Clinical trial protocol

STEP COACH RCT

Step **t**arg**e**ts for **p**atients with **c**oronary artery disease: t**o**wards better physical activity **a**dheren**c**e following cardiac re**h**ab – A randomised controlled trial

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PROTOCOL TITLE: Step targets for patients with coronary artery disease: towards better physical activity adherence following cardiac rehab – A randomised controlled trial

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	Adverse Event
CAD	Coronary artery disease
CCMO	Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek
CR	Cardiac rehabilitation
CVD	Cardiovascular disease
DSMB	Data Safety Monitoring Board
EPD	Electronic patient file; in Dutch: Elektronisch patiëntendossier
GDPR	General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)
MACE	Major Adverse Cardiovascular Events
METC	Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie
MVPA	Moderate-to-vigorous intensity physical activity
Review committee	Medical research ethics committee (MREC) or CCMO
(S)AE	(Serious) Adverse Event
SIT LESS	**S**itting **I**nterruption **T**reatment as a persona**L**iz**E**d **S**econdary prevention **S**trategy
Sponsor	The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.
STEP COACH	**S**tep **T**arg**E**ts for **P**atients with **C**oronary artery disease: t**O**wards better physical activity **A**dheren**C**e following cardiac re**H**ab
UAVG	Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet AVG
WMO	Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

SUMMARY

Rationale: Patients with coronary artery disease are strongly recommended to participate in cardiac rehabilitation programs to improve clinical outcomes. However, emerging evidence shows that participation in contemporary cardiac rehabilitation programs does not or minimally impact habitual physical activity patterns, and that time spent in physical activity often decreases after completing these programs. Hence, there is a strong need for novel, complementary lifestyle programs to improve long-term adherence to physical activity guidelines in patients with coronary artery disease, as this could attenuate disease progression and the risk for adverse health outcomes. The STEP COACH intervention aims to increase daily physical activity and support long-term behaviour maintenance in patients with coronary artery disease.

Objective: The primary aim of this study is to assess the effect of the 9-month STEP COACH intervention on the daily minutes of moderate-to-vigorous intensity physical activity compared to usual care in patients with coronary artery disease.

Study design: A randomised controlled trial comparing the STEP COACH intervention in addition to cardiac rehabilitation compared to cardiac rehabilitation alone.

Study population: Adult patients with coronary artery disease enrolled in an outpatient cardiac rehabilitation program.

Intervention: The intervention group receives a 9-month, nurse-delivered physical activity intervention in addition to cardiac rehabilitation. The program will encourage patients to progressively increase the volume (i.e. number of daily steps) and intensity (i.e. cadence >100 steps/min) of habitual physical activity. To promote behaviour change, participants will receive 3 in-person consultations and additional telephone consultations with the nurse and study team, which focus on knowledge, motivation, action planning, self-monitoring, evaluation and long-term maintenance. Participants will use their own smartwatch or smartphone to track and evaluate their habitual physical activity via an online platform. The usual care group will receive a 3-month cardiac rehabilitation program, as recommended by international guidelines .

Main study parameters/endpoints: The main study parameter is objectively measured daily minutes of moderate-to-vigorous intensity physical activity using a thigh-worn accelerometer. To achieve 90% power (alpha=0.05, two-sided), accounting for 15% drop-out and expecting a ≥10 minutes/day greater increase in physical activity in the intervention group directly after the end of the intervention (i.e. month 9), 334 participants will need to be recruited. Secondary outcomes are functional capacity, quality of life, stress levels, step metrics, 24-h movement behaviours and cardiovascular risk profile. Tertiary outcomes are the cost-effectiveness and long-term clinical outcomes during 15 years of follow-up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The nature and extent of the burden and risks associated with the

intervention and measurements are negligible since all measurements are non-invasive. Tracking physical activity with their personal device and discussing this with their coach may be perceived as time consuming by some participants. All participants will continue to receive treatment-as-usual.

1. INTRODUCTION AND RATIONALE

Coronary artery disease (CAD) remains one of the leading causes of disease burden and death worldwide [1]. Rates of recurrent myocardial infarction or fatal CAD within 5 years after myocardial infarction are high in both males (17%) and females (21%) [2]. Therefore, it is important to further improve secondary prevention.

The beneficial effects of physical activity in secondary prevention after a cardiac event are well known. A physically active lifestyle is related to a reduction of cardiovascular mortality and morbidity in patients with CAD [3-5]. Therefore, international guidelines strongly recommend exercised-based cardiac rehabilitation (CR) for patients with CAD [6, 7]. Contemporary CR programs aim to improve lifestyle habits of patients with cardiovascular disease (CVD) via a multidisciplinary program, including exercise training, psychosocial management, dietary advice, smoking cessation, and management of blood pressure, lipid spectrum and weight [8].

Although participation in a CR program reduces hospital readmissions and improves quality of life and survival in CVD patients [8], it does not impact habitual physical activity patterns in the home environment [9]. The majority of patients remain sedentary and demonstrate little to no change in moderate-to-vigorous intensity physical activity (MVPA) levels after CR [10-12]. This stands in stark contrast to professional guidelines prescribing 30-60 min/day of MVPA for CVD patients [13]. Hence, there is a strong need for novel, complementary programs to improve adherence to physical activity guidelines in CAD patients after a CR program [7].

Digital health interventions that aimed for physical activity maintenance after CR showed a small positive effect on physical activity and quality of life [14, 15]. However, the large variation in previous programs (length of program, type of services offered), makes it difficult to pinpoint the elements that make maintenance eHealth programs successful [16]. Results suggest that only interventions lasting $\geq$12 weeks are effective [17] and that use of both technology and behavioural change techniques is needed to induce the desired effects [14]. Moreover, the scalability and acceptability of the intervention is important for implementation in routine care [18]. To address these challenges, novel eHealth interventions that are accessible, appealing, and tailored to the target population and health care system are needed.

