









BMJ Open Maintenance of physical activity after cardiac rehabilitation (FAIR): study protocol for a feasibility trial

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ABSTRACT

Introduction To enhance health and prevent secondary consequences for patients with cardiovascular disease (CVD), maintenance of an active lifestyle following participation in cardiac rehabilitation (CR) is important. However, levels of physical activity often decrease after completion of a structured CR programme. Models that support long-term behaviour change with a sustained level of physical activity are imperative. The aim of this study is to evaluate the feasibility of a mobile health intervention based on the Health Action Process Approach theoretical model of behaviour change in patients with CVD for 3 months after completion of a CR programme.

Methods and analysis In a feasibility trial design, we will recruit 40 participants from CR programmes at Slagelse Hospital, the City of Slagelse (municipality), or Holbæk Hospital. After completing the standard structured CR programme, each participant will create an action plan for physical activity together with a physiotherapist. Following that, participants are sent 2 weekly text messages for 3 months. The first text message prompts physical activity, and the second will check if the action plan has been followed. If requested by participants, a coordinator will call and guide the physical activities behaviour. The feasibility of this maintenance intervention is evaluated based on predefined progression criteria. Physical activity is measured with accelerometers at baseline and at 3 months follow-up.

Ethics and dissemination Study approval was waived (EMN-2021-00020) by the Research Ethics Committee of Region Zealand, Denmark. Study results will be made public and findings disseminated to patients, health professionals, decision-makers, researchers and the public.

Trial registration number NCT05011994.

INTRODUCTION

Background and rationale

Cardiovascular disease (CVD) is the leading cause of death worldwide¹ and the number two cause of disability-adjusted life years.² Physical activity is an important element of disease prevention and rehabilitation for patients with CVD and is associated with

Strengths and limitations of this study

- The trial involves participants taking part in structured cardiac rehabilitation programmes in both the hospital and municipality sectors.
- The intervention is based on a model of behaviour change, the Health Action Process Approach.
- Using text messages, the intervention is accessible and is expected to have low costs.
- There is no control group in the feasibility study, but the full-scale randomised controlled trial will include a control group.

reduced cardiovascular mortality and hospital admissions and improved quality of life, and physical and mental health.^{3–6} International guidelines on CVD prevention recommend that all adults perform at 150–300 min of moderate-intensity physical activity per week, 75–150 min of vigorous-intensity physical activity per week or a combination of the two.³ Exercise-based cardiac rehabilitation (CR) is class-I recommended and is implemented in most European countries.^{3–7} CR is typically delivered as a supervised center-based exercise programme of moderate to vigorous intensity multiple times per week over 3–6 months.⁸ During CR, participating patients are physically active near or above the recommended levels if adhering to exercise activities. After completing center-based CR, patients are encouraged to maintain an active lifestyle by themselves or with less supervision.⁹ Unfortunately, physical activity levels decline over time among many patients^{10–17} and may thereby increase their risk of a recurrent cardiovascular event and worsening in cardiovascular risk profile.

Mobile health is the use of mobile devices to improve healthcare and practice.¹⁸ Mobile health interventions with text messages have been widely used in overall health

promotion,¹⁹ and are effective when targeting physical activity.^{18–20} In patients with CVD, text message-based interventions running parallel to CR increase physical activity^{21–22} and appear to be cost-effective, though other studies found no effect on physical activity.²³ Recent systematic reviews^{24–25} investigating interventions specifically for the maintenance of physical activity after CR identified three randomised controlled trials (RCTs) with a mobile component.^{26–28} One RCT had positive results of text messages to maintain physical activity after CR but also major concerns due to a small sample size and high attrition.²⁶ Another investigated telemonitoring with text message feedback and showed fewer rehospitalisations and improvement in physical fitness.²⁷ A third showed improvement in physical activity from internet-based telerehabilitation with text message feedback.²⁸

Maintenance of physical activity is a challenge that, for many, requires long-term behaviour change. Behaviour change theories provide frameworks for mobile health interventions²⁹ to help achieve the intended behaviour and be more effective.³⁰ In addition to a theoretical framework, interventions may incorporate behaviour change techniques (BCTs),³¹ which act as components in the intervention to regulate behaviour.³¹ The use of a behaviour change theory and BCTs is associated with better results in promoting health behaviour change.³²

