Optimalisatie van beweeggedrag na een hartaandoening

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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.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Kransslagaderaandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22272

Bron
Nationaal Trial Register

Verkorte titel
SIT LESS RCT

Aandoening

- Kransslagaderaandoeningen

Aandoening

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

Betreft onderzoek met
Mensen

Ondersteuning

Primaire 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
Overige ondersteuning: Dutch Heart Foundation (projectnumber: 2017T051)

Onderzoeksproduct en/of interventie

- Bewegingstherapie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Gediagnosticeerd met een coronaire hartziekte (ST-elevatie Myocard Infarct (STEMI) – non-ST-elevatie Myocard Infarct (NSTEMI) – Instabiele angina pectoris – stabiele angina pectoris)

- Verwezen naar hartrevalidatie

- Ouder dan 18 jaar

- In staat om studie-gerelateerde procedures (zoals gebruik van een smartphone, internettoegang, voldoende digitale kennis, in staat om Nederlands te spreken, lezen en interpreteren) te begrijpen en uit te voeren.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Niet in staat om informed consent te geven

- Rolstoel gebonden / niet fysiek in staat om te staan of wandelen

- Taalbarrière

- Coronaire bypassoperatie verwacht binnen 8 weken na inclusie

- Hartfalen met een New York Heart Association class III of IV

- Deelname aan een andere interventie studie gericht op zitgedrag of fysieke activiteit

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep
Doel:	Preventie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	30-03-2021
Aantal proefpersonen:	212
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

Datum:	24-02-2021
Soort:	Eerste indiening
Toetsingscommissie:	METC Oost-Nederland

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49484
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten