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UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN

Instructions for completing the Research Plan are available on the HRPP website.
The headings on this set of instructions correspond to the headings of the Research Plan.
General Instructions: Enter a response for all topic headings.
Enter "Not Applicable" rather than leaving an item blank if the item does not apply to this project.

Version date:10/7/20

1. PROJECT TITLE

PEP4PA - Peer Empowerment Program for Physical Activity in Low Income and Minority Seniors [R01HL125405]

2. PRINCIPAL INVESTIGATOR

Loki Natarajan, PhD
Professor, Department of Family Medicine and Public Health

3. FACILITIES

UCSD office space: Calit2 - Atkinson Hall – 3rd and 6th floors

Intervention activities: All activities will occur at centers and/or community centers located in San Diego County

4. ESTIMATED DURATION OF THE STUDY

5 years: 12/01/2014 – 11/30/2019

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

Older adults are the least active population group in the US. Yet, research has shown that an increase in physical activity (PA) can have immediate and profound effects on cardiovascular health. Older adults who are active use significantly fewer health care resources, and with the increasing number of older adults in the US it is imperative to curb health care expenditure in this group. PEP4PA (**P**eer **E**mpowerment **P**rogram **4** **P**hysical **A**ctivity) is a multilevel intervention aimed at increasing physical activity levels in a population of low income and ethnically diverse older adults. It will be delivered in centers by trained older adults. Participants will work towards a daily increase of 2000 steps per day through self-paced incidental walking, peer led group walks, and attendance at existing center PA classes. They will also work on projects to increase opportunities to be physically active at their center or in the surrounding neighborhood.

6. SPECIFIC AIMS

In a 2-year cluster randomized controlled field trial of 465 ethnically diverse, older adults (50+ years old) in 12 low income community centers serving seniors in San Diego County we will investigate:

1. The efficacy of **PEP4PA** (**P**eer **E**mpowerment **P**rogram **4** **P**hysical **A**ctivity) to reduce disparities in PA by increasing the percentage of participants achieving 150 minutes of PA per week at 6 and 12 months. Hypothesis: Participants in PEP4PA will significantly increase PA minutes in moderate intensity (measured objectively by accelerometry) to a greater extent than older adults receiving usual care (e.g. normal PA programing) in control centers and a greater percent will meet NHANES criteria for weekly PA.
2. The efficacy of PEP4PA to improve physical functioning, blood pressure (BP), depressive symptoms and quality of life. Hypothesis: Participants in PEP4PA will significantly increase their physical functioning (measured objectively by the short physical performance battery and 6 minute walk test), decrease their systolic BP (mmHg) and reporting of depressive symptoms, and improve their quality of life scores (measured at baseline, 6 & 12 months) to a greater extent than older adults in control centers.
3. Assess the incremental cost effectiveness ratio (ICER) of PEP4PA in terms of cost per MET hour and cost per QALY compared to usual programming in the control centers at 12 months.
4. Evaluate the impact of PEP4PA on secondary outcomes such as sedentary time and sleep quality (measured by accelerometry), cognitive/executive functioning, and walking routes (from GPS) at 12 months.

Exploratory aims: 5. Examine individual, interpersonal, organizational, and environmental factors that affect implementation & behavior change. 6. Assess the efficacy, effectiveness and ICER of PEP4PA at 24 months

7. BACKGROUND AND SIGNIFICANCE

National data show that less than 3% of older adults meet PA guidelines and population PA levels have remained low despite intervention efforts. Many PA interventions are flawed because they focus on individual motivations and ignore variations in community resources, neighborhood walkability, and safety. Low income and ethnically diverse communities have disproportionately fewer resources and less supportive neighborhoods. This contributes to lower PA levels and health disparities in obesity, diabetes, hypertension and heart disease. Low income adults and ethnic minorities, therefore, present with chronic disease and loss of functioning at a younger age.

PEP4PA (**P**eer **E**mpowerment **P**rogram **4** **P**hysical **A**ctivity) builds upon our previous R01 multilevel intervention in retirement communities (MIPARC). PEP4PA will be delivered in low income, ethnically diverse centers by trained Health Coaches and center staff. PEP4PA is a comprehensive intervention that employs behavior change strategies at the individual, interpersonal and institutional level. Participants will work towards a 2000 step increase in daily steps through self-paced incidental walking, peer led group walks, attendance at existing center PA classes, and opportune breaks in sitting time. PEP4PA is therefore significant in several important ways: 1) it will impact important health outcomes in low income older adults who disproportionately burden the healthcare system, 2) it can reduce health disparities in a vulnerable population in need, 3) it can improve upon existing PA programs in centers, 4) it will improve upon existing PA interventions in older adults, and 5) it can be a model for disseminating effective peer led programs in other community settings with broad population reach.

1. PEP4PA can impact important health outcomes in older adults who burden the healthcare system

Older adults (aged 50+) who increase their PA to 3 days a week had lower healthcare spending; on average $2,200 less per year than those who remained inactive. Further, older adults who do not meet PA guidelines are more likely to fall. In 2010, the direct medical costs of falls in older adults were $30 billion. Inactive older adults are more likely to have cardiovascular disease, cancer and other morbidities such as obesity, diabetes, depression and lower cognitive functioning. Older adults will comprise 19% of the population by 2030.[i] Objective data show less than 3% are meeting PA guidelines. Given the burden of inactive older adults on the healthcare system, and the relatively low costs of PA interventions, it is imperative that a greater number of older adults have access to efficacious, evidence based PA programs. These programs are particularly important in older adults because their PA levels are naturally declining; for example the control group in MIPARC had a 20 minute/week reduction in PA over 12 months. Further, because older adults are the most inactive segment of society they will benefit most from an increase in PA. In PEP4PA, participants will be encouraged to increase daily steps by 2000 per day over their baseline, which can result in an additional 30+ minutes of activity. Such increases can reduce mortality and heart disease risk by 40%. In addition, since the PEP4PA participants spend most of their day at the center, it is feasible to institutionalize short PA breaks, such as “Take 10”, or brief standing breaks.[ii] Sedentary behavior is an independent risk factor for metabolic disease, regardless of PA status. Thus it is important to also encourage regular breaks from sitting. Our retirement community study included educational materials and behavioral strategies to reduce sitting time, and standing breaks were institutionalized in meetings and group events. PEP4PA will include a daily goal of 10 additional standing breaks.

2. PEP4PA can reduce health disparities in low income and ethnically diverse older adults

Older adults are the least active population segment. They often have difficulty accessing age appropriate health promotion resources. Accelerometer studies in older adult populations have shown disparities in PA by race and income. There are disparities by income and ethnicity in key diseases related to PA, for example obesity, diabetes, hypertension, and heart disease.[iii] Further, there are well documented disparities in environments and resources available for PA. While low income neighborhoods may have resources nearby such as parks and recreations centers, the quality of these are often low thus reducing their use for PA.[iv] Our pilot work in San Diego centers showed a >10% difference in those meeting PA guidelines across ethnicity and income groups. Low income ethnically diverse older adults were as inactive (1.3% (African American center) - 5.7% (Hispanic center) meeting guidelines) as older adults in care settings who were almost a decade older (2.0%). Further, physician diagnosed hypertension rates were 36% higher, as were those self-reporting meaningful depressive symptoms (28% difference). Clearly, there is a need for an efficacious PA program in this population group. It is our aim in PEP4PA to reduce these documented disparities in PA by increasing the number participants meeting NHANES criteria by 10-20%. Importantly, PEP4PA also identifies community barriers to PA, which

are likely to be higher around low income centers, and Health Coaches and center staff will advocate for community improvement projects. This is not only empowering, but important for the long term sustainability of PA levels.

