

Optimizing cardiovascular risk management in primary care with a personalized eCoach solution enriched by an AI-driven clinical prediction model: a study protocol of the CARRIER consortium

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Abstract

Background: Atherosclerotic cardiovascular disease poses a heavy burden on the population's health and healthcare costs. Identifying apparently healthy individuals at-risk of developing cardiovascular diseases using clinical prediction models raises awareness, facilitates shared decision-making, and supports tailored management of disease prevention. In the CARRIER project, a personalized cardiovascular risk management (CVRM) eCoach approach is co-created, in which identified individuals receive education, guidance, and monitoring to prevent atherosclerotic cardiovascular disease through existing interventions. In this approach, an AI-driven clinical prediction model calculates the 10-year risk for atherosclerotic cardiovascular disease, which supports informed decision making.

Objective: Our primary aim is to assess the effectiveness of our CVRM eCoach approach through a 10-year risk calculation of atherosclerotic cardiovascular disease, including risk factors contributing to this risk.

Methods: This pretest-posttest interventional study provides the CVRM eCoach approach for six months to 100 apparently healthy individuals visiting their General Practitioner for primary CVRM. The CVRM eCoach approach is a multicomponent eHealth solution, including a clinical prediction under intervention model that not only calculates the 10-year risk of cardiovascular disease through conventional risk factors (smoking, blood pressure, lipid profile), and individual characteristics (age, gender, socioeconomic status, physical activity and diet), but also calculates how the risk changes after hypothetical lifestyle or medical interventions. The CVRM eCoach approach include features that encourage behavioral change. Most of these features include goal setting, decision cards to help decide on an intervention, intervention monitoring, remote communication, education, all accessible from one dashboard. A practice nurse consults the individuals after risk calculation with the clinical prediction model, and uses behavioral change features, such as the decision cards to support shared decision-making. Data are primarily collected via the eCoach, after which the 10-year risk for atherosclerotic cardiovascular disease and its components are analyzed using paired sample analyses.

Results: Recruitment began in March 2024 and will continue until 100 participants have been recruited, which is expected in 2025.

Conclusions: We anticipate that our CVRM eCoach approach will be valuable in the primary prevention setting. During the crucial initial first months of habit formation, factors like education, regular check-ups via the eCoach, and clear risk communication could support individuals in sustaining their medical or lifestyle interventions. We hypothesize that there will be a slight to moderate reduction in the 10-year risk of atherosclerotic cardiovascular disease, which over time will lead to significant health improvements on a larger scale. Clinical Trial: <https://onderzoekmetmensen.nl/nl/trial/56578>; NL84584.096.23

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Abstract

Background

Atherosclerotic cardiovascular disease poses a heavy burden on the population's health and healthcare costs. Identifying apparently healthy individuals at-risk of developing cardiovascular diseases using clinical prediction models raises awareness, facilitates shared decision-making, and supports tailored management of disease prevention. In the CARRIER project, a personalized cardiovascular risk management (CVRM) eCoach approach is co-created, in which identified individuals receive education, guidance, and monitoring to prevent atherosclerotic cardiovascular disease through existing interventions. In this approach, an AI-driven clinical prediction model calculates the 10-year risk for atherosclerotic cardiovascular disease, which supports informed decision making. Our primary aim is to assess the effectiveness of our CVRM eCoach approach through a 10-year risk calculation of atherosclerotic cardiovascular disease, including risk factors contributing to this risk.

Methods

This pretest-posttest interventional study provides the CVRM eCoach approach for six months to 100 apparently healthy individuals eligible for CVRM. The CVRM eCoach approach is a multicomponent eHealth solution, including a clinical prediction under intervention model that not only calculates the 10-year risk of cardiovascular disease through conventional risk factors (smoking, blood pressure, lipid profile), and individual characteristics (age, gender, socioeconomic status, physical activity and diet), but also calculates how the risk changes after hypothetical lifestyle or medical interventions. The CVRM eCoach approach includes features that encourage behavioral change. Most of these features include goal setting, decision cards to help decide on an intervention, intervention monitoring, remote communication, education, all accessible from one dashboard. A practice nurse or physician consults the individuals after risk calculation with the clinical prediction model, and uses behavioral change features, such as the decision cards to support shared decision-making. Data are primarily collected via the eCoach, after which the 10-year risk for atherosclerotic cardiovascular disease and its components are analyzed using paired sample analyses.

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We anticipate that our CVRM eCoach approach will be valuable in the primary prevention setting. During the crucial initial first months of habit formation, factors like education, regular check-ups via the eCoach, and clear risk communication could support individuals in sustaining their medical

or lifestyle interventions. We hypothesize that there will be a slight to moderate reduction in the 10-year risk of atherosclerotic cardiovascular disease, which over time will lead to significant health improvements on a larger scale.

Trial registration

<https://onderzoekmetmensen.nl/nl/trial/56578>; NL84584.096.23

Keywords

Atherosclerotic cardiovascular disease; disease management; cardiovascular risk management; digital health; clinical prediction model; artificial intelligence, medical informatics

Introduction

Atherosclerotic cardiovascular disease (ASCVD) imposes a significant burden on both the general population and healthcare expenditure [1]. The risk of ASCVD is strongly associated with demographic factors such as age and sex, in conjunction with the conventional risk factors, such as hypertension [2], hypercholesterolemia [3], and smoking status [4]. Furthermore, non-conventional risk factors including socioeconomic status [5] as well as lifestyle factors such as diet [6] and physical activity [7] are pivotal in the progression of ASCVD. Adhering to lifestyle recommendations substantially reduces risk of ASCVD [8]. Nonetheless, the prevalence of modifiable risk factors remains alarmingly high [1].

