Targeted Health Coaching Intervention to Improve Physical Activity Maintenance and Mobility Post-Structured Cardiac Rehabilitation Programming Among Older Adults: A Pilot Study

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Purpose of the Study

To identify factors and triggers influencing physical activity (PA) participation after structured cardiac rehabilitation (CR) among older adults who have enrolled in a center-based CR program, and compare the effects of a targeted health coaching intervention versus standard care immediately following structured CR on PA maintenance and functional fitness.

Background & Significance

Approximately 800,000 individuals in the United States have a heart attack every year, with almost 1 in 4 of those individuals already having suffered a previous heart attack. Attending cardiac rehabilitation (CR) following a cardiovascular event improves cardiorespiratory fitness and health-related quality of life, as well as decreases the risk of future illness and death from heart disease. Unfortunately, once an individual finishes a CR program, continued participation in physical activity (PA) too often reverts to previous sedentary patterns, limiting beneficial health effects. Continued participation in PA post-CR is especially challenging among older adults – likely due to a lack of self-efficacy and confidence in their ability to perform PA due to either their age or other health conditions that make PA more challenging. However, the need to address other health conditions, in conjunction with the benefits of improved strength and mobility, makes continued PA participation following a structured CR program even more useful for older adults. Although individuals typically understand habitual participation in PA is good for their health, we poorly understand why some individuals successfully adhere to and maintain PA habits, while others succumb to barriers preventing them from maintaining the health benefits beyond CR. In addition to understanding factors and triggers influencing PA maintenance beyond CR, little research has developed or investigated interventions targeting this important transition period following structured CR programming to promote continued PA participation "at home". Therefore, this proposal aims to 1) identify factors and triggers influencing PA participation after a traditional 36-session CR program (Stage 0); and 2) test a targeted health coaching intervention using these identified triggers to optimize PA maintenance and mobility among older adults who completed a center-based CR program.

Design & Procedures

Target-CR will enroll up to 30 adults for this pilot study to identify 26 individuals eligible for participation. The following aims will maximize the value of the data:

Aim 1. To identify factors and triggers influencing PA participation after structured CR among older adults who have enrolled in a center-based CR program.

Aim 2. To compare the effects of a targeted health coaching intervention versus standard care immediately following CR on PA maintenance and functional fitness.

Study Procedures

Study visits are divided into five phases as detailed below.

Phase 1 – Screening/Consent: The Screening/Consent Phase will be completed virtually or in-person in 1-2 visits depending on scheduling and will take a total of about 1 to 2 hours. During this phase, the participant will be asked to do the following:

- Discuss details of the study with study staff and review/sign the consent form
- Provide contact information
- Review medical history
- Complete Mental Health Screening Questionnaire

Phase 2 – Initial Testing: The Initial Testing Phase involves one in-person visit and will take a total of about 2.5 hours. During this phase, the participant will be asked to do the following:
Qualitative Interview – Participants will complete a qualitative interview assessing factors and triggers influencing current physical activity participation. These sessions will be recorded as audio files for future reference by study staff.

- Measure height and weight
- Review medications
- Complete Paffenbarger Physical Activity Questionnaire
- Senior Fitness Test – Participants will perform a chair stand test, arm curl test, chair sit and reach test, back scratch test, 8-foot up and go test, and step-in-place test.
- Dispense Garmin activity monitor

Phase 3 – Randomization: Upon completion of the Screening/Consent and Initial Testing phases, participants will be randomized to one of two groups:

- Targeted Health Coaching (THC) Group – ~50% of study participants will be in the THC group.
- Standard Care (SC) Group – ~50% of study participants will be in the SC group.

Phase 4 – Intervention: The Intervention Phase will last about 3 months and will be different for the THC and SC groups:

- THC Group – Participants in the THC group will receive an exercise prescription (steps/day) based on their last cardiac rehabilitation session exercise prescription. Participants will be provided a Garmin wearable device to track steps/day. Additionally, participants will partake in 6 virtual or in-person health coaching sessions lasting approximately 30-60 minutes in duration. These sessions will take place approximately every other week during the 3-month intervention period.
- SC Group – Participants in the SC group will receive an exercise prescription (steps/day) based on their last cardiac rehabilitation session exercise prescription. Participants will be provided a Garmin wearable device to track steps/day. Additionally, participants will be provided with a single virtual or in-person education session, lasting approximately 30 minutes, at the beginning of the 3-month intervention period.

Phase 5 – Recurrent Questionnaire Testing: The Recurrent Questionnaire Testing Phase will occur throughout the duration of the 3-month intervention period. The questionnaire will be used to gather information on factors and triggers influencing PA maintenance. The questionnaire will be administered remotely or in-person based on participant preference at weeks four, eight, and twelve during the 3-

month intervention period. The questionnaire will be available in paper form or online and will take approximately 10 to 15 minutes each time it is completed.