3. PEP4PA can improve upon existing PA programs offered in centers

Government guidelines for PA in older adults include multiple types of PA because of the benefits of strength, balance, and aerobic activities for older adults. PA classes in centers focus on strength and balance. Our preliminary studies show that older adults attending centers with PA classes are not meeting PA guidelines for moderate intensity PA in their daily lives (only 1.3-5.7%). Additionally, we measured a typical center PA class (EnhanceFitness) and found that, in a 60 minute class, only 2 minutes was spent in moderate intensity PA. In PEP4PA, center staff will have a goal of providing high quality regular PA classes at the center. They will monitor attendance and instruction, and will be trained by Circulate San Diego, our community advocacy partner, to advocate for additional resources such as resistance bands. PEP4PA encourages participants to attend PA classes at the center but also includes pedometer logged walking so that multiple health benefits are likely to result. Importantly, because incidental steps are encouraged by pedometer self-monitoring, increasing PA is not solely dependent upon instructors' availability or class schedules. Several studies show walking is the preferred activity in seniors and is absent from centers.

Very few PA programs employ older adults to help deliver programs in community settings, despite their availability and ability to assist. Our MIPARC intervention utilizing Health Coaches resulted in a sustained 50 minute per week difference in moderate PA after 12 months, among adults with an average age of 83. Programs that have used peers have been as successful as those using professionals. Research staff-delivered programs often result in a return to inactivity for participants once the program ends. PEP4PA will employ Health Coaches and center staff to deliver the intervention and support sustainability.

4. PEP4PA will improve upon existing PA interventions in older adults and address important barriers

Recent reviews of PA interventions in older adults demonstrate that most interventions do not include: 1) ethnic minorities, 2) volunteers to help sustainability, 3) long term follow up, and 4) community advocacy. PEP4PA targets low income and ethnically diverse centers and will follow participants and Health Coaches for 24 months to assess PA and program sustainability. A major barrier for older adults' PA is safety. This includes fear of falling and physical and social concerns about neighborhood safety. PEP4PA addresses these concerns with educational content and gradual step increases, identifies and maps safe walking routes, and provides appropriately paced regular group walks. In addition, the Health Coaches and center staff will be trained by our community partner Circulate San Diego to advocate for safer neighborhood streets and parks. MIPARC demonstrated that with brief training, small but impactful community improvement projects could be achieved within 12 months (see Appendix A). Community advocacy will be more important around low income centers and PEP4PA can achieve even greater change with a 24 month intervention period.

5. PEP4PA is highly disseminable & can be a model for other community settings

The NIH & other national and international government health agencies have prioritized interventions in community settings because of their population reach, especially to those in need, and because they offer the potential for interventions to become institutionalized. We are focusing on centers to ensure a more homogeneous environment for the efficacy trial. If PEP4PA, however, proves to be an efficacious model, it could be adopted in other community settings such as YMCAs, community centers, recreation centers, clinics, churches, libraries, private recreation facilities, and senior housing. If shown to be effective in older adults in multiple settings it could also be adopted for intergenerational or youth programs, extending its reach to other population groups in need. PEP4PA is just the first step in the research process. The setting, the intervention structure, and the research design (including effectiveness and cost effective measures) demonstrate our commitment to dissemination efforts in future. In particular, the Older Americans Act Title IIID funding mechanism, that we've identified for phase 1 dissemination, reaches 8.2 million older adults. If this number of older adults increased their PA through PEP4PA, savings of over $18 billion could be achieved (based on increasing PA days to 3 and Martinsen's costs savings calculation of $2,200). We will, however, be able to provide accurate cost implications of this program from our proposed cost effectiveness analyses.

INNOVATIONS

PEP4PA advances intervention science in several meaningful ways

PEP4PA builds upon MIPARC, which was one of the first multilevel interventions that promoted change at all levels of the ecological model.[v] PEP4PA is a peer led program in low income ethnically diverse centers, thus providing greater external validity than the MIPARC researcher led program in high income retirement communities. Because PEP4PA replicates certain MIPARC program elements in a new context (centers), it increases evidence for causality.[vi] However, PEP4PA advances the science by not just replicating MIPARC but developing training for a peer led program &

assessing implementation by the Health Coaches. PEP4PA is intentionally designed to demonstrate sustainability and more efficiently move along the research continuum towards evidence based dissemination by using a train the trainer model.

PEP4PA is designed for dissemination but evaluated by research standards

A novel effectiveness-implementation hybrid design will be employed with the dual testing of clinical and implementation strategies and outcomes.[vii] Because we have demonstrated efficacy in only one setting, the retirement community, it is important to continue to assess efficacy in the new setting, low income centers. However, because it is our intention to provide an intervention that can be disseminated through existing channels – in centers, delivered by Health Coaches paid for through Older Americans Act Title IIID funds, distributed by AAAs – it is important to test the processes that will support its implementation. A hybrid design is advantageous in that it results in more rapid gains in knowledge and translation of interventions, thereby benefitting communities in need sooner. It is additionally a much more efficient use of limited resources, which is crucial given the current economic climate. We propose, therefore, to assess the intervention effects on participants' behavior and clinical outcomes using the latest objective techniques outlined below and in the methods section.

Cost-effectiveness analysis (CEA). CEA is a method measuring the relative efficiency of alternative interventions. It provides information to decision makers to help them maximize the use of scarce resources available to promote PA. CEA, however, has been largely absent in PA promotion in community settings, and even less so with low-income older adult populations. In the proposed project, we will use two common measures of cost-effectiveness, cost per MET (metabolic equivalent) hour and cost per QALY (quality adjusted life years). Cost per MET hour captures intervention efficiency in improving PA outcomes, and cost per QALY measures intervention efficiency in promoting the broader concept of quality of life. The use of common measures of cost-effectiveness will allow us to compare the efficiency of PEP4PA with other PA interventions designed for older adults and help policy makers to prioritize among evidence-based interventions.

PEP4PA combines Social Ecological theory, Empowerment theory & behavioral strategies

The Social Ecological Model provides a framework for addressing behavior change at different levels of influence, from the individual to policy. There are very few interventions that address each level. Theories such as the social cognitive theory (SCT) provide guidance for specific behavior change strategies, usually only applied to one or two levels. We are unique in applying these behavior strategies consistently across the individual, interpersonal and institutional levels of the Ecological Model. PEP4PA will employ strategies from SCT identified by Michie as having most impact on behavior change. These include goal setting, self-monitoring, feedback, positive reinforcement, social support, planning, and problem solving. Such individual change strategies are totally absent from group based PA programs in centers.

Empowerment theories create a mechanism for community participation, enhancing community problem-solving skills, providing leadership training, and creating jobs in the community.[viii] Strategies to facilitate empowerment include enhancing experience and competence, enhancing group structure and capacity, enhancing environmental support and resources, and removing social and environmental barriers.[ix] Organizational empowerment includes opportunities for members to take on meaningful and multiple roles, and a peer-based support system that helps members develop a social identity. Mentoring, supportive peer relationships, and a political consciousness have also been identified as mechanisms. Empowerment theory has not been used in previous PA research with older adults. PEP4PA will draw upon Empowerment theory and the intervention strategies and goals mirror its key elements. PEP4PA will train Health Coaches and center staff to improve their health awareness, social support skills, organizational skills, and their ability to advocate and build capacity within the centers.

