Sustaining Physical Activity

Following Cardiac Rehabilitation Completion

NCT03991715

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Cardiac Rehabilitation (CR) Pilot Intervention (IRB #16-3306)
CR Transition: NC TraCS Grant

Purpose:
The proposed study will develop and pilot test an intervention to improve exercise adherence following completion of a supervised CR program. This pilot intervention was informed by the interviews with program directors (IRB #16-2859) and focus groups conducted with cardiac rehab patients (IRB #16-3102). To accomplish this, we will pilot the intervention with 5 CR participants, starting during CR and continuing with them as they transition out of the CR program.

Participants
We will recruit participants from local CR programs, with support from CR staff. CR staff will identify participants that may be eligible and provide them with a flyer informing them of the study. We will ask the CR staff to keep track of the number of flyers that are handed out, while UNC staff will track how many email inquiries are received, and finally the number who participate. This information will be valuable for future studies.

Participants are asked to contact the PI if interested, and then will be screened for eligibility by her. The screening for eligibility will be based on a survey of questions that follow the inclusion and exclusion criteria below. If eligible, or if requested before eligibility assessment, we will provide them with the consent form. The inclusion and exclusion criteria have been developed to include a broad range of patients who graduate from CR. To enhance the applicability of the results, the criteria are designed to be inclusive of patients with multiple comorbidities.

Inclusion Criteria
Eligible participants will:
1. have a diagnosis of coronary heart disease
2. currently attend outpatient phase 2 CR in a local CR program and have at least 4 weeks left before completion
3. be >=18 years
4. own a smart phone and ability to participate in a mobile health program with access to smartphones utilizing Apple or Android platforms
5. be able to understand/write English
6. adequate clinical stability achieved in the judgment of the investigator and referring CR staff to allow participation in study assessments and the intervention
7. sign the informed consent document indicating that the patient understands the purpose of and procedures required for the study and is willing to participate in the study

Exclusion Criteria
These exclusion criteria were used from a similar study at Duke University (paper under submission). They include:
- Currently using a digital or non-digital physical activity tracker (Fitbit, Jawbone, pedometer, etc.)
- Past use of a digital activity tracker (Fitbit, Jawbone, etc.) → past use of a pedometer is acceptable
- Planned re-location within 12 weeks
- Medical procedure scheduled within next 12 weeks
- Acute symptoms of coronary artery disease
- Decompensated heart failure
- Severe valvular heart disease
- Severe pulmonary hypertension
- End stage renal disease
- Heart failure, New York Heart Association (NYHA) class IV
- Cardiac transplantation
- Visually impaired
- Current substance abuse
- Impairment from stroke, injury, or other medical disorder that precludes participation in the intervention
- Dementia that precludes ability to participate in and follow study protocols

- Inability or unwillingness to comply with the study requirements

Rationale and Risks

Outpatient CR for coronary heart disease includes aerobic exercise and risk factor counseling and/or monitoring. CR can slow or arrest coronary heart disease progression and reduce cardiac morbidity and mortality. Most outpatient CR programs consist of up to 36 sessions of supervised aerobic exercise, after which patients are prescribed aerobic exercise on their own. Unfortunately less than half of patients continue to exercise after CR completion.

This project seeks to address this drop-off in exercise following CR, but incorporating an activity tracker into CR during the sessions to self-monitor themselves, and then allowing participants to continue using it following CR to monitor changes in their own exercise. We believe the addition of an activity tracker is an intervention that does not pose greater than minimal risks to participants, with minimal risk defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".

Recruitment Process

We will recruit participants through local CR programs. Initially, we will start with only one CR program, since our sample size for the pilot study is so small (n=5). A flyer was created to provide the name of the project PI to contact by email about interest in participating. If an email is received, a reply will be given to describe the study and send the informed consent document. If the participant is interested in continuing, they will be asked to find a brief time to talk with study staff to make sure they are eligible.

Participant Contacts and Timeline

We will meet the participant at the CR facility to enroll them in the study, receive their signed consent document, provide them with a Fitbit activity tracker, and answer any questions. We will provide the participant with our contact information, so that they can call or email us at any time with their questions. We will also meet them at the CR facility when they have a final discharge meeting with CR staff, and at the end of the study. At the discharge meeting, the CR staff will provide a list of dates/times to the UNC staff that the CR participant attended CR in order to document their attendance.