Cardiovascular risk management (CVRM) aims to mitigate the impact of ASCVD at various levels, namely in individuals, specific groups with elevated risk, or at a population level. In the Netherlands, CVRM is commonly conducted in General Practitioner's (GPs) office, and largely managed by practice nurses. The target population is apparently healthy individuals, who are at heightened risk for ASCVD due to the presence of risk factors, but without established ASCVD or diabetes mellitus. According to international guidelines, CVRM initiates with a personalized risk assessment to estimate the likelihood of future cardiovascular events [9,10]. Clinical prediction models (CPMs), such as the Framingham [11] and SCORE [12,13] algorithms, assist the risk assessment by estimating individualized risks for future cardiovascular events as well as the impact on lowering these risk factors. However, lifestyle factors, such as physical activity and dietary habits are not included (yet).

The Dutch CARRIER (Coronary ARtery disease: Risk estimations and Interventions for prevention and EaRly detection) consortium is dedicated to reduce the burden of ASCVD by empowering apparently healthy individuals to adopt healthier lifestyles and mitigate their cardiovascular risk [14].

The consortium's objectives include 1) addressing ethical and legal requirements for the use of data from different sources for the CPM; 2) creating a CPM that incorporates both conventional and specific, attainable non-conventional risk factors; 3) co-creating with health professionals and patients to realize a personalized AI driven eHealth solution (eCoach) in the CVRM health care plan; and 4) evaluating the effectiveness of this eHealth solution in primary care settings. This personalized eHealth solution is designed to visualize estimated risk, support shared decision-making, provide guidance on interventions, and monitor adherence to medical and lifestyle interventions.

Our primary aim is to assess the effectiveness of our CVRM eCoach approach in primary prevention of ASCVD. Additionally, our study will qualitatively evaluate the CVRM eCoach approach with a one-time semi-structured interview with a selection of the participants and the practice nurses. The primary endpoint of the trial is the change in calculated 10-year ASCVD risk and its risk contributing risk factors, six months into the CVRM eCoach approach. Secondary outcomes encompass the qualitative evaluation interview, and health-related quality of life, user experience and healthcare satisfaction through questionnaires.

Methods

Study design

This trial adopts a multi-center, pretest-posttest interventional design. Commencing April 2024, the study will continue until the completion of recruitment, anticipated to occur in 2025. Recruitment will take place across at least four GPs offices and two hospitals situated in the southern region of the Netherlands. Potential participants are recruited from a pool of individuals registered at the participating GPs offices, who are routinely invited to the practice nurse as part of the primary prevention of ASCVD. Potential participants are also recruited at the cardiac emergency department or outpatient clinic at the hospital, in case no ASCVD is diagnosed. Approval of the study was obtained from the Medical Ethics Committee Zuyderland-Zuyd (02/02/2024, NL84584.096.23, METCZ20230114).

Study population

The study population comprises of apparently healthy individuals (without history of diabetes mellitus or ASCVD), aged 40-70, who are eligible for CVRM at the GPs office or hospital. Individuals eligible for CVRM have modifiable risk factors (e.g. smoking, hypercholesterolemia or hypertension) that elevate the risk ASCVD, and are then routinely invited and treated per the Dutch guidelines for CVRM [15]. Eligible individuals must be Dutch speaking and possess hardware such as a smartphone, computer, or tablet with internet access, along with adequate digital literacy to operate them. Exclusion criteria include language barriers preventing sufficient Dutch comprehension, and physical, psychiatric or neurological conditions that hinder completion of study procedures. In addition to the apparently healthy individuals, practice nurses involved in the study are considered part of the study population as their experiences with using the eCoach will also be included for the qualitative data collection.

Recruitment

Individuals having an upcoming CVRM consultation at their GPs office will undergo eligibility screening by the practice nurse. Eligible individuals will receive a preliminary contact by phone, preferably two weeks prior to their scheduled appointment. Individuals at the cardiac emergency department or outpatient clinic will undergo eligibility screening by their treating physician. Individuals screened from the hospital will have their CVRM consultation with one of the physicians from the hospital affiliated with the study. (see **Figure 1 for the study flowchart**). Those expressing interest in participation will receive detailed study information from the research team. Upon obtaining written informed consent, eligible individuals will be enrolled in the trial and given login credentials to the eCoach.