PEP4PA will collect state-of-the-science, objective data on PA, sedentary behavior, sleep, and location.

There has been growing interest in collecting objective behavioral data from older adults, in part because self-reports are plagued by recall bias and cognitive error.[x] Lack of concordance between subjective and objective measures of PA and sedentary behavior often yields huge discrepancies in behavioral prevalence estimates.[xi, xii] We propose to use state-of-the-science Global Positioning System (GPS) devices and hip- and wrist-worn accelerometers to provide better estimates of PA, but also to examine independent and interdependent relationships between PA, sedentary behavior, outdoor time and sleep quality.

8. PROGRESS REPORT

N/A – this is a new protocol

9. RESEARCH DESIGN AND METHODS

We will conduct a small pilot study in one senior center prior to launching the larger randomized controlled trial. The pilot will allow us to test the peer Health Coach training and other study protocols in order to make adjustments for the full study. When necessary, methods have been described individually for the two studies.

Pilot Study:

We will recruit up to 4 peer Health Coaches, 2 staff members and 50 participants for the pilot study from the Gary and Mary West Senior Wellness Center. We have been working with this center for several years on the development of a community based walking intervention in older adults. In 2013, we formed a Community Advisory Board (CAB) of older adults, center directors and other stakeholder to advise us which is held in this center. Because participants in the center have been very involved in the development of the study, we felt that it was not appropriate to include it as a study site. However, we feel that it provides an excellent opportunity to pilot test the Health Coach training, recruitment and sustainment of the program in this setting in order to inform the larger trial.

Intervention: The study will be 4 months in duration and will conducted in in English only. Health Coaches and center staff will participate for 5 months, which will include their training as leaders of the program. There will be no control condition; all those who are interested will receive the physical activity intervention as described below for 4 months.

Measures: Measurement will occur at baseline, 2 and 4 months. Participants, Health Coaches and center staff will complete surveys on their experiences in the study, their daily activities and their thoughts. Participants and Health Coaches will complete the 6 minute walk test at baseline. They will be asked to wear pedometer every day and to track their steps in logs provided by UCSD. They may be asked to complete interviews with UCSD staff on their experiences or participate in a focus group at the end of the study.

PEP4PA Intervention

We propose to study increases in moderate PA in a 2-year cluster randomized controlled field trial of 408 ethnically diverse, older adults (50+ years old) in 12 low income centers in San Diego County. Community or center participants will receive the PEP4PA (**P**eer **E**mpowerment **P**rogram for **P**hysical **A**ctivity) intervention or usual care (i.e. normal center programing) in the control condition. The centers will be randomized to either condition. Health coaches and center staff will deliver the program with the support of feedback and training from a professional UCSD Health Educator. Participants will work towards a 2000 increase in daily steps through self-paced incidental walking, peer led group walks, and attendance at existing center PA classes. Participants, Health coaches and sites' progress will be monitored constantly over 24 months with outcome measures at baseline, 6, 12,18 and 24 months in both intervention and control participants. Intervention sites will be randomized a second time at 18 months to one of two conditions: 1) financial support for the last 6 months of the program, or 2) no financial support for the last 6 months to assess the sustainability of the project. Where appropriate, activities will take place in English & Spanish. We will aim to train 4 Health coaches and 1 staff member at each site.

We have chosen to use a usual care control condition for several reasons: 1) PA classes and social events are already offered in centers, 2) to disseminate PEP4PA in future we need to demonstrate to centers the cost benefits compared to their existing PA programing, and 3) because PEP4PA employs peers & center staff, attention control is less problematic than in our previous UCSD led interventions. Finally, to support recruitment & retention in the control sites we will provide a health event (health fair, speaker on health related topic, etc.) at the end of measurement visits where we provide feedback to participants on their BP. Sites are spread across the county so we do not expect contamination with control sites. We will assess any changes to PA programming in the control sites across the 24 month period.

Spanish language: Dr Cardenas is bilingual and bicultural. She will supervise Spanish speaking staff members, for both measurement and intervention. Most of our self-report measurement outcomes are standard and have been validated in Spanish and in those with low education. Measures that are unique to the intervention will be translated and back translated to check for linguistic and cultural equivalence. Intervention materials have also been adapted, translated and back translated in our pilot work. Events will be held in both English and Spanish. In our center pilot work we found that simultaneous translation was feasible, not confusing for participants, and the slower pace supported comprehension. There were no centers with only Spanish speakers so we anticipate groups will be mixed.

Training: Peer Health Coaches and center staff will receive 16 hours of training delivered by our staff health educator over the course of 2 weeks. They will be trained in key program elements prior to recruiting center participants. Health Coaches and center staff will have to complete explicit activities in order to achieve certification to lead the program. Once certified, the Health Coaches will lead weekly case management meetings to review participant progress. The health educator will observe study activities and case management meetings and provide one on one feedback to Health Coaches as necessary. Center staff will be trained and certified in all activities so they can understand the program and play a supportive role, filling in if needed for an absent coach as needed. Health Coaches and center staff will receive additional training in community advocacy from Circulate San Diego, a local bike and pedestrian advocacy group. They will identify local barriers to PA, prioritize steps for community change, work with community partners to advocate with local decision makers, and follow up to ensure community improvement projects are completed. These projects will support safe walking. Each Health Coach will be assigned up to 10 participants that they will support throughout the program.

Intervention dose: Health Coach and center staff meetings will be weekly for the first 3 months, bi weekly for 3 months and then monthly for the next 6 months. After 12 months, the Health Coaches will continue to run the program with only intermittent support from the health educator as needed. For participants, intervention activities will remain at the daily level, including using pedometers, having daily goals, participation in daily activities such as Take 10 breaks, attendance at group walks and normal center PA classes, and recognition of efforts through weekly prizes and bi-weekly goal tracking with their Health Coach.

Intervention activities:
Participants will receive the behavioral strategies outlined below to increase their moderate intensity PA and reduce sitting time. The main goal is a 2000 daily step increase, achieved through the activities outlined below. All participants receive the same goal which adds to the group cohesion. Further, the goal can be achieved gradually within 6 months with a 100 step increase per week. This schedule is easy to communicate and can be repeated by participants after illness to get them back on track.

Goal setting	2000 daily step increase from incidental walking & group walks, group PA class, Take 10 breaks & 10 standing breaks/ day.
Monitoring/evaluation	Pedometers to monitor steps. Simple functioning checks e.g. timed walk/balance test to show progress.
Feedback	Graphs of daily steps overtime. Review of progress & verbal positive reinforcement from Health Coaches bi-weekly.
Rewards/Recognition	Weekly prizes for step achievements. Weekly celebration board of participant achievements and group step progress e.g. on a map around US. Certificates for goal achievement. Monthly celebration lunches.
Social support	Health Coach & staff encouragement. Group walks at appropriate levels and other group activities/events led by Peers. Group sharing of challenges/solutions. Sharing of achievements with family.
Role models/success stories	Health Coaches model step goals. Hear about others who meet goals/overcome challenges during group sharing. Review testimonials from MIPARC participants. Record and review testimonials from PEP4PA participants.
Positive experience	Fun events & supportive atmosphere in center. Well organized walks with different abilities accounted for. SMART goals that are challenging but achievable. Clear short and long term goals i.e. 100/day extra each week to meet 2000/day extra.

