PHYSICAL ACTIVITY ASSESSMENT, PROMOTION AND MONITORING IN A PREVENTIVE CARDIOLOGY CLINIC: A PILOT STUDY

Principal Investigator:	Margaret M. McCarthy, PhD, RN, FNP-BC Rory Meyers College of Nursing 433 First Avenue New York NY 10001 mmm529@nyu.edu 212-992-5796
Additional Investigators: [PI at additional sites, etc. as applicable]	Co-I Stuart Katz, MD NYU Langone Health Cardiology 530 1st Avenue, New York, NY 10016 Stuart.katz@nyulangone.org 646-501-0119
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1.0	April 21 2020	Final version
2.0	February 5 2021	1. Modification to data collection methods 2. adding Spanish language surveys and consents
3.0	January 18, 2022	3. Revision to replacement of subjects section
4.0	May 25 2022	4. Adding the nurse practitioner from the Center for Prevention of CVD (study site) to the interviews

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), 21 CFR Parts 50, 56, 312, and 812 as applicable, any other applicable US government research regulations, and institutional research policies and procedures. The International Conference on Harmonisation ("ICH") Guideline for Good Clinical Practice ("GCP") (sometimes referred to as "ICH-GCP" or "E6") will be applied only to the extent that it is compatible with FDA and DHHS regulations. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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List of Abbreviations

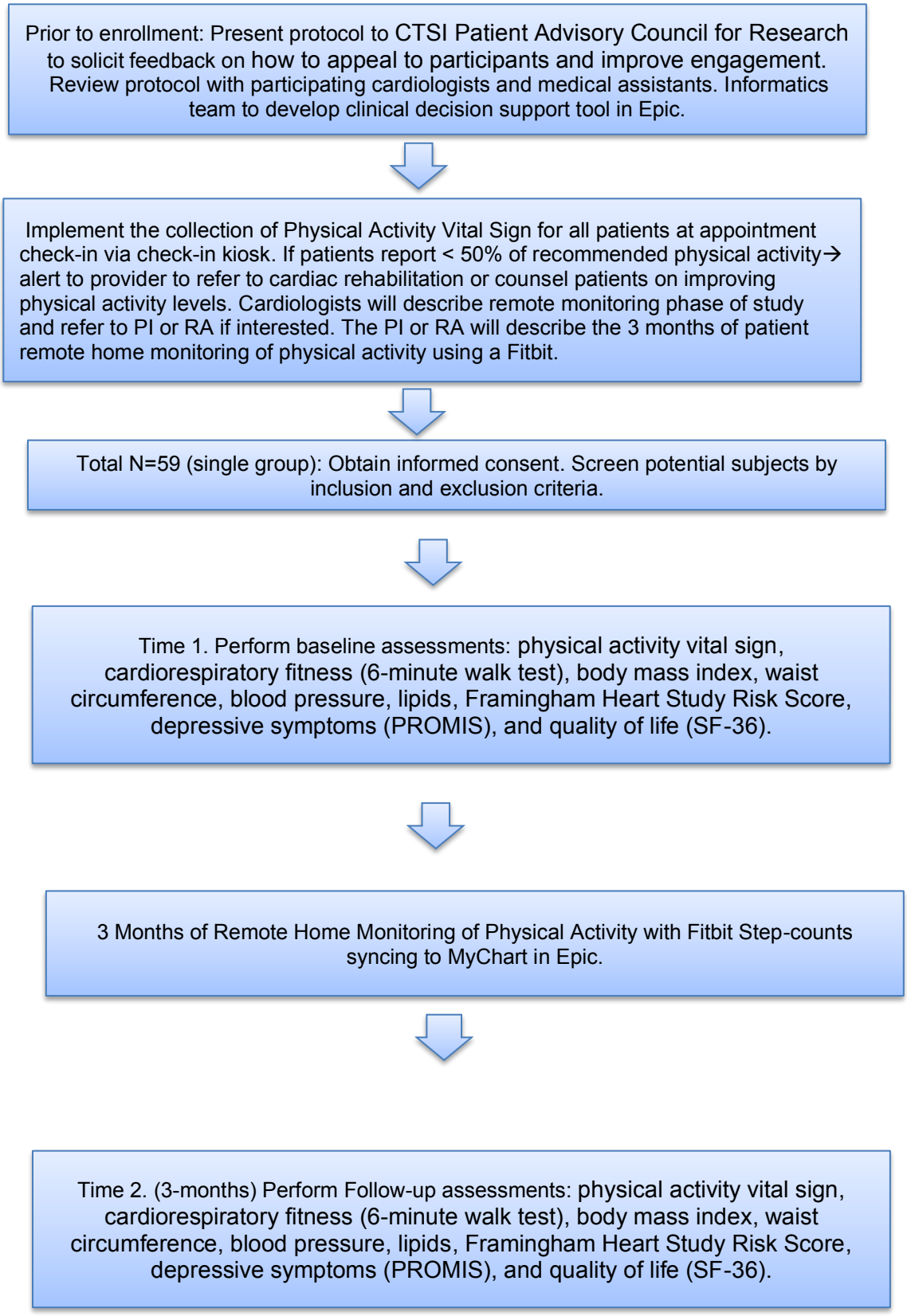
PA: physical activity.
PAVS: physical activity vital sign
EHR: electronic health record

