



A community-based positive psychology group intervention to promote physical activity among people with metabolic syndrome: Proof of concept results to inform a pilot randomized controlled trial protocol

Rachel A. Millstein^{a, c, *}, Anne N. Thorndike^{b, c}, Sonia Kim^a, Elyse R. Park^{b, c}, Jeff C. Huffman^{a, c}

^a Department of Psychiatry, Massachusetts General Hospital, United States

^b Department of Medicine, Massachusetts General Hospital, United States

^c Harvard Medical School, United States

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ABSTRACT

Background: Community-based physical activity interventions can offset the burden of developing chronic diseases. Positive psychology (PP) interventions may improve health behaviors, but little is known about their effectiveness in community-based prevention settings. A multilevel PP-based intervention has never been studied in people at risk for chronic diseases.

Purpose: The aim of the trial is to demonstrate feasibility, acceptability, and improve physical activity. The purpose is to describe the theory, design, and rationale of the randomized controlled trial (RCT) phase of an iteratively developed physical activity intervention for metabolic syndrome. The feasibility results of the proof-of-concept phase are presented.

Methods: Participants are adult primary care patients at community health centers with metabolic syndrome and low physical activity (target n = 64). The 8-week group intervention consists of weekly physical activity goal-setting and self-monitoring, positive psychology activities, and neighborhood walks. Participants rate feasibility and acceptability of sessions. Pre-post-intervention, and 24 weeks later, participants complete accelerometers, questionnaires, and biometrics.

Feasibility results: Eight participants enrolled and seven completed. The median number of group sessions attended was 7 out of 8. Average ease and usefulness of sessions were rated as 7.0 (± 0.5)/10 and 8.1 (± 1.0)/10, respectively, indicating feasibility and acceptability. Average pre-post physical activity increased by 2152 steps and 29.25 min of MVPA/week.

Discussion: This proof-of-concept trial demonstrated high feasibility and acceptability, with increased physical activity. These positive findings suggest that the RCT phase will show high feasibility, acceptability, and initial impact on physical activity.

1. Introduction

Approximately 34% of US adults are at high risk for developing chronic diseases, and prevalence is projected to increase, particularly in communities with limited resources [25,40,57]. Metabolic syndrome (MetS) is a constellation of conditions (e.g., obesity, hypertension) that increases the risk of developing chronic diseases like type 2 diabetes and cardiovascular disease [52]. Health behaviors, including physical activity, are critical for reducing the development of MetS and related diseases [31,42], but most people don't achieve recom-

mended activity levels [23]. Multiple factors influence physical activity, from individual to communities [47,49]. Intervening on physical activity at multiple levels can reduce morbidity, mortality, and health care costs [22,31].

At the individual level, emotions and motivation are primary drivers of healthy behaviors [53]. Positive psychology (PP) constructs such as optimism, self-esteem, and positive affect are associated with lower risk of developing MetS [7,61] and adherence to physical activity and health behaviors [26,33,44,56]. PP interventions increase positive psychological states (e.g., optimism, positive affect) through

* Corresponding author. Massachusetts General Hospital, 5 Longfellow Place, #215, Boston, MA, 02114, USA.

E-mail address: ramillstein@mg.harvard.edu (R.A. Millstein).

structured activities such as increasing awareness of positive events and cultivating optimism [6,18,51]. A related intervention is Motivational Interviewing (MI), a patient-centered approach to behavior change that clarifies motivation, ambivalence, and goals [38]. MI has been used to help people increase physical activity and other health behaviors [19]. Combining PP and MI may leverage the complementary strengths of both strategies to influence change more than either approach alone [26].

The ecological model emphasizes interpersonal (social) and built environment levels of influence on physical activity [49]. Community-based chronic disease prevention interventions can reach underserved populations [2,14] and offer support for engaging in healthy behaviors [35,41]. Social support is a consistent predictor of sustained physical activity [3,36], whereas loneliness is associated with an increased likelihood of meeting criteria for MetS [60]. Relationships between built environment features (e.g., sidewalks, walkable destinations) and physical activity are well established [3,8,9,45] and can be identified using neighborhood walkability assessments to identify opportunities for local physical activity [10,48].

The goals of this study are to describe the design and development of the Move More, Feel Well: MAPP (Motivation, Audit, and Positive Psychology) study randomized controlled trial (RCT). MAPP is a community-based PP-MI multilevel intervention for sub-optimally active people at risk of developing chronic diseases (MetS). The intervention is an 8-week PP-MI group-based walking program in community clinics within a large healthcare system. The results of the proof-of-concept feasibility study that informed the pilot RCT are also presented.

2. Methods

2.1. ORBIT model and study development

Following the progressive Obesity-Related Behavioral Intervention Trials (ORBIT) model for developing health behavior interventions [20], the first phase of MAPP development (ORBIT phases 1a and 1b; see Fig. 1) was qualitative research to gather interview data on partic-

ipants' experiences of living with MetS (revised manuscript under review), which informed the development of the second phase proof-of-concept intervention study (ORBIT phase IIa: preliminary testing of a proof-of-concept study). The intervention was further refined after the proof-of-concept study. Determining study feasibility and acceptability were the primary aims of the proof-of-concept study. The pilot RCT for which the protocol is described herein represents phase IIb of the ORBIT model for preliminary testing of pilot studies). The description of the studies will be presented in the following sequence: 1) development of the RCT intervention, 2) a summary of the proof-of-concept study methods and findings, 3) a description of changes made from the proof-of-concept phase to inform the RCT protocol, and 4) the RCT data analysis plans. Of note, the intervention content, recruitment strategies, and measures were largely the same in the proof-of-concept study (ORBIT IIa) and pilot RCT (ORBIT IIb), with changes between the two phases described following the proof-of-concept study results.