The study timeline is as follows:

- Approximately 2-4 weeks before completion of the CR program: complete enrollment and survey 1; start wearing tracker
- Receive weekly reports at CR regarding how tracking is progressing
- At discharge (on or near their last day of CR), a study staff person will be present at this meeting; they will be asked to complete survey 2
- The intervention kicks off at discharge with CR participants receiving a weekly contact with feedback on their progress and advice from peers on potential barriers to continuing physical activity
- 6 weeks post discharge: intervention ends
- 4 weeks later: final contact with participant, complete survey 3, ask for any final feedback and disconnect from study tracking

Email script to reply to those who inquire about participation

Dear <name>,

Thank you for your interest in participating in this research study. We are seeking a few cardiac rehabilitation patients who are willing to wear an activity tracker during the course of the study, which starts during your cardiac rehabilitation program and continues for 10 weeks after discharge. Our goal is to help you make a more successful transition from the cardiac rehabilitation program to exercising on your own.

We could meet you at <name> Cardiac Rehabilitation Program either before or after one of your sessions to review the study procedures, answer any questions, and enroll in the study. At that session, we will ask you to also complete a survey. You would be asked to wear the activity tracker for the rest of your time in cardiac rehabilitation until the study ends about 10 weeks after cardiac rehabilitation. For the first 6 weeks, we will provide feedback to you each week on how your exercise is progressing or maintaining since cardiac rehabilitation. We would meet with you two other times and ask you to complete surveys at each time. Your

study participation would end at 10 weeks after cardiac rehabilitation, but you will be able to keep the activity tracker and continue to use it if you wish.

Thanks in advance for your consideration, and I look forward to hearing from you.
Sincerely,
<name>
<title>

If interested: Request to speak with them on the phone to check the eligibility criteria. Send the patient the consent form. If eligible and if a date is open, schedule with the patient.

If not interested: Do not contact participant again and thank them for their time.

Items we will collect and keep on an Excel spreadsheet (password protected computer)
Date of inquiry
Location of CR program
Name
Contact information – address, phone, email
Call notes
Screening criteria: inclusion and exclusion criteria as listed in earlier sections
Activity tracker number
Assignment of ID
Height and weight (to set-up the Fitbit)

All research data collected from this study (Fitbit data, surveys) will be coded with the use of ID and not with any identifiers. We will not retain identifiable information from the participants until they consent in the study. We will keep track of the screening of eligibility, but will not keep name or contact information if they are deemed not eligible.

Coordination Between UNC and RTI International (RTI)
This proposal is unique in that it involves collaboration between UNC and RTI. The division of responsibilities is as follows:

- The recruitment and screening of participants for eligibility will be led by UNC.
- RTI will set up the Fitbit accounts and take care of any technical issues related to Fitbit wear.
- A RTI and UNC staff person will meet with the participant(s) together to instruct them on the wear and charging of the activity tracker. Both will be available for any questions during the study.
- RTI will monitor the Fitbit accounts during the course of the study.
- Deidentified data from the activity tracker will be analyzed at both UNC and RTI.

Description of the Fitbit Activity Tracker and Features
Fitbit claims over 9.5 million active users. This volume of adoption has permitted the company to test and apply various improvements to the core feature set and user-experience design based on actual user input that are far beyond the achievable within the scope of any research pilot. Therefore, rather than pursue development of a *de novo* behavioral intervention, we will seek to leverage existing features of the Fitbit platform.

We will focus primarily on the application of three major components of the platform: goal setting, passive tracking, and social features. The steps below describe the manner in which devices will be configured in a manner consistent with limiting disclosure of personal information; creating a private pilot group on the Fitbit platform; orienting participants to the hardware and software; tailoring feedback to the individual; and data collection.

1. Device configuration and account creation

We have selected the Fitbit Alta HR for data collection (see image from Fitbit).

