Personalized self management support for chronically ill patients using the screeningtool SeMaS.

No registrations found.

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

Summary

ID

NL-OMON26503

Source
Nationaal Trial Register

Health condition

Patients suffering from chronic conditions, including astma, COPD, diabetes mellitus, and people with (an increased risk of) cardiovascular diseases (CVR).

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre, IQ healthcare, Nijmegen, The Netherlands
De Ondernemende Huisarts (DOH), Eindhoven, The Netherlands
Source(s) of monetary or material Support: Foundation Robuust, Eindhoven, The Netherlands
Philips Research Eindhoven, The Netherlands

Intervention

Outcome measures

Primary outcome

The difference in the level of patient activation after six months compared between the

intervention and control arm, measured with the PAM-13 questionnaire.

Secondary outcome

The difference in these variables when comparing intervention to the control arm:

1. Number of completed individual care plans at t=6m;

2. The number of referrals to self management interventions (group courses and internet coaches) in the study period;

3. Adherence to these interventions in the study period;

4. The number of referrals to informative websites in the study period;

5. The number of consultations in the general practice and emergency care in the study period;

6. Rapid assessment of physical activity (RAPA) at t=0 and t=6m;

7. Rapid eating assessment for participants – short version (REAP-S) at t=0 and t=6m;

8. 10-item behavior change consortium questionnaire (smoking) at t=0 and t=6m;

9. S-TOFHLA (health literacy) at t=0 and t=6m;

10. Number and type of psychosocial factors from the SeMaS that is discussed with the patient at the planned check-up appointment at t=0.

Study description

Background summary

BACKGROUND:

The number of patients with one or more chronic diseases is rising. In several standards of care there is a focus on enhancing self management. We applied the concept of personalization on self management support and developed a self management screening questionnaire (SeMaS). The main research objective is to assess the effectiveness of the SeMaS questionnaire and subsequent personalized self management on patients' self management behaviors.

METHODS:

A cluster randomized controlled trial will be set up in 15 general practices in the Netherlands. The practices are all group practices, and member of one care group. The practices will be assigned to the trial arms by stratified randomization. The strata are determined by the participation of the practice nurses in a course for behavioral change, and the nurse's time available per patient. Patients can be included if they are over 18 years of age, have at least one chronic conditions and have a checkup appointment with the practice nurse in the inclusion period. The intervention consists of screening patients with the SeMaS questionnaire, producing a profile with the abilities or barriers for self management. Patients will receive tailored feedback. Practice nurses are trained in using the profile to enhance self management of the patient. The use of individual care plans and self management interventions is stimulated. In the control arm patients will receive care as usual. Patients of both trial arms will be asked to fill in the SeMaS questionnaire and additional questionnaires at inclusion and after 6 months. The primary outcome is the difference in change in the level of patient activation (PAM-13) at the individual level. Secondary outcomes include patient measures for lifestyle factors, and process measures from medical record data analysis.

DISCUSSION:

This manuscript presents the protocol for a cluster randomized clinical trial of personalized self management support using the SeMaS questionnaire in patients with chronic conditions in primary care. By carrying out this study, scientific evidence is built for the effectiveness of personalized self management support.

Study objective

Application of the SeMaS questionnaire and subsequent personalized self management support will be more effective in enhancing patients' self management behaviors than care as usual.

Study design

Patient questionnaires at t=0 and t=6 months.

Test-retest: Standard questionnaire at t=0, retest questionnaire (only SeMaS) at t=2 weeks.

Medical record data extraction: from t=0 to t=6 months.

Intervention

The intervention will be delivered on cluster level in the primary care practice. The intervention consists of personalizing self management support using the results of the SeMaS questionnaire. The results are represented in a report with a graphic profile of the

patient and tailored advice to enhance self management, consistent with a manual.

The practice nurses in the intervention arm will receive a manual that indicates which profiles are suitable for self management, which are suitable with minor barriers, and which are unsuitable for self management at this time. The manual also contains suggestions for personalized self management support, such as the creation of individual care plans, options to influence the barriers for self management, and the referral to self management interventions.

Intervention practice nurses and GPs will receive a two-hour training session before starting the trial, consisting of an introduction to the SeMaS screening instrument, demonstration of a consult with a SeMaS report and skills practice using role play. The practice nurses will be specifically instructed on the options for personalized self management support. Subsequently, all intervention practices will be visited to provide further support in working with the SeMaS. The user manual and examples of reports with suggestions for personalized self management support will be discussed.

During the study period, practice nurses of the intervention arm will receive a report with the profile of the patients who filled in the questionnaire. Patients will also receive tailored feedback.

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Eligibility criteria

Inclusion criteria

1. Age: 18 or older;

2. Sex: male or female;

3. Having at least one chronic condition, including astma, COPD, diabetes mellitus, increased cardiovascular risk;

4. Having a check up appointment with the practice nurse in the primary practice in the inclusion period.

Exclusion criteria

1. Age: below 18 years old;

2. Not able to communicate in Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2013
Enrollment:	700
Type:	Anticipated

Ethics review

Positive opinion
Date: 18-04-2013
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	NL3765
NTR-old	NTR3960
Other	E12EL06 : 2012/561
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A