Protocol Summary

Title	Physical activity assessment, promotion and monitoring in a preventive cardiology clinic: a pilot study.
Short Title	PAVS in Cardiology
Brief Summary	This is a pilot study implemented physical activity assessment, promotion and monitoring in patients. Patients will be assessed by the physical activity vital sign (PAVS) during check-in for their appointment. During their visit with the cardiologist, a clinical decision support tool will alert the cardiologist to patients achieving low (<50% of recommended) physical activity. The cardiologist may refer the patient to cardiac rehabilitation if appropriate and/or counsel them to increase their physical activity levels. The patients may opt to enroll in the monitoring phase of the study. They will be given a Fitbit pedometer and their Fitbit account can sync to their MyChart account. After that sync, the patients step counts will be available for their cardiologists to review as needed.
Phase	Clinical study Phase 1
Objectives	There are two objectives for this study. Objective 1: Test the preliminary clinical efficacy of a PA promotion intervention on patients' cardiovascular risk profile (PA, cardiorespiratory fitness, BMI, waist circumference, blood pressure, lipids and Framingham Heart Study Risk Score). Objective 2: Evaluate the implementation feasibility of the PA promotion intervention. The Practical, Robust Implementation and Sustainability Model (PRISM) will be used to guide the implementation, and evaluate the intervention's reach, efficacy, adoption, implementation and maintenance for both HCPs and patients, in addition to qualitative feedback on acceptability.
Methodology	This study is a pilot feasibility study implementing physical activity assessment, promotion and monitoring in a cardiology clinical setting.
Endpoint	The primary endpoints include: physical activity levels (step-counts), cardiorespiratory fitness, BMI, waist circumference, blood pressure, lipids and Framingham Heart Study Risk Score For our secondary endpoints we will conduct a process evaluation we will evaluate the intervention's reach, efficacy, adoption, implementation and maintenance using The Practical, Robust Implementation and Sustainability Model (PRISM).
Study Duration	A study duration of three years will include development of the clinical decision support tool, training clinic staff on intervention, recruitment, and data collection and analysis.
Participant Duration	Each participant will be in the study for 3 months. Baseline data collection is at Time 1; followed wearing the Fitbit for 3 months; and follow-up data collection at Time 2 (3 months).

Population	We will recruit 59 males and females age > 18 being seen in the NYU Langone Center for Prevention of Cardiovascular Disease (4F). Participants have cardiovascular disease or cardiovascular disease risk factors.
Study Site	NYU Langone Center for Prevention of Cardiovascular Disease (4F)
Number of participants	59 participants in one site
Description of Study Agent/Procedure	The intervention consists of physical activity assessment promotion and remote home step-count monitoring in a clinical cardiology center.
Reference Therapy	This is a one-group study. There is no comparison group.
Key Procedures	Key procedures include assessment of physical activity; counseling by the cardiologist if physical activity levels are <50% of recommended; remote home monitoring via Fitbit sync to MyChart.
Statistical Analysis	Paired t-tests will be used to assess changes in average PA from week 2 to three-month follow-up using PAVS and Fitbit Zip data. Paired t-tests will be used to assess changes in readiness to change number, the 6MWT, BMI, waist circumference, systolic and diastolic BP, lipids, and Framingham Heart Study Risk Score. To assess meaningful improvement in CRF, we will report the percent of participants who achieve a clinically important difference of 25 meters in the 6MWT. Bivariate analyses will compare all CVD risk factors, as well as other potential confounders (e.g. age, sex, race/ethnicity, depressive symptoms, comorbidities), between those who achieve PA recommendations and those who do not. Preliminary effect sizes of change in PA (step counts) will be generated following the Physical Activity Change Detection (PACD) approach. Aim 2 is to conduct a process evaluation of the intervention. Implementation data will be evaluated using the PRISM framework.

Flow diagram Single Group



1 Key Roles

PI: Margaret McCarthy, PhD, RN, FNP-BC,
Assistant Professor
NYU Rory Meyers College of Nursing.
433 First Ave
NY, NY, 10010
212-992-5796
mmm529@nyu.edu

Mentor for K23 Mentored Patient-Oriented Research Career Development Award

Co-I Stuart Katz, MD
NYU Langone Health
530 1st Avenue, Skirball 9N
New York, NY 10016

NIH Point of Contact: NINR Program Director: Amanda Price, PhD
National Institute of Nursing Research National Institutes of Health
31 Center Drive, Room 5B03
Bethesda, MD 20892-2178
301-496-0207
Amanda.Price2@nih.gov

2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature and Rationale

Physical inactivity is the fourth leading cause of death worldwide.[1] Despite the numerous benefits of routine physical activity (PA) (e.g., lower risk for heart disease, stroke, type 2 diabetes, and depression), only half of U.S. adults achieve the recommended levels of PA: [2] a minimum of 150 minutes/week of moderate-to-vigorous PA.[3] Meeting PA guidelines could result in significant improvements in body fat, body mass index (BMI), blood glucose, and cardiorespiratory fitness.[4] Improving these risk factors would lower the risk of cardiovascular disease (CVD) and stroke, the two leading causes of death in the U.S.[5]
The American Heart Association (AHA) and American College of Cardiology have recommended that healthcare providers (HCPs) counsel patients on adopting PA guidelines. [6] While PA counseling trends are improving, little has been done in terms of routinely assessing PA in a standardized way.[7] The first step in promoting PA is to assess patients' current habits.[8] A 2018 AHA scientific statement on assessing and promoting PA in healthcare settings suggested use of the electronic health record (EHR) for self-report and activity trackers (e.g. Fitbit) for monitoring. [9]

The purpose of this feasibility study based on the Chronic Care Model[10] is to address the low levels of PA in adults by testing a PA promotion intervention based on an EHR clinical decision support tool. This tool will facilitate HCPs in assessing and promoting patients' PA, and in turn patients will be involved in negotiating ways of increasing PA, which may improve their CVD risk profile. Clinical decision support tools have been used to screen for CVD risk and can play an important role in improving patient outcomes, particularly when the patient is involved.[11] In

response to the major health problem of physical inactivity, the 3-question physical activity vital sign (PAVS) was developed to assess PA duration and intensity.[12,13]

