Evaluation of a proactive preventive program in patients with medically unexplained physical symptoms.

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Primary objective: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?Secondary Objectives: 1. What is the...

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

Summary

ID

NL-OMON46266

Source
ToetsingOnline

Brief title
PARASOL

Condition

- Other condition

Synonym
Medically Unexplained Physical Symptoms

Health condition

patiënten met uiteenlopende somatisch onvoldoende verklaarde lichamelijke klachten

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: SIA RAAK NWO

Intervention

Keyword: blended care, intervention, multidisciplinary, MUPS

Outcome measures

Primary outcome

Quality of life, measured with the RAND-36 health survey

Impact of symptoms measured with the adequate relief question

Secondary outcome

- Severity of symptoms, defined as self-perceived pain and fatigue in the past week, will be measured with an 11-point numeric scale (score 0-10)

- Severity of psychosocial symptoms will be measured with 4DKL questionnaire.

- Health care use and indirect costs through illness and absenteeism will be measured with TIC-P questionnaire to evaluate cost-effectiveness in terms of costs per *Quality Adjusted Life Years (QALYs)

- Physical behaviour will be measured with the Activ8 activity monitor. The Activ8 is a valid measurement in detecting lying/sitting, standing, walking, running and cycling.

- Measure of perceived health will be more specifically measured with the EQ5D questionnaire.

- Self-efficacy will be measured with the Hei-Q questionnaire

- Illness perceptions will be measured with the Brief Illness Perception Questionnaire.

- Efficacy, barriers and facilitators of the PARASOL intervention according to participating subjects and professionals will also be determined, using the *System Usability Scale (SUS)*. The SUS will be completed at T1, at the end of the PARASOL program.

Study description

Background summary

Medically unexplained physical symptoms (MUPS) are a serious problem in primary care, with a spectrum from mild to moderate or chronic MUPS. The burden of chronic MUPS is substantial for patients, health care professionals and the society. Therefore, early identification of patients with moderate MUPS to prevent chronicity is needed. Recently a new screenings method with acceptable prognostic accuracy was developed using data from the electronic medical record of the general practitioner. Furthermore, we developed a proactive blended and multidisciplinary preventive intervention to reduce complaints of moderate MUPS and to prevent chronicity, called the PARASOL intervention. The expectation is that this blended care will promote self-management. However, the (cost)effectiveness of this PARASOL intervention needs to be established. It is hypothesised that the PARASOL intervention, focused on modifiable prognostic risk factors of chronic MUPS in which principles of the modified consequence model, central sensitisation, cognitive behavioural approach and graded activity are integrated, 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 objective

Primary objective:
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?

Secondary Objectives:
1. 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?
2. What is the cost-effectiveness of the PARASOL intervention in patients with moderate MUPS compared with usual care?

Study design

cluster randomized clinical trial

Intervention

Subjects of the experimental health care centers will follow the PARASOL intervention. The PARASOL intervention will take 12 weeks with:
4 sessions with the mental health nurse (30 minutes per sessions)
5 sessions with the physical therapist (30 minutes per sessions)
Total of 4.5 hours

Weekly online modules: duration of 1-1.5 hour weekly (max 12-18 hours)

Study burden and risks

Benefits:
Subjects randomized in the PARASOL intervention can have beneficial effects of the intervention on their experienced quality of life, severity of symptoms and adequate relief. There are no benefits of participation during the study for subjects randomized in the control group. However, subjects of the control group will be offered the complete PARASOL intervention or only the online part of the PARASOL intervention after the last follow-up measurement, twelve months after completing the baseline measurements.

Risks:
The study is carried out with adults. The risks for the subjects are minimal because of the low burden of the intervention for the subjects in the experimental group. Additionally, the subjects in the experimental group will not impose any kind of restrictions. The focus in the PARASOL intervention will be on modifiable prognostic risk factor of chronic MUPS through graded activity, coaching using face-to-face contact and an eHealth module, based on current literature, guidelines and focus groups with experts. Additionally, there are also no risks or any kind of restrictions for the subjects in the control group, since they will receive care as usual. The duration of the sessions with the physical therapist and mental health nurse will take 30 minutes per session. The duration of the online part of the PARASOL intervention will take one hour weekly. Filling in questionnaires at baseline, after three and twelve months will take 30-45 minutes. The adequate relief question will be completed more often and will take a maximum of 5 minutes each time. The adequate relief question will be completed weekly between T0 and T1, and monthly between six and twelve months after baseline. Subjects will also complete the questionnaire on health care use and indirect costs six and nine months after baseline, which will take approximately 15 minutes.
Additionally, subjects have to wear the Activ8 activity monitor to measure physical behaviour at baseline, after three and twelve months for one week. The

Activ8 will be worn for three weeks totally. Wearing the Activ8 activity monitor has a low burden since the Activ8 can be worn in the pants pocket and does not have to be recharged during the week.

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

Subjects will be selected and identified with the PRESUME screening method.
In order to be eligible to participate in this study, a subject must meet all of the following criteria; the subjects have to:
- be 18 years or older
- not suffering from chronic somatic or psychiatric disease
- have five or more consultations with the GP in the past twelve months of which at least three of those consultations are with one of the 104 ICPC codes suggestive of MUPS.;Health

care centers in primary care are eligible to participate if all relevant disciplines (general practitioner, physical therapist, mental health nurse) are available and willing to participate.

Exclusion criteria

Eligible subjects will be excluded when the subject has:
- insufficient mastering of the Dutch language
- no access to the internet.;Furthermore, all identified subjects using the PRESUME screening method will be screened by their GP. Subjects identified with moderate MUPS will be excluded if one or more of the following criteria apply:
- received a medical explained diagnosis between identification using the PRESUME method and the time of inclusion.
- complaints with a shorter duration than one month, in which more diagnostic evaluation of the symptoms is needed.
- unable to participate according to the GP, f.i. because of a life threatening condition, a short life expectancy, an experienced life event in the past month or a subject had followed a multidisciplinary intervention in the past 12 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2017
Enrollment:	248
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	07-06-2017
Application type:	Amendment
Review commission:	METC NedMec

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	NL57931.041.16