2.1.1. Intervention development and theoretical models

The MAPP intervention for the pilot RCT (ORBIT model phase IIb; Fig. 1) was developed based on existing theory and tailored for the MetS population using qualitative patient interviews (ORBIT model phases 1a and 1b) and the feasibility/acceptability of the proof-of-concept study (ORBIT model phase 2a). The PP exercises were adapted from evidence-based interventions and based on previous work with medical patients [6,18,26,28]. The physical activity goal setting and self-monitoring content was created using a patient-centered MI approach [30]. PP and MI have been shown to integrate effectively in prior studies of medical populations based on a previously published model [26,27] (Fig. 2). Briefly, increasing positive psychological states through PP interventions, such as optimism and determination, may increase motivation and adherence to health behaviors [51]. Simultaneously, MI helps reduce ambivalence, increase self-efficacy, and combined with behavioral goal-setting, allows people to move toward valued goals [30,37], such as increased physical activity and improved health. Furthermore, increased salience of positive emotions during physical activity can increase conscious and non-

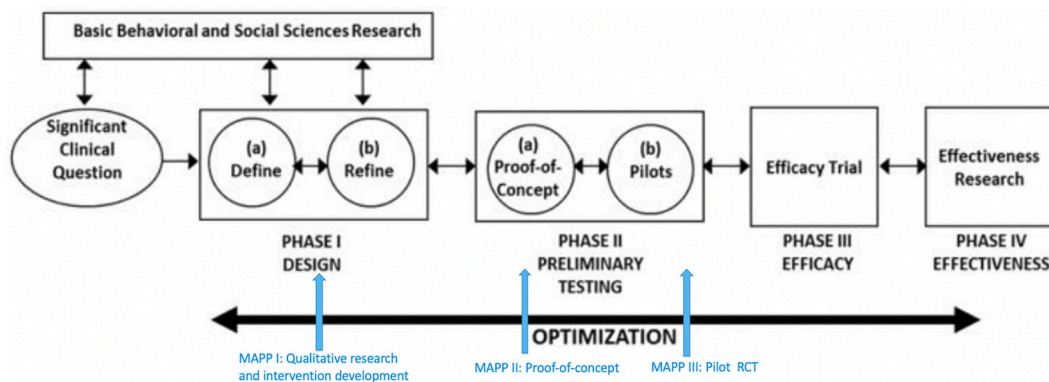


Fig. 1. The ORBIT model of behavioral intervention development [20], with arrows indicating the stages of development in the present study.

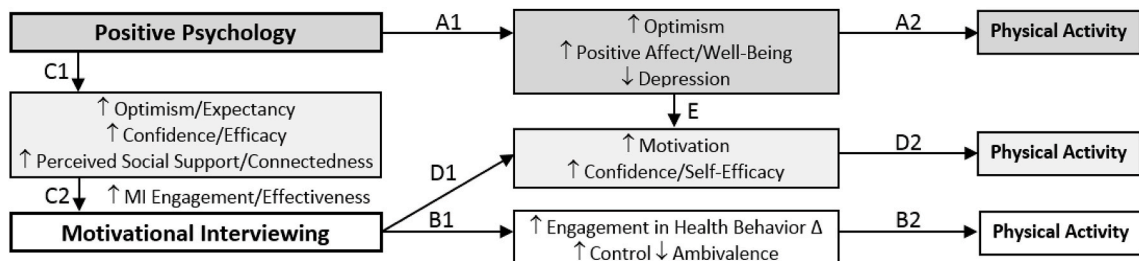


Fig. 2. PP-MI's effects on physical activity. Model originally presented in Ref. [26].

conscious motivation and reinforce the behavior as described in the Upward Spiral Theory of Lifestyle Change [56]. Building upon these models, the present intervention expands beyond the individual level and broadens its scope to incorporate the interpersonal targets of social benefits in a group intervention, which are widely used in health behavior change programs, emphasizing social support, peer motivation, and accountability (e.g., the Diabetes Prevention Program [21]). Further expanding through the levels of the ecological model of health behaviors [49], MAPP also includes a focus on education, exploration, and assessment of each clinic's surrounding neighborhood built environment and walkability (Fig. 3). To assess neighborhood walkability (features that support walking, such as sidewalks and crosswalks), during the midpoint of the intervention, participants are asked to walk a new route in their neighborhood and use the MAPS-Mini audit tool [48] to evaluate their walking environment. Finally, to further support behavioral rehearsal and self-efficacy [37], each session includes a 30-min group walk around the clinic neighborhoods or equivalent indoor activity in case of inclement weather.

2.1.2. Intervention content

Each session is 90 min long, with 8 intervention sessions plus one consent session prior to beginning the study. All participants receive a manual to keep and record their weekly activities. The MI-based physical activity education and goal-setting section of the intervention (Table 1) was designed to provide physical activity education and support for individualized weekly goal setting. Participants are given a Fitbit Alta™ (or equivalent wrist-worn Fitbit if models change during the study) to keep, to self-monitor their physical activity for the duration of the study and thereafter. Each week, they are asked to track their steps and physical activity using log sheets in the manual and set a SMART (Specific, Measurable, Attainable, Relevant, and Time-based) goal.

The PP section (Table 1) was adapted from prior PP intervention studies [6,15,26,28] and focused on positive emotions achieved during and after present and past physical activity. The PP exercises are ordered and paired with a relevant physical activity topic (e.g., perseverance and setting a SMART goal). Participants are encouraged to use the PP skills regularly outside of the group sessions by becoming more aware of different positive thoughts and feelings as they occur, expanding their vocabulary of positive emotions, and noticing positive feelings during and after their physical activity. Based on feedback from the proof-of-concept study, the manual includes basic nutrition

education (USDA Healthy Plate, serving sizes, sources of sodium and sugar) as “bonus pages” for participants’ reference, but these are not discussed in the weekly intervention sessions. See Fig. 4 for the manual table of contents.

