Self-management for CVR-patients

No registrations found.

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

Summary

ID

NL-OMON21033

Source
Nationaal Trial Register

Brief title
Vaat in Zicht

Health condition

Cardiovascular Risk

Sponsors and support

Primary sponsor: Radboud University Medical Center Nijmegen
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

We will use the following outcome measures:

1) The Patients Activation Measure (PAM-13) to measure self-management

2) The RAND-36 to measure health related quality of life

3) Self-efficacy for coping with CVR in daily life

4) The MMAS-8 to measure medication adherence

5) Lifestyle for patients with CVR (smoking, alcohol use, physical activity, eating habits)

6) The Patient Efficacy in Patient-Physician Interactions (PEPPI-5) to measure patients'efficacy in obtaining medical information and attention to their medical concerns from physicians.

Secondary outcome

The process of the intervention will be evaluated on actual use and added value of the e-health self-management support program “Vaat In Zicht”, and dropping out of the intervention. Both patients and nurses will take part in the evaluation. Qualitative data on the feasibility of the intervention will be obtained via nine semi-structured interviews. The patients will be interviewed about their experience using the intervention asking questions on worthiness, time consumption and relevance. The actual use of the intervention will be monitored quantitatively during the intervention period counting data on frequency of the patients’ visits to the online self-management program.

Study description

Background summary

Introduction: Cardiovascular diseases are one of the most common causes of death from chronic conditions. In the Netherlands approximately one million people suffer from cardiovascular risk and 107 people die every day. Because of the large impact of cardiovascular risk (CVR), there is a growing interest in self-management for patients with CVR. To support self-management behavior for patients with CVR, an e-health self-management program has been developed. In this study, we will evaluate the feasibility of the e-health self-management program and estimate important outcome measures in an early randomized controlled trial.
Objective: 1) To pilot test an e-health self-management support program for patients with cardiovascular risk; 2) to explore effectiveness and effect size of the e-health self-management support program; 3) identify outcome measures most likely to capture potential benefit; 4) evaluate continued participation or dropping out of the intervention; 5) explore nurses’ changing roles and activities in the light of e-health intervention.

Study design: The intervention will be tested in an early randomized controlled trial with a six and twelve month follow-up from baseline.

Study population: 200 patients with cardiovascular risk, 18 years of age and older, ability to speak and read the Dutch language are eligible for inclusion in the trial. All nurses at the outpatient clinics will be included.

Intervention: On top of usual care the treatment group will receive a e-health self-management program. The intervention consists of six modules and strategies to support the behavioural change and maintenance of self-management behaviour.

Outcome: We will measure self-management behaviour (PAM-13), quality of life (Rand-36), self-efficacy for coping with CVR in daily life, medication adherence (MMAS-8), lifestyle for patients with CVR and communication (PEPPI-5).

Study objective

The aim of the pilot trial is to:

1. evaluate the potential effectiveness and effect size of the online self-management program for patients with Cardiovascular Risk

2. to identify outcome measures most likely to capture potential patient benefit;

3. to evaluate continued participation or dropping out of the online self-management program.

Study design

Baseline data collection will start in October 2014.
Patient's characteristics will be assessed together with the baseline outcome measures, via an online questionnaire. Repeated measures will be executed at six months and twelve months after baseline. The estimated time to fill out the questionnaire is 30 minutes.

Intervention

All participants will receive usual care, consisting of regular care and treatment at one of the four outpatient clinics in the Radboudumc.

In addition to the care as usual, participants in the intervention group will receive the e-health self-management support program (the intervention). The intervention, the e-health self-management support program for patients with CVR entitled "Vaat In Zicht", consist of six modules: 1) coping with the disease; 2) setting limits in daily life; 3) healthy food; 4) healthy exercise; 5) coping with lifestyle; and 6) communicating with health professionals. Behavior change strategies to support the behavioral change and maintenance of self-

management behavior consist of: 1) providing general information and increasing memory and/or understanding of transferred information to increase patients knowledge; 2) creating awareness by risk communication, self-monitoring of behavior, feedback of behavior; 3) influencing subjective norm by providing information about peer behavior and mobilizing social norm; 4) changing attitude by reevaluation of outcomes, self-evaluation and persuasive communication; 5) increasing self-efficacy by modeling and guided practice; 6) goal setting is used to change patient's intention and to maintenance changed behavior and to prevent relapse.

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Eligibility criteria

Inclusion criteria

- CVR Patients;

- an age of 18 years or older;

- the ability to speak and read the Dutch language;

- the availability of a computer.

Exclusion criteria

- Patients receiving psychiatric treatment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-09-2015
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	NL5303
NTR-old	NTR5412
Other	: 2015-1908 CMO

Study results