We plan a feasibility trial to test and evaluate our intervention before conducting a definitive full-scale RCT to investigate the effect of the intervention. The intervention has multiple interacting components and is complex according to the Medical Research Council guidance for designing complex interventions.³³ The guidance advises for feasibility studies to learn and prepare for RCTs.³³ A feasibility trial will allow us to examine the feasibility of the intervention, including acceptability, context and setup, and individual components of the intervention, and provide a solid foundation for a future RCT. In addition, a feasibility trial will provide information on parameters needed for a more precise sample size calculation for the future RCT.³⁴

Objective

The aim is to evaluate the feasibility in terms of recruitment, retention, data completeness, intervention delivery and compliance, and acceptability of a mobile health intervention based on the Health Action Process Approach (HAPA) theoretical model of behaviour change in patients with CVD for 3 months after completion of a CR programme. Furthermore, to elicit feedback that will inform refinement of the intervention.

Trial design

The study is a single-group multisite feasibility trial. Participants will be recruited from hospital and municipality-based phase II CR and offered the intervention for 3 months following completion of the rehabilitation programme. In addition to the feasibility outcomes, planned outcomes in the definitive RCT, including physical activity, physical

function, quality of life and harms. To evaluate feasibility, assessments will be made during the trial and at 3 months follow-up. In a future RCT, a longer follow-up period will be included to determine the effect on maintenance. For reporting, we adapt the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guideline for reporting protocols of clinical trials³⁵ to this feasibility trial protocol.³⁶ The study is registered on ClinicalTrials.gov (NCT05011994).

METHODS AND ANALYSIS

Study setting

We will conduct the study at Slagelse and Holbæk Hospitals, Region Zealand, and in the City of Slagelse (municipality). In Region Zealand, both hospitals and municipalities conduct structured phase II CR. Following the national rehabilitation guidelines in Denmark, the Department of Cardiology, Slagelse Hospital, stratifies patients with CVD to rehabilitation at the hospital or in the municipality, with municipalities receiving patients expected to be of lower risk for a cardiovascular event. Standard phase II CR consists of supervised exercise-based CR based on national clinical guidelines.³⁷ At Slagelse Hospital, patients with CVD referred to CR are offered 8 weeks of group-based exercise (1-hour duration two times weekly) that focuses on aerobic exercise and resistance training. Physiotherapists instruct patients from the start of CR to consider possibilities for continued physical activity after completing the rehabilitation programme. During the CR programme, patients are provided guidance on choosing the type, intensity and frequency of physical exercise. Patients are also provided with a log to record their exercise progress and are encouraged to engage in home exercise. CR in the City of Slagelse mirrors that of Slagelse Hospital and also has a duration of 8 weeks. For CR at Slagelse Hospital and in the municipality of Slagelse, planned exercise activities end with the rehabilitation programme, and patients will have to engage in other physical activities. At Holbæk Hospital, patients typically receive 6 weeks of exercise-based CR at the physiotherapy department followed by another 6 weeks of physical exercise in the municipality if the patient's municipality offers it. All in-person visits in the study take place at the same locations where participants participated in CR. On a national level, there are currently no standardised maintenance programmes for physical activity after the completion of CR.

Eligibility criteria

Patients are eligible for participation in the trial if fulfilling all inclusion criteria and no exclusion criteria at the time of inclusion.

Inclusion criteria

- ▶ Age ≥ 18 years.
- ▶ Participant in an exercise-based CR programme in either hospital or municipality setting.

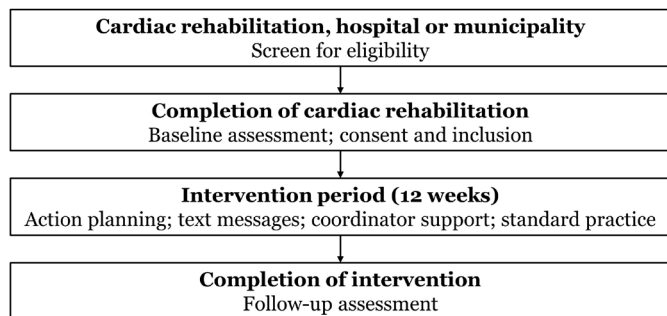


Figure 1 Study flow chart.

- ▶ Access to a personal mobile phone with a Danish telephone number.
- ▶ Able to walk 3 m without assistance.

