Tailored intervention to improve cardiovascular risk management in primary care.

No registrations found.

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

Summary

ID

NL-OMON23209

Source
Nationaal Trial Register

Brief title
Cardiovascular disease, tailored implementation of chronic diseases, general practices, practice nurses, tailored implementation program, e-health, physical activity, motivational interviewing

Health condition

Een interventie programma op maat gericht op de praktijkondersteuner en patient met hart- en vaatziekten of een hoog risico hierop.
tailored intervention program aimed at practide nurses and patient with cardiovascular diseases or at high risk

Sponsors and support

Primary sponsor: the study is conducted by the research team of UMC St Radboud, department IQ Healthcare
Source(s) of monetary or material Support: The study is funded by the European Union Framework 7programma within the theme HEALTH.2013.3.1-1 under grant agreement no 258837.

Intervention

Outcome measures

Primary outcome

The primary outcome refers to the professional performance of practice nurses and reflects application of recommendations for personalized counselling and education of CVRM patients. As a primary outcome, a dichotomous score is created for measurement in each patient, reflecting adequate or inadequate performance. We considered practice nurses¡¦ professional performance to be adequate when at least one of the following conditions are met:

1) There is a record in the patients¡¦ medical file or other healthcare provider-based records that the patient has received advice on at least one lifestyle item as specified in prevailing guidelines of CVRM; diet, smoking or physical exercise, and which are relevant for the individual patient in the previous six months. Also at least one target for improving an aspect of lifestyle is recorded. This target is made up to maximal 15 months ago. When a patient has a perfect lifestyle then that will be recorded.

2) There is a notation in the patients¡¦ medical file that the patient has none, mild or major depressive symptoms and that the patient has been referred to E-health, a physical exercise group, or depression treatment respectively.

Secondary outcome

The secondary outcomes consist of the following:

• Practice nurses

Quality of effective referral:
Using data from patients¡¦ medical files and the patient questionnaires, we will assess whether practice nurses referred patients to treatment options (E-health, a physical exercise group, or depression treatment) in accordance with our recommendations on depressive symptoms. This measurement of quality represents correct referral and is thus an extension of measurement of referral as defined in the primary outcome.

Quality of motivational interviewing:

For assessment of quality of motivational interviewing skills, audio taped interviews of practice nurses in the intervention group and control group will be transcribed verbatim and will be coded by trainers using the Motivational Interviewing Treatment Integrity (MITI) code.

Results of these coding will be compared with baseline after six months.

- Patients

Cardiovascular risk predictors

Using prevailing risk estimation tables (based on the Euro score data), the following parameters are used for calculation of the risk score for patients at high risk for CVD; age, gender, smoking status, systolic blood pressure and total cholesterol/ HDL- cholesterol ratio). For patients with established CVD smoking status, systolic blood pressure and total cholesterol/ HDL- cholesterol ratio will be used. Change of the parameters will be measured before and after implementation of the tailored intervention.

Self-management:

Using a composite questionnaire, we will assess whether patients applied lifestyle advices for improving their self-management. This questionnaire will be send at the start of the implementation program and after six months. The questionnaire will be sent to the patients home address.

Study description

Background summary

Background

Cardiovascular disease (CVD) is worldwide an important cause of mortality. In The Netherlands, CVD is the leading cause of death for women and the second cause of death for men. Recommendations for diagnosis and treatment of CVD are not well implemented in primary care. In this study we aim to examine the effectiveness of a tailored implementation program targeted at practice nurses to improve healthcare for patients with (high risk for) CVD.

Methods/Design

A two-arm cluster randomized trial is planned. We offer practice nurses a tailored program to improve adherence to six specific recommendations related to blood pressure and cholesterol target values, risk profiling and lifestyle advice. Practice nurses are offered training and feedback on their motivational interviewing technique and an e-learning program on cardiovascular risk management (CVRM). They are advised to screening for

presence and severity of depressive symptoms in patients. We also advise practice nurses to use selected E-health options (selected websites and twitter consult) in patients without symptoms of depression. Patients with mild depressive symptoms are referred to a physical exercise group. We recommend referring patients with major depressive symptoms for assessment and treatment of depressive symptoms if appropriate before starting CVRM. Data of 900 patients at high risk of CVD or with established CVD will be collected in 30 general practices in several geographical areas in the Netherlands. The primary outcome measure is performance of practice nurses in CVRM and reflects application of recommendations for personalized counselling and education of CVRM patients. Patients¡¦ health-related lifestyles (physical exercise, diet and smoking status) will be measured with validated questionnaires and medical record audit will be performed to document estimated CVD risk. Additionally, we will survey and interview participating healthcare professionals for exploration of processes of change. The control practices will provide usual care.

