

Heart failure and promotion of physical activity before and after cardiac rehabilitation (HF-aPProACH): a study protocol

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Abstract

Aims Lifestyle changes, such as increasing physical activity (PA), are a cornerstone of treatment of patients with chronic heart failure (HF). However, improving PA in HF patients is challenging, and low participation rates for cardiac rehabilitation (CR) as well as relapse to low PA levels after CR are major issues. We designed a randomized controlled trial to investigate if PA monitoring with motivational feedback before and after centre-based CR in HF patients with reduced ejection fraction (HFrEF) will lead to a clinically meaningful increase in physical fitness.

Methods and results A randomized controlled trial will be conducted in a sample of 180 HFrEF patients (New York Heart Association Class II/III) who are referred to 12-week standard CR. Patients will be randomized (2:1) to (1) standard of care (SoC) plus wearing a PA monitoring device (Fitbit Charge 3) with personalized step goals, feedback and motivation or (2) SoC only. The intervention lasts ± 7 months: 4–5 weeks before CR, 12 weeks during CR and 12 weeks after CR. Measurements will take place at three time points. The primary endpoint is the change in the distance in 6-min walking test (6MWT) over the entire study period. Other endpoints include step count, grip strength, quality of life and all-cause mortality or hospitalization.

Conclusions HF-aPProACH will provide novel information on the effectiveness of remote PA stimulation and feedback before, during and after standard CR using a commercially available device to improve physical fitness in HFrEF patients.

Keywords Chronic heart failure; Physical activity; 6-min walk test; Fitbit; Telemonitoring; Motivational feedback

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Introduction

Heart failure (HF) is a condition with a high healthcare burden.¹ According to the European Society of Cardiology Heart Failure Long-Term Registry comprising 12 440 patients from 211 cardiology centres in Europe, the composite of 1-year all-cause mortality or HF hospitalization rate was 36% among acute HF patients and 15% among chronic HF patients.¹ Treatment of chronic HF is mainly focused on improving guideline adherence and achieving optimal medical

therapy to decrease symptoms and disease progression and hereby improving quality of life. A major additional treatment strategy is to advocate for exercise training and cardiac rehabilitation (CR). Piepoli et al.² showed that CR reduced the risk of all-cause mortality and hospitalization with 28% in a chronic HF population. Additionally, exercise rehabilitation significantly improves quality of life and physical function.³ Specifically in heart failure with reduced ejection fraction of <40% (HFrEF), the 2016 European Society of Cardiology (ESC) guidelines for HF treatment provided a Class 1A

recommendation for regular aerobic exercise to improve functional capacity and symptoms.⁴ Despite shown benefit and guideline-based recommendation, less than 20% of the chronic HFrEF patients participate in a condition-specific CR programme.⁵ Additionally, maintaining increased physical activity (PA) after completion of CR is challenging in a chronic HF population.⁶

Face-to-face counselling during and after CR was found to slightly increase PA level, specifically the time in prolonged moderate-to-vigorous PA (MVPA).⁶ Due to the current technological development in consumer electronic devices, there are opportunities to provide remote counselling. We believe feedback through a commercial device could be a less labour intensive method of improving and maintaining PA. The use of PA devices adheres to the principles of temporal self-regulation theory.⁷ These devices allow for personalized goal-setting, self-monitoring of behaviour and provide the user with motivational feedback. Furthermore, we have observed that there can be a significant time gap between referral and start at CR. We hypothesize that addressing this time gap and the period after CR could improve adherence to PA. Against this background, we designed *Heart Failure and Promotion of Physical Activity before and after Cardiac reHAbilitation* (HF-aPProACH). This will be a randomized controlled trial in patients with HFrEF to study the effects of daily remote PA monitoring in combination with motivational feedback on adherence to PA and participation in CR.

Study design

Study setting

HF-aPProACH is a prospective, randomized, unblinded, controlled clinical trial. The study will be performed at Erasmus MC, Rotterdam, The Netherlands, with a possible extension to other hospitals in the Rotterdam area and in cooperation with Capri Cardiac Rehabilitation Centre Rotterdam (provider of standardized outpatient CR according to ESC guidelines⁴). The current study design paper is written according to the SPIRIT 2013 guidelines,⁸ and HF-aPProACH has been registered in the Netherlands Trial Register (trialregister.nl, ID: NL8190, date registered: 28-nov-2019).

