Evaluation of a proactive program to prevent chronic pain, fatigue and/or dizziness

No registrations found.

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

Summary

ID

NL-OMON29481

Source
Nationaal Trial Register

Brief title
PARASOL

Health condition

Medically Unexplained Physical Symptoms (MUPS)

Somatisch Onvoldoende verklaarde Lichamelijke Klachten (SOLK)

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: SIA RAAK Publiek

Intervention

Outcome measures

Primary outcome

impact of symptoms and quality of life

Secondary outcome

severity of symptoms, general health, physical behaviour, illness perceptions, self-efficacy and cost-effectiveness

Study description

Background summary

1. Background

Medically unexplained physical symptoms (MUPS) are an important health problem in primary
care, with a spectrum from mild to chronic. The burden of chronic MUPS is substantial for patients, health care professionals and society. Therefore, early identification of patients with moderate MUPS is needed, enabling prevention of chronicity. We developed the PRESUME screenings method using data from the electronic medical record of the general practitioner and
demonstrated its prognostic accuracy to identify patients with moderate MUPS. In the next step
we developed a proactive blended and integrated mental health and physiotherapy intervention
program (PARASOL), to reduce complaints of moderate MUPS, stimulate self-management and
prevent chronicity. The primary objective of this study is to investigate the effectiveness of the
blended PARASOL intervention on the impact of symptoms and quality of life in patients with moderate MUPS compared with usual care.

2. Research questions

1. What is the effectiveness of the PARASOL intervention on impact of symptoms and physical
and mental dimensions of quality of life in patients with moderate MUPS compared with usual care?

2. What is the influence of the PARASOL intervention on severity of symptoms, general health,
physical behaviour, illness perception and self-efficacy in patients with moderate MUPS compared with usual care?

3. What is the cost-effectiveness of the PARASOL intervention in patients with moderate MUPS
compared with usual care?

3. Study design

We will perform a multicenter cluster randomized clinical trial. Adult patients with moderate MUPS will be identified in electronic medical record data using the PRESUME screening and proactively recruited for participation in the study. Cluster randomization will be performed at the
level of the participating health care centers. In total 248 patients with moderate MUPS (per arm
124 patients) are needed. The PARASOL intervention is a 12-week blended primary care program consisting of four face to face consultations with the mental health nurse and five physiotherapy sessions, supplemented with a web-based program. The web-based program contains of (1) information modules and video's on self-management and educative themes, (2)
video's and instructions on prescribed home exercises and (3) assignments to gradually increasing physical activity program. The program is directed at patients' perception of symptoms, and modifiable prognostic risk factors for chronicity using therapeutic neuroscience
education and encouraging self-management as well as an active lifestyle using a cognitive behavioural approach and graded activity. Primary outcomes are impact of symptoms and quality of life. Secondary outcomes are severity of (psychosocial) symptoms, general health, physical behaviour, illness perceptions, self-efficacy and cost-effectiveness. All measurements
will be performed at baseline, three and twelve months after baseline. Retrospective cost questionnaires will also be sent at six and nine months after baseline, used for the cost-effectiveness analysis.

Study objective

Medically unexplained physical symptoms (MUPS) are an important health problem in primary care, with a spectrum from mild to chronic. The burden of chronic MUPS is substantial for patients, health care professionals and society. We developed a proactive blended and multidisciplinary preventive intervention to reduce complaints of moderate MUPS and to prevent chronicity, called the PARASOL intervention. It is hypothesised that the PARASOL intervention can reduce impact and severity of symptoms and increase quality of life, general health, physical behaviour, illness perception and self-efficacy in patients with moderate MUPS.

Study design

Three moments (0, 3 and 12 months) will be used for data collection. In addition, cost

questionnaires will also be sent at 6 and 9 months. Furthermore, impact of symptoms will be measured weekly between 0 and 3 months, and monthly between 6 and 12 months.

Intervention

The PARASOL intervention is a 12-week blended primary care program consisting of four face to face consultations with the mental health nurse and five sessions of physical therapy, supplemented with a web-based program.

The control group will get care as usual without any restrictions.

Contacts

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Eligibility criteria

Inclusion criteria

- ≥18 years,

- ≥5 general practice consultations during the past twelve months

- mastering of the Dutch language

- access to the internet.

Exclusion criteria

Not applicable.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-03-2017
Enrollment:	248
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-10-2017
Application type:	First submission

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
NTR-new	NL6581
NTR-old	NTR6755
Other	METC : 16/532

Study results