Exclusion criteria

- ▶ Insufficient Danish language proficiency to read and understand text messages and questionnaires.
- ▶ Cognitively or mentally unable to participate.
- ▶ Terminal patients with a life expectancy of less than 3 months.

Recruitment and participant timeline

Flow of participants is shown in [figure 1](#).

Study participants will be recruited from among heart patients enrolled in a CR programme at three recruiting sites: Slagelse Hospital, City of Slagelse or Holbæk Hospital. At each site, physiotherapists conducting the

CR programme will screen for eligibility among CR participants. Eligible patients are approached about study participation by the screening CR physiotherapist and given written information. Subsequently, oral information is given by a research or clinical staff member involved in the study. Informed consent is collected before baseline assessments. Patients are considered included after completing the baseline assessment. [Figure 2](#) shows the participant timeline, inspired by the SPIRIT guideline.³⁵

Interventions

Study participants will receive an intervention that consists of action planning, text messages and coordinator support starting immediately after CR completion. BCTs are included in the contents of the intervention. The intervention is an addition to standard practice and does not replace any existing treatment offers.

Theoretical framework

The intervention is based on a theoretical model of behaviour change in the form of the HAPA^{38,39} ([figure 3](#)). The HAPA model has two phases: motivational and volitional.^{39–41} Successful progression through both of these phases results in long-term behaviour change. Since elements relating to the motivational phase (eg, outcome expectancies and risk perception) is already implemented in the initial CR through national clinical guidelines,³⁷ our focus have been on the volitional phase (see [table 1](#)). Action planning is a key element in

	STUDY PERIOD																
	Screening			Inclusion	Intervention												Close-out
TIMEPOINT, weeks	-4	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13
ENROLMENT:																	
Screen for eligibility	●	●	●	●													
Informed consent	●	●	●	●													
End of CR program					●												
STUDY INTERVENTION:																	
Action planning					●												
Text messages					●	●	●	●	●	●	●	●	●	●	●	●	●
Coordinator support					●	●	●	●	●	●	●	●	●	●	●	●	●
ASSESSMENTS:																	
Accelerometer, thigh (1 week)				●												●	
Accelerometer, wrist (3 weeks)				●	●	●	●								●	●	●
Feasibility outcomes				●	●	●	●	●	●	●	●	●	●	●	●	●	●
Clinically assessed outcomes					●											●	
Patient reported outcomes				●											●		
Other outcomes				●	●												●

Figure 2 Participant timeline. CR, cardiac rehabilitation.

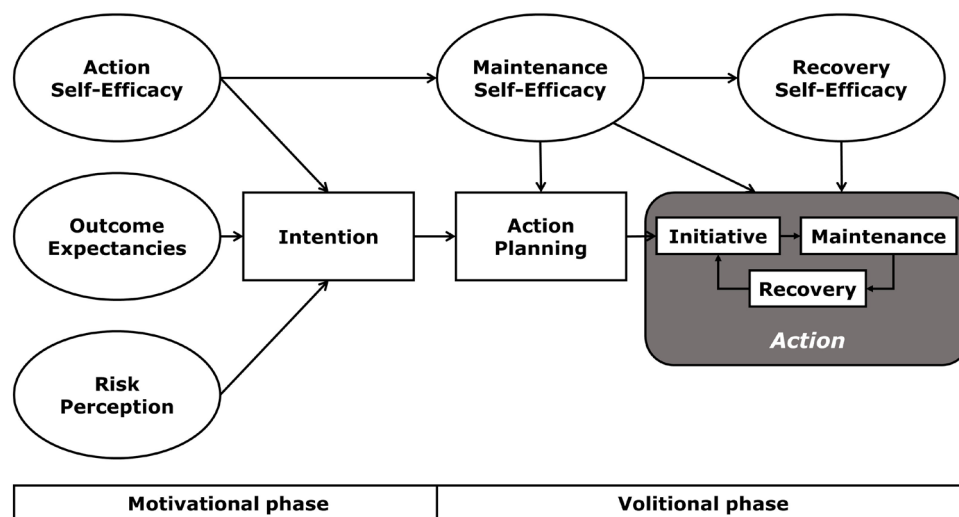


Figure 3 The Health Action Process Approach model adapted from Schwarzer.³⁹

HAPA that bridges the intentions developed in the motivational phase with behaviour in the volitional phase.^{39 40} Perceived self-efficacy (the belief in own capability to perform a given action)³⁹ is another central concept in HAPA, and is essential in the process of changing behaviour.⁴¹ We will measure self-efficacy and try to enhance it to promote physical activity. Understanding the nature of the behaviour and the context in which it occurs is essential in developing more effective interventions to change that behaviour.⁴² There is growing consensus that attempts to change behaviour should draw on theories of behaviour and behaviour change.⁴³ Recent advances in the design of behaviour change