Eligibility criteria

The target population consists of outpatients with stable chronic HFrEF, according to ESC guidelines,⁴ who will be referred to CR and consent to participation.

Inclusion criteria

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

- Age between 18 and 85 years.
- Diagnosis of clinically stable chronic HFrEF, with LVEF < 40%⁴ and no hospitalization in the previous month.
- New York Heart Association (NYHA) Class II/III.
- Referral to CR.
- Sufficient understanding of the Dutch language, both verbal and in writing.
- Access to a smartphone with SMS functionality and a personal computer with Internet access and an email address.

Exclusion criteria

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

- Patients who participated in a CR programme within the last year.
- End-stage renal disease requiring dialysis.
- Comorbidities/conditions precluding exercise training.
- Life expectancy shorter than 1 year.
- On the waiting list for a heart transplantation or other major surgery planned within the next year.
- Actively using a smartwatch (possible interference with current intervention).

Treatment

All study participants will be managed at the discretion of the treating physician, based on the prevailing ESC guidelines,⁴ and regardless of allocation and participation in a CR programme (standard of care [SoC]).

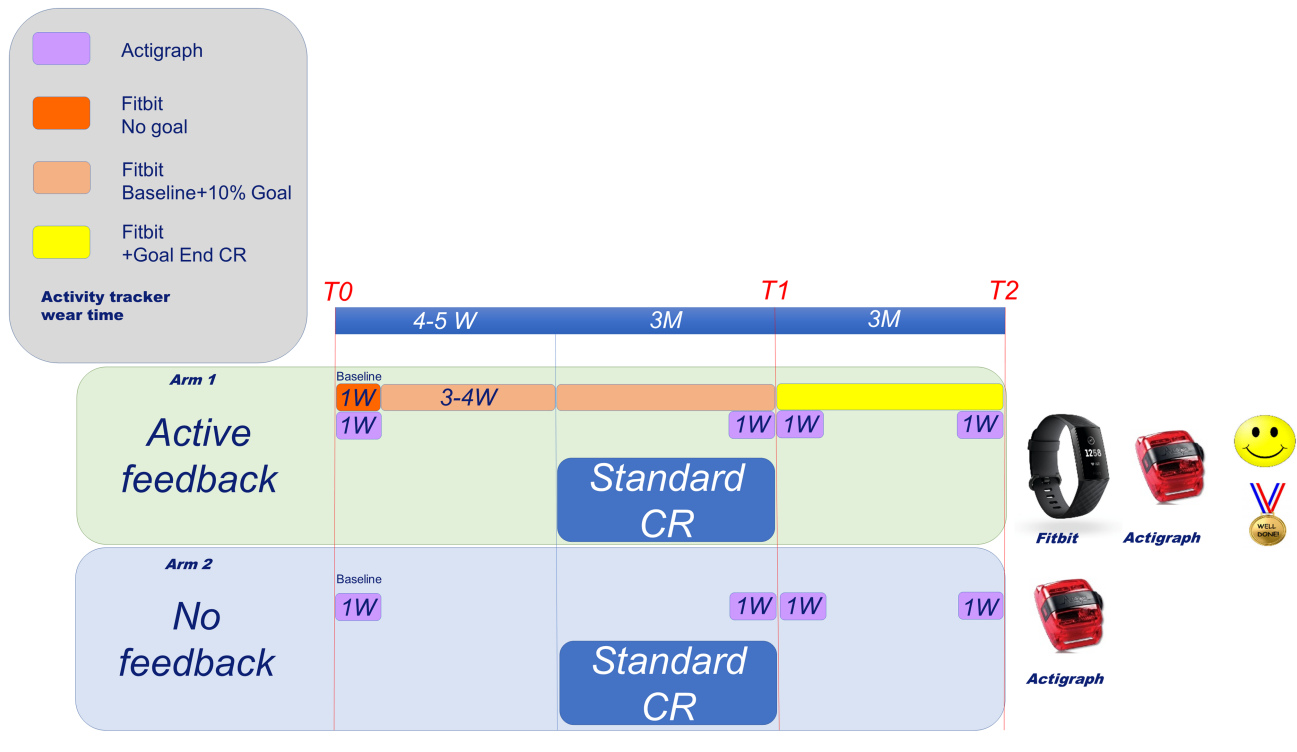
Participants will be randomized (2:1) to the intervention arm receiving active motivational feedback on their PA before and after completion of the CR programme or the control arm (SoC without feedback). *Figure 1* shows a visual representation of the study design.

