WorRI in MUS

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25858

Source
Nationaal Trial Register

Health condition

Medically Unexplained Symptoms (MUS) are symptoms without a clear medical, organic cause.

Keywords:
- Worry reduction intervention
- Medically unexplained symptoms
- Primary Care
- Feasibility study

Dutch:
- Piekerreductie interventie
- Onverklaarde lichamelijke klachten
- Somatisch Onvoldoende verklaarde Lichamelijke Klachten (SOLK)
- Eerstelijnszorg
- Haalbaarheidsstudie

Sponsors and support

Primary sponsor: Radboud University Nijmegen, Medical Center
Source(s) of monetary or material Support: Radboud University Nijmegen, Medical Center

Intervention

Outcome measures

Primary outcome

Feasibility and acceptability: feasibility and acceptability of the WRI will be measured primarily with in-depth semi-structured interviews in which four GPs and approximately ten (depending on the approval of the patients) MUS-patients will be invited to take part. A Likert-scale (ranging from 0 [not satisfied at all] to 5 [very satisfied]) for patient satisfaction with the intervention will be used firstly to select MUS-patients for the interviews, to be able to recruit patients in such a way, that data saturation will be achieved; this procedure is called purposive sampling and is often used in selecting participants for interviews in qualitative research. Patients that score a 1 (not satisfied at all) or a 2 (not satisfied) will be approached to take part in the interviews as unsatisfied patients. Patients that score a 4 (satisfied) or 5 (very satisfied) will be approached to take part in the interviews as satisfied patients. All MUS-patients will fill in the Likert-scale, and all of them will be approached to take part. However, including patients for the interviews will stop when data saturation is achieved. Questions that will be asked in the interviews include for example: 'What were your main experiences with the intervention?', What are positive/negative sides of the intervention?'. Additionally, a VAS will be used to assess the feasibility and ease with which GPs could include patients in the study, ranging from 0 (not easy at all) to 10 (very easy). Also, the percentage of patient withdrawal will be assessed. Timepoint for Likert-scale: T2. Timepoint for interview: T3.

Secondary outcome

Somatization, distress, depression and anxiety: to assess somatization, distress, depression and anxiety, the Vier-Dimensionele Klachtenlijst (4DKL) will be used. Timepoint: T1 and T2.

Perceived symptom severity: patients will first be asked to pick their two most disturbing physical complaints and for these two, perceived symptom severity will be assessed with a VAS ranging from 0 (no symptoms) to 10 (very severe symptoms). Timepoint: T1 and T2.

Spirituality: spirituality will be measured with two scales (Trust and Acceptance; 8 items in total) of the Spiritual Attitude and Involvement List (SAIL). Timepoint: T1.

Worry frequency, worry duration, affect, success of postponement: an app for experience-sampling (ESM) will be used to reliably assess worry frequency, worry duration, affect and success of postponement of worrying during the day. All participants will be randomly prompted eight times a day (between 08:00 – 22.00) to respond to questions regarding these variables. Timepoint: every day of the intervention period (6 days).

Repetitive negative thinking: the tendency to engage in repetitive negative thinking is one important other study parameter which will be measured at baseline to account for. This will be assessed with the Dutch version of the Perseverative Thinking Questionnaire (PTQ-NL). The PTQ-NL is a reliable and valid instrument for measuring the tendency to engage in repetitive negative thinking. The PTQ-NL consists of 15 items which have to be scored on a 5-point Likert scale (1 = never to 5 = almost always). Timepoint: T1.

Demographic data: sex, age, marital status, social economic status, and number of MUS. Timepoint: T1.

Study description

Background summary

Rationale: One in five people presenting with somatic complaints in primary care, has Medically Unexplained Symptoms (MUS). General Practitioners (GPs) cannot adequately help these people due to the vague nature of these symptoms, which often leads to unnecessary referrals and unproductive medical procedures. Therefore, MUS are responsible for high healthcare costs. Currently, Cognitive Behavioural Therapy (CBT) is the treatment of choice for MUS, however, improvements are modest and MUS-patients are known to be resistant to psychological treatment. Therefore, there is a need for acceptable interventions.
Objective: To study the feasibility and acceptability of a simple Worry Reduction Intervention (WRI) and of study procedures to set up a larger trial among MUS-patients in primary care.

Study design: A feasibility study in which MUS-patients will all be randomized to either the intervention group (care as usual by GP + WRI) or the control group (care as usual by GP).
Study population: MUS-patients will be recruited by GPs. Four GPs will each identify four MUS-patients (aged 18-80 year). These MUS-patients will be invited to participate.

Intervention: The intervention consists of an instruction to postpone worries during the day to a 30-minute ‘worry-window’ in the late evening, in which patients are allowed to worry. The WRI will last six days and patients are able to do the WRI in their usual environments.

Main study parameters/endpoints: 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 Likertscale, percentage of patient withdrawal and perceived symptom severity, measured with a VAS, will be assessed.

Study objective

Primary 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.

Secondary Objective(s): 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.

There are no specified hypotheses because of the exploratory nature of this feasibility-study.

Study design

T1: pre-measure (within 1-2 weeks after entrance clinic)

T2: post-measure (after 6 days of intervention/control and experience sampling)

T3: interview (within 1-2 weeks after ending intervention)

Intervention

Worry Reduction Intervention (WRI):

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 selfchosen 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.’ Participants will be advised not to plan their worry window within an hour before bedtime.

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.

Patients in the intervention group will receive the WRI in addition to the usual care they receive of their GP. Patients in the control group will only receive care as usual by their GP. This group will be offered the WRI after this period.

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Patients in the age group of 18-80 years;

2. Patients with MUS, as identified by their GP, which is currently the standard way of establishing presence of MUS.

These MUS-patients should have, at least, one medically unexplained symptom in one of the following categories of MUS (deduced from the Patient-Health Questionnaire-15; a validated questionnaire for somatisation in primary care):

a. Stomach pain

b. Back pain

c. Pain in arms, legs, or joints (knees, hips, etc.)

d. Headaches

e. Chest pain

f. Dizziness

g. Fainting spells

h. Heart pounding or racing

i. Shortness of breath

j. Constipation, loose bowels, or diarrhea

k. Nausea, gas, or indigestion

l. Tiredness or having low energy

m. Sleeping problems

And the GP cannot find any physical disease or pathology for that complaint And functional constraints in daily life due to the complaint

3. Patients with an iOS or Android smartphone to their use

Exclusion criteria

1. Patients younger than 18 or older than 80 years;
2. Patients suffering from chronic diseases or serious physical illness;

3. Patients with medically explained symptoms;

4. Patients with mental retardation;

5. Patients with severe psychiatric disorders (e.g. major depression)

6. Patients with insufficient ability to speak and/or write Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2016
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42750
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5706
NTR-old	NTR5859
CCMO	NL56230.091.15
OMON	NL-OMON42750

Study results