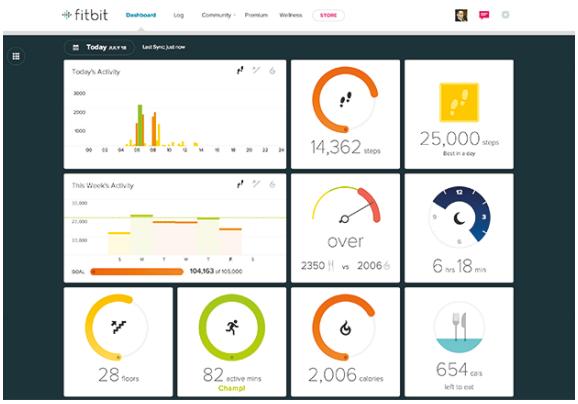
This model features:

- All-Day physical activity tracking
- Automated sleep tracking
- Heart rate measurements
- Reminders to move
- SmartTrack auto exercise recognition
- Up to 7 days of battery life
- Syncs wirelessly to computers and >200 other devices

The Charge 2 devices will be configured in advance using study-assigned identifiers based on our documented procedure (Ortiz et al, 2016). Only UNC will have access to names and emails of participants. RTI will not retain names or emails of participants. All collected data will be de-identified and only associated with an RTI assigned study ID. RTI will have access and collect the participant's data through their online Fitbit account. Fitbit online accounts allow users to download their collected activity data. These accounts will be initiated and monitored by RTI throughout the study. After the study concludes RTI will disconnect the participant's Fitbit from the RTI-based account and no further data will be able to be accessed, collected, or downloaded from participants by RTI.

2. Orientation and Tailoring

Intake visits will be scheduled at the CR site either before or after their session. During these visits, participants will be issued their Fitbit device, assisted with setup on their personal smartphone, oriented to the device and software, and will enter individual data to tailor their user experience. Participants will be asked to provide basic anthropometric measurements (e.g., age, height, weight, stride length) to complete customization of their user account for the study; inclusion of such body measurements is recommended by the manufacturer to improve the accuracy of tracking devices. This is also the time when participants will complete an interviewer-administered questionnaire.



The Fitbit platform enables users to set a variety of activity goals, including steps, floors climbed, distance, calories burned, or active minutes and to monitoring their progress toward achievement of an individualized goal. Individually tailored daily and weekly physical activity goals will be established by CR program staff for all participants. Participants will be oriented to the type of feedback (e.g. messages or notifications) and reward mechanisms (e.g., badges and virtual awards) associated with the Fitbit user experience. These mechanisms provide ongoing, individual input on progress toward achieving daily and weekly physical activity goals, as shown in the dashboard. Messages to participants provide encouragement for individuals who have not yet reached a predefined level of physical activity and issue awards, such as virtual badges and positive affirmation, to those on achieving their benchmarks. Participants will be sent reminders to move when they have been sitting for too long during the intervention phase after CR discharge.

Key features to review with the participants:
Keep blue tooth on.
The device is water resistant but not waterproof.
Charging of the battery each day (the website indicates 5 days of wear possible)
Tracking information on a mobile device vs. computer

A fact sheet will be provided to help participants recall this information.

3. Data collection

Each participant will receive individual instruction and assistance installing the native Fitbit app on their Android or iPhone device. Staff will assist with this process during the group training session. The application will be configured to the study-assigned identifiers described in step one and be setup such that it will not obtain any additional information such as access to contacts, social platforms, or photos on the participants' phones. Participants will be instructed to wear the Fitbit device as much and as consistently as possible throughout the study, removing the device only to shower, swim, and to charge when low battery is indicated.
Specific recommendations from Evenson, et al (2015) will be delivered to participants, including: Wear the tracker in the same position each day; enter your details and sync; wear it on the non-dominant wrist; use add-on features and obtain software updates, when available.

4. Group

A private Cardiac Rehab Group (CRG) has been created on Fitbit that is not publicly discoverable and can only be joined by invitation from study staff. The CRG will only include the 5 participants recruited into the pilot and will be preconfigured using the devices setup for the study. We will promote the use of messaging between the study staff and the individual participant. The weekly message will include graphics on their physical activity over time, feedback on their progress with physical activity (Appendix 1), and graphics on any other behaviors they are tracking (weight, sleep, blood pressure, and glucose). The message will also address any potential barriers to reaching their physical activity goals. Participants will be able to email back to our staff with any questions. We will record observations of individual and group platform interactions to characterize engagement and report as descriptive statistics. The screen captures provide an example of the daily leaderboard and group features in the Fitbit platform and are for illustrative purposes only.

Alternatively, if the participant does not receive emails via the group settings, then we will email the information directly.

5. Fitbit Dashboard

Our primary interest is in tracking physical activity and sedentary behavior. However, we will give participants the option at any time to also track weight, sleep, blood pressure, and glucose (if diabetic). We will provide them with weekly, and as data accumulates, month summaries of their weight, sleep, blood pressure, and glucose.