Intervention with active feedback on PA

The intervention arm consists of three phases, with a total duration of ± 7 months, and will receive feedback through a smartwatch (Fitbit Charge 3). This device will be worn during all phases and measures step count. After the first week of baseline measurements, participants will receive automatic visual feedback via their Fitbit smartwatch and Fitbit app (through linked mobile phone) on their performance and the achievement of the personal daily activity goal throughout the whole intervention period.

Phase I (approximately 4–5 weeks) is the period between study inclusion and the actual start of CR. The daily activity (step count) will be measured using the Fitbit smartwatch.

Figure 1 Overview study design. CR, cardiac rehabilitation; M, month; T, measurement point; W, week. Vital parameters and physical fitness (6MWT and grip strength) will be assessed at T0, T1 and T2. Additionally, questionnaires will be sent out electronically at these time points, and patients will be allowed 1 week time to complete them.



Measurements during the first week after inclusion will be considered baseline. Subsequently, the daily activity level goal is remotely set as 110% of the average baseline step count (approved by treating physician) and after which the participant will receive motivational feedback.

Phase II (12 weeks) is the period encompassing the standard CR programme for HF rEF patients, with the addition of wearing the Fitbit smartwatch. CR entails 12 weeks of exercise training. In addition, the CR participants receive education on (secondary prevention of) cardiovascular disease and its consequences, follow patient-tailored lifestyle programmes (such as smoking cessation or stress reduction programmes) and receive individual psychosocial guidance when applicable.⁹ During this phase, the participants still have access to their daily step count via the Fitbit smartwatch and mobile phone, and they will continue to receive motivational feedback based on the pre-set step count goal as determined in Phase I.

Phase III is the 12-week period after completion of the standard CR. The daily activity goal during this phase is set to the average daily activity (step count) that was achieved in the last week of Phase II. Daily motivational feedback will be provided based on this new activity goal.

Control treatment

The control group will receive SoC (which includes a CR programme) only. This group will not wear a Fitbit smartwatch, will not receive pre-set activity goals and will not have insight in their daily number of steps throughout Phases I, II and III (as described above).

Outcomes/study endpoints

There will be three measurement points, namely, T0, baseline, referral to CR; T1, end of CR; and T2, end of study (see *Figure 1* for study overview). The primary study endpoint is the difference in distance during the 6-min walk test (6MWT) between T0 and T2. This test will be performed under strict supervision of a trained healthcare professional. The 6MWT was found to be a reliable and valid test in mild-to-moderate chronic HF patients.¹⁰

Secondary endpoints include:

- 1 Active participation in the CR programme: This will be measured through attendance of exercise training sessions during the CR programme. Completion of CR is considered

as a minimum attendance of 75% of CR sessions, according to Sunamura *et al.*¹¹

- 2 PA: Step count, total time spent in MVPA, light PA and sedentary behaviour expressed as a percentage of total daily wear time measured by the ActiGraph GT3X. The device will be worn at T0, T1 and T2 as depicted in *Figure 1* by both the intervention and the control group. It will be worn on the right hip clipped on the belt or with an elastic band during waking hours for 7 consecutive days at T0 and T2 and for 14 days around T1. Patients will be advised to remove the device before bed time, showers or swimming.
- 3 Grip strength: This is an objective measure of general physical fitness. A lower grip strength has been associated with higher mortality risk.¹² Grip strength will be assessed using a Jamar[®] hydraulic hand dynamometer and will be examined for both hands three times alternately, starting with the dominant hand. The mean grip strength (kg) of the three attempts of each hand will be used.
- 4 Composite of all-cause mortality or HF hospitalization during follow-up.
- 5 Disease-specific quality of life and psychosocial measures: Study participants will be asked to fill out a set of questionnaires at T0, T1 and T2, which will be sent electronically as a set in a predefined order. Patients will have 1 week to complete them and will be allowed to save (between questionnaires) and resume at a later time point within this period.

