A Technology-Based Adaptive Intervention to Promote Cardiovascular Health after Completion of Cardiac Rehabilitation (Mobile4Heart)

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Background

While numerous studies have examined barriers to cardiac rehabilitation (CR) and patient outcomes immediately following CR, few have investigated long-term adherence to secondary prevention behaviors and outcomes of patients who complete CR. Ongoing maintenance of physical activity after CR is an important part of preventing secondary cardiac events in patients with ischemic heart disease. However, it is well-documented that after discharge from a CR program, many patients return to a sedentary lifestyle. Applying mobile heath strategies as a method of increasing adherence by providing education and support holds much promise.

Close monitoring after CR completion has been shown to be an effective strategy for improving patient adherence to program recommendations. In addition, interventions involving continued communication between patient and health care provider post-immediate discharge decreases hospital readmissions. Post-CR monitoring through mobile technology may be an effective strategy for improving patient adherence.

Our central hypothesis is that monitoring and promotion of health-related behaviors by increasing patient-provider communication through a mobile device after discharge from a CR program increases adherence to a 'heart healthy' prescription over an extended period of time. Through a mixed-methods study design, we will examine the efficacy of mobile technology to promote secondary prevention behaviors including physical activity as an extension of an outpatient CR program. The intervention includes use of a mobile phone app (MVN) for physical activity and healthy lifestyle behaviors such as medication adherence, nutrition, stress management, smoking cessation, etc. We will apply an adaptive design that accounts for varying levels of adherence from baseline to 2 months (N=60).

The specific aims of this randomized clinical trial comparing the intervention group (MVN app and Fitbit) to the control group (pedometer only) will:

1. Evaluate differences in physical activity.
   H_o: The MVN group will have more physical activity (measured by an activity tracker) and better 6 minute walk tests compared to Usual Care.
2. Determine differences in depression and self-efficacy to continue exercise.
   H_o: The MVN group will have less depression and higher self-efficacy compared to Usual Care.
3. Assess usability and satisfaction with using a smartphone application for participation in a post-CR cardiac health program.
   H_o: The MVN group will report high usability and satisfaction with the MVN app.

Study Design
Mixed methods study with a randomized controlled trial and usability study with individual interviews.

Selection of Subjects / Setting
We plan to enroll up to 60 participants from John Muir Medical Center (JMMC). JMMC is a non-profit, community hospital system consisting of two large medical campuses and 3 CR locations (Brentwood, Concord, Walnut Creek). Participants will be randomized through a computer program to either the intervention group (Mvn app) or control group (usual care).

Inclusion criteria:

1. ≥18 years of age
2. History of cardiovascular disease that qualified patient for cardiac rehabilitation (i.e., ischemic heart disease, history of unstable angina, systolic heart failure with ejection fraction =/< 35% and Class II to IV symptoms, coronary artery bypass graft surgery, valve replacement)
3. Within eight weeks of completing outpatient cardiac rehabilitation

Exclusion criteria:

1. Cognitive impairment
2. Lack of English proficiency/literacy
3. Clinically conditions including:
    a. Unstable arrhythmias, aortic stenosis, thrombophlebitis, dissecting aneurysm or symptomatic anemia
    b. Active infection
    c. Uncontrolled hypertension: resting diastolic >100 mmHg, systolic >180 mmHg
    d. Decompensated heart failure NYHA Class 3-4
    e. Current unstable angina (No chest pain for a month)
    f. 2nd or 3rd degree heart block
    g. Uncontrolled high grade exercise-induced ventricular ectopy-hemodynamically stable

Both Usual Care and MVN Intervention groups

- Upon completion of the CR program, participants will be given their standard instructions and educational handouts
- Individuals will meet with their nurse or other health care provider in an exit interview to review their exercise progress, discuss their future exercise goals and plans, and receive referrals to additional medical services they might need after discharge from the program.
- Baseline clinical measurements, including a 6 minute walk
- An activity tracker will be given to each participant. Participants randomized to the intervention group will receive a Fitbit and instructions on how to sync their data. Participants randomized to the control group will receive a basic pedometer with a paper diary to record their step counts each day.
- Questionnaires will ask about health care utilization, physical activity, quality of life, and self-efficacy.
- The clinical measurements and psychosocial questionnaires will be taken again at 2-months.
- Participants will be paid $50 in the form of a gift card for each month they complete. Participants that participate in the individual interview will receive an extra $25 card. Participants in the intervention group will be allowed to choose whether they would like to keep the Fitbit or receive the gift cards. Participants in the control group will be allowed to keep their pedometer and will also receive the gift cards. If a participant withdraws from the study before month two, they will be asked to return their devices.

MVN Group Only:

- During the final week of outpatient cardiac rehabilitation, the MVN application will be downloaded on to the participant's smartphone or tablet. If the participant does not have a smartphone or tablet, a smartphone will be provided to them for the duration of the study. The participant will be required to return the smartphone at the end of their participation in the study.

- Each participant's individualized instructions for post-cardiac rehabilitation will be integrated into the MVN application including daily medication reminders, physical activity prompts, educational materials, and patient-reported outcome assessment of behavior and psychosocial status.
- Text messages or phone calls will be used on an ad hoc basis to provide positive feedback to the participant. Frequency of messages will depend on adherence level (adaptive intervention).
- We will apply an adaptive intervention: a sequence of decision rules that specify how the intensity or type of treatment should change depending on the patient's needs. We are developing sequential, multiple assignment, randomized trials (SMART) to enable scientists to build adaptive interventions. Interventions that adapt at the right times can improve participant outcomes (e.g., intensifying for people who do not respond to the initial treatment) while decreasing the cost and burden of the intervention (e.g., stepping down treatment for responsive participants).
- Regular messages will be based on the American Heart Association Simple 7 Principles (3 times a week on random days and between 9am-6pm). Examples include prompting participants to engage in physical activity, track their medicine at certain times of the day, engage in healthy eating habits, or provide participants with a homework assignment to reinforce educational content regarding risk management.
- Any patient reports of chest pain or acute shortness of breath will immediately prompt an automated message on the app to call 911 or their cardiologist/primary care provider. The consent will specify the research members including nurse will only monitor app use but not play an integral role in provided one-on-one coaching.
- A registered nurse or nurse practitioner will be available to triage patient entries once a day (mid-afternoon). Two-way messaging between the participant and the nurse will be available to provide opportunities to answer more specific questions.
- Technical support will be provided by Moving Analytics who has developed and own the MVN app.
- We will assign patients to a group of 6 individuals to offer social support and a "buddy system", which will be a feature in the secure MVN app. Ideas for these groups may be sharing exercise tips/goals/progress, recipes, etc. The groups will be formed with consecutive enrollment. The function of the social group will be iterative with regular feedback from the group members that will be sent to the research assistant to improve this feature.
- Up to six participants from the intervention group will be asked to complete an individual interview to assess the feasibility of and their satisfaction with the mobile app over the two month period.

Study Activities:

Activity	Usual Care	MVN	Intervals
MVN mobile app		X	Intervention period
Educational materials	X	X	Baseline
Activity tracker	X	X	Intervention period
Step count diary	X		Intervention period
Physical activity prompts		X	Intervention period
Nurse feedback (through app or by phone)		X	Intervention period
Psychosocial questionnaires	X	X	Baseline, Month 2

Blood pressure/heart rate	X	X	Baseline, Month 2
Weight	X	X	Baseline, Month 2
6 minute walk	X	X	Baseline, Month 2

Intervention period: 2 months