Cues/reminders	Phone calls from Health Coaches to remind participant to attend center events, bi-weekly in person check ins, timers for standing breaks & Take 10 breaks, pedometers (with 7 day memory) & logs for steps. Promotional materials in Center.
Planning/scheduling	Planning attendance at events, reviewing steps across day with pedometer, planning when to get steps.
Problem solving	Work on overcoming barriers in bi-weekly review with Peer leader. Learn how others overcome barriers. Reduction of barriers e.g. crossing times, lack of equipment through community projects led by Center Staff and Health Coaches
Relapse prevention	100 step goal schedule for returning to normal after illness. Set goals for how to maintain step increases. Continued monitoring from pedometer and Health Coaches.

Health Coaches will have a clear role and be trained to conduct the expected activities. The 4 Health Coaches at each site will be responsible for about 9 participants each. They will review individual step goal progress with participants bi-weekly, lead group walks twice a week & organize other activities & events such as celebratory lunches to maintain motivation. Health Coaches will communicate educational tips and lead discussions before & after events. Videos of expert PA content & answers to high level PA questions will be provided by UCSD staff as needed. Each week coaches will recognize participants' individual & group achievements through prizes and a celebration board that is housed in a focal point of the center. After advocacy training to all participants by Circulate San Diego, Health Coaches and participants will decide if they'd like to work on a community project to reduce barriers to walking. Finally, they will work to build capacity for center participants to help with program elements, e.g. maintaining celebration board, organizing lunches etc. All intervention sites will receive $750($250 every 6 months up to 18 months) to support promotional activities. Sites randomized to receive funding in months 18--24 will receive an additional $250. We will provide a tablet for every peer health coach enrolled and a printer for intervention sites to create the educational & promotional materials and to help track participants' goals and attendance. Computer training is included.

Center staff will have a clear role and be trained to conduct the expected activities. In particular, the staff will be responsible for institutional level activities. Staff will review the quality and quantity of PA classes offered and work to optimize attendance and PA levels in these, and where necessary advocate for additional resources to support improvements such as instructor training or equipment. Staff will provide a supportive center atmosphere with positive verbal reinforcement and promotional materials, making sure PA events are well advertised. Center staff will provide alternative activities when PA instructors are unavailable, e.g. evidence based exercise videos for older adults..

Study Outcomes (all devices & outcome measures have been tested in low income pilot centers)

Measurement: Measurement occurs at baseline, 6, 12, 18 and 24 months. The measurement procedures are split into two visits; both held in the center facilities. In the first visit, participants are given devices and complete a written survey. The hip mounted accelerometer and GPS are worn on a single belt for at least 10 hours a day and will be worn at the beginning of the study, 6, 12, 18 and 24 months. A wrist worn accelerometer is worn 24 hours a day and will be worn at the beginning, 6, 12, 18 and 24 months. Participants are expected to wear the devices for 7 days. In the second visit, participants complete the functioning tests. Participants and health coaches complete all measures; staff members will only complete surveys and have their blood pressure measured.

Activity outcomes

Minutes of moderate PA: The primary outcome of this study is moderate PA minutes per day. As Troiano' s population level monitoring of PA has shown, it is important to use objective measures of PA to gain an accurate assessment of PA minutes.[12] We will use the Actigraph 3X-plus model and process the data with the Actigraph Actilife 6.9.2 software. We will use 90 consecutive zeros with a 2 minute threshold to screen for non-wear time.[xiii] The data will be aggregated from 30 Hertz to 60 second epochs to match currently defined cut points. Participants will be required to wear the hip meter for a minimum of 10 hours a day. Measurement staff will assure that participants understand how to properly wear the monitor at the baseline assessment and they will receive multiple calls to ensure compliance. Participants are asked to re-wear the device if the criteria are not met on at least 4 days. We will use cut points recently developed for older adults[xiv] to determine time in the different PA intensities. In MIPARC participants walked the timed 400m walk at counts below the moderate cut off for adults (1952 counts per minute; CPM) suggesting this cut off would not capture purposeful walking in older adults (see Appendix G). PA will, therefore, be defined as >1041 CPM. Activities <100 CPM will be

classified as sedentary.[xv] Average daily minutes at different intensities will be calculated. To provide perspective on disparities reduction, we will assess the percent of participants who meet PA guidelines following the data processing decisions used in NHANES, including 10 min bouts & 30 minutes on 5/7 days.

PA location/routes: Participants will wear the Qstartz BT1000X GPS device. A GPS device logs *X,Y* location coordinates, distance, speed, elevation, and time. The Quartz has an accuracy of 3 meters. We configure the device to record additional satellite information which enables us to detect indoor and outdoor locations. The device will record every 15 seconds. The Qstartz GPS is smaller than a cell phone and is worn inside a pouch on the same belt as the accelerometer at all times. Participants must charge this device every evening, and we have developed protocols to maximize compliance. Our NIH funded PALMS software will allow us to merge the GPS data with the time stamped accelerometer data. PALMS has flexible data processing parameters to assess transportation modes, time spent in locations, routes and distances travelled (See Appendix H). We will assess changes in walking routes over time, and in relation to community projects.

Sedentary behaviors: will be assessed by self-report, and the accelerometer. We have adapted the Sedentary Behavior Questionnaire[xvi] for older adults in our MIPARC study. It assesses sedentary behaviors such was sitting while eating, reading, watching TV, etc. *Sleep quality*. Self-reported sleep quality will be assessed by the NIH Promis Sleep Disturbance short form-6.[xvii] Sleep quality is related to energy, fatigue with exertion, mood, and pain – each of which may influence involvement in PA. PA, and timing of it, may in turn influence sleep quality.[xviii] Because reporting errors of sleep behavior may be exacerbated among older adults, particularly among those with mild dementia,[xix] we will also use wrist-based actigraphy to measure sleep parameters. Wrist-based actigraphy is a valid measure of sleep parameters.[xx] We have analyzed accelerometer sleep data in two existing studies (TREC (U54 CA155435), and IWATCH (CA164993)).
Cardiovascular outcomes *Blood pressure*: Increased walking has been shown to decrease blood pressure.[xxi] Blood pressure will be measured with a portable Critikon Dinamap 8100 noninvasive blood pressure monitor. After a 5-minute rest, 3 consecutive measurements will be taken at 1 minute increments. Systolic, diastolic, and mean arterial pressure will be recorded and the 3 readings will be averaged. *Cardiorespiratory Fitness:* is an essential part of functional capacity in an older population and has been shown to improve with PA interventions.[xxii] Cardiorespiratory fitness will be measured with the 6 minute walk test(Troosters et al. and Harada et al.)
Height and weight will be measured at baseline. We will collect by self report at 6, 12 18 and 24 months.
Physical, cognitive & emotional functioning *Physical functioning*: Functional performance will be measured with the Short Physical Performance Battery (SPPB).[xxiii, xxiv] The SPPB evaluates balance, gait, strength, and endurance by examining ability to stand with the feet together in the side-by-side, semi-tandem, and tandem positions; time to walk 8 feet; and time to rise from a chair and return to the seated position 5 times.The SPPB will be collected at baseline..
Cognitive functioning:[xxv, xxvi, xxvii, xxviii] *Depression* will be measured with CESD short form.[xxix] See Appendix D for surveys.