interventions have emphasised the importance of classifying intervention components (BCTs)³¹ and mapping the intervention components onto mechanisms of change.⁴⁴ Using theory to develop behaviour interventions provides a valuable approach for identifying the key modifiable determinants of behaviour and designing interventions to target these determinants. We used a bottom-up funnel approach to decide on a theoretical framework, considering several theories (social cognitive theory, self-efficacy theory, ecological models, self-determination theory and the transtheoretical model) before deciding on HAPA as the best fit for the intervention. HAPA has seen frequent use in prior interventions

Table 1 Behaviour change techniques used in the intervention according to the behaviour change technique (BCT) taxonomy V1 by Michie *et al*³¹

BCT with codes	Intervention content	Application	Relation to the HAPA model (figure 3)
1.4 Action planning	Action planning	Action planning of physical activity at the start of the intervention	Action planning: maintenance self-efficacy (volitional phase)
1.6 Discrepancy between current behaviour and goal	Text messages	Follow-up text messages (figure 4) draws attention to the fact that physical activity plans were not reached	Recovery self-efficacy (volitional phase)
2.3 Self-monitoring of behaviour	Text messages	Participants note and reply each week to text messages on whether plans for physical activity were reached	Maintenance self-efficacy (volitional phase)
3.1 Social support (general)	Coordinator support	The coordinator offers support and guidance on physical activity by phone	Maintenance self-efficacy; recovery self-efficacy (volitional phase)
3.2 Social support (practical)	Coordinator support	Coordinator helping to establish contact with local activities involving physical activity	Maintenance self-efficacy; recovery self-efficacy (volitional phase)
7.1 Prompts/cues	Text messages	Text messages prompt participants to do physical activity	Maintenance self-efficacy (volitional phase)
10.3 Non-specific reward	Text messages	Positive reinforcement via text message when replying that plans were carried out (figure 4)	Maintenance self-efficacy (volitional phase)

HAPA, Health Action Process Approach.

to maintain or promote physically active behaviour.^{45–49} Coping planning is an add-on to action planning in the HAPA model,³⁹ but is not included in our intervention, as we sought to limit the number of elements included at the onset of the intervention.

Behaviour change techniques

BCTs are a standardised way of describing the smallest active components in the intervention that facilitates a behaviour change.³¹ The intervention contains seven different BCTs as per the the BCT taxonomy by Michie *et al.*³¹ All parts of the intervention incorporate BCT components to help change and/or maintain physical activity behaviour. Table 1 shows an overview of BCTs included in the intervention. Action planning is a BCT in itself, whereas text messages enable the use of BCTs such as prompts to do physical activity and rewards in the form of positive reinforcement.

Action planning

Action planning is a central component in the HAPA theoretical model that involves setting a plan for specific behaviours⁵⁰ to translate intentions into action.⁴⁰ Action planning has been found to improve adherence to CR,⁵¹ and therefore, it may also enhance maintenance of physical activity after CR. With the help of a physiotherapist, participants create an action plan at the onset of the intervention. At Slagelse Hospital, RMA (physiotherapist) or a research physiotherapist helps participants with action planning in the study; at the City of Slagelse and Holbæk Hospital, action planning is done by the physiotherapists conducting CR together with the patient. In action planning, the following will be specified:

- ▶ What types of physical activities are planned? (up to three)
- ▶ For each activity: when will the activity be done?
- ▶ For each activity: where will the activity be done?
- ▶ For each activity: With who will the activity be done?

A template with the points above will be used to create action plans in a face-to-face setting with the physiotherapist. Physiotherapists assisting with action planning receive verbal and written instructions beforehand, including a list of potential activities they can suggest to participants as part of the instructions for the template. There will be no specific requirements to the qualifications of these physiotherapists. For the types of activities in the action plans, we consider physical activity in the broadest terms leaning on both the WHO⁵² and a broader view of physical activity.⁵³ Working in the garden and playing with grandchildren (if walking and/or running) are examples of activities of moderate intensity.⁵⁴ Participants take their action plans home with them, and a copy is stored securely. Action plans are created to cover the 12-week intervention period and beyond. As part of *Coordinator support* (see below), participants may be guided to changes in their action plan, and participants themselves are free to change their action plan as they wish.