Technological advancements of wearables and smartphones in the last decade have provided new possibilities in monitoring physical activity metrics such as step metrics (i.e., daily steps, cadence, etc.) [19-21]. Steps are an easy-to-understand metric [22] and can be continually and passively tracked over long periods of time [23]. Moreover, walking forms the main part of daily

physical activity across all age groups [24] and is a safe and feasible activity for almost all patients [25]. Recent large-scale population studies show that small increases in daily step count (500-1000 steps/day) already reduce mortality and morbidity risks [26-28], with additional health benefits when walking at a higher intensity or speed [26, 28, 29] and in longer bouts [30]. Given these highly relevant benefits, increasing step volume and intensity in patients with CAD is a promising new area of focus to improve physical activity maintenance after CR.

Therefore, we developed an in-person delivered 9-month physical activity intervention integrated in routine cardiac rehabilitation programs with an add-on eHealth component to prompt, monitor and coach behaviour change. The ***S****tep* ***T****arg****E****ts for* ***P****atients with* ***C****oronary artery disease: t****O****wards better physical activity* ***A****dheren****C****e following cardiac re****H****ab*' (STEP COACH) intervention will start simultaneously with the traditional CR program. The program builds on the previously developed and evaluated SIT LESS intervention, which effectively reduced sedentary behaviour in CAD patients enrolled in CR using a 3-month hybrid behaviour change intervention [31]. Here, we will investigate the effect of the STEP COACH intervention on MVPA in patients with coronary artery disease 9 months after the start of the CR program. Our innovative and evidence-based behaviour change intervention aims to increase MVPA via step-based monitoring during the first 6 months of the intervention and strives for behavioural maintenance during the last 3 months of the intervention.

2. OBJECTIVES

Primary Objective:

The primary aim of this study is to assess the effectiveness of the 9-month STEP COACH intervention on thigh-worn accelerometer derived moderate-to-vigorous intensity physical activity (in min/day) in patients with coronary artery disease. For this purpose, patients will be randomized to contemporary CR (i.e. usual care group) or contemporary CR + STEP COACH (i.e. intervention group).

We hypothesise that participants in the intervention group will show an additional increase of 10 min/day of MVPA compared with the usual care group at 9 months (end of the STEP COACH intervention).

Secondary Objectives:

Secondary aims of our study are to compare the STEP COACH intervention versus usual care on **1) longitudinal changes in physical activity characteristics**, as measured at baseline, at 3 months (directly after the end of CR), 9 months (end of intervention) and 12 months (follow-up), **2) functional capacity**, as measured by an interval shuttle walk test, **3) quality of life**, as measured by the MacNew questionnaire, **4) stress levels**, as measured by hair cortisol, **5) step metrics** (e.g., number of daily steps, steps per minute, peak cadence, minutes at different cadence thresholds) and **6) 24-hour movement behaviours** (composition of sleep, sitting, and physical activity).

Tertiary Objectives:

Tertiary aims of our study are to compare the STEP COACH intervention group versus usual care group on **1) cost-effectiveness**, and **2) long-term clinical outcomes** (all-cause and cardiovascular mortality, rehospitalisation and Major Adverse Cardiovascular Events (MACE) during 15 years of follow-up).

3. STUDY DESIGN

We will perform a multi-centre randomised controlled trial with two arms to determine the effectiveness of the 9-month STEP COACH intervention on MVPA (in min/day) in patients with CAD who participate in CR. The usual care group will receive contemporary CR, whereas the intervention group will receive contemporary CR and the STEP COACH intervention (Fig. 1).