Fitbit Dashboard and Reports

Measure	Display and Report Items
Activities	Steps, floors, calories burned, distance, logged common activities
Weight	Weight chart, Measurement history, Weight badges, Achievements
Sleep	Hours of sleep
Blood pressure	Systolic and diastolic blood pressure
Glucose	Glucose readings

6. Data extraction

Study staff will manually export data from the five accounts one time, at the end of the pilot for analysis. Data will include physical activity metrics attributed to the study-assigned identifier and will not include any additional personal information on the user.

7. Close-out

On completion of the pilot (~10 weeks post CR discharge), participants will retain the Fitbit device and will be provided with instructions on how to convert registration from the study-assigned convention to create their own personal account.

8. Time commitment

Summary of Initial Training Session: this session occurs with approximately 2-4 weeks left of CR for the participants (25 minutes)

- 5 minutes to review the consent form, answer questions, and collect signed forms
- 5 minutes to receive their assigned Fitbit when entering the study, review features of the tracker and how they will be used
- 5 minutes to install the app to their phone
- 10 minutes to complete survey 1

During the Study

- <1 minute to occasionally sync the Fitbit with the participant's online account throughout the study
- If RTI staff notice that the Fitbit is no longer being worn, then staff will contact the participant to inquire as to why

At CR Discharge

- Study staff will join in on this meeting between a CR staff person and patient in order to hear the discharge instructions and exercise advise given in order to support those goals after CR
- 10 minutes to complete survey 2

Summary of Close-out Session: this session occurs when participants are 10 weeks from their CR program discharge date (15 minutes)

- 5 minutes to disconnect the Fitbit from RTI-based accounts to leave the study
- 10 minutes to complete survey 3

Appendix 1: Examples of general messaging by past experience (related to physical activity) using four groups. These messages will be tailored to the participant's progress.

Group 1: Goals are being met regularly and have had a successful past week	Group 2: Goals are being met regularly but they had an unsuccessful past week	Group 3: Goals are not being met regularly but they have had a successful past week	Group 4: Goals are not being met regularly and they are having an usuccessful past week
You are on the right track!	Keep staying strong. You will be on your way to a healthier new you!	New activities can be challenging to do. Take it one day at a time!	We know this is tough but stay strong!
You are on your way to a healthier new you!	If you're having trouble, message a friend. This support will help keep you on track.	Keep staying strong. We know it is not easy, but it is totally worth it.	Hang in there! It could be worse. No one says it will be easy, but they do say it is worth it!
You are going to set a great example for your spouse/partner, children, or other loved ones. Thank them in advance for helping you meet your goals.	We know how you are feeling. Think about what you are gaining. Stay focused. It will get easier!	There are so many benefits to exercise. Tell a friend what you look forward to most!	Your journey to a healthy lifestyle might be a struggle, but looking back it will be well worth it.

Tips for adding steps

- Walk the dog with the whole family

- Instead of calling friends, take a walk together to catch up.
- Park your car as far away as possible so you have to walk a longer distance from your destination. Even better, walk or cycle to run errands.
- Walk up and down the field while watching your child(ren) or grandchild(ren) play sports.
- Replace a coffee break with an outdoor walk—or take the coffee with you on your walk.
- Walk the golf course instead of using a cart.
- Choose the stairs instead of the elevator or escalator.

Keep Moving at Home & In the Community

- Keep a list of quick activities, like squats or stretches, near the remote so that you can be active during commercial breaks.
- Wash the car.
- Plant and care for a vegetable garden (then cook the vegetables for healthy meals).
- Start your day with a morning stretch or end your day with calming yoga
- Sign up for dance lessons with a friend.
- Experience the great outdoors and go for a hike, walk, or bike ride.

Analysis Plan

The following dates will be specified for analysis, corresponding to three time periods:

- Pre-intervention: during cardiac rehabilitation starting on the day the activity tracker was given to the last day of cardiac rehabilitation (e.g., discharge)
- Intervention: day following cardiac rehabilitation discharge to the day the last (sixth) report was sent
- Maintenance: day following the last report to the last day of tracking by study staff

The outcomes tested include physical activity (defined by the activity tracker as very active minutes/day) and steps per day. Independent variables include differences between study periods in terms of intercepts and slopes (i.e., as interaction terms). We will include days that have at least 500 steps, as days with less than 500 steps probably indicate nonwear. Mixed model trajectory analysis will be used to test the effect of the intervention on the two outcomes.