Feasibility and acceptability of a web-based physical activity for the heart (PATH) intervention designed to reduce the risk of heart disease among inactive African Americans

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Protocols for the intervention and control groups.

After randomization, each participant in the intervention group will be given a password-protected profile to access the PATH website and a detailed orientation on how to use all the resources included in PATH (see Table 1). The control group will be introduced to *Be Active Your Way* booklet and newsletters which they will be encouraged to use for 12 weeks while awaiting the intervention.

The treatment group: The PATH group will be granted password protected access to one of the 3 PATH levels based on their baseline fitness status. The intervention is designed to help participants increase their baseline PA via health coaching, self-monitoring and pragmatic workout videos that provide convenient options for overcoming socio-environmental barriers to PA. After randomization, the PA coach will work with each participant to develop their PA prescription guided by the FITT-VP principle[1] which recommends the frequency, intensity, time/duration, type, volume and progression of PA regimen. The goal of the exercise prescription will be to increase baseline MVPA by ≥60min/week or 6000 steps/week over the course of the study. Our PA prescription process will begin by identifying a suitable PATH level for each participant based on their estimated maximum rate of oxygen consumption during incremental exercise (VO_2 max).[1] The VO_2 max will be predicted using a validated non-exercise prediction model for peak VO_2 (VO_2 peak) whose covariates include sex, age, waist circumference, resting heart rate and PA index.[2] Individuals with predicted VO_2 max ≤ 35th percentile rank for their age and gender will be assigned to the Beginner PATH level (includes light intensity PA <3 METs). Those with VO_2 max between 35th and 75th percentile rank will be assigned to Intermediate PATH level which includes moderate intensity PA (3-6 METs) in addition to the Beginner PATH content. Participants with VO_2 max greater than 75th percentile rank will be assigned to Proficient PATH level which includes vigorous intensity PA (>6 METs) in addition to the Intermediate PATH content. After assigning PATH level, the PA coach will guide each participant in selecting their weekly PA goal and will help them plan to start slow with a plan to establish regular exercise frequencies of 3-5 days every week. The coach will also guide participants to select activities with intensity that help them progress along the PA continuum (i.e., sedentary to light PA to MVPA). To foster safety, participants will be instructed to use the Borg Rating of Perceived Exertion (RPE) Scale[3] as a guide for adjusting the intensity of their PA regimen. The scale ranges from 6 (no exertion at all) to 20 (maximal exertion) and is embedded with each workout video on PATH. Specifically, the participants will be asked to maintain PA at perceived exertion ratings between 12 to 14 (i.e., moderate level of intensity) on the RPE Scale. To ensure gradual progression in PA intensity, each participant's progress will be reviewed every 2 wks, and more intensity will be allowed, including transition to the next PATH level, when most workouts within the assigned PATH level are perceived to be "very light" (≤9 on the RPE Scale). Participants will be requested to rate each workout they engage in on the RPE scale. This method will ensure that the prescribed PA regimen for each individual is based on their physical ability and fitness status. Although the PA coach will provide solid examples of the combination of workout videos that could help participants attain their personalized goals, each participant will have access to all resources within their PATH level and will be encouraged to select a PA regimen that includes their preferred workout videos and other types of PA appropriate for their fitness. The workouts that are recommended by the PA coach and those selected by each participant as favorites will be featured on the personalized PATH dashboard. Box 1 illustrates a PA prescription for Mary, where in the first 2 wks her PA regimen includes her usual walks (40 mins of MVPA/wk or 4000 steps/week) and 10 mins of additional dance workouts each week.

Box 1. Mary's PA prescription

Mary is a 45-year old woman with a VO_2 max of 25.1 (5th percentile). She reports 40 mins of MVPA & 4000 steps derived from walking for 20 mins twice/week. Her preference is to ↑ her PA by using dance workout videos. The PA coach will assign Mary to Beginner PATH level based on her VO_2 max, and work with her to develop a plan to ↑ her MVPA by 60 mins/week or 6000 steps/week at the end of study:

- ✓ Gradually increase PA **frequency** (e.g., an additional day of PA every 4 wks)
- ✓ Set limits for PA **intensity:** start with workouts that she can do at perceived exertion ratings between 12 to 14. The progress will be reviewed every 2 wks, with more intensity allowed when most workouts within the assigned PATH level are perceived to be "very light" (9 on the RPE Scale).
- ✓ Gradually increase the **time**. The duration of her PA regimen can be increased by 10 mins of MVPA or 1000 steps every week for the first 6 wks, then maintain.
- ✓ Recommend workout videos with **types** of PA that align with her goals. The coach will recommend specific workouts that can help Mary attain her goals, but she will have an option to select her favorite workouts at any time.
- ✓ Flexible strategy for attaining desired PA **volume**. Mary can attain the desired volume of weekly PA by either ↑ her routine walks or via her favorite workouts.
- ✓ Evaluation of **progress** every 2wks. The PA coach with call Mary twice a month to review and revise the PA prescription based on the progress made. After 6 successful weeks, Mary can focus on maintaining her MVPA at 100 mins/wk or 10,000 steps/wk. She can also continue with the gradual increase in PA volume.