2.2. RCT participants

2.2.1. Study criteria

Study criteria and recruitment are nearly identical for the proof-of-concept study and the RCT. Participants are eligible if they have at least three of five MetS conditions, including hypertension (systolic blood pressure ≥ 130 mm Hg and/or diastolic blood pressure ≥ 85 mm Hg or be on blood pressure medication), hyperlipidemia (high-density lipoprotein (HDL) cholesterol < 40 mg/dL in men or < 50 mg/dL in women), high cholesterol (serum triglycerides ≥ 150 mg/dL), elevated blood glucose (fasting plasma glucose > 100 mg/dL), or high BMI (≥ 29.1 kg/m² for men and 27.2 kg/m² for women) [52]. Participants can have two MetS conditions if they have PCP approval. All participants must meet the low physical activity inclusion criteria of not meeting national recommendations, e.g., < 150 min/week of moderate-vigorous physical activity (MVPA) [43], as measured by the International Physical Activity Questionnaire-Short Form (IPAQ-SF) [34]. The IPAQ-SF measures self-reported aerobic physical activity in the past 7 days in the domains of vigorous activity, moderate activity, and walking. Exclusion criteria based on chart review and PCP confirmation include: having diagnosed diabetes (hemoglobin A1c: ≥ 6.5 or blood sugar ≥ 126 mg/dl) or cardiac diseases, having medical illnesses that will likely lead to death within 6 months, being under current treatment for cancer, liver, or renal disease, not having a telephone, being unable to participate in physical activity, or are being unable to speak, read, or write English.

2.2.2. Recruitment and enrollment

Participants are adult outpatients who have a primary care physician (PCP) at the ethnically and economically diverse community health centers within the healthcare system. Potential participants are identified through systematic searches using the healthcare system's secure online medical record query tool, the Research Patient Data Registry (RPDR), study staff recruiting at tables in the clinics, flyers posted at the clinics, and PCP referrals. All participants must be approved by their PCPs prior to enrolling. This is done by sending an email to PCPs with a list of potentially medically eligible patients

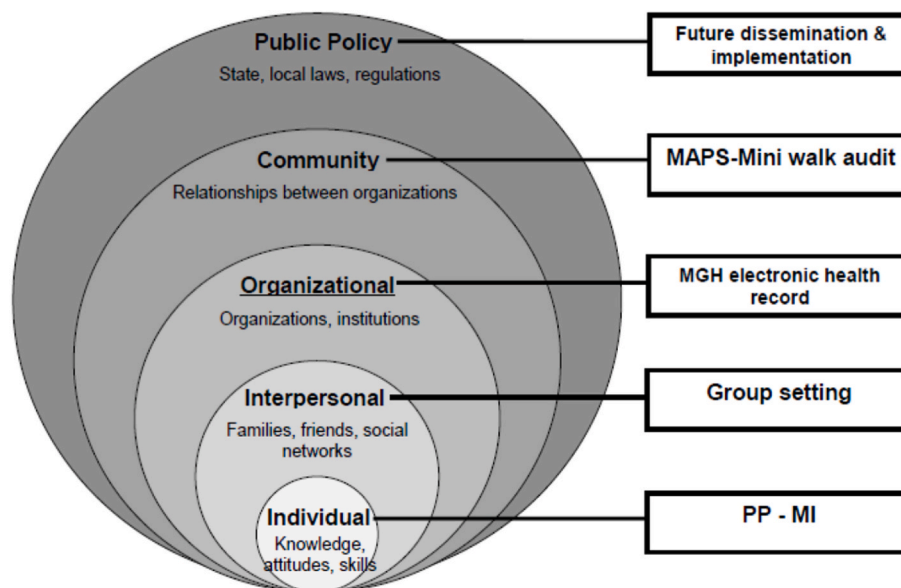


Fig. 3. Multilevel ecological model as applied to The Move More, Feel Well: MAPP Study.

Table 1
RCT intervention session content.

Session	Motivational Interviewing Topic	Positive Psychology Topic
1	Moving for Better Health and Small Steps	Gratitude for Health/Positive Feelings from Exercise
2	Setting a SMART Physical Activity Goal	Perseverance
3	Barriers and Problem Solving	Using Personal Strengths to Meet Your Goal
4	Finding New Routes	Enjoyable and Meaningful Physical Activities
5	Using Neighborhood and Social Resources	Remembering Past Successes Around Exercise
6	Reducing Your Sitting Time/Standing Breaks	Capitalizing on Goals and Health
7	Strength Training and Equipment	The Good Life
8	Managing Slips	Planning for the Future

(from the RPDR search) and asking PCPs to approve or deny the study's contact with their patients. Once approval is received, opt-out letters are sent to those patients such that the PCP has knowledge of the study before potential participants. Recruitment began in June of 2019 and is expected to continue through July of 2021 or until 64 participants are recruited. Eight participants are randomized to each group, nested within clinics.

Eligible patients identified through the RPDR are mailed opt-out letters. Patients who do not opt-out from study-related contact and are approved for potential participation by their PCP are contacted by a study coordinator. Participants are excluded at the time of screening if they show cognitive impairment on a six-item screen [12] or report

150 or more minutes per week of MVPA (Fig. 5). Of note, due to recent changes mandated by our healthcare system's COVID-19 safety precautions, all study procedures from March 2020 until further notice, will be completed remotely using virtual video sessions, consenting, and screening. All participants sign an informed consent form or may have documentation of verbal consent if consenting remotely. All study procedures were approved by our healthcare system's Institutional Review Board. This study is registered at clinicaltrials.gov (proof-of-concept study: NCT [removed for blinding], and RCT: NCT [removed for blinding]).

2.2.3. Randomization

After completing the phone screen, eligible and interested participants are asked to attend an in-person (or virtual if conducted during COVID-19) session to complete informed consent, baseline questionnaires, randomization, and biometrics (weight, blood pressure) (Fig. 6). After completing consent and all baseline measures, participants are randomized to either the immediate or waitlist control group. Randomization was created by a random number generator in Microsoft Excel and is structured in blocks of 8 based on recruitment targets at each clinic.