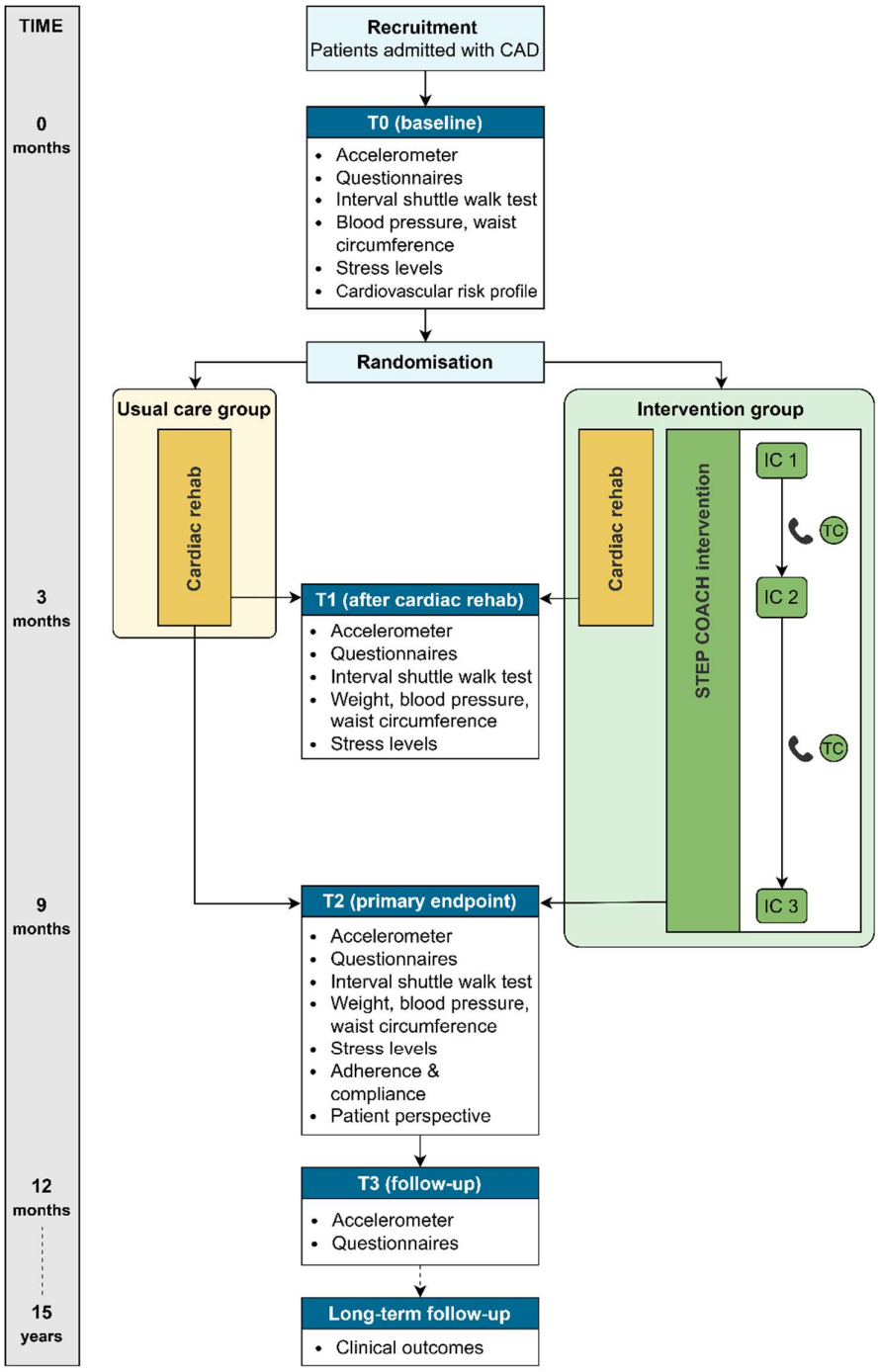


Figure 1. Study design. Dark blue boxes indicate measurement timepoints. Yellow boxes indicate usual care, green boxes the STEP COACH intervention program. CAD = coronary artery disease; IC = in-person intervention consultation; TC = telephone consultation.

Recruitment and inclusion

Hospitalised patients with CAD who will be referred to CR will be screened for eligibility in the study. If deemed eligible, the patient will be approached for participation by their treating physician or a staff member of the study team, who will provide both verbal and written information about the study. Participants will have appropriate time to consider participation. If a patient is willing to join, we will obtain informed consent.

Baseline study visit and randomisation

During baseline measurements, all participants will fill out several questionnaires, perform a walk test, and wear an accelerometer on their thigh during the first 8 days after their hospital discharge (T0, Fig. 1). We will also measure blood pressure and waist circumference, and take a hair sample from the occipital region for assessment of stress levels using cortisol measurement. Altogether, these procedures will take approximately 60 minutes and take place during the hospitalisation.

Before the start of the CR program, the research team randomly allocates the participants in a 1:1 ratio to the STEP COACH intervention plus CR program (intervention group) or to the CR program only (usual care group) with random block sizes of 4 to 6 participants. Allocation is stratified by sex (male vs. female) and hospital site, and is concealed using a computerised algorithm (Castor Electronic Data Capture, Ciwit B.V., Amsterdam, The Netherlands).

Treatment

- *Usual 3-month CR program (intervention and usual care group)*
  Both groups will receive usual care, consisting of a comprehensive CR program with a total duration of approximately 3 months, as recommended by contemporary international guidelines for patients with CAD to improve clinical outcomes [32]. The CR program consists of individual consultations with the nurse specialist on lifestyle, medical and psychosocial wellbeing, and an outpatient exercise program with a physiotherapist.

- *STEP COACH intervention (intervention group)*
  Participants randomised to the intervention group will receive the 9-month, nurse-delivered STEP COACH intervention in addition to usual care (i.e., a CR program). The STEP COACH intervention is a hybrid behaviour change program, which consists of 3 in-person consultations, telephone coaching in combination with text messaging and an online platform for physical activity tracking. The program aims to increase the volume and intensity of habitual physical activity.

Study visits at month 3, 9 and 12

The study visit at month 3 takes place at the end of the CR program (T1, Fig. 1). The study visit at month 9 takes place at the end of the STEP COACH intervention (T2, Fig. 1). These study visits will take approximately 30 minutes. All participants will fill out a short questionnaire, perform a walk test, and wear an accelerometer on their thigh for 8 days. We will measure blood pressure, body weight and waist circumference, and take a hair sample from the occipital region for assessment of stress levels using cortisol measurement. During the study visit at month 9, we will ask participants in the intervention group about their perceptions of the STEP COACH intervention.

The study assessment at month 12 takes place at home and takes approximately 20 minutes (T3, Fig. 1). We will send participants an accelerometer by post, which they will wear for 8 days. Participants will receive instructions on how to attach the accelerometer themselves, and how to send it back. Moreover, participants fill out a short questionnaire.

Long-term follow-up (15 years)

To a maximum of fifteen years of follow-up, clinical outcomes will be evaluated by reviewing the electronic patient file (EPD) for MACE and unplanned hospitalisations, consulting the Central Bureau for Statistics (The Hague, The Netherlands) for mortality data, and consulting Vektis (Zeist, The Netherlands) for health insurance claims data.

4. STUDY POPULATION

4.1 Population (base)

In this randomised controlled trial, we will include 334 participants (167 in each arm) with CAD and who are referred to the CR program. The treating physician, or someone to whom (s)he has entrusted this task will approach the patient and will give information about the study. In the previously successful SIT LESS intervention [31], we included 6 to 7 participants per week in two local hospitals (Bernhoven, Rijnstate). We expect a similar inclusion rate for the present study and will additionally expand our inclusion to a third hospital (CWZ). Therefore, we do not expect any problems to reach our target number of included participants (see also section 4.4).