The PA prescription will be revised after every 2 weeks based on the progress made. Those who manage to increase PA by ≥10 minutes each week of MVPA or 1000 steps for 6 consecutive weeks will attain the study goal and their plan for the remaining study period will be to maintain the improved PA regimen. However, the participant can opt to continue with gradual increase in PA volume. To simplify access and support PA maintenance, the workout videos are organized in specific categories (e.g., walking, dance, steps aerobics) and can be sorted by duration and METs. To reduce risk of injury, the amount and intensity of PA will be increased gradually over the course of the study, as advocated by ACSM.[4] Although there are no established standards on how to increase PA gradually, available evidence suggests that it is safe to increase

MVPA by about 10 minutes or 1000 steps every week.[4,5] Each participant will be provided near real-time data on their progress towards their weekly and monthly goals on the PATH dashboard. *To complete the PA prescription, participants will provide their preferred schedule for receiving PA reminders and twice a month phone calls from the PA coach to monitor progress and revise PA goals*. Participants will also be given contacts of the PA coach with instructions to reach out if they need help before scheduled calls. During the study period, participants will be encouraged to adhere to their PA goals and share their experiences on the PATH community forum moderated by the study staff. At the end of the study, we will survey participants for feedback on resources that were most helpful to them and ideas for improving the PATH intervention.

Wait-list control group: Participants in this group will not have access to the PATH intervention until after 12 weeks when they cross over. After randomization, the control group will be provided with a copy of the *Be Active Your Way* booklet, developed by the Centers for Disease Control (CDC) to help individuals integrate PA in their daily lives.[6] The key strategies used in the booklet are outlined in Box 2. We have chosen this control strategy to mirror usual care where patients are provided with self-help handouts. The *Be Active Your Way* booklet was selected because it is evidence based, free to download and recommended by the CDC as a pragmatic self-help resource for promoting PA.[6] In addition, the control group will receive bi-weekly newsletters focusing on general health. The control group data will help contrast the important aspects of our study, including differential ActiGraph use and retention rates between the control and intervention groups, as well as the trend in PA and cardiometabolic risk changes. After 12 weeks, the outcome assessments will be done, and the control group will be given access to the PATH intervention. Once given access to PATH, participants will be subject to all the study procedures described for the treatment group. No follow-up is planned after the post-intervention assessments for both the intervention and control groups.

Box 2. Be Active Your Way get started plan

- ✓ **Goal:** Build up your PA routine over time.
- ✓ **Start by doing what you can** & then look for ways to do more. If you have not been active for a while, start out slowly. After several wks or months, build up your activities, then do them longer & more often.
- ✓ **Walking is one way to add PA to your life.** When you first start, walk for 10 mins a day on a few days during the first couple of weeks.
- ✓ **Add more time and days.** Walk a little longer. Try 15 min instead of 10 mins. Then walk on more days/wk.
- ✓ **Pick up the pace.** Once this is easy to do, try walking faster. Keep up your brisk walking for a couple of months. You might add biking on weekends for variety.

Expected results, potential pitfalls and solutions: Although a wait-list control design may artificially inflate the intervention effects in an efficacy trial,[7] our feasibility study primary focus is on within-group changes. Therefore, a wait-list strategy may enhance retention and help control for passage of time and assessments[8] without impacting study outcomes. Another potential pitfall is recruitment. However, based on our experiences, we do not anticipate significant difficulties recruiting women, but more proactive strategies will be needed to recruit men and minorities. To address the challenge, we have built relationships with strategic community stakeholders such as barbershops where men frequent, and the CTSI Community PARTners core which specializes on recruiting minorities. In addition, the remote nature of the intervention is likely to make the study appealing to men and other underserved populations with low participation in biomedical research. These strategies will help us attain our recruitment targets. To foster safety, our exclusion criteria will help exclude individuals who are unfit to engage in unsupervised PA. Moreover, the PA prescriptions will be personalized according to ability and preference. All participants will be educated on PA safety using ACSM Guidelines[4] and will be given non-slip exercise mats.

Screening assessments – Questionnaires will be used to assess barriers to exercise self-efficacy, PA readiness, medical history and risk of diabetes, PA habits, sleep patterns, depressive symptomatology, diet, fatigue, and stress. Table 1 outlines the specific data collection instruments and their timeline. These data will be used to evaluate eligibility and to describe lifestyle and other cardiometabolic factors typically related to PA.