2.2.4. Control condition

A waitlist control design is used to ensure that all participants receive the intervention and to have a suitable comparison group. Participants complete self-report instruments at baseline prior to randomization. Participants are randomized to either the immediate or waitlist condition. Those in the waitlist control group are given self-report assessments at the same times as the immediate group, at start of the

Table of Contents

Session One: Date _____	page #
Moving for Better Health and Small Steps/Gratitude for Health	9
Session Two: Date _____	
Setting a SMART Physical Activity Goal/Perseverance	28
Session Three: Date _____	
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Session Four: Date _____	
Finding New Routes/Enjoyable and Meaningful Activities	56
Session Five: Date _____	
Using Neighborhood and Social Resources/ Past Successes	71
Session Six: Date _____	
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3: Additional Strength Exercises	137
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5: Finding New Walking Routes	139
6: Using Positive Psychology Skills in Daily Life	140

Fig. 4. Intervention manual table of contents.

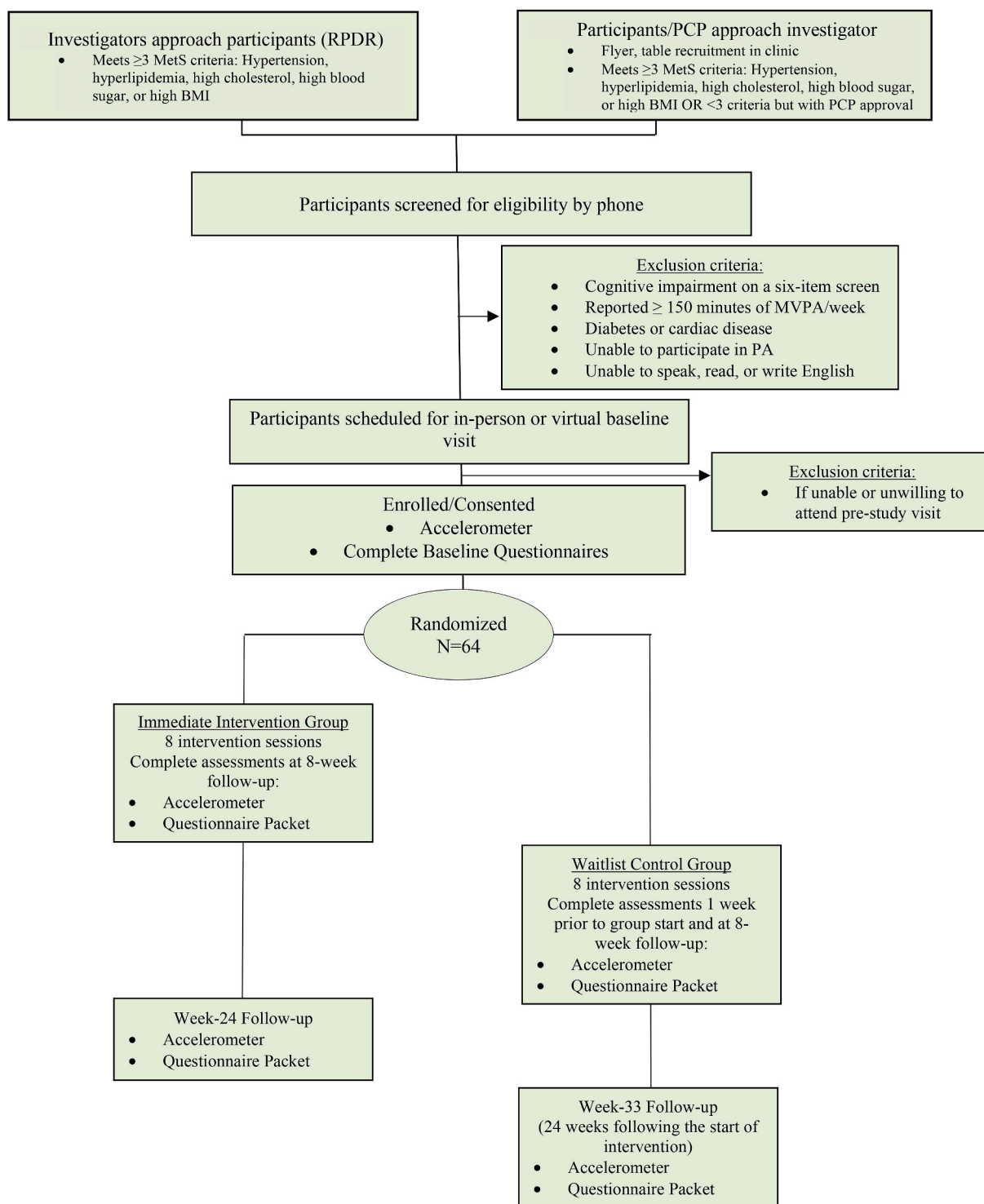


Fig. 5. CONSORT flow diagram for the MAPP RCT.

intervention, conclusion of intervention, and 24 weeks later (Fig. 6). Waitlist control participants are given their Fitbits at randomization so that both the immediate and control participants have a Fitbit and equal opportunity to self-monitor physical activity from the start of the study. Treatment condition is not blinded to participants or investigators. The PI runs the intervention groups so blinding is not possible. The immediate group begins the week after randomization, and the control group begins the week after the immediate group intervention ends (e.g., groups are staggered by 8 weeks).