4.2 Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:

- Hospital admission for CAD (ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI), unstable angina pectoris (UAP), or stable angina pectoris (AP)) **and/or** having undergone a percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG);
- Referral to cardiac rehabilitation;
- 18 years of age or older;
- Able to understand and perform study related procedures.

4.3 Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:

- Unable to give informed consent;
- Wheelchair-bound / not physically able to stand or walk;
- Language barrier;
- CABG surgery expected within 8 weeks after inclusion;
- New York Heart Association class III or IV heart failure;
- Participation in another interventional study targeting physical activity;
- Already adhering to physical activity guidelines (i.e. on average >8,000 steps/day (smartphone) or >10,000 steps/day (smartwatch or smartband) in the 6 months prior to inclusion).

4.4 Sample size calculation

We based our sample size calculation on our primary outcome: MVPA expressed in minutes per day. Our study aims that the intervention group will show an increase that is at least 10 min/day greater than the increase of the usual care group. Multiple large epidemiological studies showed that an increase of 10 min/day in MVPA is associated with a lower mortality risk [33, 34] and CVD incidence [35], and better cardiometabolic health [36].

We expect a standard deviation of 26 min/day for the MVPA change scores from baseline to post-intervention [37]. We computed this estimate from a large database with clinical trials that measured physical activity in CVD patients before and after CR programs using thigh-worn accelerometers (protocol reviewed by medical ethical committee: #2025-18512). We also defined our sample size calculation for an alpha error of 5%, 90% power. We used the formula from Twisk [38] (equation 11.1) for our calculation, since this equation can be applied for experimental studies with a continuous outcome variable, an equal number of subjects in the intervention and usual care group, and one primary endpoint.

Based on these parameters, 284 participants are needed. With an expected drop-out of approximately 15%, we aim to include 334 participants (167 participants per study arm). Given the current enrolment in CR in participating hospitals (±80 patients/month) and assuming a 30% consent rate, a recruitment period of 14 months would be enough. This number of participants and the recruitment period is feasible in terms of costs and manpower and is ethically justifiable in terms of burden to the participants in relation to the scientific gains to be made.

5. TREATMENT OF RESEARCH PARTICIPANTS

After inclusion, participants will be randomly allocated to either the 9-month intervention group (CR program + STEP COACH intervention) or the usual care group (CR program). All participants participating in this study will receive feedback on their physical activity behaviour patterns after completion of the study (i.e. after the study visit at 12 months, T3).

Usual care (all participants)

All patients will receive usual care and will be seen by their cardiologist and/or general practitioner as clinically appropriate. Usual care consists of a comprehensive CR program with a total duration of approximately 3 months. Participation in CR programs holds a Class 1A recommendation in the European Society of Cardiology (ESC) guidelines on CVD prevention [32]. The Royal Dutch Society for Physical Therapy (KNGF) developed a Guideline on Cardiac Rehabilitation for Dutch clinical practice, stressing the importance of personalised CR programs to improve and maintain lifestyle behaviour for patients with CAD [39]. As part of the CR program, one to three individual consultations are scheduled with the CR nurse focussing on lifestyle, medication and psychosocial wellbeing. The nurses contributing to the prevention program are registered nurses with experience in the care of cardiac patients. Participants are offered an outpatient exercise program, consisting of ~12 supervised one-hour exercise training sessions across six weeks. If indicated, the standard CR program can be extended by a dietary module, psycho-educative prevention module and psychological module or by additional consultations with the CR nurse.

STEP COACH intervention

The STEP COACH intervention consists of a 9-month, nurse-delivered program that is offered alongside regular CR (usual care, as described above). The STEP COACH intervention aims to increase habitual physical activity, by encouraging participants to initially increase their physical activity volume (i.e., increased number of daily steps) and subsequently their physical activity intensity (i.e., increased number of minutes per day spent at a cadence of 80-100 steps/minute). This additional focus on habitual physical activity is important, as participation in a CR program reduces hospital readmissions and improves quality of life and survival in CVD patients [8], but does not impact habitual physical activity patterns in the home environment [9].

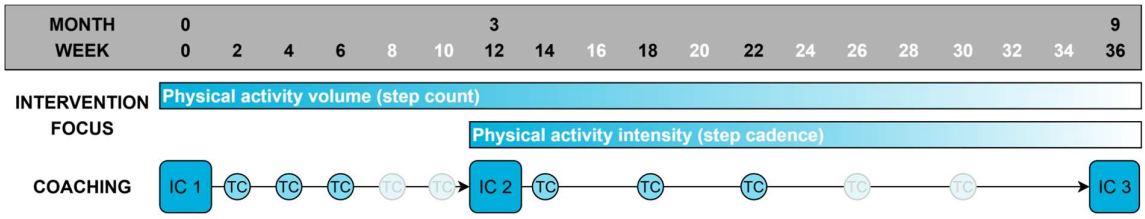


Figure 2. Intervention design. The STEP COACH intervention focuses on an increase in step count (volume, month 0-9) and step cadence (intensity, month 4-9). Weeks with white numbers indicate no scheduled in-person or telephone contact with the participant. IC = intervention consultation (in-person), 30 minutes; TC = telephone consultation, 10 minutes (greyed-out circles indicate optional telephone sessions).

Intervention focus

During the CR program (i.e. month 0-3) we will only focus on increasing physical activity volume, quantified as step count, to create a habit (Fig. 2) [40-42]. Our program complements the CR program, which learns participants to exercise safely and regain confidence in their bodies under the supervision of physiotherapists. We extend this process by supporting participants in their home environment. From month 4 to 9, we will also focus on increasing physical activity intensity, quantified by step cadence. We will gradually increase the amount of time participants spend at a cadence of ≥80 to ≥100 steps/min [43].

Intervention development

To achieve the goal of progressively increasing habitual physical activity, we will support participants in the intervention group through behaviour change techniques. We used an intervention mapping adaptation framework [44] to adapt a previously successful lifestyle intervention (i.e. SIT LESS) into the STEP COACH intervention. The SIT LESS intervention effectively reduced sedentary behaviour in CAD patients enrolled in CR using a 3-month hybrid behaviour change intervention, which was added to the traditional CR program [31]. The intervention consists of structured modules with visual materials (1. Knowledge & Information; 2. Motivation; 3. Planning & Self-Efficacy; 4. Self-Monitoring; 5. Learning & Problem Solving; 6. Maintenance of Behaviour Change), which are based on a thorough understanding of the barriers and facilitators that drive physical activity behaviour in CAD patients and potent behaviour change methods to modify those [45]. Hence, we adapted SIT LESS to STEP COACH in close collaboration with patients, healthcare professionals and behavioural scientists with the aim to sustainably increase the time spent MVPA in patients with CAD.

Intervention coaching

Participants in the intervention group will receive 3 in-person coaching sessions of 30 minutes each (IC 1, IC 2, IC 3; Fig. 2). During the first intervention consultation at the start of the CR

program (IC 1, Fig. 2), the trained and dedicated CR nurse will explain the influence of physical activity on health and the participant's heart disease, discuss their personal goals and motivation, and set action plans for increasing habitual physical activity in collaboration with the participant. Moreover, the CR nurse will connect the participant's own smartwatch or smartphone with an online platform.

The second intervention consultation at the end of the CR program (IC 2, Fig. 2) will focus on physical activity intensity (i.e., step cadence), as from month 4 onward, participants will be encouraged to increase the time spent at a moderate-intensity step cadence (≥80 to ≥100 steps/min) [43]. Participants will also discuss the data collected with their own device. These data offer a good basis for discussing whether their action plans worked for them, what barriers they are experiencing and how to overcome these, and reinforcing behaviour change (i.e., an increase in habitual physical activity). Moreover, this consultation focusses on the transition from the supervised CR program to the home environment of the participant, by discussing the participant's social environment and physical activity initiatives in the participant's neighbourhood.

During the third intervention consultation at the end of the intervention (at 9 months) (IC 3, Fig. 2), participants will evaluate their progress since the second consultation. Moreover, this consultation focusses on strategies for behavioural maintenance, as the support from the study team comes to an end.

In addition to the in-person consultations, participants will receive additional support. For this we will use telephone consultations (TC, Fig. 2) and text messaging. After week 1, participants will receive a text message to check if everything works well with the online platform. After week 2, 4 and 6, short telephone calls are planned to evaluate the progress with the participants and set a new step count goal. In week 8 and 10, participants will receive a text message informing them about their new step goal. Only if necessary, a telephone goal will be scheduled. We will follow a similar calling and text messaging schedule after the second in-person consultation, with an extra focus on step cadence goals. By applying this 'coaching on demand' approach we aim to gradually decrease the support of the study team, thereby fostering independent maintenance of physical activity behaviour.

Online platform

Participants will use their own smartwatch or smartphone to track their physical activity. The main benefits of using people's own device are that they use a device and interface they are already familiar with and that they do not need to return the device at the end of the

intervention. In the first consultation session, the CR nurse will connect the participant's device with a device-agnostic online platform called WeGuide (Fig. 3) (https://www.weguide.health/). This platform allows participants and caregivers to monitor step volume, step intensity, daily minutes of MVPA, and, if available, heart rate, and to set physical activity goals. The data from the online platform is used to evaluate the participant's progress during in-person and telephone consultations.



Figure 3. Online platform WeGuide. This is an example of a web-based visual report regarding physical activity derived from the participant's device. The platform allows the caregiver to update the physical activity goals for the participant during the intervention. Participants can monitor their heart rate ('hartslag', left graph), step count ('stappen', middle graph), step cadence ('snelle stapminuten', right graph), and minutes of MVPA (not depicted).

5.1 Investigational product/treatment
Not applicable.

5.2 Use of co-intervention (if applicable)
Not applicable.

5.3 Escape medication (if applicable)
Not applicable.

6. INVESTIGATIONAL PRODUCT
Not applicable.

7. NON-INVESTIGATIONAL PRODUCT
Not applicable.

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter/endpoint

The primary outcome is the difference between the STEP COACH intervention group and the usual care group in change of moderate-to-vigorous physical activity (minutes/day) from before the CR program to after the STEP COACH intervention (9 months after baseline), as measured by a thigh-worn accelerometer.

8.1.2 Secondary and tertiary study parameters/endpoints

Secondary outcomes of our study are differences between the intervention and usual care group for changes in:

- **Functional capacity**, as measured with the interval shuttle walk test;
- **Quality of life**, measured through the MacNew questionnaire;
- **Stress levels**, measured through hair sampling form the occipital region and subsequent cortisol assessment;
- **Step metrics** (e.g., number of daily steps, steps per minute, peak cadence, minutes at different cadence thresholds);
- **24-hour movement behaviours**, with primary interest in physical activity behaviours, and also sedentary and sleep behaviours;

Tertiary aims of our study are differences between the intervention and usual care group in:

- **Cost-effectiveness**;
- **Incidence of clinical outcomes** (all-cause and cardiovascular mortality, rehospitalisation and MACE) during 15 years of follow-up.

8.1.3 Other study parameters

Other study parameters are:

- **Patient characteristics** such as age, sex, height, weight, cardiovascular risk factors, medical history, medication use, echocardiography data, coronary angiography data, laboratory values (e.g. cardiac biomarkers), and cardiorespiratory fitness test outcomes will be derived from the EPD.
- **Body measurements**, namely weight, blood pressure and waist circumference.
- Symptoms of **anxiety and depression**.
- Factors contributing to experienced personal health, namely the **social environment, financial resources and health literacy**.