Measures of adherence and acceptability (Aim 1). Wrist-worn ActiGraph GT9X will be used to measure PA outcomes. Throughout the 12-week Study, participants will be asked to self-monitor their daily PA. The PA tracker will be worn on the wrist for at least 10 hours per day when a participant is awake. The tracker will be connected to the CenterPoint app which will help the study team monitor the participants' progress throughout the study. Two weeks and one week before the end of the study, the study team will send reminders to participants (via text message, email, phone call and push notification) to wear their PA tracker for 7 days before they are scheduled for their end of study assessment. Adherence to PA self-monitoring will be indicated by the number of weeks with ≥4days (3 weekdays and 1 weekend day) of valid wear time (≥10hrs). PATH utilization data will be collected via Web analytics, while a post-intervention survey will assess intervention acceptability.

Measures of PA and cardiometabolic outcomes – administered at baseline and 12 weeks (Aim 2). Body weight (assessed via Fitbit Aria 2 digital scale), waist circumference (assessed via Perfect Waist Tape Measure) and blood pressure (assessed via Omron Model BP7450) assessment will be done by the participant using the equipment shipped to their address by the study, and under the supervision of the study team via HIPAA compliant zoom video conference. The instructions for weighing will include asking participants to wear light clothing and stand bare feet on the scale's footpads. The recorded weight will be available to the study team immediately and via Fitbit API. When taking the blood pressure, the participant will be instructed to apply the cuff

on the left bare arm, ensuring that nothing is constraining the arm above the cuff. The easy-wrap ComFit cuff used in Omron Model BP7450 fits standard to large adult arms ranging from 9 to 17 inches in circumference.[6] After applying the cuff, the participant will be asked to relax, sitting in a chair with both feet resting flat on floor and back straight and supported. After resting for at least 5 minutes with the left arm resting comfortably on a flat surface at heart level, the participants will be asked to turn on the BP machine which will be programmed to take 3 measurements at one-minute interval. Any participant with two readings of elevated BP (>130/80) will be referred to their PCP for management. Blood samples for glycated hemoglobin (HbA1c) and lipids (LDL, HDL, and total cholesterol) will be collected via fingerstick using HemaSpot SE kits which will be mailed to participants ahead of baseline assessment. The samples will be mailed to the lab for analysis using established protocols for dry blood spot method. Type 2 diabetes risk score will be calculated using the ADA risk calculator with covariates that include; age, sex, family history of diabetes, history of hypertension, obesity, and PA.[15] PA measures: Barriers to exercise self-efficacy will be assessed via BARSE scale,[16] while ActiGraph GT9X will be used to assess participants' PA patterns including steps, light PA and MVPA. These metrics will be calculated using Freedson adult VM3 cut points.[18] For Aim 2, only the 7- day Actigraph data collected during baseline and 12-wks assessments will be used. Since PATH is expected to increase baseline MVPA by ≥60mins or 6000 steps at the end of the study, percent adherence will be calculated as: [(Post-intervention MVPA - Baseline MVPA) / MVPA goal] × 100 (e.g., [(140-90)/60] ×100 = 83% (The same formulae will be used for steps). Pre and post-intervention VO_2 max will be calculated using the non-exercise prediction model for VO_2 peak.[2] described earlier.

Data/Collection Tool	Baseline	3 months
Screening Questionnaires		
Sociodemographic Questionnaire	X	
Medical History Questionnaire	X	
Physical Activity Readiness Questionnaire	X	
American Diabetes Association Risk calculator	X	X
Barriers Self-efficacy Scale	X	X
Paffenbarger Exercise Habits Questionnaire	X	X
PROMIS SF Sleep Disturbance Questionnaire	X	X
PROMIS SF Sleep-Related Impairment Questionnaire	X	X
Automated Self-Administered 24HR Dietary Recall	X	X
Center for Epidemiologic Studies Depression Scale	X	X
NIH Toolbox Perceived Stress	X	X
Pittsburgh Fatigue Scale	X	X
Physical activity index	X	X
Modified Activity Questionnaire (MAQ)	X	X
Cardiometabolic Assessments		
Zoom supervised self-administered Blood Pressure	X	X
Zoom supervised self-administered Weight	X	X
Zoom supervised self-administered waist circumference	X	X
Height (self-reported)	X	
Glycated hemoglobin (dry blood spot)	X	X
Total cholesterol	X	X
HDL cholesterol	X	X
LDL cholesterol	X	X
Predicted VO_2 peak*	X	X
Accelerometer data on sleep and physical activity	X	X
Randomization via zoom	X	
Intervention Satisfaction Questionnaire		X

Notes: *VO_2 peak for men = 100.27-(0.296*age) -(0.369*waist circumference) - (0.155*resting heart rate)+(0.226*PA-index**); * VO_2 peak for women = 74.74-(0.247*age)-(0.259*waist circumference)-(0.114*resting heart rate)+(0.198*PA-index)