Phase 6 – Follow-up Testing: Follow-up testing includes the same tests completed during the initial testing phase, excluding the qualitative interview. The repeated tests will be completed in one in-person visit that will take a total of 1 to 2 hours.

Selection of Subjects

Inclusion Criteria:

- Willingness to provide informed consent to participate in the Target-CR Study
- Must be able to read and speak English well enough to provide informed consent and understand instructions
- Age ≥60 years
- Diagnosed with coronary heart disease
- Of adequate clinical stability to allow study participation
- Own a smartphone device for application download

Exclusion Criteria:

- Planned relocation during the 5-month study period
- Medical procedure scheduled within the 5-month study period that may limit physical activity (i.e., joint replacement)
- Decompensated heart failure
- Heart failure – New York Heart Association class IV
- Severe pulmonary hypertension
- End-stage renal disease
- Cardiac transplantation
- Impairment from stroke, injury, or other medical condition that would prevent participation in the intervention
- Dementia that would prevent participation in the intervention and following study protocols
- Any other illnesses that, in the opinion of the local clinician, would negatively impact or mitigate participation in and completion of the protocol
- Psychiatric illness (self-report and screening)
- Hospitalization for any psychiatric condition within one year (self-report)
- Integrative Health Coaching Mental Health Screening Questionnaire score >4 (screening), if not currently in treatment
- Participation in an inpatient substance abuse rehabilitation program within one year
- Exclusion criteria will primarily be identified by way of a phone screen process conducted by a designated member of the study team; however, medical record review may be used to confirm the presence/absence of certain medical conditions listed as inclusion/exclusion criteria.

Subject Recruitment and Compensation

Potential subjects for this study will be recruited from the Duke Cardiopulmonary Rehabilitation clinic at Croasdaile. Potential participants will initially be identified by study staff and cardiac rehab staff familiar with the study. The study may be introduced to the potential participant during the course of their cardiac rehabilitation program or they may be contacted by phone, email or snail mail after they have completed their cardiac rehab program.

The PI will coordinate with the Clinical Operations Supervisor and Manager of the Cardiopulmonary Rehabilitation clinic to identify patients approaching the completion of their cardiac rehabilitation program who may be interested in the research study. If the individual meets most of the inclusion/exclusion criteria, the subject will be invited to attend a private study information session conducted by the PI or designated member of the study team to learn the details of the study. We will allow up to 60 minutes for the subjects to read the consent, ask questions and decide whether or not they are willing to participate in the study.

Participants will receive compensation for completing each scheduled study visit for a maximum of $150. In addition, participants will keep the wearable device ($165/device) they were provided for the intervention.

Data Analysis & Statistical Considerations

The Target-CR study will collect both qualitative and quantitative data, utilizing demographic, behavioral/psychosocial, activity, and functional fitness measurements. This is a pilot intervention trial, thus the number of subjects randomized will be ~26 across the 1-year funding period with a target of 13 participants in each group. Given this is a pilot grant, this data will be utilized for future study development of effect sizes and power.

Data from Aim 1 will be utilized in two ways:

- To inform the health coach what the current barriers and triggers influencing the participant's ability to perform physical activity after structured CR. This will be discussed with the participants randomized to the THC group in their initial health coaching session.
- Develop the common themes of factors and triggers reported in this population. We will conduct a thematic analysis utilizing the baseline qualitative interview transcripts and two personnel. The personnel assigned for thematic interpretation will follow a step-by-step process: 1) familiarization with the transcript data; 2) develop an initial set of codes representing observed data meanings and patterns; 3) collate data excerpts by code; 4) group codes into potential themes; 5) review and revise themes with co-transcribing personnel. From this, we will assess the most common baseline self-reported factors and triggers influencing PA participation. Analyses will be focused on descriptive data including frequencies of the common themes identified.

For Aim 2, our statistical approach will be as follows:

We will classify maintenance in two ways – 1) using mean steps/day over the 3-month intervention period; and 2) calculated as (steps/day completed) divided by (steps/day prescribed) times 100 and average this metric over the 3-month study period. Data will be analyzed using Intent-to-Treat and statistical significance will be set at 0.05. We will assess the following:

Primary outcome: Within-group differences in maintenance metrics and Senior Fitness test scores (THC group n=13 vs. SC group n=13). Using 80% power at alpha level 0.05, we should be able to detect an effect size around 0.62 for analyses of pre-to-post change scores using steps per day as the primary outcome using paired t-tests, paralleling published findings.

Secondary outcome: Between-group differences in maintenance metrics and Senior Fitness Test scores (13 vs. 13)