According to the AHA physical inactivity is a major modifiable risk factor for CVD.[14] Despite the strong evidence regarding the hazards of physical inactivity half of U.S. adults do not achieve the recommended levels of PA.[2] Moving individuals out of the lowest category of cardiorespiratory fitness results in the greatest reductions in all-cause mortality.[39] and can be achieved with increased PA.[4] HCPs are in a position to influence this process by routinely counseling patients on this important CVD risk factor.
The U.S. 2018 PA Guidelines for Americans recommends 150 minutes/week of moderate intensity PA or 75 minutes/week of vigorous intensity PA, or an equivalent combination of both, with vigorous activity weighted twice that of moderate.[3] Improving rates of HCP counseling on PA is one of the objectives of Healthy People 2020.[15] The U.S. Preventive Services Task Force recommends referring adults with CVD risk factors seen in primary care to behavioral counseling interventions to promote PA for CVD prevention.[16] HCPs can be instrumental sources of health guidance for their patients, but they do not routinely counsel patients on PA.[15,17] PA counseling (face-to-face or by phone) offered on multiple occasions in primary care settings resulted in improved PA levels at 12 months in previously sedentary adults.[18] Primary care behavioral counseling for CVD prevention was also associated with a 35-minute/week (95% CI: 22-47) improvement in PA levels.[19] While the use of brief one-time counseling has not been shown to be enough to effect long-term change, routine office-based screening and advice coupled with ongoing support has been effective in improving PA.[17] The AHA recommends the use of goal setting, self-monitoring, follow-up, and feedback when promoting PA.[20] In adults with CVD, wearing an activity tracker coupled with PA advice resulted in greater improvements in cardiorespiratory fitness (CRF) as compared to those not wearing an activity tracker.[21] This proposal will address the gap in routine PA counseling with an intervention that standardizes the assessment, promotion and monitoring of PA in the clinical setting through utilization of the EHR.
The PAVS is a valid clinical tool to assess PA[22] which can be the basis for PA promotion and counseling. Several large healthcare systems have implemented the PAVS for assessment of PA.[7] Data from almost 20 hospitals indicate the PAVS has strong face and discriminant validity (between groups of patients with differing activity levels).[23] However, despite strong endorsement from the AHA,[6] many HCPs continue to describe barriers to PA counseling, including lack of time, required counseling skills, reimbursement and routine screening of PA.[24] This proposed intervention, embedded in the EHR, expands upon the current use of the PAVS and may help to overcome the existing barriers to addressing PA. In a systematic review of behavior change techniques used in eHealth PA interventions in adults with CVD, providing information on health consequences, goal-setting and self-monitoring were the three most common behavior change techniques used.[25] Our intervention will educate the patient on PA recommendations, help them set goals, and employ a self-monitoring tool that has the added benefit of PA data syncing to the EHR.

2.2 Potential Risks & Benefits

2.2.1 Known Potential Risks

Potential risks associated with this research are fatigue from data collection, inconvenience caused by the need to schedule visits, and loss of confidentiality. There are also inherent risks to participating in physical activity. This will be minimized with the appropriate clinical judgement of the physician in the physical activity promotion process. There is a slight risk of loss of confidentiality in the data collection from the electronic health record, but this will be minimized

by the collection of de-identified data only. There are some risks during the fingerstick blood collection of lipids and glucose. With respect to fingerstick blood collection in general (requiring a small sample size of 40μL of blood), some participants may experience temporary discomfort. Some may bruise. Extremely rare risks associated with a fingerstick are bleeding, feeling lightheaded, hematoma, or infection. This risk will be minimized by following established hospital protocols for fingerstick blood collection.

2.2.2 Known Potential Benefits

There may not be direct benefit to patient subjects of this study. However, subjects may increase their physical activity levels enough to reduce their cardiovascular risk by reductions in weight, blood pressure or hemoglobin A1c or improvements in lipids. Subjects may gain of sense of contribution to the process of improving physical activity assessment and promotion.

3 Objectives and Purpose

The purpose of this feasibility study is to implement a physical activity intervention in a preventive cardiology clinic to assist HCPs in assessing, promoting and monitoring their patients' PA.

3.1 Primary Objective

Aim 1: Test the preliminary clinical efficacy of a PA promotion intervention on patients' cardiovascular risk profile (PA, cardiorespiratory fitness, BMI, waist circumference, blood pressure, lipids and Framingham Heart Study Risk Score).

3.2 Secondary Objectives (if applicable)

Aim 2: Evaluate the implementation feasibility of the PA promotion intervention. The Practical, Robust Implementation and Sustainability Model (PRISM)[26] will be used to guide the implementation, and evaluate the intervention's reach, efficacy, adoption, implementation and maintenance for both HCPs and patients, in addition to qualitative feedback on acceptability.

4 Study Design and Endpoints

4.1 Description of Study Design

This is a one-group, pre-post, single-center phase 1 clinical trial feasibility study based on the Chronic Care Model.[10] This study has two phases.
Phase 1: The PI will train the medical assistants on the collection of the PAVS (in case the patient had not entered the kiosk data). The PI will meet the CTSI Patient Advisory Council for feedback on how to appeal to participants and improve engagement. The PI will review the plan and the American College of Sports Medicine exercise screening guidelines with the cardiologists and elicit final questions or feedback.[27]
Phase 2: Each patient in the Center is seen by the medical assistant for the assessment of their vital signs and confirmation of the PAVS completion in the check-in kiosk. During the patient's visit with the cardiologist, an EHR decision support tool will be presented as an alert to the cardiologist for patients who are not achieving at least **50%** of recommended PA levels. This threshold was chosen for two reasons. A higher threshold (e.g. < 90%) would create many more alerts for the cardiologist and possibly lead to 'alert fatigue'. Second, <u>our focus will be on the least active patients</u>. The cardiologist will choose and acknowledge the PA promotion recommendations they discussed with the patient: #1) patients with a diagnosis appropriate for cardiac rehabilitation[28] will be given a suggested verbal and/or electronic referral to cardiac

rehabilitation services; and/or #2) patients who are not eligible for a cardiac rehabilitation referral (or do not want to attend) will be given a verbal recommendation to start engaging in PA, or increase intensity and/or duration of PA with an agreed upon goal for the next 3 months. Patients who should not increase PA due to certain medical diagnoses (e.g. aortic stenosis, unstable angina) will be excluded. The cardiologist will inform these patients about the remote PA monitoring.
Upon contact, the PI will describe the study, and if patients agree to participate, obtain consent, enroll the participant and collect baseline data. The PI will give participant a Fitbit Zip, set up an account with a study ID and ask them to wear the Fitbit Zip during all waking hours. NYU Langone has implemented integration of Fitbit Zip data into the EHR which requires the patient to sync their Fitbit account to the patient portal (MyChart) once and step counts will then sync to EHR and can populate the cardiologists' note.