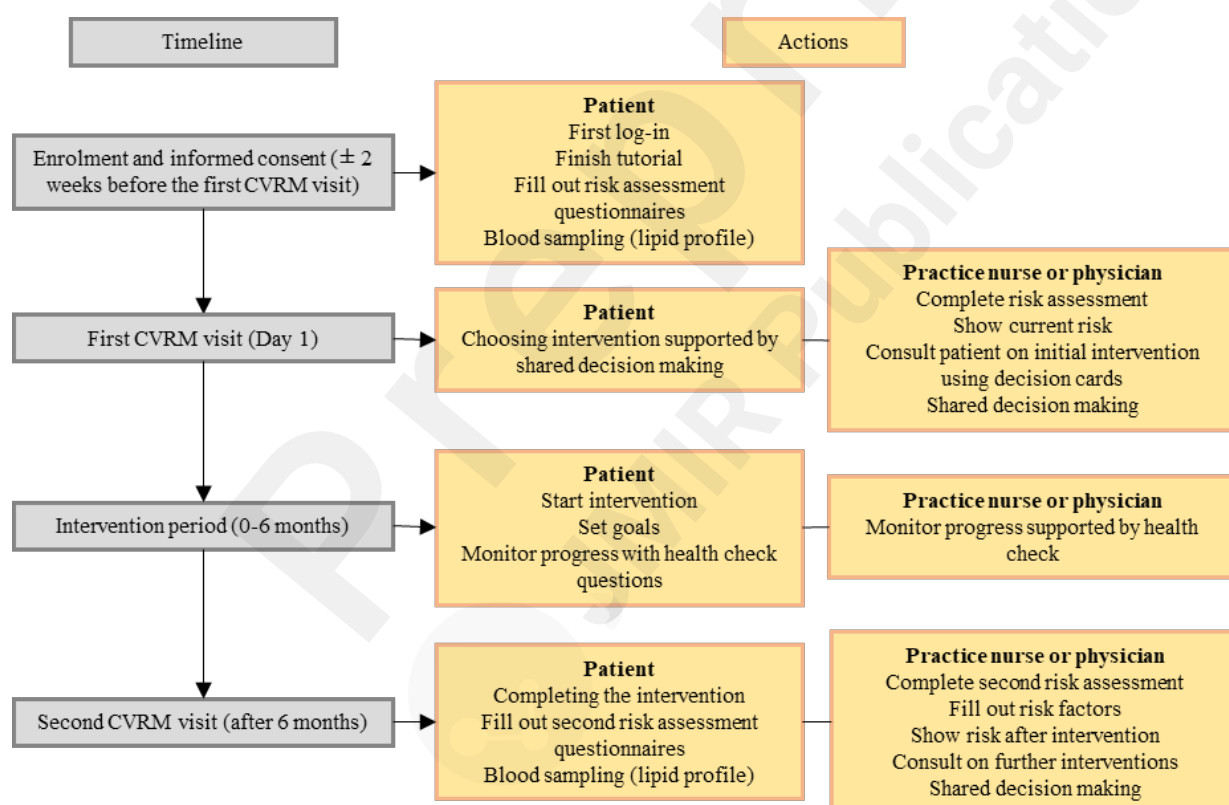


Figure 1 Flowchart of the study and the CVRM eCoach approach

The CVRM eCoach approach

The eCoach is accessible via smartphone, tablet or a desktop computer. Each participant has their own account and platform interconnected to a separate platform accessible to their practice nurse or physician. In these platforms, participants and practice nurses or physicians can perform the actions

as described in the remainder of this section and in **figure 1**. A built-in tutorial guides participants through the platform's functionalities, and they complete their part of the first risk assessment. This includes information known to the participant, which are age, gender, ZIP-code for socioeconomic status [16], smoking status, physical activity measured via the CHAMPS questionnaire [17], and dietary intake measured via the Eetscore Food Frequency Questionnaire (FFQ) [18].

At the first CVRM visit, the practice nurse or physician completes the risk assessment by filling out the blood pressure measurement and lipid profile into the eCoach, along with blood pressure medication and lipid lowering medication. Once completed, the CPM computes the 10-year ASCVD risk, which is graphically depicted in the eCoach dashboard (**Figure 2**). A drop-down menu is available for each risk factor, allowing participants and practice nurses to interactively view the estimated impact of any interventions, which are displayed as "risk after intervention". Adjustments can be made for the variables smoking status, blood pressure, LDL-cholesterol levels, physical activity, and dietary habits. After risk assessment, the practice nurse and participant can use the so-called "decision cards" offering various lifestyle or medical intervention options to achieve desired goals (e.g. smoking cessation assistance from a specialized nurse) (**Figure 3**). Each decision card offers seven attributes of information, which include 1) a short description of the intervention, 2) the group size, 3) the (online) location, 4) the duration, 5) the costs (if any), 6) the necessity for a referral, and 7) a link to provide the first step towards starting the intervention. All interventions are part of routine or existing care, with the eCoach primarily aimed at creating awareness, inciting action, facilitating shared decision-making, monitoring progress, and promoting adherence.