- **Cardiovascular risk profile**.
- The **participants' perspectives** on the intervention.
- **Adherence and compliance** to the cardiac rehabilitation program and STEP COACH intervention.

8.2 Randomisation, blinding and treatment allocation

After informed consent is obtained, patients will be randomly assigned to either the intervention group or the usual care group with random block sizes of 4 to 6 participants. Allocation is stratified by sex (male vs. female) and hospital site, and is concealed using a computerised algorithm (Castor Electronic Data Capture, Ciwit B.V., Amsterdam, The Netherlands). Participants and CR nurses cannot be blinded to the group allocation given the nature of our physical activity intervention. Data processing will be blinded for the research team by using an automatised script based on unique participant identification numbers, independent from the randomisation procedure.

8.3 Study procedures

Overview of all scheduled assessments

Study visit	Baseline (T0)	End of CR (T1)	End of intervention (T2)	Follow-up (T3)	Long-term follow-up
Month	**0**	**3**	**9**	**12**	**15 years**
Patient characteristics	X				
Body measurements	X	X	X		
Physical activity and step metrics	X	X	X	X	
Functional capacity	X	X	X		
Stress levels	X	X	X		
Questionnaires	X	X	X	X	
Cardiovascular risk profile	X				
Adherence and compliance			X		
Participant perspectives			X		
Cost-effectiveness	X	X	X	X	X
Clinical outcomes					X

Patient characteristics and body measurements

Patient characteristics such as age, sex, height, weight, cardiovascular risk factors, medical history, medication use, echocardiography data, coronary angiography data, cardiorespiratory fitness test outcomes and laboratory values (e.g. lipids, blood count, inflammatory markers, kidney function and cardiac biomarkers) will be derived from the EPD. All these data are routinely collected in all patients. The cardiorespiratory fitness test is performed as part of usual care by the physiotherapist before the start of the cardiac rehabilitation program. Characteristics that are susceptible to change, such as weight, waist circumference and resting blood pressure, will be reassessed at T1 and T2 during the study visit. Body weight (kg) will be measured using a calibrated scale. Waist circumference will be measured midway between the lower rib margin and iliac crest.

Physical activity and step metrics

We will objectively measure minutes of MVPA, 24-hour movement behaviours and step metrics for 8 consecutive days at all timepoints (T0, T1, T2, T3). We will use the validated physical activity monitor Axivity AX3 (Axivity AX3, Axivity Ltd, Newcastle upon Tyne, United Kingdom; Fig. 4), which contains a tri-axial accelerometer [46, 47]. Different types and intensities of physical activity, sedentary behaviour, and sleep, can be accurately classified using open-source processing software, such as ActiPASS [48, 49]. The Axivity is small (23 x 32.5 x 7.6mm) and waterproof, and can be attached to the thigh of the participant with hypoallergenic tape (Tegaderm, 3M).

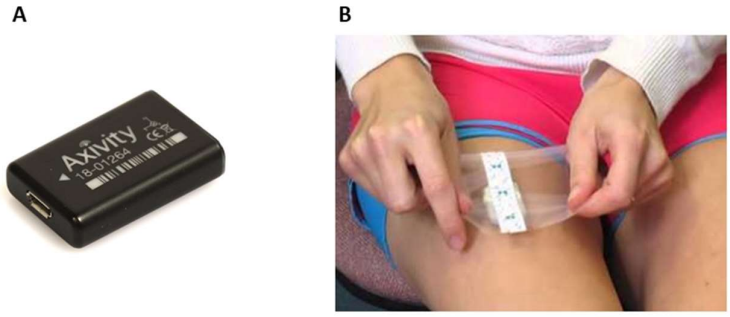


Figure 4. Axivity AX3. (A) This physical activity monitor (23 x 32.5 x 7.6mm) will be used to objectively measure physical activity and (B) can be attached to the thigh using hypoallergenic tape

For the baseline measurement we will attach the Axivity during hospitalization. Participants will be asked to wear the Axivity until 8 days after discharge. After wearing the Axivity for 8 consecutive days after discharge the participant can remove the Axivity and take the device to the first consultation with the CR nurse. For the measurements at month 3 (after CR, T1) and 9 (after intervention, T2) we will attach the Axivity during the study visit in the hospital.

At month 12 (follow-up, T3) we will send the Axivity to the participant's home, together with instructions on how they can attach the monitor themselves. After the assessments at T1, T2 and T3 participants will send the monitor back to our institute by post.

Functional capacity

We will determine functional capacity with the interval shuttle walk test at T0, T1 and T2. The interval shuttle walk test is a 12-level test (1 minute at each level), where the participant walks back and forth along a 10-meter course at a progressively increasing speed. The test stops when the participant is no longer able to maintain the walking pace, or when the participant completes level 12. This test correlates well with maximal and symptom-limited maximal exercise tests, and is reproducible and easy to perform for both the participant and therapist, according to the Royal Dutch Society for Physical Therapy (KNGF) Guideline on Cardiac Rehabilitation [39].

Stress levels

A small hair sample (approximately 100 strands) will be cut from the posterior vertex of the scalp, as close as possible to the skin at T0, T1 and T2. The sample will be stored in a sealed, labelled envelope at room temperature until batch analysis for cortisol levels.

Questionnaires

Participants will be asked to complete a questionnaire at T0, T1, T2 and T3. The questionnaire at baseline (T0) consists of the MacNew, EQ-5D-5L, HADS, 4 subdomains of the CPHQ2.0, and some general questions on personal characteristics and lifestyle factors. This questionnaire takes approximately 20 minutes. The questionnaires at T1, T2 and T3 consist only of the MacNew and EQ-5D-5L, and takes approximately 10 minutes.

