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

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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.

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

Summary

ID

NL-OMON49484

Source
ToetsingOnline

Brief title
SIT LESS RCT

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: cardiac rehabilitation, coronary artery disease, prevention, sedentary behaviour

Outcome measures

Primary outcome

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 outcome

Secondary outcomes are quality of life, the Patient Activation Measure (PAM), which is validated to assess patients* competency for self-management and light and moderate-to-vigorous physical activities, number of (prolonged) sitting bouts and cardiorespiratory fitness. Tertiary outcomes include incidence of adverse outcomes during 5 years of follow-up.

Study description

Background summary

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.

Study 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.

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.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• 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

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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

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

Ethics review

Approved WMO Date:	24-03-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22272
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL72604.091.20

Study results

Results posted: 28-02-2023

First publication
28-02-2023