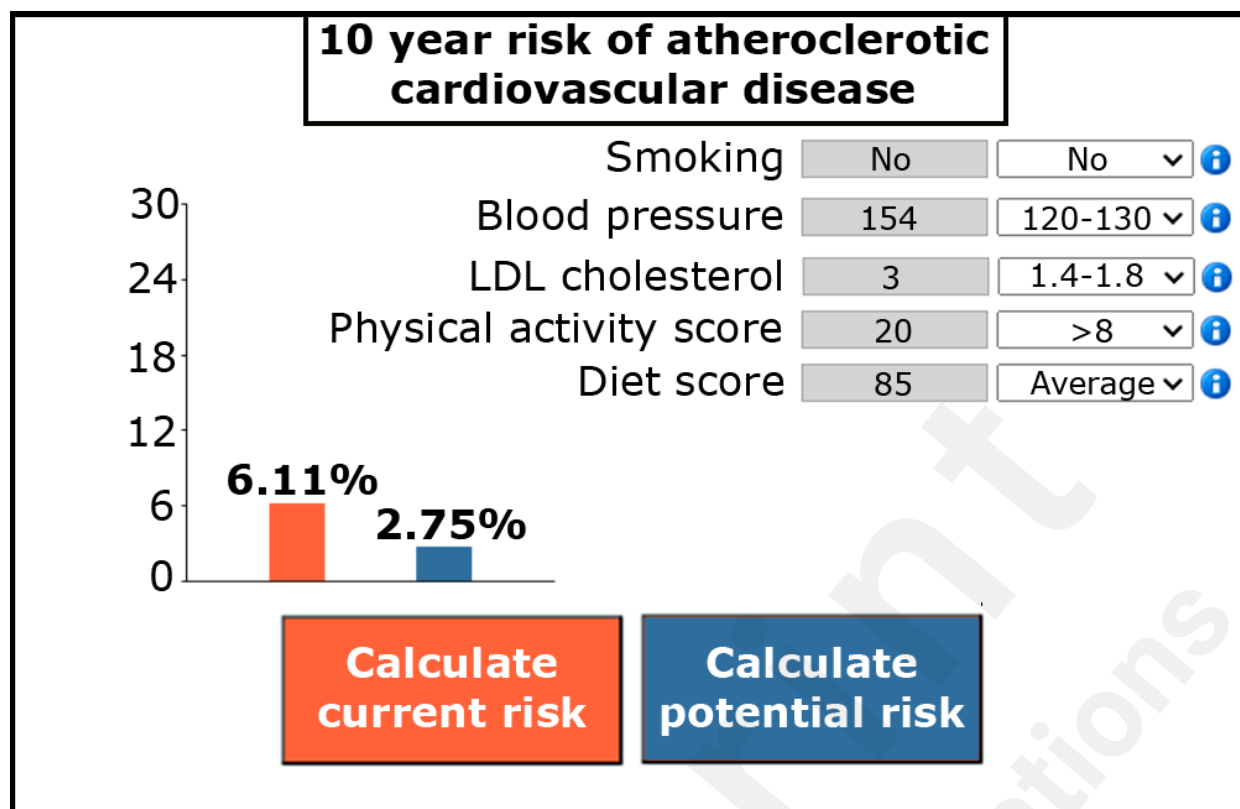


Figure 2 Risk calculation menu (translated from Dutch to English; enlarged and simplified for readability). The risk profile indicates the current (left drop-down menus) and potential risk (right drop-down menus) of ASCVD, which allows risk comparison after potential targets are achieved.

Decision card - Smoking					Physical activity Healthy Diet Blood Pressure Lipid Profile
Intervention	Smokefree! You too?	Quit smoking outpatient clinic	The Stopcoach	Practice nurse outpatient clinic	
What	Personal guidance to permanently quit smoking	The outpatient clinic provides personal guidance with a coach	The Stopcoach is an app that helps you prepare your quitting attempt. There are exercises and ways to communicate with others	The practice nurse guides you to quit smoking	
Individual or group	Individual OR Group	Individual	Individual	Individual	
Where	Several locations OR App	Hospital and via telephone	App	GP and via telephone	
Duration	6 or 7 times	1 year	8 weeks	3-5 visits	
Costs	Covered by insurance	Covered by insurance	Free download	Covered by insurance	
Referral	No referral required	By GP or specialist	Not referral required	Not referral required	
Link	Link to brochure	Hospital website	Stopcoach android Stopcoach iPhone	None	

Figure 3 Decision cards (translated from Dutch to English; enlarged for readability). The figure shows an example of a decision card that displays four available smoking cessation interventions. Other decision cards include physical activity, healthy diet, blood pressure and lipid profile.

Subsequent to the initial CVRM visit, participants can utilize the eCoach to track the evolution of their lifestyle or medical interventions. The eCoach prompts participants with simple weekly

inquiries. Examples of inquiries could ask the participant if they picked up their medication (if applicable) or visited the website for their chosen intervention (if applicable). Practice nurses can review responses, which are color-coded as red (requires attention), orange (may require attention), or green (requires no attention). This facilitates early detection of potential challenges the participant faces for their intervention. Practice nurses could encourage participants, when necessary, on the non-content related aspects of the intervention (e.g. remind them to pick up medication or visit the website of the chosen intervention).

Participants can guide through the eCoach using the menu, depicted with simple symbols at the bottom of the screen (**Figure 4**). The task menu displays incomplete tasks, including health check questions, educational materials disseminated by the practice nurse, and goals formulated by the participant. The goals menu features short-term and long-term goals, along with previously accomplished objectives. The messaging feature enables participants to communicate with the practice nurse, and vice versa. Practice nurses have the additional capability to broadcast messages to all their participants, such as promoting local health events or sharing informative articles on cardiovascular health. Risk factor statuses are represented on a sliding scale for participants in the eCoach, representing progress compared to previous measurements. The sliders turn green to denote improvement and red to indicate deterioration. Utilizing the concept of shared decision-making between the participant and caregiver, an intervention domain and corresponding strategy can be selected to contribute to ASCVD risk reduction.

Six months into the CVRM eCoach approach, participants undergo a second and last CVRM visit, during which the practice nurse provides consultation on the progress of their 10-year cardiovascular risk profile. This involves a risk reassessment identical to the first visit.



Figure 4 Screenshots of the eCoach (translated from Dutch to English; enlarged for readability). The icons in the bottom row menu represent from left to right; 1) Tasks; 2) Goals; 3) Dashboard (including risk factors); 4) Messages; 5) Education; and 6) Settings.

Clinical prediction model

We developed the CPM [19] that estimates baseline 10-year ASCVD risk based on a set of conventional risk factors, individual characteristics, and medication. The complete list of predictors of the baseline risk model are age, gender, socioeconomic status, systolic blood pressure, use of blood pressure medication, total cholesterol, high-density lipoprotein, use of lipid-modifying agents, smoking status, moderate-vigorous physical activity (as measured using the CHAMPS questionnaire [17]), and diet (using the Eetscore FFQ [18]). In addition, the model is a prediction under

intervention model [20] that is able to estimate the effect of combinations of hypothetical lifestyle interventions such as lowering high blood pressure and increasing exercise.

We used the concordance index (c-index) to assess the discriminative performance of the model, which we internally validated using 10-fold cross-validation. The resulting model based on a complete case analysis using the follow-up data available at the time of development achieved a mean c-index of 75.7 (95% CI: 65.8-85.6) in the validation sets.