2.3. Data collection and outcomes

2.3.1. Data collection timing and payment

Participant sociodemographic information, current medications, medical history, and current medical status are obtained from participant self-report and the electronic medical record. Participants complete assessments including wearing the accelerometer for one week before the start of the intervention (baseline) and after the completion of the intervention (after week 8) and at week 24 to assess sustainability of effects. The control condition also has a 24-week follow-up

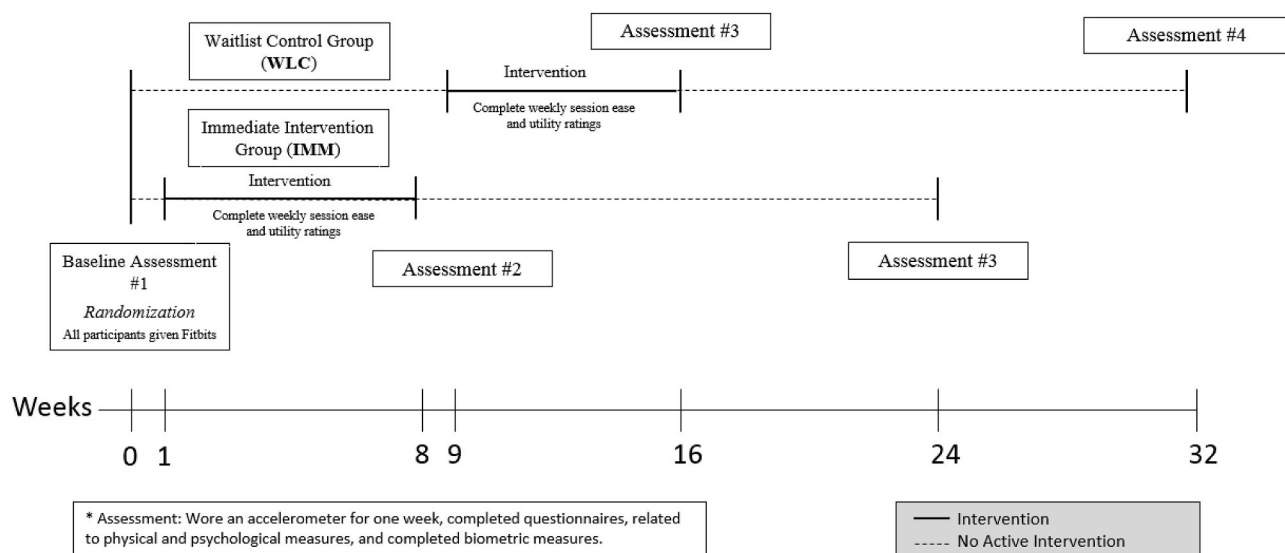


Fig. 6. Study timeline.

that occurs at week 33, or 24 weeks after the start of their intervention group. Participants are paid \$25 per assessment (complete Actigraph and questionnaires), for a total of up to \$75 in the immediate group (three assessment timepoints) and \$100 in the waitlist control group (four assessment timepoints); see Fig. 6 for a study timeline.

2.3.2. Intervention feasibility

Intervention feasibility is the primary study outcome. It is measured by calculating the number of intervention sessions attended by each participant.

2.3.3. Session acceptability

To measure acceptability, after completing each weekly session, participants are asked to rate the ease (“How easy was it to complete this session?”) and utility (“How useful was this session?”) of the sessions on a scale of 0 (very difficult/not helpful) to 10 (very easy/very helpful).

2.3.4. Feasibility of outcome measures

To examine the feasibility of study outcome measures, the percent of pre- and post intervention questionnaires completed and accelerometer use are measured.

2.3.5. Session impact

Participants are asked to rate their happiness and optimism (0–10) before and after each session, which are used to calculate immediate impact.

2.3.6. Process evaluation and fidelity

After each session, participants complete a 6 item questionnaire rating attributes of the session on a continuum from 1 to 7 with their response to the session. The constructs measured are ease, value of the session, pleasantness, happiness, excitement, and confidence.

Treatment fidelity is assessed using weekly fidelity checklists created for this study and adapted from previous research [26]. A research coordinator present at the sessions rates the interventionist (PI and/or trained psychologist substitute) on a 7-point scale for each of the two components, PP and MI, and the total score is calculated out of 14 fidelity points.

2.4. Outcome measures

2.4.1. Physical activity and diet

Objective physical activity is assessed using Actigraph GT3x+ accelerometers (Actigraph LLC, Pensacola, FL). We require at least four valid days (defined as at least 600 min of wear time) for the accelerometer data to be included in analyses, based on established recommendations and prior studies [11,29]. Measures include steps per day, average daily minutes of light physical activity (defined as 100–1951 counts/minute), moderate to vigorous physical activity (MVPA; ≥ 1952 counts/minute), and sedentary time (<100 counts/minute) [24]. Actilife version v6.13.3 is used to analyze the raw Actigraph data in 60 s epochs. In addition, self-reported physical activity is measured using the IPAQ-SF [34].

Barriers to completing physical activity are measured using the Barriers to Being Active Quiz [13], a 21-item measure exploring seven main categories of barriers, including lack of time, energy, and resources.

Diet is assessed using the (CDC_s2017) Behavioral Risk Factor Surveillance System (BRFSS) Fruit and Vegetable Module to measure fruit and vegetable intake ((CDC, 2011). The National Cancer Institute's Percentage Energy from Fat Screener [55] is also used to measure percent calories from fat by estimating people's typical percentage of energy derived from eating common fat-containing foods.

2.4.2. Psychological outcomes and quality of life

Psychological outcomes are measured using self-report questionnaires to assess dispositional optimism, state optimism, positive affect, health-related quality of life (HRQoL), anxiety and depression. Dispositional or trait optimism is measured using the Life Orientation Test-Revised (LOT-R) [50], a well-validated 6-item instrument. State optimism is measured using the State Optimism Measure (SOM) [39], which aims to capture the changeable nature of optimism based on time and situation. Positive affect is measured using the 10 positive affect items on the Positive and Negative Affect Schedule (PANAS) [59]. HRQoL is assessed via the well-validated Medical Outcomes Study Short Form-12 (SF-12) [58], which has been associated with mortality in cardiac patients. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale (HADS) [5], a well-validated schedule used in many studies with medical patients. This questionnaire is administered in-person with a psychologist (PI; blinded) before the beginning of first session to screen for depression

and determine if any additional follow-up or mental health referrals are needed.