4.2 Study Endpoints

4.2.1 Primary Study Endpoints

For this feasibility study, we will implement the intervention (PA assessment using the PAVS; counseling by the cardiologists; and PA monitoring of patients wearing a Fitbit) for 12 months. Patient subjects who enroll in the PA monitoring will wear the Fitbit for 3 months.
Primary endpoints include: patients' cardiovascular risk profile (PA, cardiorespiratory fitness, BMI, waist circumference, blood pressure, lipids and Framingham Heart Study Risk Score).

4.2.2 Secondary Study Endpoints

We will evaluate the implementation feasibility of the PA promotion intervention. The Practical, Robust Implementation and Sustainability Model (PRISM)[26] will be used to guide the implementation, and evaluate the intervention's reach, efficacy, adoption, implementation and maintenance for both HCPs and patients, in addition to qualitative feedback on acceptability.

5 Study Enrollment and Withdrawal

Cardiologists from Preventive Cardiology that have agreed to participate in this pilot study will have the study described and will sign an informed consent. Patient participants are those patients being treated in Preventive Cardiology. Their cardiologist can inform them of the study and given them the PI's contact information or introduce them to the PI or RA if they are present in the clinic. All patients who achieve < 50% of recommended PA and do not meet any of the exclusion criteria will have the study described to them. The PI or RA will confirm inclusion and exclusion criteria.

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:
Adult patients in the Center who are age 18 and above will be assessed with the PAVS as part of routine care. To enroll in the home monitoring of PA:

1. Patients must achieve < 50% of PA recommendations according to PAVS screening questions
2. Have a cellular phone with data plan or a computer to sync Fitbit data
3. Speak English or Spanish
4. Be willing to wear a Fitbit Zip for 3 months

5.2 Exclusion Criteria

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

1. Adults with a physical disability or medical diagnosis limiting their ability to exercise (e.g. wheelchair bound, aortic stenosis, unstable angina)
2. Planned surgery within three months
3. Those with decisional incapacity therefore unable to comply with study requirements (i.e. related to cognitive deficits or psychiatric diagnosis)
4. Pregnant or breastfeeding women.

5.3 Vulnerable Subjects

No vulnerable subjects are included in this study.

5.4 Strategies for Recruitment and Retention

Appropriate patients will be invited to participate by the cardiologist during the visit. They will be given a study information flyer and contact information of the PI, who will screen for inclusion/exclusion criteria. The informatics team at NYU Langone may also provide a list of patients on a monthly basis who achieve < 50% of recommended PA. This will facilitate recruitment in the event of virtual visits when the patient fills out the PAVS via MyChart.
The PI will contact the individual cardiologist by email to inform them of the intent to recruit their patient into the remote monitoring study. If the cardiologist has any objections, they can inform the PI. The 'Friendly' Letter to the Provider is attached. If met, the PI will enroll them in the study. If the PI is not immediately present in the Center, the interested patient will be given the PI contact information. The PI will also access the expertise of the NYU School of Medicine CTSI Recruitment and Retention Unit as needed for both recruitment and retention. Description of the study and consent for participation will take place in one of the offices in the Preventive Cardiology Center. The PI may also describe the study over the phone to patients who call after being referred by their cardiologist.
Retention strategy: While subjects are wearing the Fitbit they will be contacted the first week to check in and see if they have any questions. They will be contacted as needed over the 3 months if the PI or RA notice they are not wearing the Fitbit daily to troubleshoot ideas to improve their Fitbit wear time.
Our target sample size is 59 subjects. Our target is to enroll 2-3 subjects per week. When the PI or RA is not present in the clinic, a study flyer will be left with the cardiologists and staff.

5.5 Participation

Baseline data collection will take place on the day of consent. Each subject will be asked to wear a Fitbit pedometer for 3 months. Follow-up data collection will take place as close to the 3-month date as possible.

5.6 Total Number of Participants and Sites

This is a single site study conducted at the Preventive Cardiology Center (4F). All 59 subjects will be enrolled at this site.
Recruitment will end when approximately 59 subjects are enrolled. It is expected that approximately 59 participants will be enrolled in order to produce 47 evaluable subjects. We have anticipated approximately 20% attrition.

5.7 Participant Withdrawal or Termination

5.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

5.7.2 Handling of Participant Withdrawals or Termination

Subjects that withdraw from the study will continue to receive usual care from their cardiologist. Every effort will be made to capture the reason for subject withdrawal and to ascertain if any adverse events or serious adverse events occurred, which would be immediately reported to the IRB and study sponsor. Subjects who fail to comply with baseline data collection activities after signing the consent, despite several efforts to contact the subject with no response from the subject, will be replaced.

5.8 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the IRB and funding agency. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.
Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

Study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the sponsor, IRB and/or FDA.

5.9 Study Behavioral or Social Intervention(s)

This study is testing a behavioral intervention that includes assessment (using PAVS), promotion (by the cardiologists) and monitoring of PA (by Fitbit) for patients seen in Preventive Cardiology Center.

5.9.1 Administration of Intervention

This intervention will be incorporated into clinical care in the Preventive Cardiology Center. The patient will answer the 3-question PAVS: 1) “On average, how many days per week do you

engage in PA or exercise?"; 2) "On average, how many total minutes of PA or exercise do you perform on those days?"; and 3) "Describe the intensity of your PA or exercise (light=casual walk, moderate=brisk walk, or vigorous=jogging)" in the EHR when they check in for their appointment. During their clinical visit with their cardiologist, if they achieve < 50% of recommended PA on average, the cardiologist will make a referral to cardiac rehabilitation (if appropriate) or make a PA recommendation to increase intensity or duration of PA. The patient can choose to participate in the remote monitoring using the Fitbit activity monitor. The Fitbit data will sync to their MyChart account in the EHR.

5.9.2 Procedures for Training Interventionalists and Monitoring Intervention Fidelity

The PI will conduct intervention fidelity checks on a monthly basis. The PI will be given a monthly report generated from the Epic analyst team which will include data on completion of the PAVS questions and the cardiologists' referral system for PA. If use of the PAVS or referral system is < 80% for the month, the PI will meet with the medical assistant or cardiologist to discuss strategies to improve use. If the patient subject does not wear the Fitbit for at least 5 days per week, they will be contacted by the PI or RA to discuss strategies to improve adherence.