To assess health-related quality of life (QoL), two questionnaires will be used, namely, EuroQol Five Dimensions (EQ-5D) and Minnesota Living with Heart Failure Questionnaire (MLHFQ). The EQ-5D is a validated questionnaire assessing general QoL.^{13,14} A score will be assigned on five health levels (mobility, self-care, daily activities, pain and anxiety/depression). Additionally, the perceived health status will be scored on a scale of 0–100. Disease-specific QoL will be assessed using the MLHFQ. The MLHFQ is a validated 21-item questionnaire which is used to assess the health-related QoL on several domains; physical, emotional, social and mental.^{15,16}

Anxiety and depression will be examined with the Hospital Anxiety and Depression Scale (HADS).¹⁷ The questionnaire exists of an anxiety scale and a depression scale, both constructed out of seven items, where every item is scored on a 4-point Likert scale (0–3).¹⁸ To assess the level of fatigue, the Fatigue Severity Scale (FSS) will be used.^{19,20} The questionnaire has nine questions about the experienced severity of fatigue in the past week. Fear of movement or kinesiophobia is a common problem in patients with cardiac diseases, and this might influence adherence to CR.²¹ This will be assessed through the Tampa Scale for Kinesiophobia (TSK-NL Heart questionnaire),^{21,22} consisting of 17 questions with a 4-point answer scale. Lastly, self-efficacy is measured using the General Self-Efficacy Scale (GSE). In this questionnaire, 10 propositions are stated on how a person thinks and acts, and

this is often applied in patients with chronic diseases or who experienced a stressful life event.²³ Finally, we will add the International Physical Activity Questionnaire (IPAQ), consisting of 31 questions to assess subjective PA level.²⁴

Devices

The Fitbit Charge 3 consumer activity monitor (Fitbit, USA) will be used in the intervention group to provide daily activity goals and feedback on activity.

The ActiGraph GT3X activity monitor (Actigraph Corp, USA) will be used to objectively measure PA in both the intervention and control arm. The ActiGraph is a widely used accelerometer and has been validated.²⁵ Furthermore, the Actigraph was found to be the most accurate device for measuring step count in a multi-device comparison study for measuring 24 h of sleep, sedentary behaviour and PA measurement.²⁵

Recruitment and consent

Recruitment of participants will take place during regular outpatient clinic visits. Eligible patients will receive detailed patient information explaining the study procedure and other relevant information and will be given sufficient time to consider participation. Written informed consent will be obtained prior to enrolment in the study.

Study randomization

Participants will be allocated in a 2:1 (intervention:control) fashion with block randomization. The allocation process will be performed by the ALEA software (Alea Clinical BV, The Netherlands). Blinding is not possible in this study due to the setup and usage of Fitbit activity trackers.

Data management

To manage the data, several systems will be used. The questionnaires will be sent out and processed with the GemsTracker system (Version 1.8.2). Clinical information will be entered in OpenClinica (OpenClinica, Version 2.1, USA) database. To monitor PA data from the Fitbit, the Fitbit website is used on the individual level. Additionally, Fitabase (Small Steps Labs LLC, USA) is used to collect (aggregated) data of all intervention participants in one database. ActiGraph data will be processed by the ActiLife software (Actigraph Corp, USA).

Sample size

The sample size is set at 180 participants: 120 participants will be randomly allocated to the intervention arm with active motivational feedback, and 60 participants to control arm. This number includes an attrition rate of $\pm 10\%$, so 160 participants will be available for analysis. This number is sufficient to demonstrate an anticipated difference of 45 meter in mean change in the 6MWT distance (primary endpoint) between intervention and control (power 80%, two-sided alpha 0.05), which is considered a clinically meaningful difference in HF patients.²⁶ HF patients with an average PA level, based on the HF-ACTION trial, walk on average 368 m (standard deviation [SD] = 97 m) during a 6MWT.²⁷

Ethics

The study will be conducted according to the principles of the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act (WMO). HF-aPProACH has been approved by the Medical Ethical Committee of Erasmus MC (NL68986.078.19, MEC-2019-0114).

Data protection

To ensure data safety and adhere to the General Data Protection Regulation (GDPR) rules, together with a data security officer, a Data Protection Impact Assessment (DPIA) and data security assessment have been performed on Fitbit and Fitabase.

Statistical methods

Normality will be visually assessed using histograms and Q-Q plots. Continuous variables will be presented as mean and SD or median and interquartile range (IQR) as appropriate. Differences in continuous variables between the two arms will be tested using Student *t*-test or Mann-Whitney *U* test, as appropriate. Categorical variables will be presented as count and percentage. Differences in categorical variables between the two arms will be tested using chi-square test or Fisher's exact test, as appropriate.

