Heart Failure and Promotion of Physical Activity before and after Cardiac reHabilitation

Gepubliceerd: 28-11-2019 Laatst bijgewerkt: 19-03-2025

We hypothesize that physical activity (PA) monitoring with motivational feedback (using an activity tracker) before and after centre-based CR in patients with HFrEF (NYHA class II/III) will lead to a clinically meaningful increase in the 6MWT....

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24242

Bron
NTR

Verkorte titel
HF-aPProACH

Aandoening

Heart Failure, Patients with chronic HFrEF (ischaemic or non-ischaemic)

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: H2020-Bigmedilytics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

6MWT

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Heart failure is a severe chronic disease with a great health care burden. Frequent (re-)hospitalizations and a high mortality remain an important issue. Optimal medical therapy (OMT) and lifestyle changes such as increased physical activity (PA) are the cornerstones of treatment. Based on the European Society for Cardiology (ESC) guidelines, regular aerobic exercise, for example within a centre-based cardiac rehabilitation (CR) is recommended for all Heart Failure patients with reduced Ejection Fraction (HFrEF) patients. Several studies have shown that PA is just as effective as medical therapy and can lower hospital admissions and decrease mortality. However, physical activity in this group of patients is challenging as both low participation rates for CR and relapse to low physical activity levels after CR are major issues. This study aims to demonstrate that monitoring physical activity in combination with motivational feedback benefits the level of participation in centre-based CR and, hence, the outcomes for these HF patients.
Objective: To investigate in our defined HF patient population if monitoring in combination with motivation on physical activity leads to an increase in enrollment rate for cardiac rehabilitation and sustained physical activity after cardiac rehabilitation as measured by the 6MWT.
Study design: The proposed study is a randomized controlled trial with a follow-up of at least 6 months. A total of 180 patients will be randomized to 2 arms in a 2:1 fashion: (1) Physical activity monitoring device with feedback and motivation; (2) Physical activity monitoring device without feedback and motivation. Both arms will have standard of care (SoC), including standard cardiac rehabilitation (specific for HF) according to the Dutch guidelines along with OMT as prescribed by the treating physician. The enrolment period will be 12 months. Additional measurements will take place at 3 time points: at baseline (within 6 weeks after inclusion), at the end of CR (16-20 weeks after inclusion) and at the end of follow-up (3 months after CR or at least 6 months after inclusion).
Study population: Patients aged 18-85 years with chronic HFrEF (NYHA class II and III) who have a clinically stable condition, an indication for physical exercise and CR, will be eligible to participate in this study. All included patients are required to have provided written informed consent.
Intervention: All patients in both arms of the study will wear an Actigraph activity tracker for physical activity monitoring. In addition, only the intervention arm will also wear a Fitbit smartwatch on which they will receive automated motivational feedback based on a goal for physical activity (step count), set by the treating physician before and after CR.

Doel van het onderzoek

We hypothesize that physical activity (PA) monitoring with motivational feedback (using an activity tracker) before and after centre-based CR in patients with HFrEF (NYHA class II/III) will

lead to a clinically meaningful increase in the 6MWT. Contributing factors to this objective are an expected improved participation rate in CR and a maintained PA after CR.

Onderzoeksopzet

• T0: At inclusion.
• T1: At completion* of CR, or for patients who did not start or did not complete CR, this will be at 16-20 weeks after inclusion.
• T2: 3 months after completion of CR, or for patients who did not start or did not complete CR, this will be 7 months after inclusion.

Onderzoeksproduct en/of interventie

The intervention arm will be stimulated to become more active. This will be achieved through visualization of step count on the Fitbit smartwatch and mobile phone and by receiving feedback on daily step count goals on the Fitbit smartwatch and mobile phone.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥ 18 years, ≤ 85 years.
2. Patients with chronic HFrEF (ischaemic or non-ischaemic) from the outpatient clinic.

3. NYHA class II/III.
4. Indication for and referral to CR (first time or last CR was more than 1 year before inclusion).
5. Clinically stable (no hospitalization in the month prior to inclusion).
6. At least 1 cardiology-related hospitalization in 1 -12 months prior to inclusion.
7. The patient should be willing and able to cooperate with study procedure (use activity tracker/device, fill out questionnaires, comply with the required follow-up visits and sign informed consent.
8. Sufficient understanding of Dutch language, both spoken and written.
9. Access to a smartphone with SMS functionality and a personal computer with internet-access and an email address.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with acute HF, HFpEF or HFmEF.
2. Patients who are currently or have been (< 1 month) hospitalized.
3. End stage renal disease requiring dialysis.
4. Other comorbidities/conditions precluding exercise training.
5. Patients with a life expectancy <1 year.
6. Patients on the waiting list for a heart transplant or other major surgery planned <1 year.
7. Patients already actively using their own smart watch.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-12-2019
Aantal proefpersonen:	180

Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	28-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49839
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8190
CCMO	NL68986.078.19
OMON	NL-OMON49839

Resultaten