Effectiveness of a personalized eCoach for cardiovascular risk management targeting primary prevention in general practice*

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON56578

Source
ToetsingOnline

Brief title
CARRIER

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
artherosclerotic cardiovascular disease (ASCVD), heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: NWO Big Data & Health

Intervention

Keyword: Cardiovascular risk management (CVRM), Effectiveness, Personalized eCoach, Primary prevention

Outcome measures

Primary outcome

The primary outcomes of the effect evaluation are changes in individual risk factors and the general risk of atherosclerotic coronary disease after six months. Changes in risk factors are measured by LDL-cholesterol, (systolic) blood pressure, smoking status, physical exercise measured using the CHAMPS questionnaire and the dietary change measured using the **eatscore** questionnaire. Changes in the risk of atherosclerotic coronary disease is measured using the risk score via the eCoach

Secondary outcome

The secondary outcomes of the effect evaluation are quality of life (EQ-5D questionnaire), satisfaction of the care delivered and the user-experience of the eCoach (questionnaire, focus groups).

The user-experience of the eCoach will be evaluated in individual interviews and focus groups with the practitioner*s assistant (N = 4) and participants (N = 20).

Study description

Background summary

Cardiovascular disease is an important health issue, prominently in the region

of **south-Limburg** the Netherlands. Unhealthy lifestyle plays a prominent role in the development of cardiovascular disease. Cardiovascular risk management (CVRM) faces a variety of challenges.

Current risk models for CVRM only focus on demographic features (like age and gender) and conventional risk factors (like hypertension, hypercholesterolemia and smoking). A risk profile that weighs unconventional risk factors (like residence, education, income and physical activity) could lead to a more accurate prediction model of personal risk. Moreover, it could provide insight on the effects of potential lifestyle changes.
The output of the current risk models are mainly focusing on the health care provider, not the patient. Risk communication should be adjusted to the patients* needs. Patients should understand their risk for developing cardiovascular disease, understand the urgency for healthy lifestyle changes and motivate to start lifestyle changes. However, risk awareness is just part of CVRM. The first step towards lifestyle adjustment proves the hardest for most, but is an important one. People might find by the amount of lifestyle interventions available overwhelming, which makes finding the right intervention challenging for both the health care professional and the patient. Proper tools to that help find the right intervention, tailored to the patient, could be useful.

CARRIER offers a personalized eCoach for transmural networks for CVRM (both in primary and secondary prevention). The first phase of the CARRIER project is the development of the eCoach, iterated and co-created with the users, and specifically tailored to atherosclerotic coronary disease. The eCoach will be implemented in the consult with the patients (prediction model, risk communication, guidance in choosing a lifestyle intervention) and offers supports afterwards (information modules, periodic monitoring and follow-up). Previous, relatively small studies have provided knowledge in the different usability aspects. The eCoach is optimized based on the technical and content-related points of improvement found by these previous studies.

Study objective

The objective of the study is to evaluate the benefit of the eCoach in the general practitioner*s office within cardiovascular risk management. Specifically, the eCoach evaluates the effect on individual risk factors and the risk on developing atherosclerotic coronary disease. Secondary objectives of the effect evaluation include quality of life, satisfaction of the care delivered and the user-experience of the eCoach.

Study design

The effect evaluation will take place in the eastern region of **South-Limburg**, in cooperation with two to four general practitioner*s offices. The

duration of the study for each individual patient comprises of six months. The design of the study is a one group pretest posttest design; an interventional study in which all participants are provided with the eCoach.
First contact with potential participants is at the CVRM outpatient clinic. The practitioner*s assistant calculates the risk for atherosclerotic coronary disease, explains the outcomes of the risk calculation with the patient and the impact of lifestyle changes on their risk for atherosclerotic coronary disease. Next, the practitioner*s assistant and the patient use the **choice guide (NL: keuzehulp)** of the eCoach to select a tailored (pre-existing) intervention and fill out the periodic monitoring in the eCoach. The practitioner*s assistant and patient schedule a new appointment in six months for evaluation, new risk calculation and follow-up.
Measuring moments are scheduled at baseline (first contact), three months and six months. Content of the measuring moments include digital questionnaires, (group) interviews and log files.

Intervention

The eCoach comprises of a web-application, partly accessible for the healthcare professional and partly for the patient. After inclusion, by the practitioner*s assistant or the scientist registers the patient for the eCoach. Two weeks prior to the CVRM outpatient visit, the patient is informed about the study, is requested to log into the eCoach and is requested to fill out a screening questionnaire (part 1). The screening questionnaire consists of questions about age, gender, occupancy, smoking habit, physical activity and diet. The patient is also requested to come in for CVRM blood sampling (LDL-cholesterol).

During the CVRM outpatient visit, the practitioner*s assistant fill out part 2 of the screening questionnaire. Part 2 of the questionnaire involved blood pressure, cholesterol status and use of medication. Based on the answers of the screening questionnaire, an individual risk score on atherosclerotic coronary disease is calculated. Additionally, the individual risk is calculated after applying hypothetical lifestyle changes, which including quitting smoking, increasing daily physical activity, healthy dieting and changes in blood pressure or cholesterol levels. The dashboard displays these risks, in which hypothetical changes in risk factors provide insight on the actual change in risk for atherosclerotic coronary disease. The patient and the practitioner*s assistant decide on a risk factor they want to tackle, after which a tailored intervention in chosen.

Depending on the chosen risk factor from the **choice card (NL: keuzekaart)** could help decide on an intervention. The **choice cards** contain information about the variety of lifestyle interventions (e.g. online versus offline, individual versus group, short versus long, reimbursed or not). Moreover, the first step to start the intervention is mentioned (e.g. downloading an app, applying on a website, referral by healthcare professional or recipe for a medication). The practitioner*s assistant could provide alternative

interventions not offered on the **choice card**, if desirable.

After the CVRM visit, the patients starts the intervention. The patient will receive weekly monitoring in the first month via the eCoach (with a short questionnaire), after which they receive monthly monitoring until the end of study at six months. The healthcare professional can monitor the questionnaires remotely. The message function of the eCoach serves the purpose of premature contact if desirable.

After six months, the participant is invited for the second CVRM visit. Before the visit, the patient is requested to fill out the screening questionnaire again (part 1) and the practitioner*s assistant will fill out part 2 of the questionnaire. The personal risk is re-calculated, re-evaluated and follow-up after the study is discussed.

Study burden and risks

The risk for participation is minimal. The current health status of the patients in the starting point, from which the study designs the intervention. During the CVRM consultation, individual risk (for atherosclerotic coronary disease) is discussed with the patient and the influence of tackling specific risk factors on that risk. The patient and the practitioner*s assistant decide on the risk factor they want to tackle, after which a tailored intervention is chosen (with the highest chances of succesful behavioural change). Presenting the patient with their risk for atherosclerotic coronary disease could frighten patients. The practitioner*s assitent will pay attention to this and acts accordingly. Moreover, the eCoach provides the opportunity to message the practitioner*s assitent to ask questions during the monitoring period. The advantage of participation is to increase awareness of the participant*s personal risk on developing atherosclerotic coronary disease, tools to tackle this risk and interventions that help tackle this risk. Participating in the intervention should create awareness, motivation and knowledge on how to tackle atherosclerotic coronary disease.

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

Aged 40-70 years
Visiting CVRM consultation at general practice

Exclusion criteria

Diagnose Artheroscleroc Cardovascular Disease (ASCVD)
Diagnose Diabetes Meltius (DM)
Insufficent mastery of Dutch language
Insufficient digital skills
No access to hardware (smartphone, computer, tablet-pc) with internet connection
Known cognitive impairment

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2023
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	SanaCoach CVRM
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-02-2024
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date:	19-03-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL84584.096.23