We developed Fine-Gray [21] competing risk models using data from the Maastricht Study [22], a population-based cohort study including approximately 9,000 individuals. To create the ASCVD outcome and the competing risk outcome (e.g. mortality due to a different cause), we enriched the data from The Maastricht Study with data from Statistics Netherlands and hospitalization data from the Dutch Hospital Data foundation [23-26]. To estimate the effect of lifestyle interventions, the parametric g-formula, as described by Hernán and Robins [27] was used. Variable selection was driven by expert consensus on relevant confounders, predictors, and the lifestyle interventions targeted by the CARRIER project (e.g. smoking cessation, physical exercise and diet).

In terms of the effect of lifestyle interventions estimated by our model, the hazard ratios (HRs) for smoking cessation and diet improvement were in line with published literature. Our model estimated a HR of 0.47 linked to smoke cessation. A meta-analysis by Mons et al. reported a HR of 2.07 (comparing current smokers to never-smokers) [28], which is inversely comparable to the HR in our model. Our model estimated a HR of 0.96 on diet with an increase of 1 standard deviation in the Dutch Healthy Diet Index equal to the 0.96 estimated by Struijk et al. [29]. However, the effect of physical activity estimated by our model was negligible. This might be due to measurement errors related to self-reported physical activity compared with actual physical activity. To address this, we used the HR published by Ramakrishnan et al. [30] on a study using accelerometer measured

physical activity on UK Biobank participants. In addition, our model included a HR of 0.80 for each 10 mmHg systolic blood pressure reduction [31] and a HR of 0.79 for each 1 mmol/l reduction in low-density lipoprotein [32]. This is in line with the risk estimations applications supported by the ESC (U-prevent).

Measurements

Quantitative data are collected via online questionnaires, blood sampling and physical examinations at baseline (T0) and 3 months (T1) and 6 months (T2) after baseline (**table 1**). The primary outcome includes the change in estimated 10-year ASCVD risk six months after utilizing the CVRM eCoach approach as measured by the CPM. The CPM includes age (years), sex (male/female), socio-economic status, lipid profile (HDL and total cholesterol), blood pressure (in mmHg), lipid lowering and blood pressure lowering medication (yes/no), smoking status (current/ex/never), physical activity as measured with the CHAMPS (moderate to vigorous physical activity in hours/week) [17] and dietary status (0-160 score) according to the Eetscore FFQ [18,33].

Secondary outcomes encompass the presence of cardiovascular risk factors (smoking, hypertension, hypercholesterolemia, physical activity and diet) that are used for the CARRIER CPM, health-related quality of life measured with the EQ-5D-5L [34], and usability as measured with the system usability scale [35]. In addition to relevant demographics at baseline, such as living situation (single/living together with/without children and/or partner), highest education achieved (e.g. primary school, high school, university) and working status (retired/unemployed/employed + hours work per week), two 6-item questionnaires are sent out to participants to test digital literacy and satisfaction with healthcare.

Moreover, qualitative data regarding usability and feasibility are gathered after completing the six-month follow-up, for which participants and practice nurses are requested to participate in a one-time

interview to evaluate the CVRM eCoach approach. The topics of the interview include 1) the CPM/risk prediction, 2) communication features, 3) user interface, 4) content, 5) time consumption, and 6) health awareness. Interviews will be audio recorded and answers to the questions will be annotated fully, clustered and reported within the previously mentioned topics. We will be using a thematic analysis approach [36].

Table 1: SPIRIT figure for the CVRM eCoach approach

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	Close-out
TIMEPOINT	-2 weeks	Day 1	0-6 months	6 months
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
First log-in eCoach				
Allocation		X		
ASSESSMENTS:				
10-year risk score of ASCVD*		X		X
CHAMPS questionnaire		X	X	X
Eetscore FFQ		X	X	X
INTERVENTIONS:				
Lifestyle or medical intervention, not part of, but supported by the CVRM eCoach approach				
QUESTIONNAIRES:				
Digital literacy questionnaire		X		
EQ-5D-5L questionnaire		X		X
System Usability Scale				X
Satisfaction with healthcare				X
OTHER:				
Experiences with eCoach use				X

*10-year risk score of ASCVD includes age, gender, socioeconomic status, systolic blood pressure, use of blood pressure medication, total cholesterol,

high-density lipoprotein, use of lipid-modifying agents, smoking status, moderate-vigorous physical activity (as measured using the CHAMPS questionnaire), and diet (using the Eetscore FFQ)

Sample size calculation

Previous research [37] showed a treatment effect of -2.7 (95% CI -3.3, -2.2) of 10-year risk of ASCVD in high-risk participants using mobile technology and smart devices in addition to usual care treatment. The risk score before and after treatment with the mobile technology and smart devices was 14.6 (95% CI 9.5 – 21.2) and 13.4 (8.6 – 18.2). However, differences exist as our study focuses on primary prevention with likely lower-risk participants (<10% 10-year ASCVD risk) and a more comprehensive risk model including modifiable factors like diet and physical activity. We assume a standard deviation of 4.5 on treatment effect and a precision or margin of error of 1. $n = (Z^2 * \sigma^2) / E^2$, where Z = Z-score associated with the chosen confidence interval (95% CI) (1.96), σ the estimated standard deviation (4.5) and E the margin of error (1). This results in a sample calculation of 78 participants, adjusted to 100 to account for potential missing data, with replacements considered for early dropouts.

Statistical analysis

Descriptive statistics will be used to report baseline characteristics. A paired sample T-test will be performed for at least the 10-year ASCVD risk assuming normality. Individual components, including systolic blood pressure, use of blood pressure medication, total cholesterol, high-density lipoprotein, use of lipid-modifying agents, smoking status, moderate-vigorous physical activity will be evaluated using the McNemar's test for dichotomous outcomes, and paired sample t-test for continuous variables. An ANOVA analysis will be performed at least on Eetscore FFQ results and CHAMPS questionnaire results. A p-value of 0.05 or less will be considered significant in all analyses.