Medication usage: Medications will be assessed by an in person medication inventory as described as reliable and valid in the Cardiovascular Health Study (Pstay et. al.,1992). During the in person visit while participants are performing other standard tests, a research assistant will note all the medications and doses on a standard written study form. In this way, collection of the medical data will cause no additional burden to the participant. Once all medications are noted, the research assistant will check whether any medications are missing. Dr Unkhart will review the medications before data entry and only blood pressure medications will be included in analyses.

Cost-effectiveness Measures will provide cost and effectiveness information to help community health leaders and centers to replicate and disseminate the PEP4PA intervention. We will use a center perspective, which could also serve as a basis for future CEAs with broader perspectives such as health care system or social perspective. Two ICEA measures will be calculated: cost per MET hour and cost per QALY. These two measures are chosen as they are standard measures in CEA literature in promoting PA. A MET represents the ratio of energy expended divided by resting energy expenditure. MET hours are derived by multiplying METs associated with the type and intensity of the PA by the time spent on the PA. The type, intensity and time of PA will be derived from the Actigraph 3X-plus model as described above. QALYs will be estimated using the EuroQual (EQ-5D).[xxx] The EQ-5D is a preference-based index that values health on a 0 (dead) to 1 (perfect health) scale to represent 5-dimensional health state descriptions for each participant. U.S. normative data for the Eq-5D has been developed based on national surveys. [xxxi] Intervention costs will be estimated from the study using standard financial accounting methods. From a center perspective, cost will account for all direct resources needed to conduct the intervention. It will not include cost spent by the intervention participants such as

participants' time on exercise. Study specific costs, e.g. measurement, will also be excluded from the estimate of intervention costs. Appendix I contains the list of costs.

Participant level mediators & moderators (see Figure 1) *Pain:* Older adults experience pain regularly, with an increased prevalence among those living in facilities.[xxxii] Pain interference or the impact of pain will be assessed with the PROMIS-Pain Impact Short Form-6 which assesses pain interference in the past 7 days.[xxxiii] *Fear of falling:* has been related to PA in older adults.[xxxiv] We will employ the 7-item Short Falls Efficacy Scale-International (FES-I) that has been shown to have excellent reliability and construct validity.[xxxv] *Neighborhood perceptions:* The widely used NEWS-A[xxxvi, xxxvii, xxxviii] will be used to assess perceptions of residential neighborhood environment variables including walkability, aesthetics, and perceived safety from traffic and crime. The NEWS was adapted for seniors. [xxxix] *Psychosocial:* Self efficacy and social support from family and friends for PA will be measured with established psychometrics.[xl, xli] *Demographic characteristics*: Participants will provide demographic characteristics including: gender, age, education, marriage, income, ethnicity, car and scooter use, and use of walking aides. *Health Status:* will be measured with a subset of the NHANES 'medical conditions' survey. *Intervention* mediators and moderators are outlined below in process measures. Process, fidelity and effectiveness measures Because this study employs a hybrid efficacy/effectiveness design, in addition to the carefully measured outcome measures above, we will also track intervention process and implementation effectiveness outcomes. We will use the REAIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) to assess processes and outcomes at the individual (participants), interpersonal (health coaches) and institutional (staff and center) level. See Table 6 for details. A mixed methods design will be employed using qualitative and quantitative data collection methods. Participants will complete short evaluations of each event they attend to provide feedback to the Health coaches as well as satisfaction scales when they complete study measures at 6, 12 and 24 months. Peers, staff and MTs will rate their satisfaction with the training and their confidence & belief in their effectiveness. Characteristics of the Health coaches, staff, and Center resources will also be assessed as moderators. *Group cohesion*: will be measured by a subset of items from the Group Attitude Scale (GAS) used to assess attraction to a group.[xlii] Items include: "I like my group"; "I look forward to coming to the group"; "I feel involved in what is happening in my group"; "I feel included in the group". See Appendix D for an example Health coach survey. Health coaches and center staff will be trained in the importance of evaluation techniques and be provided with tools to help them track their time, interactions with participants, event attendance, and community project progress. The intention is that these tools will serve as monitoring tools for tracking achievements and to reinforce continued implementation. We will encourage multi-media tracking of participant and project successes using photos and video testimonials. These are not only important for recognition of success but stories also can be employed to support future dissemination and influence decision makers. MTs will check that the evaluation tools are being used. Data will be recorded in a customized program on a tablet provided to each site. Data will be emailed to UCSD monthly over the 24 months. Health coaches may choose to keep using the tablets until the study ends at every site in December of 2019. Participants will be asked if they would like their data deleted from the tablet database after the 24 month study ends at their site. Their signature will be obtained on a form at the 24 month measurement visit. During the basic training and first 12 weeks of the study, MT and Health coach activities will be observed and recorded to provide feedback to the leaders on their skills and to ensure intervention fidelity; found to be important by others.[xliii] In addition to systematic tracking as part of the intervention delivery, UCSD research staff will conduct focus groups & interviews at 12 and 24 months with participants, MTs, Health coaches, and center staff and directors to better understand individual, interpersonal and institutional factors that may influence study adoption and implementation. We will ask respondents about their experiences in delivering PEP4PA and what factors either enhanced or detracted from implementation. See Appendix D for a discussion guide. We will investigate organizational make-up and polices to assess what procedural, funding and structural supports would be required for wider dissemination.

Statistical Analysis

Dr. Natarajan will be the lead statistician and be responsible for generating randomization allocation sequences, supervising data analysis, and developing and implementing novel methods. She will be blinded to intervention condition. Summary statistics will be calculated; groups will be compared on baseline characteristics; variables that are not balanced across study arms will be adjusted for in subsequent analyses. The primary analysis will use the intent-to-treat principle.

Aim1 & 2 Analysis Plan: Aim 1 will test the efficacy of the PEP4PA intervention on PA, and will compare the PA intervention group to the usual care control group on minutes/day of PA and % meeting NHANES criteria measured

by accelerometry over 6-12 months. A mixed effects regression model will be used with post-intervention PA at 6 & 12 months as the dependent variable and intervention arm (active vs control) as the independent variable, with baseline PA as a covariate. Gaussian link function will be used for the continuous PA outcome; a binomial link will be used for the binary outcome (meeting vs not meeting guidelines). A random effect for site (center) and a subject-specific intercept (nested within site) will be added to the model to adjust variance estimates for clustering within site and within individuals over time. Additional covariates such as gender and age, and any factors found to be imbalanced between treatment arms at baseline will be included to examine the impact of covariates on estimated treatment effects. Aim 2 assesses the efficacy of the PEP4PA to improve physical functioning, blood pressure, depressive symptoms & quality of life and will compare these outcomes between treatment and control arms using the same approach as Aim 1.