Discussion

Tailored interventions can improve healthcare. An understanding of the methods to reach the improved healthcare can be improved. This research provides a share to it. Identification of the determinants of practice and developing implementation interventions are two steps who were finished. The subsequent step is implementation of the tailored intervention program.

Study design

In each general practice measurements on practice nurses and patients are performed at baseline and at follow-up after six months.

Intervention

Practice nurses will be guided by a professional trainer who is affiliated with MINTned (Dutch association of trainers in motivational interviewing). The trainer will provide feedback directly after two consecutive consultations by using the Behaviour Change Counselling Index (BECCI) code. During this procedure, the practice nurse can directly apply feedback and feel confident that she applied it appropriately. Previous research has shown that providing feedback is effective for improving motivational interviewing techniques among nurses and that there is room for improvement.

For enhancing knowledge of CVRM we recommend a recently launched e-learning program. This program is specifically designed for practice nurses by the Dutch College of General Practitioners and consists of several modules with information about tasks areas of practice nurses involved in CVRM. At the end of every module, the practice nurse is required to answer several questions.

A short instruction will be offered which emphasizes advantages of using E-health in primary care and describes how this medium can be used effectively by patients. During this instruction, we will recommend the following websites which are selected after careful exploration of available options: thuisarts.nl (general practitioner at home, developed by the

Dutch College of General Practitioners), and hartenvaatgroep.nl(heart and vessel group) which contain carefully selected and reliable information on health and disease for both patients and the general public. These websites are easy to use by patients and searches can be completed by using search terms or by clicking organs on a picture of a human body. Practice nurses will discuss the opportunities to access the internet with the patients.

In addition to using informative websites, practice nurses are asked to notify patients on a Twitter-consult. In this Twitter-consult, a general practitioner will answer questions about CVRM.

- No depressive symptoms

Patients without symptoms of depression are considered to be capable for a more independent approach in changing and managing their health behaviors. Therefore, they will be referred to several E-health options. These will consist of educational websites, as mentioned in the E-health training for practice nurses, on which patients can search for information suited for individual goals in CVRM and the Twitter-consult. Although the latter is not particularly emphasized in prevailing guidelines, research found that internet interventions can reduce cardiovascular risk and reduce the number of visits to healthcare providers.
Furthermore, and for providing additional support, patients will be given a card on which websites, dates of the Twitter-consult, and target values for blood pressure and cholesterol are stated. This card will be the size of a credit card so that it is easy for patients to keep it with them and use it as a reminder for treatment targets and sources of information to reach their treatment goals.

- Mild depressive symptoms

Practice nurses are recommended to refer patients with mild symptoms of depression to a physical exercise group. A physical exercise group can be particularly suited for these patients as it combines social support and physical exercise which both have a beneficial effect on cardiovascular health and on depressive symptoms. The specific form of this exercise group will depend on what is available in the local community in which the practice is situated. Examples are exercise groups led by physical therapist or exercise groups at the local gym.

- Major depressive symptoms
In patients with major depressive symptoms, practice nurses are recommended to refer these patients as appropriate within their practice and not to start CVRM until relief of depressive symptoms has been achieved.

Contacts

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Eligibility criteria

Inclusion criteria

Eligible patients will be extracted from the medical records by using International Classification of Primary Care (ICPC) codes, K74-K76, K85-K92, K99.1 and T93. Eligible patients are adults aged 18 or older, have a high risk of CVD (but no known CVD) or established CVD and are capable of providing informed consent. Patients at high risk have a risk score of 20% or higher of morbidity and mortality due to CVD based on age, gender, smoking status, systolic blood pressure and total cholesterol/ high density lipoprotein (HDL) cholesterol.

Exclusion criteria

Exclusion criteria are: [1] diabetes mellitus, [2] pregnancy and lactation, [3] terminal illness, [4] cognitive impairments, access and [5] poor language skills. Patients with diabetes mellitus will be excluded because this illness has its own guideline/standard of care.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Placebo

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-07-2013

Enrollment: 30

Type: Anticipated

Ethics review

Positive opinion

Date: 11-07-2013

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	NL3906
NTR-old	NTR4069
Other	258837 : MEC 2013/229
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A