Text messages

Two autogenerated text messages are sent weekly for 12 weeks (figure 4). The first weekly message prompts physical activity. The second asks if physical activity plans were reached. If participants reply 'yes', an automatic reply with positive reinforcement is generated. If participants reply 'no', an automatic reply asks if the participant wish to be contacted by a health professional coordinator (see *Coordinator support* below). Text messages have proven to be useful in increasing physical activity with ischaemic heart disease,^{21 22} and we expect that text messages also are useful in maintaining physical activity habits, which smaller studies have pointed to in a population with mixed diagnoses.²⁶ The text messages constitute a key component of the behaviour change intervention, and serve multiple purposes related to the applied BCTs by (1) prompting physical activity; (2) providing general encouragement; (3) pointing out the potential discrepancy between current and planned behaviour; (4) allowing for self-monitoring of behaviour via texts correspondence. Further, the text messages support behaviour encouraged during preceding CR programme, extend the contact between participants and a health professional (coordinator) and helps to identify participants having difficulties meeting physical activity plans. At the same time as action planning, a physiotherapist registers the participant's phone number and first name, after which the participant will receive the autogenerated text messages. Participants receive oral and written instructions from the physiotherapist on how to reply to text messages. The 12-week text-message period is counted from the first week the participant receives both text messages, that is, if a participant starts the intervention on a Thursday, they do not get the Wednesday message (figure 2), and the 12-week intervention duration will be counted from the following week. For personalisation, each text message addresses the participant by first name and has the name of the primary researcher (RMA) as sender. To allow flexibility and pragmatism, the City of Slagelse will use their existing text message provider, gruppe-sms.dk (Computopic), which is different from the provider used at the two hospital sites, sms-track.com (SMS-Track). For the purposes of this study, the differences between the two providers are as follows: (1) participants from the City of Slagelse has to type 'FAIR 1' instead of '1' and so on; and (2) participants from Slagelse and Holbæk Hospitals receive a text notice in case of unrecognised replies, for example, yes instead of 1 telling to only reply with either '1' or '2'.

Coordinator support

The intervention involves possible contact with a coordinator physiotherapist who is trained in study procedures. A research physiotherapist located at Slagelse Hospital handles coordinator support for both Slagelse and Holbæk Hospitals. In the City of Slagelse, coordinator support is conducted by the same physiotherapists from municipal CR who assist participants with action planning.

**Message 1. Prompt physical activity:
Wednesdays at 15:00 p.m.**

Hi [first name]
Remember your physical activity plans.
Best regards,
Rune Andersen, The FAIR project

**Message 2. Follow-up on the action plan:
Sundays at 11:00 a.m.**

Hi [first name]
Did you achieve your plans for physical
activity the past week?
Reply with 1 (for yes) or 2 (for no), so I
know how you're doing.
Best regards,
Rune Andersen, The FAIR project

1

Congratulations on reaching your
plans. Keep up the good work!
Best regards,
Rune Andersen, The FAIR project

2

Do you wish to be called up in the coming
week for a talk about your physical activity
plans?
Reply with 1 (for yes) or 2 (for no).
Best regards,
Rune Andersen, The FAIR project

1

We will call you one of the following
days and leave a message if we're
unable to get a hold of you.
Best regards,
Rune Andersen, The FAIR project

2

Completely OK. If you want to be
called up, you can answer yes
another time.
Best regards,
Rune Andersen, The FAIR project

Figure 4 Text message templates translated from Danish.

With a remote intervention, we deem it important to include both a human and a health professional aspect in the form of the coordinator. In addition, we expect the coordinator to facilitate greater use of existing activities in the community and municipalities. The coordinator has the following functions:

- ▶ Call participants replying to texts that they wish to be contacted.

- ▶ Help participants establish contact with local activities involving physical activity.
- ▶ Follow-up on and assist with possible adjustment of participants' action plan.
- ▶ Offer general guidance in physical activity.