5.9.3 Assessment of Subject Compliance with Study Intervention

If the patient subject has less than 5 days of valid Fitbit wear (less than 10 hours/day) for the week, the PI or RA will call the patient subject and discuss strategies to improve adherence. We will use utilize the resources of the NYU Recruitment and Retention Unit as needed. We will follow up with the patient subjects with the method they prefer (phone, email, text) for Fitbit data collection and to schedule the follow-up data collection at 3 months.

6 Study Procedures and Schedule

Baseline visit: After their visit with their cardiologist, interested patient subjects will have the study described and consent and enrollment in the study if desired. Baseline data collection will take place. For the next 3 months the patient subject is asked to wear the Fitbit and sync to their app on their phone. At 3 months patient subjects will return to the clinic for follow-up assessment.
A sample of 10 patient subjects will be asked to provide feedback about the study at this follow-up visit. A semi structured interview guide will be used to obtain feedback about the intervention from their perspective. Upon study completion, qualitative interviews using a semi-structured interview guide with the three cardiologists and the one nurse practitioner in the Center who works with one of the cardiologists will explore the acceptability, clinical utility and usability of the implementation.

6.1 Study Procedures/Evaluations

6.1.1 Study Specific Procedures

Phase 1. The PI will train the medical assistants on the collection of the PAVS (in case the patient had not entered the kiosk data). The PI will meet the CTSI Patient Advisory Council for feedback on how to appeal to participants and improve engagement. The PI will review the plan and the American College of Sports Medicine exercise screening guidelines with the cardiologists and elicit final questions or feedback.[29]

Phase 2. Each patient in the Center is seen by the medical assistant for the assessment of their vital signs and confirmation of the PAVS completion in the check-in kiosk. During the patient's visit with the cardiologist, an EHR decision support tool will be presented as an alert to the cardiologist for patients who are not achieving at least **50%** of recommended PA levels. This threshold was chosen for two reasons. A higher threshold (e.g. < 90%) would create many more alerts for the cardiologist and possibly lead to 'alert fatigue'. Second, our focus will be on the least active patients. The cardiologist will choose and acknowledge the PA promotion recommendations they discussed with the patient: #1) patients with a diagnosis appropriate for cardiac rehabilitation[30] will be given a suggested verbal referral to cardiac rehabilitation services; and/or #2) patients who are not eligible for a cardiac rehabilitation referral (or do not want to attend) will be given a verbal recommendation to start engaging in PA, or increase intensity and/or duration of PA with an agreed upon goal for the next 3 months. Patients who should not increase PA due to certain medical diagnoses (e.g. aortic stenosis, unstable angina) will be excluded. The cardiologist will inform these patients about the remote PA monitoring. Upon contact, the PI will describe the study, and if patients agree to participate, obtain consent, enroll the participant and collect baseline data. The PI will give participant a Fitbit Zip, set up an account with a study ID and ask them to wear the Fitbit Zip during all waking hours. NYU Langone has implemented integration of Fitbit Zip data into the EHR which requires the patient to sync their Fitbit account to the patient portal (MyChart) once and step counts will then sync to EHR and can populate the cardiologists' note. Participants will be given the first compensation for their time ($50 gift card) at completion of this baseline visit. One week after enrollment, a follow-up call will be made to the participants to answer questions. The PI will review the PA data weekly to ensure that participants are correctly wearing the Fitbit Zip and data are being downloaded and synced. The PI will make follow-up reminders as needed. Data will be downloaded from each participant's record at the end of three months. At three months, the PI will meet with the participant to collect follow-up data and provide the second incentive of $50. Qualitative interviews to assess the acceptability of the intervention (including previous use of smart devices) will be collected in a purposive sample (n=10) of participants with varying levels of PA and varying degrees of adherence to the Fitbit Zip. The participant may keep the Fitbit.
In the event virtual recruitment and data collection is needed due to Covid-19 restrictions, or to minimize the amount of in-person time involved for the consent, the PI will discuss the study by telephone with the interested patient. If they meet inclusion criteria they will be sent via email an electronic link to the consent on REDCap (REDCap consent link attached). The PI will discuss the study and review the consent with the interested patient by telephone page by page. If the patient is interested in participation, they can electronically sign their consent.

Measures:

Baseline visit after consent and enrollment in the study. Data collection will include:
Physical Activity Vital Sign (PAVS): 3 questions as described above when patients check in for their clinical appointment.
Stages of Change will be assessed with a Readiness to Change Ruler.[31] A straight line is drawn on paper representing the process of change (from 1= 'not ready to change' to 10='already changing').
Cardiorespiratory fitness (CRF) will be measured by the six-minute walk test, a valid and reliable measure for use in field testing of CRF.[32] The 6MWT will be conducted in a quiet hallway using a 30-meter track with standard instructions.[33]
BMI will be calculated by height and weight measured at the time of the Center visit on a balance beam scale.
Waist Circumference will be measured to the nearest inch using standard technique.[34] Blood pressure (BP) will be measured in right arm (unless contraindicated) after sitting for 5 minutes and repeated after a 5-minute interval. Both will be recorded and the average used in analyses.