Environmental barriers and neighborhood walking resources are assessed using four subscales from the Neighborhood Environment Walkability Scale-Abbreviated (NEWS-A) [46], which measures various aspects of the built environment related to walking, such as traffic and crime safety.

2.4.3. Biometrics

Weight (Ozeri Bathroom Scale Model #ZV23-W) and blood pressure (OMRON 3 Series Automatic Blood Pressure Monitor Model BP710 N) are measured at baseline, conclusion of intervention, and at 24-week follow up and are confirmed, if necessary, using data available in the electronic medical record. Confirmation is required if participants' home or study visit biometric measurements vary from those reported in the most recent clinical visit, with clinical visit data considered more accurate.

3. Proof-of-concept study description and findings that informed the pilot RCT

3.1. Proof-of-concept study methods

For the proof-of-concept study (ORBIT phase IIa), feasibility and acceptability were the primary outcomes. The feasibility and acceptability hypotheses were that a majority of participants would complete at least 75% of sessions with scores on the ease and utility of the sessions rated at least 7 out of 10. In addition, we aimed to assess the feasibility of data collection and explored pre-post effects of the intervention on objective physical activity, self-reported psychosocial measures, weight, and blood pressure.

We recruited participants in June 2018 for the first clinic group (round 1) and January 2019 for the second clinic group (round 2). The intervention was modified after feedback from the round 1 group, to align relevant PP and MI topics each week and adding the consent session prior to beginning the intervention due to difficulty completing all material in week 1. Feasibility and acceptability were assessed using descriptive statistics as described in the RCT methods. Assessments were completed one week prior to beginning the intervention and after the conclusion of the intervention (week 8). The Community Healthy Activities Model Program for Seniors (CHAMPS) [54], a 41-items self-report physical activity measure that includes strength and flexibility items, was used in addition to the IPAQ.

To examine the pre- and post-intervention effects on mean physical activity, additional health behaviors, psychological outcomes, and biometrics (blood pressure and weight), paired t-tests and effect sizes (Cohen's *d*) were calculated. All statistical tests were two-tailed, and $p < .05$ was considered significant. Given the small sample sizes, effect sizes were considered to be more informative than *p*-values.

3.2. Proof-of-concept study participant characteristics

We approached 39 participants across two primary care clinics within our hospital's outpatient community clinics who were potentially eligible for the proof-of-concept study based on MetS medical criteria. The inclusion/exclusion criteria were the same as those described in the RCT methods above. Of those, 11 people were interested and screened. Of those, 8 participants were eligible, interested, and enrolled (4 from each clinic). One participant dropped out after the first session, leaving 7 completers. All participants were females with overweight or obesity (BMI mean: 35.1 ± 3.8 , range: 27.2–38.1), and a mean age of 63.3 years old (standard deviation; SD = 3.6). A majority of participants (85%; $n = 6$) were White, one identified as Hispanic/Latina, and one identified as Native American. Besides overweight/obesity, the most common metabolic syn-

drome conditions were hypertension ($n = 6$; 85%) and hyperlipidemia ($n = 3$; 43%). Two participants had a diagnosis of depression (28%) and four had a diagnosis of an anxiety disorder (57%) based on medical records.

3.3. Primary aim (feasibility and acceptability)

Eight participants enrolled across both groups (one at each primary care clinic), and one dropped out after the first session. The median number of sessions attended was seven, or 96.4% of sessions per person, above the *a priori* feasibility threshold of 75% of sessions. From the post-session acceptability scores, the mean rating of session ease was 7.0/10 (SD = 0.5), and the mean utility rating was 8.1/10 (SD = 1.0), both at or above the *a priori* threshold of 7/10 (Supplemental Figs. 1 and 2). For feasibility of outcome measures, the remaining seven participants completed 87.5% of follow-up self-report assessments, and 71.4% had complete accelerometer data. In terms of immediate impact, all sessions showed increased happiness and optimism scores (Supplemental Table 1).

3.4. Secondary aim (pre-post changes in study outcomes)

3.4.1. Physical activity (Table 2)

Accelerometer-measured MVPA increased from an average of 75.3 (SD: 72.8) minutes per week at baseline, to 109.6 (SD: 83.2) minutes per week at follow-up, an average increase of 34.3 min per week ($d = 0.38$; Table 2). Accelerometer-measured steps increased from a mean of 4352.3 (SD: 1877.2) and median of 4213.5 per day to a mean of 6504.1 (SD: 4747.6) and a median of 4906.0 per day. The mean increased by 2151.8 steps per day, approximately one mile ($d = 0.41$). Accelerometer-measured sedentary time increased by an average of 142.5 min per week, from 1029.3 (SD: 133.0) minutes per week at baseline, to 1171.8 (SD: 243.4) minutes per week at follow-up ($d = 0.57$). Self-reported MVPA increased from 15.0 (SD: 19.4) minutes per week at baseline to 349.3 (SD: 224.3) minutes per week at follow up ($d = 2.10$); one outlier was truncated to the next highest value. Due to scoring difficulty and incomplete data, the CHAMPS self-reported activity was not included. Four Barriers to Being Active Quiz subscales decreased with a large effect size ($d \geq 0.50$): social influence ($d = 0.50$), lack of resources ($d = 0.60$), lack of willpower ($d = .87$), and lack of skill ($d = 1.06$).

Table 2

Proof-of-concept study changes in physical activity and biometric measures.