Analysis of the primary outcome, the distance on 6MWT, will be done using multivariable linear mixed effect (LME) models. Covariates that will be included in the models are age, sex, HF duration, HF hospitalizations, NYHA class, LVEF, HF medication and comorbidities (such as diabetes, hypertension, atrial fibrillation, COPD, renal disease and malignancy). The secondary endpoints (step count and health-related QoL) will be analysed by similar LME models. CR enrolment rate will be tested using logistic regression. Depending on

the number of endpoints, the composite endpoint of all-cause mortality and hospitalization will be studied with a Cox proportional hazard model. In all analyses, treatment allocation will be a key determinant.

Patterns of missing data will be reviewed to determine whether data are missing at random, and if so, multiple imputation using chained equations (MICE) will be used.

A two-sided *P*-value of < 0.05 will be considered significant for all tests. SPSS Statistics 25 for Windows (IBM Corp., Armonk, New York) will be used for data preparation and descriptives. Advanced statistical models will be performed using R Statistical Software (Vienna, Austria).

Discussion

HF-aPProACH aims to contribute to the ongoing search for successful initiatives to improve enrolment in CR and adherence to PA in patient with HF_{rEF}. Although both PA and CR have a Class I Level A recommendation in HF_{rEF} patients,⁴ enrolment in and adherence to CR as well as maintaining the achieved level of PA after CR in this patient population remain challenging. Low enrolment rates in CR is a multifactorial problem caused by low referral rate²⁸ by cardiologists and patient intrinsic factors such as low motivation.⁹ We hypothesize that the period between referral to and enrolment in CR is also a crucial period contributing to this phenomenon. To keep the patients engaged in and motivated to the process, we included this period in the intervention. Therefore, the overall goal of HF-aPProACH is to assess the effect of personalized step goals and motivational feedback before, during and after CR on adherence to PA (during and after CR) and participation in CR. This is a novel approach to employ a commercially available device for providing motivational feedback in addition to around current national guideline-based, centre-based CR in HF_{rEF} patients.

A related study protocol was proposed by Vetrovsky et al.²⁹ for two multicentre randomized controlled trials to investigate motivational feedback on functional capacity in HF patients with or without preserved LVEF. This includes a 6-month personalized pedometer-based walking intervention with weekly step goals combined with regular, behavioural face-to-face sessions with a physician and phone contact with a research nurse. In contrast, HF-aPProACH will utilize a self-sustaining feedback system with minimal need for face-to-face contact with healthcare givers using a Fitbit smartwatch. If proven effective, this intervention will be easy to implement in the standard care of HF_{rEF} patients without increasing the healthcare workload. In addition, as opposed to Vetrovsky et al.,^{4,9} our study will include SoC centre-based CR according to the guidelines. This provides a unique opportunity to address the crucial periods before and after CR. Our study will therefore contribute to the

existing knowledge on the effect of using a commercially available smartwatch in promoting and motivating PA before, during and after CR in HFrEF patients with NYHA II/III.

Our study has several strengths. Firstly, the commercial Fitbit device is low cost, easily accessible and interpretable as well as widely available for patients. Consumer devices are being deployed for medical use more frequently,³⁰ therefore we chose a Fitbit (commercial device) instead of a dedicated research device. The Fitbit is able to accurately track steps, has a strong agreement with ActiGraph and importantly, showed to be sufficiently accurate in providing motivational feedback on step count in the elderly.³¹ Secondly, as of yet, not much research has focused on the period between referral to CR and actual start of CR³²; however, this is a critical time window for enrolment in CR. Enrolment and attendance rates could possibly be increased by intervening in this time window. Therefore, we will investigate the effect of motivational feedback prior to CR enrolment in addition to during and after CR in HF-aPProACH. Last but not least, our intervention is easy to implement in regular care and is not a large burden on healthcare personnel.

However, we also acknowledge a few limitations of our study. Firstly, HF-aPProACH is focused on HFrEF patients, consequently limiting generalizability to all HF patients. Secondly, the level of PA also depends on intrinsic motivation. Considering our proposed study will be conducted in a randomized fashion, we expect this effect to be evenly distributed across the two arms. Lastly, compliance to wearing the devices can be challenging. Randomization and correction in post-processing of the data by using device wear time should sufficiently address this issue. Last but not least, patients will

have to be able to understand mobile technology and properly use the device, which can be more challenging in some patients. To address this, we provide clear step-by-step information on how to use the devices.

In conclusion, HF-aPProACH will provide novel insights into the effects of providing daily motivational feedback through a commercially available smartwatch on PA in HFrEF patients before, during, and after CR, as well as on enrolment in CR.

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Conflict of interest

None declared.

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