The MacNew questionnaire assesses physical, emotional and social quality of life through 27 questions. The questionnaire was originally designed and validated for patients with myocardial infarction [50], but has also been validated in patients with angina pectoris and heart failure [51].

We will use the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L) to assess the participant's health state. The scores from the EQ-5D-5L are used in the cost-effectiveness analysis (see below). The EQ-5D-5L assesses 5 health domains (1 question per domain) (mobility, personal care, usual activities, pain/discomfort and anxiety/depression), and asks people to rate their health on a visual analogue scale (VAS) from 0 to 100 [52, 53].

We will use the validated 14-item Hospital Anxiety and Depression Scale (HADS) [54] to assess the participant's anxiety and depression at baseline. To further assess factors contributing to experienced personal health, we will use 4 subdomains from the validated Context-sensitive Positive Health Questionnaire (CPHQ2.0) at baseline [55]: **social acceptance** (3 questions)**, social support** (3 questions)**, financial resources** (2 questions) and **health literacy** (2 questions). We will not assess the other subdomains (relaxation, enjoyment, vitality and mobility), because these domains are already covered in the MacNew questionnaire.

Cardiovascular risk profile

We will determine the cardiovascular risk profile with the SMART2 risk score before the CR program (T0). The SMART2 risk score uses the following inputs: demographics (age, sex), smoking status, clinical history (diabetes, years since first cardiovascular event, cardiovascular diagnoses), systolic blood pressure, and laboratory values (creatinine, high-sensitivity CRP, total cholesterol and HDL cholesterol) [56, 57]. Laboratory values will be derived from the EPD, as these values are routinely collected. The risk score estimates the 10-year risk for recurrent vascular events on a scale of 0 to 100%.

Adherence and compliance, and patient perspectives

We will assess the adherence and compliance of participants for both the cardiac rehabilitation program and the STEP COACH intervention by evaluating metrics such as the number of visits attended, phone calls that are made, delivered intervention modules, and number of physical activity goals (step volume and cadence) reached. We will collect data on participants' perspectives of the STEP COACH intervention with a custom-made questionnaire and/or semi-structured interviews.

Cost-effectiveness

We will use the results of the EQ-5D-5L questionnaire to convert the participants' health state into quality-adjusted life years (QALYs). The costs considered for the cost-effectiveness analysis of the RCT are direct costs of the STEP COACH program and of the care utilisation from baseline (T0) to follow-up (T3). We will derive the care utilisation costs from the EPD and Vektis (Zeist, The Netherlands) for health insurance claims data.

Clinical outcomes

Clinical outcomes such as all-cause mortality, cardiovascular mortality, rehospitalisation and recurrence of acute coronary syndromes will be evaluated by checking the EPD and/or by consulting the Basisregistratie Persoonsgegevens and/or Central Bureau for Statistics

(The Hague, The Netherlands) and/or Vektis (Zeist, The Netherlands) for the vital status of study participants to a maximum of 15 years of follow-up.

8.4 Withdrawal of individual research participants

Participants can leave the study at any time for any reason without any consequences if they wish to do so. The investigator can decide to withdraw a participant from the study for urgent medical reasons.

8.4.1 Specific criteria for withdrawal (if applicable)

After the subject has given informed consent, the subject is irrevocably admitted to the trial. Even if the subject is withdrawn from receiving further intervention, documentation according to the study protocol must be as complete as possible.

A subject can or will be withdrawn from the study:

- Upon request of the subject
- In case of drop-out from the general CR program within the first 2 weeks of the physical activity program

8.5 Replacement of individual research participants after withdrawal

Subjects who are withdrawn or excluded within the first 2 weeks after inclusion will be replaced without a maximum. The study burden is negligible up to this point. If subjects will drop out after this period, we have already taken this into account in our sample size calculation.

8.6 Follow-up of research participants withdrawn from treatment

After withdrawal, the reason will be documented carefully and patients will be followed up if medically necessary. After withdrawal from the study, subjects will not receive any study related documents and no physical tests will be performed. To assure that the documentation is as complete as possible according to the study protocol, we will still assess clinical outcomes (e.g., MACE) after withdrawal, unless indicated otherwise by patients after withdrawal.

8.7 Premature termination of the study

Given the fact that this study is non-invasive and burden for participants is very low, no significant risks are expected within this study. We do not expect that early termination of this study is required. In the unlike case of premature termination, the reason will be examined and possibilities for later continuation will be investigated.

9. SAFETY REPORTING

9.1 Temporary halt for reasons of research participant safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise participant health or safety. The sponsor will notify the review committee without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the review committee. The investigator will take care that all participants are kept informed.

9.2 AEs, SAEs

9.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a participant during the study, whether or not considered related to the intervention. All adverse events reported spontaneously by the participant or observed by the investigator or his staff will be recorded up to 30 days after the participant's last study assessment (T3). Any AEs occurring beyond this period are reasonably considered unrelated to the study procedures.

9.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

The sponsor will record SAEs within 7 days of first knowledge for SAEs that result in death or are life threatening. All other SAEs will be recorded within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events. SAEs presented to the investigator or their staff from 30 days after the participant's last study assessment (T3) onwards will no longer be recorded, as these events can reasonably be considered unrelated to the study procedures.

9.3 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist. SAEs need to be reported until 30 days after the participant's last study assessment (T3), as defined in the protocol.

9.4 Data Safety Monitoring Board / Safety Committee

We assess the risks regarding this study as negligible. We assess our risk classification as insignificant risk and following the NFU guidelines we will not install a Data Safety Monitoring Board or Safety Committee.

10. STATISTICAL ANALYSIS

Statistical analyses will be performed using RStudio 2025.09.1 or further (Posit Software, PBC, Boston MA, USA). Continuous variables will be presented as mean ± standard deviation or median [interquartile range]. Categorical variables will be expressed as numerical values and percentages. Percentages will be calculated on the number of non-missing observations. In all cases the number of missing values will be specified. All statistical tests will be two-sided and P-values less than 0.05 will be considered as statistically significant.