Discussion

This manuscript outlines the study protocol for a multi-center, pretest-posttest interventional trial investigating the impact of our CVRM eCoach approach on reducing the estimated 10-year ASCVD risk in apparently healthy individuals. The eCoach was developed through a co-creation process involving participants, caregivers, healthcare providers, eHealth developers and researchers. This collaborative approach aimed to tailor the intervention to align with individual needs and preferences of participants, while also considering the daily practices of involving primary prevention. The final personalized eCoach includes several key features: 1) a risk assessment based on a newly developed **CPM** that incorporates personalized risk factors and lifestyle variables; 2) a dashboard that visualizes the personalized risk and facilitates **risk communication**, showing both the current risk and potential reductions through hypothetical interventions; 3) intervention **decision cards** to help participants and healthcare providers in selecting interventions tailored to the participant's specific characteristics; and 4) adherence **monitoring** to track the participant's compliance with the selected interventions.

The CPM has been developed by the CARRIER consortium on data from the Maastricht Study, enriched by data from Statistics Netherlands and hospitalization data from the Dutch Hospital Data foundation [23-26]. By employing artificial intelligence, the model is constructed to estimate ASCVD risk in apparently healthy individuals [14] and trained on data from a cohort of Dutch patients enrolled in the Maastricht Study, a local cohort study [22]. In selecting variables for the CPM, we prioritized those that are readily available or easily obtainable during routine CVRM visits. This model therefore incorporates not only conventional risk factors but also publicly available socioeconomic data through the participant's zip code [16], along with data on physical activity and dietary habits, using validated questionnaires (even though these might be prone to recall and social desirability biases). By integrating lifestyle factors into the models and dashboard, we aim to

improve the precision of risk estimation, while also highlighting potential risk reduction for participants and encourage greater adherence to recommended lifestyle goals. To ensure feasibility in primary care settings, we chose not to include data from advanced imaging techniques such as coronary CT imaging [13,38,39] or additional laboratory measurements such as proteomes [40] and lipoprotein a [13], despite their known potential to improve risk estimation. Future steps for the CPM include model validation, model comparison to established risk models (e.g. SCORE2), and a model impact analysis. In an ideal situation, data from existing users allow for the model to be updated as well.

The dashboard with personalized risks needs to create awareness and incite action. Effective risk communication is pivotal in prevention, as it bridges the gap between medical knowledge and public understanding. This involves clearly conveying the actual meaning of personalized risks (being more personalized but still only risks which may not be realized), the urgency to change lifestyle behavior (even if figures seem to be rather small) and to show potential benefits (that are relevant to the individual participant). A combination of different communication formats, e.g. percentages and visuals, is advisable [41]. In this case, the dashboard can be used as a starting point for the conversation. Essential is conveying the information meeting the needs of the target population [42] to improve health literacy. Tailoring communication strategies to account for an individual's cultural, social, and educational background might further enhance receptivity and adherence to preventive measures.

Numerous medical and lifestyle interventions are available to reduce the risk of ASCVD, yet many individuals are unaware of their options or lack sufficient knowledge about the pros and cons of each alternative. This often results in uninformed decisions that do not align with the individual's circumstances and needs [43]. A personalized care approach can help healthcare professionals guide

apparently healthy individuals in choosing and adhering to suitable lifestyle interventions [44]. Decision support tools, such as patient decision aids and decision cards [45], are emphasized when discussing available treatment alternatives. These tools provide balanced and neutral information on relevant options, helping patients make informed healthcare decisions. Decision aids provide in-depth information and support complex decision-making processes with detailed explanations and interactive features. In contrast, decision cards are typically concise and visually straightforward, often presented on a single card, and function as a quick-reference tool for specific choices or actions. In the CVRM eCoach approach, five decision aid cards were integrated for the key intervention domains, including smoking, physical activity, diet, blood pressure, and lipid profile. These cards were created by the study team, tested with end-users and customized to fit our regional healthcare context.

Achieving durable behavior change is essential for reducing the risk of future cardiovascular diseases. Our study incorporated several behavior change techniques to promote long-term adherence, including self-monitoring, performance feedback, goal setting, information on the consequences of behaviors, and guidance on how to perform the desired behaviors [46]. Research suggests that combining eHealth interventions with face-to-face contact can significantly enhance adherence [47]. To further support adherence, our practice nurses and physicians are available throughout the six-month follow-up period to provide ongoing monitoring, support, and answers to any questions participants had.

What do we expect to learn from this study

The primary outcome of this study is the change in estimated 10-year ASCVD risk from baseline to six months after the initiation of the eCoach solution. While the ultimate goal is to reduce actual ASCVD events, such outcomes require long-term follow-up, which was not feasible at this stage. Therefore, our focus is on reducing the estimated risk, with the expectation that this reduction will

ultimately translate into a decrease in actual events, increases community health and decrease healthcare costs on a population level [48]. Moreover, we aim to address individual risk factors, enhance health-related quality of life, assess user experience, and evaluate healthcare satisfaction. Insights gained from these latter two endpoints may provide valuable feedback for refining future CVRM decision making processes for interventions tailored to this population.

Future perspectives

In light of constrained financial and human resources, innovative solutions are increasingly imperative to augment our healthcare services [49,50]. Future CMPs may be fully integrated with hospital Electronic Health Records (EHRs) and automatically extract relevant data from them as well as wearable devices, integrating longitudinal laboratory results, vital signs, physical activity levels, socioeconomic factors, and environmental variables. This comprehensive data collection has the potential to enhance the early detection of individuals at risk for ASCVD.