Measure	Pre-test mean (SD)	Post-test mean (SD)	Δ	t	<i>d</i>
<i>Biometrics</i>					
Weight (lbs)	201.2 (24.4)	197.4 (22.2)	-3.77	2.33 (*)	0.95
Systolic blood pressure (mmHg)	131.6 (23.6)	129.2 (12.1)	-2.4	0.37	0.16
Diastolic blood pressure (mmHg)	87.6 (7.4)	78.2 (1.9)	-9.4	1.52	0.68
<i>Accelerometer-measured physical activity</i>					
Moderate-vigorous physical activity (MVPA) (min/week)	75.3 (72.8)	109.6 (83.2)	34.3	1.0	0.38
Steps/day	4336.6 (1888.2)	6432.5 (4785.9)	2065.9	1.1	0.41
Sedentary time (min/day)	1029.3 (133.0)	1171.8 (243.4)	142.5	1.5	0.57
<i>Self-reported physical activity</i>					
International Physical Activity Questionnaire (IPAQ) (min/week MVPA)	15.0 (19.4)	349.3 ^a (224.3)	334.3	3.88**	2.10

** $p < .01$, (*) $p < .10$.^a One outlier was truncated to the next highest value.

3.4.2. Diet

Self-reported vegetable consumption improved by 0.4 servings per week with a large effect size ($d = 0.53$). Self-reported fruit consumption and energy from fat consumption did not change with a meaningful effect size. See Table 3 for details.

3.4.3. Psychosocial variables

Most of the psychosocial and health behavior variables improved (Table 3). Those with large effect size changes (Cohen's $d \geq 0.5$) from baseline to follow-up were dispositional optimism ($d = .53$), depression ($d = .62$), state optimism ($d = 0.72$), mental HRQoL ($d = 0.73$), and positive affect ($d = 0.88$). As the NEWS-A neighborhood assessment subscales did not change, the results are not reported.

3.4.4. Biometrics

Average weight decreased 2.6 pounds ($d = 0.95$), systolic blood pressure decreased 2.4 mmHg ($d = 0.16$), and diastolic blood pressure decreased 9.4 mmHg ($d = 0.68$) (Table 2). A.

4. Adaptations from the proof-of-concept phase to the RCT phase

The intervention was adapted between proof-of-concept groups (rounds 1 and 2) by further tailoring the content to this population, re-ordering the topics to promote better group cohesion, and clarify-

Table 3

Proof-of-concept study self-reported psychosocial and health behavior variables.

Barriers to Being Active Quiz					
Lack of Time	2.00 (2.52)	2.29 (1.98)	0.29	0.35	0.13
Social Influence	3.43 (2.30)	2.29 (1.89)	-1.14	-1.71	0.50
Lack of Energy	1.29 (2.56)	1.86 (1.95)	0.57	0.7	0.25
Lack of Willpower	5.86 (0.69)	2.14 (1.35)	-3.71	-7.84**	0.87
Fear of Injury	1.43 (1.62)	1.14 (1.21)	-0.29	-0.79	0.20
Lack of Skill	2.71 (1.70)	1.14 (1.21)	-1.57	-2.42 (*)	1.06
Lack of Resources	2.71 (2.75)	1.43 (1.27)	-1.29	-1.65	0.60
<i>Diet</i>					
Fruit Consumption (BRFSS screener; servings/day)	1.25 (1.51)	1.07 (0.88)	-0.18	-.54	.14
Vegetable Consumption (BRFSS screener; servings/day)	1.50 (0.33)	1.90 (0.69)	0.40	1.16	.53
Percent energy from fat (NCI)	3.91 (2.76)	3.38 (1.12)	-.53	-.54	.20
<i>Mental health</i>					
Dispositional Optimism (LOT-R)	11.71 (2.81)	10.14 (3.08)	-1.57	-1.18	.53
Positive Affect (PANAS)	36.14 (5.05)	40.71 (5.28)	4.57	1.60	.88
Quality of Life (SF-12 Mental Health)	48.19 (8.18)	54.18 (8.18)	5.99	2.40(*)	.73
Quality of Life (SF-12 Physical Health)	41.92 (5.98)	44.60 (9.90)	2.68	.60	.33
State Optimism (SOM)	27.75 (6.70)	31.75 (3.95)	4.00	1.76	.72
Anxiety (HADS)	6.71 (1.98)	5.57 (2.76)	-1.14	-1.54	.47
Depression (HADS)	4.57 (2.88)	2.43 (1.81)	-2.14	-1.67	.62

** $p < .01$, (*) $p < .10$. Note: NCI: National Cancer Institute, LOT-R: Life Orientation Test-Revised, PANAS: Positive and Negative Affect Schedule, SF-12: Short Form-12 Item Scale, SOM: State Optimism Measure, HADS: Hospital Anxiety and Depression Scale.

ing instructions that were confusing. In addition, due to survey length and participant burden, the CHAMPS is not used in the RCT. The positive results of these feasibility and acceptability measures suggested that the adapted version of the intervention was suitable for use in the next phase RCT. Exit interviews completed by blinded assessors further suggested that an additional session should be added to reduce the amount of material presented each week and that participants wanted some diet information. Therefore, in the RCT, the additional pre-visit consent session was added, and the dietary information sheets were included in the manual as described above. Beyond the high feasibility and acceptability, the positive effects on happiness and optimism and improvements in the outcomes suggested that the intervention should be made available to all participants in the RCT. Therefore, the decision was made to have the control group be a waitlist, rather than the initially proposed enhanced usual care condition.

5. Planned RCT data analysis

5.1. Feasibility and acceptability

All analyses will be completed with the 64 randomized participants. To assess the primary outcome of feasibility, the number of sessions attended by each participant is recorded and descriptive statistics will be calculated. The *a priori* threshold established for feasibility is that a majority of participants ($\geq 50\%$) would attend at least 6 out of the 8 sessions. To further test feasibility, we will use a one sample test of proportions with 0.5 as the null hypothesis, with type one error of 0.05 and power of .80. Acceptability of each session is assessed by descriptive statistics of session ease and utility, with an *a priori* threshold of at least 7/10 [15]. To further assess acceptability, we will estimate the mean score using a random effects model with a random intercept for patient to account for the repeated acceptability measurements from each participant. Pre-post-session happiness and optimism are also calculated for each session using descriptive statistics. Descriptive statistics will be used to calculate the percent of participants who completed the assessments.