Aim 3 Analysis Plan: Assess the incremental cost effectiveness ratio (ICER) of PEP4PA in terms of cost per MET hour and cost per QALY compared to usual programming in the control centers at 12 months. Drs. Shi and Gilmer will be the lead health economists on this project and will be responsible for supervising cost data collection and conducting CEA at 12 & 24 months. The CEA will follow well-established guidelines developed by Drummond et al., and Haddix et al., including identification of all relevant costs and consequences for the intervention, accurate measurement in appropriate effectiveness units, sound valuation, and sensitivity analysis to test uncertainties. The final outcome of the CEA is ICER, the ratio of the differences in costs and effectiveness. Two ICEA measures will be evaluated in this project: cost per MET hour and cost per QALY. To allow comparisons to other PA interventions, cost per QALY derived from this study will be compared to subjective thresholds of the value of health care ($50,000 per QALY).We propose to use $1.16 per MET hour cost, the median ICER of community support PA program in community setting, as a tentative cutoff for comparison. To account for non-parametric nature of the data, we will use bootstrap to create confidence intervals for the mean costs and effectiveness for the each comparison. A scatter plot of 5000 bootstrapped ICER will be generated by drawing a random sample with replacement. The CEA results will be presented in a cost-effectiveness acceptability curve. The uncertainty of the parameters will be explored in sensitivity analysis. The impact of time spent in the cost will be tested.

Aim 4 Analysis Plan: This aim assesses the efficacy of the PEP4PAintervention on other PA outcomes (step counts, sedentary time), psychosocial and lifestyle measures (cognitive/executive functioning, sleep quality), and walking routes (measured by GPS devices). As in Aim 1, mixed effects models will be fit for each outcome at 6 & 12 months (dependent variable), with adjustment for baseline level, group, and other covariates. In addition, because several of these outcomes are likely correlated (e.g., sleep, sedentary time), we will apply statistical methods for multiple outcomes i.e. O'Brien's test which is a weighted linear combination of t-statistics for each outcome and multivariate repeated measures models which will be used to examine treatment effects on the vector of outcomes over time.

Aim 5 (*Exploratory aims*) We will examine *quantitative* participant and intervention mediators and moderators (see Figure 1) of behavior change and implementation success. Moderators will be tested by including interaction terms between the putative moderator and treatment condition in the models. Mediation will be assessed using path analysis. To examine multiple mediators, we will extend the above analysis to a multiple mediation framework for multilevel data. We will apply bootstrap methods to resample and refit mediation models to compute standard errors and examine consistency of results. We will also fit Bayesian graphical networks (BN). Qualitative data will be reviewed using standard content analysis procedures. The 'authenticity' of emergent themes will be checked using validation procedures.

Aim 6 The modeling approaches in Aims 1-4 will be expanded to include the 18 and 24 month data.

Sample size estimates We determined sample size for the primary outcome (Aim 1) of improving PA over 12 months. In preliminary analysis of our MIPARC study, we observed (i) a mean 40 min/day difference between intervention and control groups for LMPA at 6 months (SD = 57 min/d), yielding an effect-size of 0.7, and (ii) an intraclass correlation (ICC) of 0.07 for center clustering effects on LMPA (in our pilot study in low-income seniors this ICC < 0.01). 12 sites and 28 subjects/site will yield 80% power (2-sided test α =0.05) to detect conservative effect-sizes between 0.41 to 0.56 for time-averaged standardized mean differences between arms assuming center clustering ICCs ranging from 0.05 to 0.1, and autocorrelations of 0.5 to 0.8 on within-subject repeated measures of PA. Also, under these assumptions, there is 80% power to detect percentages of 20%- 25% meeting guidelines in the intervention vs 5% (based on pilot data) in the control arms at follow-up. To allow for a worst-case attrition rate of 20% by 6 months (our RC retention rate is 91% at 6 months), we aim to recruit 408 participants (12 sites with 34/site).

Missing data All outcomes will be tested using an intent-to-treat framework. Our analytic approach using mixed-models will yield unbiased results even if some observations are missing as long as the data are "missing at random", i.e., the

reasons for missingness can be predicted from observed measurements. In MIPARC differences between drop-outs and baseline factors were similar between treatment arms (i.e., treatment*arm interactions were not statistically significant). Thus, under similar assumptions the mixed model approach will give unbiased results in the proposed study. We will conduct sensitivity analyses to test for informative drop-outs and develop alternate approaches, e.g. pattern-mixture models.

10. HUMAN SUBJECTS

Community Advisory Board (CAB):
We formed a volunteer community advisory 1 year ago to inform this study's development. It is comprised of various stakeholders engaged with older adult services, including: senior and community center directors, older adults who attend centers, San Diego walk advocacy groups, and staff from the County's Aging and Independent Services. The CAB will continue to meet on a quarterly basis to provide feedback to questions about the study design and methods.

Pilot Study:
We will recruit up to 4 peer Health Coaches, 2 staff members and 50 participants for the pilot study.
Participants will be eligible if they:
- are 50 years or older
- have not had a fall that resulted in a hospitalization in the past 12 months
- able to complete a 3 meter walking test within 30 seconds
- able to read and write in English
- able to complete written surveys without assistance
- able to attend regular study activities at the center
- willing to complete study activities which are described below
- able to provide written informed consent and complete a post consent comprehension assessment
- able to commit approximately 10 hours per week to study activities *(peer Health Coach only)*
- active for 20 minutes per day on at least 3 days per week *(peer Health Coach only)*
- able to commit approximately 5 hours per week to study activities *(center staff only)*

Participants will be excluded if they: 1) are younger than 50 years, 2) have had a fall that resulted in a hospitalization in the last 12 months, 3) cannot complete the walking test within 30 seconds, 4) are not able to read and write in English, 5) are not able to complete written surveys without assistance, 6) cannot regularly attend study activities at the center, 7) are not willing to complete study activities, 8) are not able to provide written informed consent, 9) do not adequately answer questions on the post consent test, 10) cannot walk without human assistance.
Health Coaches will be excluded from that role (but will be allowed to enroll as a participant) if they: 1) are not active for at least 20 minutes on 3 days per week, 2) cannot commit to 10 hours per week for study activities for the length of the study.
Center staff will be excluded if they: cannot commit approximately 5 hours per to study activities for the length of the study.

PEP4PA Main Study:
We will enroll 465 English or Spanish speaking older adults to participate in the study. We will also recruit up to 4 health coaches and 2 staff members at each of the 6 **intervention sites only.** Control sites will not have Health Coaches or staff members enrolled in the study.

Participant Eligibility: Older adults (50+ years) who are eligible according to our criteria will be consented, enrolled and assessed. Eligibility criteria include:
- 50 years or older
- have not had a fall that resulted in a hospitalization in the past 12 months
- have not participated in UCSD's Community of Mine research study *(intervention participants only)*
- able to complete a 3 meter walking test within 30 seconds

- able to walk without human assistance (cane or walker use okay)
- able to read and write in English or Spanish
- able to complete written surveys without assistance
- able to attend regular study activities at the center
- complete study assessments and wear study devices as described
- able to provide written informed consent and complete a post consent comprehension assessment.
- able to commit approximately 10 hours per week to study activities *(peer Health Coach only)*
- active for 20 minutes per day on at least 3 days per week *(peer Health Coach only)*
- able to commit approximately 5 hours per week to study activities *(center staff only)*

Additional Staff Eligibility:
- work or volunteer full or part time at the community center
- able to read and write in English without assistance
- able to provide written informed consent

Participants who subsequently miss the baseline measurement or forget to wear the devices will not be enrolled in further assessments as we've found in previous studies that this indicates a cognitive deficit and feel the intervention would not be appropriate.