High-risk individuals will receive personalized lifestyle advice to mitigate their risk. When medication is necessary for risk reduction, patients will be referred to healthcare professionals for further discussion and guidance. This process will be supported by eHealth technologies and fully integrated patient decision aids, tailored to individual patient characteristics for CVRM. To monitor chosen interventions, wearable devices will be used to gather unique patient information about lifestyle, ensuring ongoing assessment and adjustment of personalized health strategies.

The CARRIER consortium is actively engaged in developing data infrastructures and ethical and legal frameworks for responsible data handling in healthcare. We envision a future in healthcare that is data-driven and bolstered by digital health solutions.

Declarations

Ethical approval and consent to participate

The medical ethical committee of Zuyderland medical center has approved the study protocol prior to the start of the study. All participants are required to sign informed consent before participating in the study.

Consent for publication

Not applicable

Availability of data and materials

The data sets are generated during the study. Once completed, they can be obtained from the corresponding author upon reasonable request.

Competing interests

None declared

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Authors' contributions

RM and BS are the lead authors. RM, BS, LH drafted the first version of this manuscript. RM, BS, JV, LH conceptualized the study. AD, AH, IB, MS obtained funding for the study. IB conceptualized the clinical prediction model and AB performed this analysis. All authors contributed equally when providing edits to the first and final drafts of the manuscript. All authors approved this final version of the manuscript.

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Abbreviations

AI Artificial intelligence

ASCVD atherosclerotic cardiovascular disease

CARRIER Coronary ARtery disease: Risk estimations and Interventions for prevention and EaRly detection