5.2. Outcomes

For physical activity, psychological outcomes, MetS-relevant health behaviors and MetS-relevant biomarkers, we will model the changes in the outcomes using a mixed effects model with a random intercept to account for the repeated measures on each participant and to allow for missing data. Using this analysis, we will be able to estimate both the change over time in the immediate intervention group as well as between group differences in change over time comparing the immediate intervention group to the wait list control group. For each comparison, the primary analysis will assess if there was any change from baseline (immediate group) or start of intervention (waitlist control) at either of the two follow-up time points. If a significant change is observed in this global test, we will assess which time points led to the significant difference. In addition to test of statistical significance, the effect sizes for the intervention will be estimated to aid in design of future trials. For all analyses, an intent-to-treat approach will be used to explore between-group differences, and all tests will be considered significant based two-tailed alpha level of .05. The *p*-value will be nominal, given the multiple planned comparisons, and effect sizes are considered to be more informative.

5.3. Power calculations

We will recruit 32 participants per arm in the Phase 3 RCT (total $n = 64$). For feasibility, assuming a completion rate of 74%, we will have 80% power to detect a difference from the null hypothesis of 50% with the sample size of 32 (power one proportion, Stata v15).

Power calculations for the RCT were based on effect sizes from similar prior PP-MI studies [17,28], and not on the proof-of-concept study. For acceptability, our group's prior studies in cardiac patients have observed mean ease and usefulness ratings 7.8 ± 1.5 (SD) out of 10 [17,28]. Assuming the same mean rating in our study and an average of six measurements from the 32 immediate intervention participants, this study has over 95% power to detect a mean acceptability rating of $\geq 7.0/10$. Finally, for the comparison of the intervention vs. waitlist control arms, this study is powered to detect an effect size (Cohen's *d*) of 0.71 (power two means, Stata v15). Even if the effect size of ease and usefulness is smaller than this, the results from this study will provide important estimates for the design of future studies. All statistical tests are performed using Stata 15 (StataCorp, College Station, TX).

6. Discussion

Preventing chronic diseases is of utmost importance for public health and quality of life and requires new intervention strategies. This iteratively developed multilevel community-based PP-MI physical activity intervention represents a novel approach to prevention. The proof-of-concept phase of this study demonstrated high feasibility and acceptability based on *a priori* thresholds. The immediate impact of sessions on participants' happiness and optimism were also favorable, with all sessions showing improvements on both constructs. Secondary aims to assess changes in physical activity, psychosocial constructs, and biometrics showed encouraging improvements on physical activity, positive affect, state optimism, mental health-related quality of life, weight, and diastolic blood pressure. These promising findings set the stage for the next step RCT, for which the protocol is described herein.

Our proof-of-concept study's findings are largely consistent with prior PP and PP-MI interventions among medical populations. A recent meta-analysis of PP interventions among clinical populations found small-moderate effect sizes (.23-.36) on mental health outcomes such as well-being, depression, and anxiety [18]. The present study also found improvements on depression, anxiety, and components of well-being, such as mental health-related quality of life, dispositional, and state optimism, with large effect sizes. While PP-MI combined represents a newer intervention, the present study is consistent with prior PP-MI trials in patients with acute coronary syndrome and heart failure showing high feasibility and acceptability, improved positive affect, depression, and anxiety [15,16,28]. In terms of health behavior outcomes, prior PP-MI studies among patients with cardiovascular diseases have shown improvements in adherence to health behaviors, such as taking medications, adhering to a low-sodium diet, and engaging in self-reported physical activity [16,27]. The present study builds on prior PP-MI interventions by expanding the levels of influence to include social support (groups) and exploration of the built environment walkability and behavioral rehearsal (weekly group walks).

This MetS multilevel intervention framework is a useful model for making sustainable changes by intervening at multiple targets that circumscribe behaviors like physical activity [49]. Individual interventions are rarely sustainable in isolation, but interventions that include changing social norms or providing social support, in combination with improvements to the built environment and policies, can create lasting changes in behaviors like physical activity [47,49]. Using this framework, the present intervention uses the ORBIT model of sequential intervention development [20] by first tailoring the individual-level PP-MI content for this largely sedentary population based on qualitative interviews (manuscript under review) and the PP and MI content that can be effective for individuals. Regarding PP, the upward spiral theory of lifestyle change suggests that when people are aware of positive emotions experienced during a health behavior (e.g., physical activity), the behavior is reinforced and continued [56], such that an intervention focused on promoting well-being could then

amplify. Increased positive affect also increases people's internal emotional and cognitive resources, which can increase the salience of the positive emotions gained from a health behavior, and the cycle allows participants to be able to set and achieve realistic goals, attune to positive emotions experienced during activity, and feel greater pride, determination, and optimism about their physical activity. At the group level, the social support gained from the group sessions was another notable strength, which is reflected in the BBAQ social support subscale improvement and such support has been associated with maintaining health behavior change [4,32]. Finally, the weekly group walk introduced participants to new places to be active in their local environments, reinforced their ability to walk safely, and allowed them to build additional self-efficacy for finding ways to walk despite their prior barriers.

6.1. Limitations

Limitations of the proof-of-concept study included a small sample size and a potential lack of generalizability to men (all participants were women). Conclusions drawn from the proof-of-concept study will need to be replicated and expanded upon in the pilot RCT in order to proceed to larger trials of efficacy and ongoing feasibility. Stratification by age and gender will be planned in future, larger studies like a next step ORBIT phase 3 efficacy trial.

6.2. Recommendations

The next step of this study's development is completing the RCT phase of this intervention, as described in the present protocol. The goals of this phase will be to explore effects of the intervention between groups and determine if larger scale recruitment and retention are feasible. If the RCT shows efficacy in these community settings, it can help this at-risk population improve the behaviors that can prevent the development of chronic diseases.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2020.100626>.

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