Total cholesterol, HDL, and triglycerides will be measured by CLIA-waived Alere Cholestech LDX® Analyzer which is certified by the Center for Disease Control's Lipid Standardization Program and Cholesterol Reference Method Laboratory Method Network. This will be measured by a single fingerstick using standard aseptic technique.
The Framingham Heart Study Risk Score (10-year risk) will be calculated using the appropriate risk model based on participants' age, gender, diabetes status and prior coronary heart disease.[35] Two covariates that have an inverse association with PA, depressive symptoms and general health-related quality of life,[36,37] will be assessed.
Depressive symptoms will be measured by the PROMIS Depression Short Form 6a, a reliable (α =.92) 6-item survey with strong convergent validity (α =.72-.84) which assesses negative views of self, social cognition, decreased positive affect and engagement[38] and is also available in Spanish.[39] It will be scored with REDCap auto-score.
General health-related quality of life will be measured by the common data element 36-Item Short Form Health Survey (SF-36) v-1, a reliable measure (α =.90) of physical and mental health with strong criterion validity, which is also available in Spanish.[77-80] PROMIS surveys will be scored using the REDCap auto score for accuracy.
Clinical data will be collected from the EHR including potential confounding variables: age, sex, race/ethnicity, primary diagnosis, smoking status, and comorbidities (summarized as continuous data by the Charlson Comorbidity Index).[40]
Sociodemographics, collected using common data elements survey[41] and clinical data from the EHR will be collected at baseline. Fitbit steps will be collected daily for 3 months.
All other data will be collected baseline and at 3 months.
In the event all data collection must be remote or the subject prefers remote data collection, the PI will use baseline data from the electronic health record. The six-minute walk test can be administered remotely via an app on the subject's mobile phone with the distance walked emailed to the PI. BMI and blood pressure taken on the day of their recent clinical visit will be used for baseline data. A measuring tape will be mailed to the participant with instructions on measurement of waist circumference using standard technique. The PI or RA can schedule a videoconference to review the technique of measuring waist circumference. The most recent total cholesterol, HDL, and triglycerides results from the EHR will be used. All other baseline data collection will remain as planned.
If at 3-months remote data collection continues for a subject, the six-minute walk test will be done remotely with the mobile app. BMI and blood pressure will be used from the most recent office visit, as close to the 3-month follow-up date as possible. The patient will measure waist circumference as directed using standard technique and reviewed via video conference. The next available lab data for total cholesterol, HDL and triglycerides will be used. All other 3-month data collection will remain as planned.
If at 3-months in-person data collection is possible, the PI will resume in-person data collection as planned and meet the subject at the preventive cardiology center for data collection.
The PRISM[26] will be used to collect process evaluation data throughout the implementation. This will include data on the reach (proportion that participate in intervention), efficacy (success rate if implemented as designed), adoption (proportion that adopt intervention), implementation (extent to which intervention is implemented as intended) and maintenance (extent to which program is sustained over time) of the PA promotion intervention

6.1.2 Standard of Care Study Procedures

Patient subjects will continue to see their cardiologists for routine clinical care according to their diagnosis.

6.1.3 Screening

Screening: the RA or PI or evaluate each potential patient subject to determine eligibility before the study is described.

6.1.4 Enrollment/Baseline

Enrollment/Baseline Visit (Visit 1, Day 0)

- Obtain informed consent of potential participant verified by signature on study informed consent form or on the REDCap electronic consent form.
- Verify inclusion/exclusion criteria.
- Obtain demographic and clinical information
- Collect baseline data (surveys, fingerstick lipids, six-minute walk test, waist circumference, body mass index)

6.1.5 Final Study Visit

Final Study Visit (Visit 2; 3 months after baseline visit +/- 2 weeks)

- Record adverse events as reported by participant or observed by investigator.
- Collect follow-up data (surveys, fingerstick lipids, six-minute walk test, waist circumference, body mass index)

6.1.6 Withdrawal/Early Termination Visit

If the patient subject terminates the study early and is willing to participate, the PI will collect follow-up data if the patient subject has completed at least 2.5 months of follow-up.

7 Assessment of Safety

7.1 Specification of Safety Parameters

Patient subjects will be counseled on PA by their cardiologist. If they experience any adverse events (for example transient or new chest discomfort) they will be instructed to call their cardiologists immediately. If they experience a severe adverse event (chest discomfort that does not go away or last longer than usual), they will be instructed to activate the emergency response system. The cardiologists will counsel the patients on PA and to monitor for any adverse events during PA.

7.1.1 Definition of Adverse Events (AE)

An **adverse event** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

7.1.2 Definition of Serious Adverse Events (SAE)

Serious Adverse Event
Adverse events are classified as serious or non-serious. A **serious adverse event** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as **non-serious adverse events**.

7.1.3 Definition of Unanticipated Problems (UP)

Unanticipated Problems Involving Risk to Subjects or Others
Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

7.2 Classification of an Adverse Event

7.2.1 Severity of Event

For AEs not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

7.2.2 Expectedness

PI Margaret McCarthy, in consultation with the DSMB will be responsible for determining whether an AE is expected or unexpected. The patient-subject's cardiologist will also be consulted. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study agent.

7.3 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an AE or SAE may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor. All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate RF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE. UPs will be recorded in the data collection system throughout the study.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

7.4 Reporting Procedures – Notifying the IRB

Adverse Events. We do not anticipate any life-threatening adverse events for this proposed research project. In the event an adverse event or serious adverse event occurs, this will be reported immediately to the Data Safety Monitoring Board, the NYU IRB and to the sponsoring agency. A thorough investigation will be initiated, including review of the protocol to insure no undue exposure to risk occurred.

7.4.1 Adverse Event Reporting

Protocol for Adverse Events. If a patient participant experiences an adverse event during physical activity (e.g. experiencing a fall or musculoskeletal injury), they will be instructed to contact their physician immediately. If the event is an emergency that requires immediate medical attention (e.g. chest, jaw or arm pain, severe shortness of breath, rapid heart rate) they will be instructed to activate the emergency response system (e.g. call 911). The PI will monitor all reports of adverse events or serious adverse events related to this intervention. In the event an adverse or serious adverse event occurs, this will be reported immediately to the Data Safety Monitoring Board, the NYU IRB and to the sponsoring agency. A thorough investigation will be initiated, including review of the protocol to insure no undue exposure to risk occurred.

7.4.2 Serious Adverse Event Reporting

The protocol for serious adverse events will follow the same protocol for adverse events. If the event is an emergency that requires immediate medical attention (e.g. chest, jaw or arm pain, severe shortness of breath, rapid heart rate) they will be instructed to activate the emergency response system (e.g. call 911). The PI will monitor all reports of adverse events or serious adverse events related to this intervention. In the event an adverse or serious adverse event occurs, this will be reported immediately to the Data Safety Monitoring Board, the NYU IRB and to the sponsoring agency. A thorough investigation will be initiated, including review of the protocol to insure no undue exposure to risk occurred.