Participants will be excluded if they: 1) are younger than 50 years, 2) have had a fall that resulted in a hospitalization in the last 12 months, 3) have participated in the UCSD Community of Mine research study (intervention participants only), 4)cannot complete the walking test within 30 seconds, 5) are not able to read and write in English or Spanish, 6) are not able to complete written surveys without assistance, 7) cannot regularly attend study activities at the center, 8) are not willing to complete study activities, 9) are not willing to complete study assessment and wear study devices 10) are not able to provide written informed consent, 11) do not adequately answer questions on the post consent test, 12) cannot walk without human assistance.
Health Coaches will be excluded from that role (but will be allowed to enroll as a participant) if they: 1) are not active for at least 20 minutes on 3 days per week, 2) cannot commit to 10 hours per week for study activities for the length of the study. For Spanish Speaking Sites, if they do not read, write, and speak both English & Spanish fluently.
Center staff will be excluded if they: cannot commit approximately 5 hours per to study activities for the length of the study

Participants do not need clearance from a primary care provider to participate as we anticipate that many in this low income population will not have a provider. While the falls risk criteria and ability to walk without the human assistance may exclude some participants who would benefit from a PA program, given that the intervention encourages unsupervised walking, this precaution is necessary to mitigate the risk of enrolling individuals for whom a walking program would be unsafe. In addition to the screening criteria, we will provide all eligible participants for the intervention study with the DHHS Physical Activity Guidelines Guidelines (http://www.health.gov/paguidelines/guidelines/) so that they may decide if the program is acceptable.

11. RECRUITMENT AND PROCEDURES PREPARATORY TO RESEARCH

Pilot Study:
The pilot study will be conducted at the Gary and Mary Senior Wellness Center. We have been working with them for several years and they host the Community Advisory Board (CAB) that we created to inform this study. The center has agreed to participate in the pilot program. Four Health Coaches have already expressed interest as they have been participating in the CAB and are familiar with the program. The center director will identify a staff member who can devote 5 hours per week for the 5 month study. The health educator will train the staff member and Health Coaches, who will then recruit study participants from the center through methods that they agree upon. We will allow up to 50 older adults to participate.

PEP4PA Main study:

Potentially eligible community or centers were contacted during the proposal process and their willingness to participate will be confirmed. We will ensure that sites have at least 1 staff member who can participate in the study, have an available meeting space, and have or are willing to provide an exercise class at their center. Randomization occurs at the study site level, once centers sign a memorandum of understanding agreeing to either condition. Participants are therefore randomized before their baseline measurements. Site level randomization is necessary as the intervention involves center staff and changes to the environment in and around the centers. Cross contamination would be unavoidable with participant level randomization. A permuted block design will ensure equal numbers of sites are in the intervention and control condition. Intervention sites will be randomized a second time at 18 months to one of two conditions: 1) financial support for the last 6 months of the program, or 2) no financial support for the last 6 months, in order to assess the sustainability of the project. The site memorandum of understanding will include this second randomization, which will be revealed at the 18 month measurement time point.

Centers have been identified in neighborhoods where the average annual household income is low (8 sites in neighborhoods with under $35K average household income, and 4 under the $49k median for San Diego county). From the 12 sites currently identified, 3 are in neighborhoods that are predominantly Latino and 2 in predominantly African American neighborhoods. Thirteen centers have already provided letters of support included in this application. In our pilot work and through the Community Advisory Board we formed, we have spent time getting to know staff, center attendees, and developing trust within the community. Centers are required to provide at least one staff member to attend training and help implement the intervention at the institutional level.

Once centers are randomized we recruit the peer Health Coaches. Health Coaches are expected to be PA role models and able to lead group walks. Peers are identified from observations at the site, as well as from staff and member recommendations. Health Coaches complete a brief interview to ascertain eligibility and then commence their 2 week training. Participant recruitment in the centers occurs through word of mouth, flyers, information tables, social media and presentations. In order to recruit residents who may not normally attend the center, we will place advertisements in local publications and media, at churches, in HUD housing complexes, and, if necessary, mail boxes. We will announce informational talks through twitter and posts on our research group Facebook page. No personal information will be collected; it will serve as a place to communicate about the study and opportunities to attend events to find out more information. We will also use marketing company data to identify participants meeting the age criteria (50+), with an address in the zip code surrounding the center. This method, which has been successfully implemented by the PI, allows researchers to reach a large number of potential participants who live in communities surrounding participating centers. The marketing company uses public data sources such as census data, survey reported data, and the white pages. We have purchased the marketing list for use in study #140510, thus there is no additional cost to utilizing the list.

People who meet the age criteria will first receive a letter from the study team explaining 1) the study, 2) the participant selection process, 3) that they will receive a follow up phone call. The letter will inform them about the opportunity to participate in the study. The letter will clearly specify that participation is completely voluntary and will also explain the procedures for having their name removed from our recruitment list if they do not want to be contacted. This procedure has been used by colleagues in random sampling of community members through the use of publicly available lists. This method allows individuals to notify us that they do not want to be bothered. If a potential participant calls or e-mails asking to be removed from the recruit list, their request will be immediately respected and no attempt will be made to recruit the person into the study. Two to three days after expected delivery, trained recruitment staff will contact each target telephone number. Up to 3 calls will be made for each selected individual.

Upon reaching a potential participant over the phone or in-person, recruitment staff will, introduce the project, notify them of upcoming recruitment or screening events taking place in their community, and ask if they are interested in being contacted for future studies. We will record the names and phone numbers of those that are interested in taking part in this or future studies. No study screening will be conducted over the phone. A message will be left on the second attempt with information about how to sign up and no further contact will be made. Trained staff will not recruit reluctant individuals to the study and will respect requests by potential participants who are not interested in participating. We feel that these protocols provide potential participants with an up-front method of saying no in order to increase an individual's ability to shield his/her privacy.

We aim to recruit 34 participants per center to complete the intervention and assessments. Since all activities occur at the center, other center attendees not eligible and enrolled can participate in intervention activities if they complete the center's normal activity waiver. They will not be assessed by UCSD staff. We will recruit & train up to 4 Health Coaches at the 6 intervention sites only.

12. INFORMED CONSENT

The study will be explained to older adults, in the appropriate language, at the community or center that they attend prior to the collection of any information. Due to the older age of this study population, participants will also complete a post consent assessment which tests their decisional capacity. Confidentiality and what will happen to the data, storage, access, and how it will be used are all explained in the consent form.

Eligibility for the study will be determined in two phases. In Phase I, potential study participants will provide verbal consent to be screened on initial eligibility criteria, in person by CITI trained and certified research staff using a structured and HRPP approved script. We are requesting a waiver of written consent for the screening of potential participants because the screening presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Potential subjects who meet the criteria listed above and are able to complete the Timed up and Go test in less than 30 seconds will be given a consent form to read. Trained staff will then review the consent form with participants verbally and administer the post consent test one on one. Once participants have signed the consent and passed a decisional capacity test to demonstrate that they have understood the study and their involvement, they will be given a sealed pedometer (Pilot study and physical activity group participants only) to determine their baseline walking level and will complete a survey.

Those participating in the larger PEP4PA main study will also receive accelerometers and a GPS device to wear for 7 consecutive days. Participants will then return 7 days later and those who successfully wore the devices will be enrolled into the study and will complete the remaining baseline measures. Participants in the pilot study will not wear any devices beyond the pedometer, so this step is not necessary.

13. ALTERNATIVES TO STUDY PARTICIPATION

The alternative to participating in this study is to choose not to participate.