Coordinators receive written instructions consisting of a 1-page information sheet on the points above including instructions for before, during and after calling

Table 2 Progression criteria

Outcome	GREEN: proceed to RCT	AMBER: amend when proceeding to RCT	RED: issue must be solved before proceeding to RCT
Recruitment	Mean of ≥ 0.75 recruited participants per week per site	Mean of 0.5–0.74 recruited participants per week per site	Mean of < 0.5 recruited participants per week per site
Attrition/retention through follow-up assessment session	$\geq 80\%$ retention of participants through follow-up	50%–79% retention of participants through follow-up	$< 50\%$ retention of participants through follow-up
Accelerometer data completeness	Accelerometer data from both baseline and follow-up available on $\geq 80\%$ of completing participants	Data available on 50%–79% of completing participants	Data available on $< 50\%$ of completing participants
Response rate on patient-reported outcomes	$\geq 90\%$ of participants attending baseline and follow-up assessment return patient-reported outcomes	75%–89% of patients attending baseline and follow-up assessment return patient-reported outcomes	$< 75\%$ of participants attending baseline and follow-up assessment return patient-reported outcomes
Coordinator time spent, minutes per participant throughout the intervention	Mean coordinator time spent of ≤ 30 min per participant	Mean coordinator time spent of 31–60 min per participant	Mean coordinator time spent of > 60 min per participant
Response rate (adherence) to weekly follow-up messages (<i>message 2, figure 4</i>)	$\geq 75\%$ of patients respond to at least 75% of messages	50%–74% of patients respond to at least 75% of messages	$< 50\%$ of patients respond to at least 75% of messages
Acceptability of text message component	$\geq 75\%$ of participants find text messages acceptable	50%–74% of participants find text messages acceptable	$< 50\%$ of participants find text messages acceptable

RCT, randomised controlled trial.

participants. Coordinators are also given verbal instructions in conducting coordinator support. Participants are contacted by the coordinator if either (1) the participant replies in text messages that they wish to be contacted or (2) the participant does not answer text messages for two consecutive weeks. In this regard, answering no to the initial question of whether plans were reached but not answering the follow-up question is counted as not answering. Each participant will only be called once due to not answering text messages but can be called multiple times if they request it by replying to texts.

Outcomes

Progression criteria

To evaluate the feasibility of the intervention and its readiness to be tested in a subsequent RCT design, we have set progression criteria using a GREEN, AMBER or RED system,⁵⁵ shown in [table 2](#). We also evaluate the intervention on secondary outcomes (online supplemental table 1). In addition to the outcomes listed in this section, we plan a qualitative evaluation using patient interviews, which will add valuable information about the feasibility and acceptability of the intervention. Qualitatively we will investigate how people with CVD experience participating in the FAIR project (the present study). Knowledge of what physical activity and intervention participation mean to participants' daily lives will be provided.

List of outcomes

We show a complete list of outcomes to be collected in online supplemental table 1, including instruments and timing of outcome measurement.

Sample size

The feasibility trial is not designed to incorporate hypothesis testing, rather the progression criteria, supported by the qualitative interviews, are our primary way of evaluating the feasibility of the intervention, and most of these specify a proportion of our sample that must meet the criteria. We aim for a sample size that balances certainty, ethical considerations (eg, patients' time) and resource usage. In terms of certainty, that is, CIs around these proportions, there are diminishing returns with an increasing sample size and each additional participant in the sample narrowing the CI less than the previous one. We plan to recruit 40 participants, which gives us an acceptable level of certainty for evaluating the progression criteria. For example, if we have a sample size of 40 and a proportion of 0.75 (the GREEN threshold for several of our progression criteria), the lower confidence limit will be 62% using normal approximation and well within the AMBER range. In this example, we would have decent certainty that they are not in the RED range ($< 50\%$ in this example). This holds true even if using more conservative methods for calculating the CIs.⁵⁶ We

also estimate that 40 participants will provide a sufficient sample to recruit from for a qualitative evaluation. Additionally, a sample size of 40 participants is very reasonable to detect GREEN, AMBER and RED signals with our most common choice of progression criteria limits (ie, a RED upper limit of 50% and GREEN lower limit of 75%–80%) according to the overview by Lewis *et al.*⁵⁷