7.4.3 Unanticipated Problem Reporting

Incidents or events that meet the OHRP criteria for UPs require the creation and completion of an UP report form. It is the site investigator's responsibility to report UPs to their IRB and to the DCC/study sponsor. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are SAEs will be reported to the IRB and to the DSMB/study sponsor within 1 day of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB and to the DSMB study sponsor within 2 days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within<insert timeline in accordance with policy> of the IR's receipt of the report of the problem from the investigator.

7.5 Reporting Procedures – Notifying the Study Sponsor

The study clinician will complete a SAE Form within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the SAE Form and submitted to the DSMB/study sponsor within 24 hours of site awareness. See Section 1, Key Roles for contact information.
- Other SAEs regardless of relationship will be submitted to the DSMB/study sponsor within 72 hours of site awareness.

All SAEs will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the adherence to be stable. Other supporting documentation of the event may be requested by the DCC/study sponsor and should be provided as soon as possible.

As a follow-up to the initial report, within the following 48 hours of awareness of the event, the investigator shall provide further information, as applicable, on the unanticipated event or the unanticipated problem in the form of a written narrative. This should include a copy of the completed Unanticipated Problem form, and any other diagnostic information that will assist the understanding of the event. Significant new information on ongoing unanticipated adverse effects shall be provided promptly to the study sponsor.

7.6 Study Halting Rules

Review of serious, unexpected, and related AEs by the DSMB, IRB, the sponsor(s), or the FDA or relevant local regulatory authorities may result in suspension of the study.

Examples of findings that might trigger a safety review are the number of SAEs overall, the number of occurrences of a particular type of SAE, severe AEs/reactions, or increased frequency of events.

7.7 Safety Oversight

It is the responsibility of the Principal Investigator to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan. Medical monitoring will include a regular assessment of the number and type of serious adverse events.

Safety oversight will be under the direction of a DSMB composed of individuals with the appropriate expertise, including PA, cardiovascular disease, and statistics. The DSMB will meet at least semiannually to assess safety and efficacy data of the study. The DSMB will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. At this time, each data element that the DSMB needs to assess will be clearly defined. The DSMB will provide its input to NIH.

8 Clinical Monitoring

The PI will conduct continuous site monitoring at the study site. Any adverse or serious adverse events or unexpected problems will be reported to the DSMB and IRB as noted.
If a subject has an elevated score indicating moderate or severe depressive symptoms on the PROMIS Depression Short Form (raw score > 16) there will be a protocol in place to contact the

subject to facilitate a medical referral for potential treatment. No additional clinical monitoring plan is needed.

9 Statistical Considerations

9.1 Statistical and Analytical Plans (SAP)

Aim 1. Analysis will be performed using SAS 9.4. Surveys will be administered using the Research Electronic Data Capture (REDCap) system,[42] a secure web-based tool licensed and supported by NYU. Standard descriptive statistics will be used to describe baseline sociodemographic and clinical characteristics. Mean scores and standard deviations as well as Cronbach's α will be calculated on questionnaires to confirm reliability of study instruments in our sample. Week 2 of the Fitbit Zip PA data will be used as baseline to assure the participant is accustomed to the device and to minimize the effect of reactivity, which can last approximately one week.[43] To calculate total minutes/week of PA from PAVS, the following standard calculation will be used:[44] light activity will be multiplied by 0 (light activity is not included in PA recommendations but is collected to acknowledge all attempts at PA and encourage increased intensity); moderate activity is multiplied by 1; vigorous activity is multiplied by 2 (one minute of vigorous activity being equal to two minutes of moderate activity). Paired t-tests will be used to assess changes in average PA from week 2 to three-month follow-up using PAVS and Fitbit Zip data. Using Fitabase software which allows for high resolution data, we will compare minutes of PA in three levels of intensity (light, moderate, and vigorous) as well as minutes spent in sedentary behavior. We will report the percentage of weeks each participant achieves the recommended levels of PA during the monitoring period and will assess weekly PA trends. We will compare improvements in PA by levels of protocol adoption by the HCP (e.g. 100% vs. 50% adoption). At 3 months we will compare mean minutes of moderate-to-vigorous PA between those who report achieving recommended levels of PA by the PAVS to those who do not. Paired t-tests will be used to assess changes in readiness to change number, the 6MWT, BMI, waist circumference, systolic and diastolic BP, lipids, and Framingham Heart Study Risk Score. To assess meaningful improvement in CRF, we will report the percent of participants who achieve a clinically important difference of 25 meters in the 6MWT.[45] Bivariate analyses will compare all CVD risk factors, as well as other potential confounders (e.g. age, sex, race/ethnicity, depressive symptoms, quality of life, comorbidities), between those who achieve PA recommendations and those who do not.

Preliminary effect sizes of change in PA (step counts) will be generated following the Physical Activity Change Detection (PACD) approach.[46,47] PACD is a framework for mining longitudinal PA data to detect and describe change over time. This method provides guidelines for defining time periods, detecting outliers, data smoothing, quantifying and describing change in PA patterns. Following data collection, longitudinal trends in PA will be examined descriptively and graphically to determine the optimal parameters for these analyses (e.g. window size- weekly or monthly; comparison type- baseline reference or rolling reference). An example of a possible structure is weeklong activity windows, and a static baseline reference. This would entail comparing average weekly step counts for each individual to their baseline (week 2) step counts. Significance of observed changes will be assessed, and effect sizes will be calculated to quantify the magnitude of change (e.g., Cohen's *d*). Plots of change over time will include error bars to reflect the precision of estimates. Benjamini-Hochberg method[48] will be used to control family-wise error rate for multiple comparisons. Lastly, exploratory linear regression analysis will be conducted to determine if change in average weekly PA is influenced by covariates. Change in physical activity between week 2 and 3 months will be the outcome variable, and the model will include up to 5 covariates, including week 2 physical activity to account for baseline levels of

activity. Up to 4 additional covariates will be selected from those identified in bivariate analyses of factors related to achieving physical activity goals.

