Master Your Symptoms: Personalized e-health for self-management of medically unexplained symptoms

Published: 25-06-2018
Last updated: 15-04-2024

Main objective: To assess the effectiveness of MYSelf in comparison to care as usual in improving quality of life and symptom severity. Secondary objectives: 1) To investigate which characteristics of primary care professionals (General...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Somatic symptom and related disorders
Study type	Interventional

Summary

ID

NL-OMON55818

Source
ToetsingOnline

Brief title
MYSelf

Condition

- Somatic symptom and related disorders

Synonym
Medically unexplained symptoms; unexplained physical symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Psychiatrie
Source(s) of monetary or material Support: ZonMW;Onderzoeksprogramma GGZ Middellang

Intervention

Keyword: E-health, Medically unexplained symptoms, Self-management

Outcome measures

Primary outcome

The physical component score of the Dutch version of the RAND-36 (measure of health-related quality of life) will be used as our primary outcome.

Secondary outcome

Secondary outcomes are the RAND-36*s Mental component score, symptom severity, psychological symptoms (asked with the 4DSQ), patient satisfaction, health care utilization, and productivity loss.

Study description

Background summary

Medically Unexplained Symptoms (MUS) are physical symptoms that have existed for more than several weeks and for which adequate medical examination has not revealed any condition that sufficiently explains the symptoms. MUS are the result of a complex individual interplay between biological, psychological, and social factors. Psychotherapy reduces symptoms and improves quality of life, but is only indicated for severe cases and not well accepted by patients. We developed an e-Health system, Master Your Symptoms (MYSelf), to support general practitioners in early detection and treatment of MUS. Based on patient*s responses to online questionnaires, this system generates a treatment plan consisting of a personal set of exercises and assignments to improve self-management.

Study objective

Main objective:
To assess the effectiveness of MYSelf in comparison to care as usual in improving quality of life and symptom severity.

Secondary objectives:
1) To investigate which characteristics of primary care professionals (General

Practitioners (GPs), and General practice mental health workers (GP-MHWs; In Dutch: POH-GGZ)) predict effectiveness of MYSelf; 2) To investigate which patient characteristics predict effectiveness of MYSelf; 3) To investigate the cost-effectiveness of MySelf in comparison to care as usual; 4) To investigate whether MYSelf is acceptable to patients and primary care professionals (GPs and GP-MHWs) and to assess therapeutic change mechanisms; 5) To investigate which mechanism predicts treatment outcomes.

Study design

Pragmatic randomized controlled trial.

Intervention

The research group participates in MYSelf, guided by the GP and GP mental health worker; the control group receives care as usual from the GP.

Study burden and risks

Since the questionnaires are actually part of the routine outcome monitoring, we kept the extra burden for filling out questionnaires as limited as possible. Since all exercises in our eHealth system are originally self-help exercises and participating patients in the intervention group are supervised by their GP/GP-MHW, we assume that the risks of our intervention are negligible.

Contacts

Public
Selecteer

Hanzeplein 1
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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age >= 18 years.
2.Presenting with MUS. In line with the guidelines provided by the Dutch College of General Practitioners, MUS are defined as *physical symptoms that have persisted for more than several weeks and for which adequate medical examination has not revealed any condition that sufficiently explains the symptoms* (Olde Hartman et al., 2013). Since the duration of an episode and the moment of presentation might vary per symptom, the GP will judge whether this criterion is met.
3. Main symptom concerns pain, gastro-intestinal complaints or fatigue.
4. Capable of understanding questionnaires and exercises: adequate command of the
Dutch language, no major cognitive or visual impairment.
5. In possession of an e-mail account and a personal computer, laptop or tablet with internet connection. These will be needed to access the study website, fill out questionnaires, and receive personalized feedback.

Exclusion criteria

1. Currently treated by a mental health professional with psychotherapy.
2. Presence of severe anxiety, depression, or presence of post-traumatic stress syndrome, that needs treatment according to the GP. Thus, if the GP deviates from the GP guidelines with good reason, this is not a reason for exclusion. Also, mild anxiety or depression is not an exclusion criterion.
3. Pregnancy.
4. Engaged in a legal procedure concerning disability-related financial benefits.

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):	01-04-2019
Enrollment:	165
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-11-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL61185.042.17