CPM clinical prediction model

CVRM cardiovascular risk management

Eetscore FFQ Eetscore Food Frequency Questionnaire

ESC Society of Cardiology

GP General Practitioner

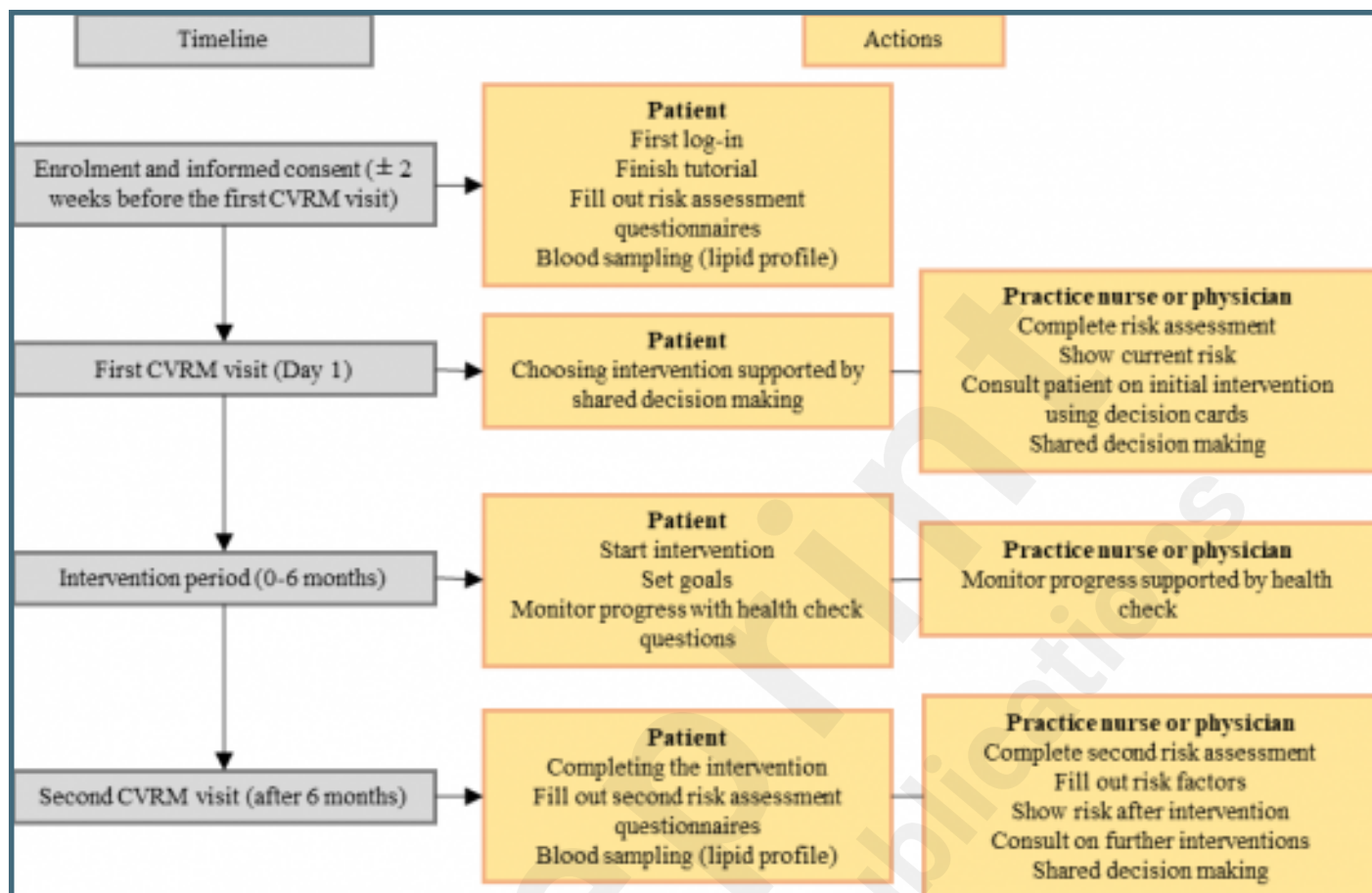
LDL Low-density lipoproteins

ZIP Code zone improvement plan code

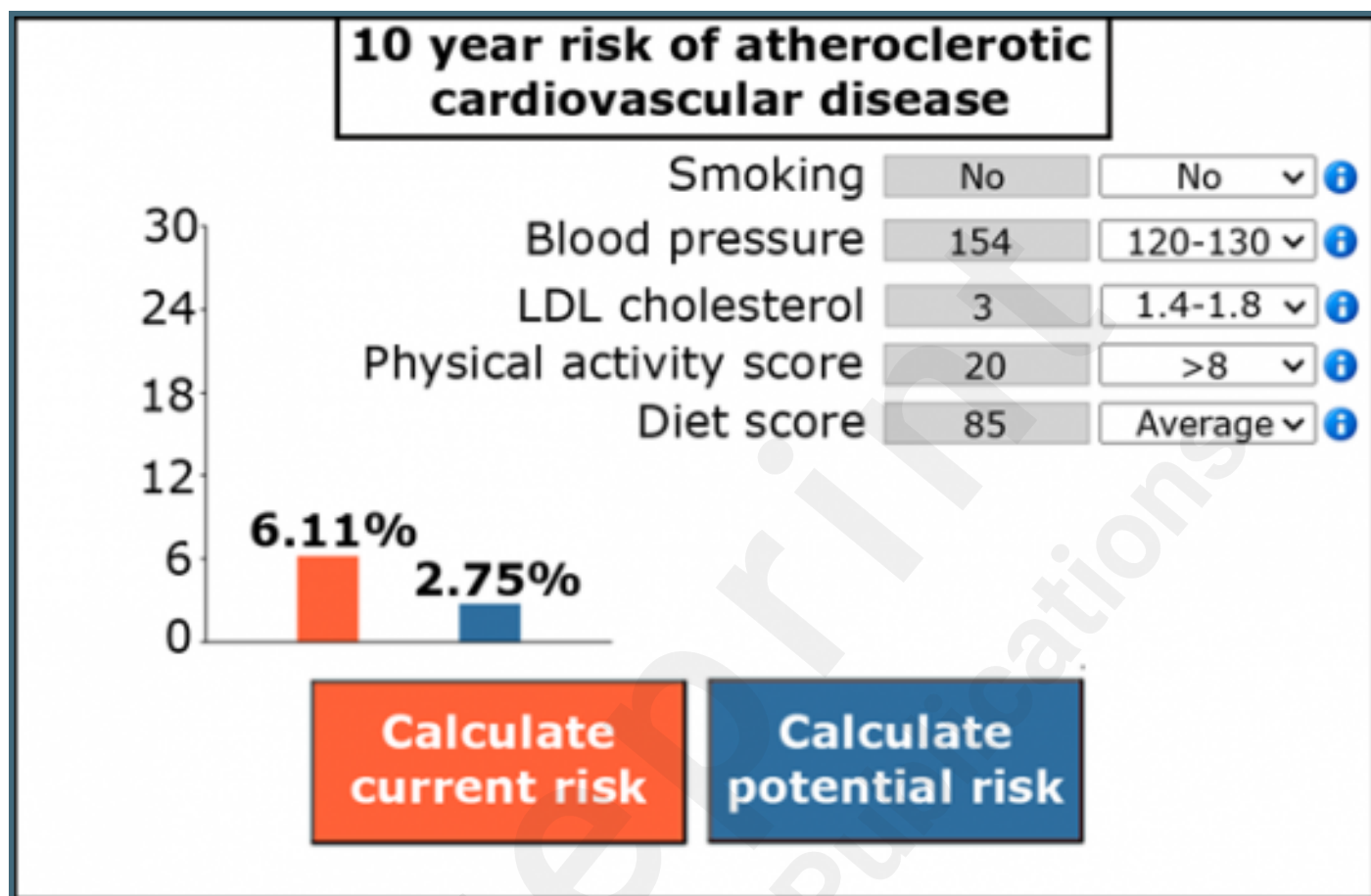
Supplementary Files

Figures

Flowchart of the study and the CVRM eCoach approach.



Risk calculation menu (translated from Dutch to English; enlarged and simplified for readability). The risk profile indicates the current (left drop-down menus) and potential risk (right drop-down menus) of ASCVD, which allows risk comparison after potential targets are achieved.



Decision cards (translated from Dutch to English; enlarged for readability). The figure shows an example of a decision card that displays four available smoking cessation interventions. Other decision cards include physical activity, healthy diet, blood pressure and lipid profile.

Decision card - Smoking					Physical activity
Intervention	Smokefree! You too?	Quit smoking outpatient clinic	The Stopcoach	Practice nurse outpatient clinic	Healthy Diet
What	Personal guidance to permanently quit smoking	The outpatient clinic provides personal guidance with a coach	The Stopcoach is an app that helps you prepare your quitting attempt. There are exercises and ways to communicate with others	The practice nurse guides you to quit smoking	Blood Pressure
Individual or group	 OR 				Lipid Profile
Where	 OR  Several locations App	 Hospital and via telephone	 App	 GP and via telephone	
Duration	 6 or 7 times	 1 year	 8 weeks	 3-5 visits	
Costs	Covered by insurance	Covered by insurance	Free download	Covered by insurance	
Referral	No referral required	By GP or specialist	Not referral required	Not referral required	
Link	Link to brochure	Hospital website	Stopcoach android Stopcoach iPhone	None	

Screenshots of the eCoach (translated from Dutch to English; enlarged for readability). The icons in the bottom row menu represent from left to right; 1) Tasks; 2) Goals; 3) Dashboard (including risk factors); 4) Messages; 5) Education; and 6) Settings.