10.1 Primary study parameter(s)

We will perform constrained (i.e. baseline adjusted) linear mixed model analyses with random intercepts to assess if the change in daily minutes of MVPA from baseline (T0) to 9 months (T2) differs between the intervention group and usual care group. This will be on an intention-to-treat basis. The model will include fixed effects for time (two levels) and treatment (two levels) as well as the unique participant identifier as a random effect. Model assumptions will be checked.

10.2 Secondary study parameter(s)

We will perform constrained linear mixed model analyses with random intercepts to assess longitudinal changes in physical activity characteristics as measured at baseline (T0), 3 months (T1, directly after CR), 9 months (T2, after intervention) and 12 months (T3, follow-up). Differences in functional capacity, quality of life, step metrics and 24h movement behaviours will be compared between baseline and the time points after CR between the intervention and usual care group using mixed model analyses using random intercepts.

10.3 Other study parameters

Explorative stratified analyses will be performed to determine the impact of age, sex, and baseline values of the outcome (i.e., minutes/day of MVPA) on the relationship between the change in physical activity and change in the outcome [10, 58-60]. Changes in other outcomes will be analysed using a similar protocol as described above unless other analyses would be more appropriate depending on the outcome (e.g. dichotomous outcomes). Incidence of adverse events (i.e. all-cause mortality, cardiovascular mortality, rehospitalisation, and recurrence of acute coronary syndromes) will be compared between the intervention and usual care group using Kaplan-Meier and (multivariate) Cox Proportional Hazard analysis.

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (World Medical Association, Helsinki, Finland, October 2024) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

11.2 Recruitment and consent

Hospitalised patients with CAD who will be referred to CR will be screened by the health care professional for eligibility in the study. If deemed eligible, the patient will be approached for participation by their treating physician or a staff member of the study team, who will provide both verbal and written information about the study. Participants will have appropriate time to consider participation. If a patient is willing to join, we will obtain informed consent.

11.3 Objection by minors or incapacitated research participants (if applicable)

Not applicable.

11.4 Benefits and risks assessment, group relatedness

Participants could benefit from the study when they increase their time in physical activity. Participants in the usual care group may also benefit from the study, because they will receive personalised feedback and advice after the last study assessment (12 months, T3). The burden of the study is low, since the study is integrated in the usual CR program, and only requires participants to come to the hospital for one extra study visit (9 months, T2). The extra time investment to participate in the study is estimated to be 7 hours in total for the intervention group and 4 hours in total for the usual care group. Moreover, the physical burden of the measurements is low. The accelerometers are of low weight and comfortable to wear. For the intervention group, monitoring of physical activity will not provide an extra burden, since participants will use their own device (smartwatch or smartphone). In conclusion, we have graded the risk profile of this study as a ‘negligible risk’, according to the NFU.

11.5 Compensation for injury

The sponsor/investigator has a liability insurance which is in accordance with article 7 of the WMO.

11.6 Incentives (if applicable)

Not applicable.

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

Data will be handled confidentially and will not be distributed to third parties. After informed consent, each participant will be given a unique code consisting of letters (the code name of the study) and a number (e.g. 001). The key linking to the patient identity will be stored in a secured file and only the involved investigators will have access to this key. Personal data will be handled in accordance with the EU General Data Protection Regulation (GDPR) and the Dutch Act on Implementation of the General Data Protection Regulation (UAVG). The research data will be stored for 15 years after finalisation of the project. The data required for the trial will be collected and stored in the electronic Case Report Form (eCRF) using Castor (Castor Electronic Data Capture, Ciwit B.V., Amsterdam, The Netherlands) and afterwards exported to RStudio 2025.09.1 or further (Posit Software, PBC, Boston MA, USA) for the analyses. Only the involved investigators will have unrestricted access to all pseudonymized data. Participants in the intervention group, the health care professional and study team will have access to the participant's physical activity data using the online platform. Data collection and storage on the online platform is GDPR compliant. Data is stored on secure servers protected with pseudonymization and encryption. Study related correspondence, signed Informed Consent forms, and source documents are to be maintained by the study site and archived in a locked cabinet for a minimum of 15 years after the end of this study. Source data will be entered at worksheets in the eCRF and afterwards exported to RStudio for the analyses.

12.2 Quality Assurance

Written procedures have been established by the principal investigator to assure the quality of the study.

12.3 Amendments

Amendments are changes made to the research after a favourable opinion by the review committee has been given. All amendments will be notified to the review committee that gave a favourable opinion. Non-substantial amendments will not be notified to the review committee, but will be recorded and filed by the sponsor.

12.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the review committee once a year. Information will be provided on the date of inclusion of the first participant, numbers of participants included and numbers of participants that have completed the trial, serious adverse events, other problems, and amendments.

12.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the review committee of the end of the study within a period of 8 weeks. The end of the study is defined as the last participant's last visit (i.e. 12 months). The sponsor will notify the review committee immediately of a temporary halt of the study, including the reason of such an action. In case the study is ended prematurely, the sponsor will notify the review committee within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the review committee.

12.6 Public disclosure and publication policy

The intention is to publish the results of this study in a peer reviewed scientific journal. All results, both positive and negative, will be published without restrictions. Authorship and manuscript composition will reflect joint cooperation between multiple investigators and sites. Authorship will be established prior to writing of the manuscript. No individual publications will be allowed prior to the completion of the final report for this study and as agreed in writing by the principal investigator. All data will be reported anonymously. This study will be registered at www.clinicaltrials.gov by the investigator to safeguard an open documentation policy and a future scientific publication.

13. STRUCTURED RISK ANALYSIS

Not applicable.

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