Sitting interruption treatment as a personalized secondary prevention strategy in patients with coronary artery disease: a randomized clinical trial

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We hypothesise that patients in the intervention group will show a reduction in sedentary time of at least 60 minutes per day after the cardiac rehabilitation program, compared to a reduction of maximally 30 minutes per day in the control group.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON22272

Source
NTR

Brief title
SIT LESS RCT

Condition

- Coronary artery disorders

Health condition

(in)stable angina, myocardial infarction, and/or after coronary revascularisation

Research involving
Human

Sponsors and support

Primary sponsor: Department of Physiology Radboud Institute for Health Sciences Radboud university medical center P.O. box 9101, 6500 HB Nijmegen +31 (0) 24 36 14 273
Source(s) of monetary or material Support: Dutch Heart Foundation (projectnumber: 2017T051)

Intervention

- Movement therapy

Explanation

Outcome measures

Primary outcome

The primary endpoint is the difference between the SIT LESS intervention group and the control group in change of sedentary behaviour (minutes/day) before and after the CR program. Sedentary behaviour will be assessed using the validated activity monitor ActivPAL micro (ActivPAL micro, PAL technologies, Glasgow, United Kingdom).

Secondary outcome

Secondary endpoints are: • Quality of life: before and after the CR program before and after the CR program compared between intervention and control group • Light- and moderate-to-vigorous physical activity: before and after the CR program compared between intervention and control group • Self-reported sedentary behaviour and physical activity: before and after the CR program compared between intervention and control group • Patients' competencies for self-management: patient activation measure before and after the CR program compared between intervention and control group • Laboratory parameters: LDL cholesterol, HDL cholesterol, total cholesterol, triglycerides, haemoglobin, leucocytes, thrombocytes before and after the CR program compared between intervention and control group • Cardiovascular risk profile: before and after the CR program compared between intervention and control group Tertiary endpoints: • Clinical outcomes (all-cause mortality; cardiovascular mortality; rehospitalisation and recurrence of acute coronary syndromes) compared between intervention and control group during 5 years of follow up Other study parameters compared between intervention and control group: • Patient characteristics such as age, sex, height, weight, cardiovascular risk factors, medical history, medication use, echocardiography data, coronary angiography data and laboratory values (e.g. cardiac biomarkers) • Results of timed up & go test + handgrip strength test before and after the CR program • Results of the process evaluation during the study period, such as the number of visits attended, phone calls that are made, intervention modules that are delivered, interviews with health care professionals and selection of patients.

Study description

Background summary

Rationale: Exercise training is the cornerstone in cardiac rehabilitation for patients with coronary artery disease. However, potential improvements in physical activity are often temporarily and most patients with coronary artery disease show high levels of sedentary time. Current cardiac rehabilitation programs do not specifically target sedentary time and no promising interventions to reduce sedentary time amongst patients with coronary artery disease have been identified in literature. We have therefore developed the SIT LESS intervention, which is based on an existing effective and cost-effective behaviour change intervention (AIMS) and has been adapted together with patients and healthcare professionals to an add-on module in cardiac rehabilitation treatment. Objective: The primary aim of this study is to compare the effect of the SIT LESS intervention versus usual treatment on sedentary time in patients with coronary artery disease directly after cardiac rehabilitation. Study design: A randomised controlled trial comparing SIT LESS to usual cardiac rehab. Study population: Patients hospitalized with coronary artery disease who are referred to an outpatient cardiac rehabilitation program. Intervention: A 12-week, nurse-delivered intervention will be provided in addition to usual treatment. During the baseline visit, nurses will use pre-tested materials for informing and motivating patients; and collaboratively set goals and plans for reducing sedentary behaviours. Patients will then receive an activity tracker that identifies bouts of physical inactivity and provides notifications to create awareness of prolonged sitting bouts in order to reduce their sedentary behaviour. During regular follow-up consultations with the nurse, personalized visual reports of (in)activity will be evaluated to enhance patients awareness of their (in)activity and identify any problems and solutions to reduce inactivity. The control group will receive usual treatment only. Main study parameters/endpoints: Primary endpoint is sitting time in minutes per day. To achieve 80% power (2-sided test, alpha 0.05), assuming 15% dropout and a reduction of at least 60 minutes per day sitting time in the intervention group (compared to expected reduction of 30 minutes per day in the control group), 212 patients will need to be recruited. Secondary outcomes are quality of life, light and moderate-to-vigorous physical activities and number of (prolonged) sitting bouts and patients' competencies for self-management, laboratory parameters (LDL cholesterol, HDL cholesterol, triglycerides, haemoglobin, leucocytes and thrombocytes) and cardiovascular risk profile. Tertiary outcomes include incidence of adverse outcomes during 5 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 the measurements are non-invasive. Using the activity monitor may be perceived as burdensome by some patients, but if patients perceive these to outweigh the benefits of the intervention they can discontinue with the monitor. All patients will continue to receive treatment-as-usual.

Study objective

We hypothesise that patients in the intervention group will show a reduction in sedentary

time of at least 60 minutes per day after the cardiac rehabilitation program, compared to a reduction of maximally 30 minutes per day in the control group.

Study design

Baseline measurements (directly after inclusion/randomization) Follow-up measurement 1 (directly after the cardiac rehabilitation/intervention period, approximately 12 weeks after randomization) Follow-up measurement 2 (approximately 24 weeks after randomization) Follow-up measurement 3 (approximately 52 weeks after randomization) To a maximum of five years of follow-up, clinical outcomes will be evaluated

Intervention

Patients that are randomized to the intervention group will receive the 12-week, nurse-delivered SIT LESS intervention in addition to the usual cardiac rehab (CR) program. During the first intervention consultation with the trained and dedicated CR nurse, patients are provided with a pocket-worn activity tracker so they will be able to review their sedentary behaviour (SB) patterns in a web-based environment. The activity tracker identifies prolonged bouts of physical inactivity, which then sends reminders to pursue patients to break up their sitting behaviour. During this first visit, the CR nurse and patients will discuss the influence of sedentary behaviour on health, patients personal goals and motivation, and collaboratively set action plans for reducing sedentary behaviour. Compared to the usual CR program, this first consultation will take approximately 30 extra minutes for patients in the SIT LESS intervention group compared with treatment-as-usual. The second and third consultation with the CR nurse will be a face-to-face consultation of 30 minutes 4-6 weeks and 10-12 weeks after the first consultation, respectively. Before the second and third consultation patients in the intervention group will be called to coach and ask them how things go and identify if there are any problems using the activity tracker. During the second and third consultation patients in the SIT LESS intervention will discuss the data collected through the activity tracker. 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 reinforce behaviour change (i.e., reductions in sedentary behaviour). During the intervention period patients have to connect the activity tracker to the cloud on a regular basis, using their smartphone.Thereby, the study team can prepare personalized feedback by the CR nurse during the next intervention consultation. If it is deemed indicated during consultations with the CR nurse, patients in the SIT LESS intervention group will receive additional telephone consultations during the 12-week intervention period, dependent on the needs of the individual patient.

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Diagnosed with coronary artery disease (ST-elevation myocardial infarction (STEMI) – non-ST-elevation myocardial infarction (NSTEMI) – UAP (unstable angina pectoris) – stable angina pectoris (AP) Referral to cardiac rehabilitation Older than 18 years of age Able to understand and perform study related procedures (i.e. smartphone availability, internet access, sufficient digital knowledge, ability to speak, read and interpret the Dutch language)

Exclusion criteria

Unable to give informed consent Wheelchair-bounded / not physically able to stand or walk. Language barrier Coronary arterial bypass graft surgery expected within 8 weeks after inclusion New York Heart Association class III or IV heart failure Participation in another interventional study targeting SB or PA

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2021
Enrollment:	212
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	24-02-2021
Application type:	First submission
Review commission:	METC Oost-Nederland p/a Radboudumc, huispost 628, Postbus 9101 6500 HB Nijmegen 024 361 3154

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Study registrations

Followed up by the following (possibly more current) registration

ID: 49484
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9263
Other	METC Arnhem-Nijmegen : METC2020-6101
CCMO	NL72604.091.20
OMON	NL-OMON49484

Study results