Data collection methods

Accelerometers

Physical activity is objectively assessed using accelerometers at baseline and follow-up. The participants are required to wear two devices. One device is worn on the right thigh using a tape solution, and a second accelerometer to be worn on the wrist in a wristband. The thigh-worn devices will provide insights into the actual type (sitting, standing, moving, walking, running and biking) and intensity of the subject's activity. In contrast, the wrist-worn device will provide information about circadian rhythms and more long-term engagement in physical activity. Both accelerometers are to be worn at all times, including sleep and water activities for 1 week straight (thigh) and 3 weeks straight (wrist), respectively. At baseline, accelerometers are worn for the last week of CR, plus an additional 2 weeks for the wrist accelerometer (figure 2). For follow-up measurements, a wrist accelerometer is sent by mail or picked up by the participant and worn for the last 2 weeks of the intervention plus an additional week. The thigh accelerometer is worn the last week of the intervention for follow-up (figure 2). At baseline, the assessor informs participants about the accelerometer measurements and instructs the participants how to return accelerometers by mail or drop-off, including written instructions. Accelerometry data reduction will be handled by a researcher that is blinded to patient characteristics and delivery of the intervention.

Clinically assessed outcomes, demographics and other outcomes

On the day of starting the FAIR intervention (the last day of CR), research or CR physiotherapists will assess outcomes of 6-min walking test, 30-s sit-to-stand test, height, weight, eligibility criteria, age, gender, heart-related diagnoses and procedures, sessions attended during CR (figure 2). All baseline clinical assessments are made prior to starting the intervention. Follow-up clinical assessments are made by research or CR physiotherapists after 11 weeks of intervention; follow-up visits also include placement of a thigh accelerometer to be worn for the last week of the intervention. For both baseline and follow-up, clinical outcomes will be assessed at the site at which participants attended CR.

Patient-reported outcomes

Patient-reported outcomes will be collected via questionnaires in the electronic data capture system, EasyTrial (easytrial.net, Aalborg, Denmark). Participants are sent a hyperlink to fill out patient-reported outcomes at baseline, in continuation of accelerometer placement 1 week

before end of CR/start of FAIR (figure 2). A link to fill out follow-up patient-reported outcomes is sent again at the end of intervention week 11. Participants will be instructed to fill out the patient-reported outcomes within the a week, and a reminder is sent on email and text message after 3–5 days if the participant has not responded.

Data management

Project data are stored in secure Region Zealand systems and under license and agreement with Region Zealand.

Statistical methods

To evaluate the progression criteria, we will calculate the proportions as outlined in table 2 including 95% CIs. For additional outcomes, we will analyse the change from baseline to follow-up. We plan to report mean change in continuous outcomes with 95% CIs calculated in R statistical software (Vienna, Austria). In addition, we will calculate Cohen's d with thresholds for interpretation of effect size of small (0.20–0.49), medium (0.50–0.79) and large (>0.80).⁵⁸ Accelerometer data will be imported via a USB port and analysed off-line.

Harms

We judge the intervention to have a very low risk of harms, as the active components are of behavioural nature, and after the initial action planning, the intervention is administered remotely. Participants may experience passing skin irritation from wearing an accelerometer on the thigh. Information on adverse events and hospitalisations during the intervention period will be collected in the electronic questionnaire at follow-up. Clinical staff will register potential deaths at follow-up assessment.

Patient and public involvement

For user involvement, we sought input on intervention design and study set-up from clinicians (physiotherapists) working in CR at hospitals and municipalities. We sought input from two patients on action planning and possible use of goal setting. We met with representatives from the Danish Heart Foundation (patient organisation) to explore how the FAIR intervention would fit into the patient organisation's activities. As part of our evaluation plans, patient perspectives are systematically captured through qualitative interviews. All quantitative and qualitative findings will be presented and debated with the involved clinicians. Inspired by the Delphi process, the clinicians' views and suggestions for improving the intervention are gathered at a workshop after the feasibility trial.

ETHICS AND DISSEMINATION

The risks associated with this study are few and small, and the potential benefits of investigating an intervention to enhance maintenance of physical activity outweigh the risk of harms to improve current practice to the benefit of heart patients. Study approval has been waived

(EMN-2021-00020) by the Research Ethics Committee of Region Zealand, Denmark. The study is approved by the Danish Data Protection Agency through Region Zealand, Denmark (REG-162-2020). All personal data will be treated with confidentiality and in compliance with current legislation. The project will conform to the principles of the Declaration of Helsinki.

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