of productivity on the work floor and high sick leave compensations. Moreover, MUS are responsible for high humanitarian costs, as evidenced by research indicating that higher levels of subjective SCs are related to a poor health-related quality of life.
Former research has established a link between worry and SCs. Following the definition of Borkovec et al., worry is a *chain of thoughts and images, negatively affect-laden and relatively uncontrollable; it represents an attempt to engage in mental problem-solving on an issue whose future outcome is uncertain but contains the possibility of one or more negative outcomes; consequently, worry is related closely to fear processing.* Worrying has been associated, amongst others, with SCs like the one*s mentioned above: fatigue, lower back pain and other pains, but also to cardiovascular disease and in general to heightened activation in the endocrinological, cardiovascular, neurovisceral and immune system. Moreover, worry has been pointed to as a central factor in multiple psychopathologies, such as Generalized Anxiety Disorder and Posttraumatic Stress Disorder. However, the link between worry and SCs does not only occur in high-level worrying; negative health consequences already occur in low-level worrying. Furthermore, the relationship between worry and negative health consequences is also described in the MUS-literature; worry is described as a precipitating factor for physical symptoms in cognitive behavioral-models of MUS.
The link between worry and SCs informed a study by Brosschot and van der Doef in which a worry reduction intervention (WRI) was tested in adolescents. In this intervention, participants in the intervention group were instructed to postpone their worries to a self-chosen, 30-minute *worry-window* in the late evening. The intervention group got the following instruction: *If you find yourself worrying, try to stop and postpone it to your 30-minute worry-window

at night.*, whilst the control group only had to register their worries.
Results showed that the intervention group reported significantly less SCs and a reduction in worry duration. Brosschot and van der Doef have replicated these promising results in a child-sample in which the instructions were adapted for this younger age group. These studies have focused on SCs, however, given the fact that worry is also described as a precipitating factor for MUS in CBT-models of MUS, we believe that manipulating worry duration with the use of the WRI, might also prove to be effective among MUS-patients.
CBT is the current intervention of choice for MUS, however, improvements of SCs are modest and MUS-patients are known to be resistant to psychological treatment, because they feel their health complaints are being categorized as *in their heads*. Furthermore, CBT is effective only when delivered by psychotherapists, which is therefore non-accessible for GPs. Other treatments and interventions that can be delivered by GPs in primary care have limited effectivity. For example, reattribution, a structured patient-focused approach for patient education on SCs, does not show consistent effects. Therefore, there is a need for acceptable interventions that can be delivered in primary care.

Study objective

The primary goal of this study is to assess the feasibility and acceptability of the worry reduction intervention among MUS-patients and GPs as implemented in primary care.
A second important goal of this study is to assess the feasibility of carrying out a randomized controlled trial in the future which will assess the (cost)efficacy of the worry reduction intervention among MUS-patients. Specifically, the objective is to assess the feasibility of the trial procedures, including the recruitment of GPs and MUS-patients, the appropriateness of the measures, and percentage of patient withdrawal during the study.

Study design

This study entails a feasibility study among MUS-patients in primary care. Participating MUS-patients will be randomized to either the intervention group (care as usual by GP + WRI) or to the control group (care as usual by GP). The WRI will be implemented in primary care and the study period will last six days.
The choice for a feasibility study was based on the fact that an intervention of this sort has not yet been tested in a primary care patient-setting before and among MUS-patients. A feasibility study is the preferred study design in preparation of future, larger randomized controlled designs, because of its ability to address the acceptability and feasibility of an intervention and of the study procedures. Qualitative aspects are added regularly to understand the perspective of health professionals and patients more thoroughly. These aspects

can help to improve the intervention and study procedures, in order to prepare it for a larger-scale randomized controlled trial.

Intervention

Participants will be asked to immediately terminate their worries during the day, if they realize they are worrying. They are further asked to postpone these worries to a self-chosen 30-minute time period at night, later to be called their *worry-window*. Participants will receive the following instruction: *Every time you find yourself worrying during the day, try to stop and postpone these worries to a self-chosen 30-minute time period at night. If you do not succeed right away, please try again.*
The instruction to postpone worries is a key component of Cognitive Behavioural Therapy (CBT) for Generalized Anxiety Disorder (GAD), which is called stimulus control. However, this instruction is modified for our goals, with a big difference lying in the fact that participants here will not receive an instruction on the timing and the content of their worry-window. The selection (and modification) of this component was made by Brosschot and van der Doef, because of its success in reducing and controlling worry.

Study burden and risks

Patients in the control group will be expected to fill in questionnaires daily for the study period (6 days) for approximately 15 minutes per day and patients in the intervention group will additionally be expected to practice for half an hour each day during the 6-day study period. Patients can practice in their usual environments.

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

- Patients consulting their general practitioner for at least one medically unexplained symptom;
- Patients in the age group of 18-80 years;
- Patients with an iOS or Android smartphone to their use for the study period

Exclusion criteria

- Patients younger than 18 or older than 80 years;
- Patients suffering from chronic diseases or serious physical illness;
- Patients with medically explained symptoms;
- Patients with mental retardation;
- Patients with severe psychiatric disorders (e.g. major depression);
- Patients with insufficient ability to speak and/or write Dutch

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-09-2016
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	12-04-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25858
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56230.091.15
OMON	NL-OMON25858