Aim 2 is to conduct a process evaluation of the intervention. Implementation data will be evaluated using the PRISM framework. All data collected monthly as outlined below will be analyzed over time to assess trends. We will collect data from the EHR on the HCP practice patterns that may inform our outcomes (e.g. # patients/week). Qualitative interview data will be analyzed using content analysis, an inductive analytic method. Cardiologist, nurse practitioner, and patient interviews will be transcribed verbatim and coded by the PI using *Atlas.ti*, a software package developed for qualitative data analysis. Preliminary analysis will include a line-by-line review that yields clusters of data that will be labeled into brief headings. Codes derived from this data will be linked to interview questions (focused on acceptability and clinical utility) and result in coding categories which will be summarized across cases. Emerging themes both within and across coding categories will be identified. Methodological rigor will be maintained through an audit trail, periodic peer debriefing and member checking that will support the credibility of the study.[49]

9.2 Analysis Datasets

This pilot study will provide preliminary effects sizes on all patient subjects and process evaluation data.

9.2.1 General Approach

This pilot study is a one-group pre-post pilot feasibility study design.

9.2.2 Adherence and Retention Analyses

Adherence to the protocol will be monitored on a monthly basis for both the cardiologists use of PA referral and counseling and patient subject use of Fitbit over 3 months and follow-up data collection. Completion/adherence data will be collected for all study endpoints.

9.2.2.1 Safety Review

The DSMB will review the occurrence of adverse and serious adverse events. This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause as determined by the DSMB.

9.3 Sample Size

The purpose of this pilot study is to test our study protocol and obtain preliminary clinical efficacy data on patient outcomes. With a type 1 error of 5% and 80% power, a sample of 59 participants will allow us to detect a minimal clinically important difference (seen in adults with CVD) in the six-minute walk test of 25 meters.[45] (effect size =0.33) There is a potential for 20% attrition based on the PIs previous work. With a type 1 error of 5% and 80% power, this sample of 47 participants will allow us to detect an effect size of 0.41 (28 meters for the six-minute walk test, an increase of 9,710 in weekly step count, and an increase of 10% of the sample achieving recommended levels of PA) and will have 80% power to detect a small effect (R^2 of .09 to .11) associated with a predictor assuming up to 4 covariates which have a combined R^2 of .4 to .2

with change in average weekly PA. Given our timeline and weekly volume of patients we believe it is feasible to enroll a sample of 59 participants.

10 Source Documents and Access to Source Data/Documents

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB, the sponsor, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

11 Quality Assurance and Quality Control

QC procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated.
Following written SOPs, the PI will verify that the clinical trial is conducted and data are generated, documented (recorded), and reported in compliance with the protocol and GCP.

12 Ethics/Protection of Human Subjects

12.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or the ICH E6.

Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

12.2 Informed Consent Process

12.2.1 Consent/Assent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study procedures, and risks are given to the participant and written or electronic REDCap documentation of informed consent is required prior to starting intervention. The following consent materials are submitted with this protocol (consent for cardiologist subjects; consent for patient subjects).

12.2.2 Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be IRB-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the trial. A copy of the signed informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

A copy of the signed informed consent document will be stored in the subject's research record or in REDCap. The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the subject's research record. Any alteration to the standard consent process (e.g. use of a translator, consent from a legally authorized representative, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

12.3 Posting of Clinical Trial Consent Form

The informed consent form will be posted on the Federal website after the clinical trial is closed to recruitment, **and no later than 60 days after the last study visit by any subject**, as required by the protocol.

12.4 Participant and Data Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study

- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, representatives of the IRB product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at NYU Langone Medical Center. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by NYU Langone Medical Center research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the NYU Langone Medical Center.

To further protect the privacy of study participants, a Certificate of Confidentiality will be obtained from the NIH. This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

13 Data Handling and Record Keeping

13.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the PI and the RA under the supervision of the PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

Clinical data (including AEs, concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into REDCap data system, a 21 CFR Part 11-compliant data capture system provided by NYU Langone Health. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

13.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close-out, 5 years after final reporting/publication, or 2 years after the last approval of a marketing application is approved for the drug for the indication for which it is being investigated or 2 years after the investigation is discontinued and FDA is notified if no application is to be filed or if the application has not been approved for such indication. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

13.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site PI/study staff to use continuous vigilance to identify and report deviations within <specify number> working days of identification of the protocol deviation, or within <specify number> working days of the scheduled protocol-required activity.

All protocol deviations must be addressed in study source documents, reported to National Institute of Nursing Research Program Official.

Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

13.4 Publication and Data Sharing Policy

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy, and the Section 801 of the Food and Drug Administration Amendments Act of 2007, requires that all clinical trials be registered in a public trials registry such as ClinicalTrials.gov, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIH IC grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

14 Study Finances

14.1 Funding Source

This study is financed through a grant from the US National Institute of Health, National Institute of Nursing Research.

14.2 Costs to the Participant

There will be no cost to participation in this study.

14.3 Participant Reimbursements or Payments

At the initial enrollment visit the patient subject will be compensated with a $50 gift card for their time and effort in completing the baseline data collection (approximately one hour) and agreeing to wear the Fitbit for 3 months. At the follow-up visit they will be compensated for their time and effort in completing follow-up data collection (approximately one hour) with a second $50 gift card. They will be able to keep the Fitbit activity tracker. The cardiologists will not receive any compensation for their participation in the study.

15 Study Administration

The following subsections should describe the governance of the study and its committee structure. Alternately, this section may describe the role of the study team, its composition (e.g., those listed in Section 1, Key Roles) and describe how study decisions and progress are communicated and reported. Some example text is provided below.

15.1 Study Leadership

The PI will govern the conduct of the study. The PI will be advised during the study implementation on a monthly basis (or more frequently if needed) by her co-I's and K23 mentors Dr. Allison Vorderstrasse and Dr. Stuart Katz.

16 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the <specify NIH IC> has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Management Unit (CIMU) with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULMC investigators will follow the applicable conflict of interest policies.

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18 Schedule of Events

Activity	Baseline Visit At Enrollment	Follow-up Visit after 3 months
Study team procedures		
Consent	X	
Clinical Data from EHR	X	
Survey completion, PAVS, six-minute walk test, lipid fingerstick collection, height, weight, waist circumference and blood pressure measured	X	X
Patient subject given Fitbit and instructions on wearing an activity tracker	X	
Interviews with patient subjects and cardiologists/nurse practitioner on the feasibility and acceptability of the intervention		X