14. POTENTIAL RISKS

The risks involved in this study are minimal as participants will be exposed to risks similar to those encountered in daily life. There is a risk of loss of confidentiality. Participants may feel uncomfortable while wearing the study sensors, though there is no known health risks associated with the battery operated devices. Participants may also experience discomfort or a sense of loss of privacy as a result of revealing their location and daily activities or answering survey questions. The GPS device collects latitude and longitude coordinates and time data when a participant is wearing the device, just like information collected by a cell phone. Combined with Geographic Information Systems (GIS), like google maps, we gain the contextual understanding of participants' movements. This data is not transmitted or viewed in real time. GPS data is stored with an identification number only on a secure server, still there is a low risk of identification if UCSD servers were to experience a data breach.

There is a risk of falls, injury or heart attack if participants begin walking more. However, if participants experience any of the following symptoms during exercise, they are advised to see a doctor.

- Dizziness or lightheadedness
- Fainting
- Lack of concentration
- Blurred vision
- Nausea
- Cold, clammy, pale skin
- Rapid, shallow breathing
- Fatigue, depression, thirst

There may be some unknown risks that are currently unforeseeable. Participants will be informed of any significant new findings.

15. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

Risks will be minimized by only enrolling participants who are able to walk independently as demonstrated in the Timed Up and Go test, can walk without human assistance, and who are not cognitively impaired, as assessed with the post consent test. Risks will be minimized by fully informing participants of the specific involvement required of them before they agree to participate according to the DHHS Physical Activity Guidelines http://www.health.gov/paguidelines/guidelines/. These guidelines don't require medical clearance to participate in physical activity. They state that for older adults without chronic conditions, physical activity is generally safe (and safer than not exercising). For those *with* chronic conditions, they should understand (1) how their condition may limit their activity, (2) do as much as their condition allows, and (3) they are advised they should be under care for their condition. We will provide this information when we ask participants to enroll in the study.

Safe walking information will be given to participants in the group meetings as well as in person from the peer Health Coaches, who will be trained to ask about pain or injuries. We will make efforts to educate participants on how to walk safely and within their physical limits. Participants will be encouraged to increase their walking gradually, beginning with only 100 additional steps per day. Participants will also be provided safety information, including: safe walking shoes, using a cane or assistive devices, crossing intersections, staying hydrated, starting slowly and being aware of symptoms. They will be informed that they may discontinue their involvement at any time.

Health Coaches will carry cell phones and first aid kits on all group walks. CPR training will be provided to any Health Coach or center staff member that wants to be certified. Were any adverse events to occur, the appropriate medical personnel will be immediately contacted. In the case of an emergency, 9-1-1 will be called and the procedures for events followed. An emergency contact will also be collected and contacted in the event of a health emergency that occurs during study participation, or in the event that a participant has not shown up to study activities and is unable to be reached by phone by our staff, center staff or their health coach.

Participants will be told that the device belt can be worn under or over clothes. They will also be provided with different wrist band options for the wrist monitor and may choose which wrist band may work best for them. They will be provided with instructions on how best to wear the devices. They will also be told that the sensors are not considered to be medical devices or significant risk devices.

Adverse Events: All events that are reported or brought to the attention of the Health Coaches, center staff or the research staff during intervention or measurement activities will be reviewed in a team meeting with the Principal Investigator and the data safety officer, Dr. Unkhart.

Safety Protocol for Depression Questionnaire: At the measurement visit, trained research staff will score the CES-D short form (a screener for depression symptoms). Participants with scores ≥10 will be permitted to enroll in the trial but will be given the following advice in private at the study visit: "Some of your responses to the survey questions suggest that you are feeling sad or down at the moment, and you may be experiencing some symptoms of depression. We would like to recommend that you talk to someone about these feelings." Participants will be given information on resources available to them through the County or their center, when appropriate. The incidence of CES-D short form scores ≥10 will be recorded in the database.

It will be explained to the subjects in clear terms, both verbally and in the written consent form, that their precise whereabouts for the entire time period the GPS device is worn will be collected. GPS data is not transmitted in real time. Any potential risk of embarrassment or privacy due to analysis with GIS data is mitigated by developing variables from the GPS data like the number of walking trips taken or average distance walked. Additionally, environmental measures created from the GIS analysis will be used in statistical modeling at the group level only, and will not be individually mapped or visualized for publication purposes.

Participants will be informed that all survey responses and data collected from the GPS device will be kept confidential within the research team, and that no material that could personally identify them will be used in any reports or publications from this study, unless explicit permission is given via written release. To reduce the risk to (and fear of) confidentiality, all subject records and data will stripped of individual identifiers following data collection. We will assign each person a study ID and all records will be coded with the study ID rather than personal identifiers. The code that links the study ID and the name will be stored in a separate place than the data file until all of the measurements are complete.

All data will be stored in locked cabinets and on a secure computer server at UCSD that can only be accessed by authorized members of the research team and university. Hard copies of informed consent statements and participant data will be kept in separate locked file cabinets. Information about subject participation may be shared with participating centers in order to promote its activities, including information like their name and attendance at events. Research staff will not share any identifiable research data collected at study assessments, like performance on the functioning tests.

Participants will also be told about the confidentiality procedures and that they have the right to refuse to answer questions or to terminate their participation in the study at any time without prejudice. The PI will assure that all human protections standards are met.

16. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

We have established an extensive protocol to protect participants' privacy. We will keep hard copies of informed consent statements and participant data in separate locked file cabinets so that individuals are not easily connected to the study results. All data will be stored on a firewall and password-protected project server at the University of California, San Diego. We will assign each person a study ID when enrolled in the study. All sensor and survey data will be stripped of individual identifiers following data collection and will be stored by ID number only. The code that links the study ID and the name will be stored in a separate place than the data files. Name and address will only be kept for those individuals who are enrolled into the study or who have indicated that they would like to be contacted for future studies. For people who are ineligible and do NOT want to be contacted for future studies, their name, phone number and date of birth will not be entered into our databases and only their age, race/ethnicity and reasons for ineligibility will be retained. Paper data collection forms for these people will be destroyed. All data will be kept in locked cabinets at the study office, accessible only by investigators and project staff. Participant data may be shared with other researchers for future analyses at the PIs discretion. They consent to this use. Participants may elect to have their data deleted from the database associated with the tablets used by the health coaches at the 24 month measurement. Finally, participant data will not be sold or exchanged with anyone and data sharing as per NIH requirements will be performed within strict protocol-driven procedural guidelines. UCSD staff will not share any identifiable sensor or survey data with study sites.

The PI will assure that all human protections standards are met.

17. POTENTIAL BENEFITS

Participants may or may not receive any benefit from participating in the study.

The main benefit of this study is the development of a sustainable program that community centers may use to promote physical activity among older adults. Such an intervention is necessary to help promote healthy behaviors in large populations and prevent chronic illness and cognitive decline. By participating in this study, participants will gain knowledge of their own exercise habits and ways to improve them. There is a potential for multiple health benefits to occur in all participating individuals. In this age population in this setting, health is likely to be on the decline, walking can prevent this decline and in some cases reverse it.

18. RISK/BENEFIT RATIO

The known risks to participants are outweighed by the potential benefit to research.

19. EXPENSE TO PARTICIPANT

There is no expense to participant other than time.

20. COMPENSATION FOR PARTICIPATION

CAB:
Participants in the CAB who would like to accept payment for their time will receive $50 at each meeting for a total of $200 per year.

Pilot Study:
Participants in the pilot study will receive $10 when upon completion of study the assessments at the beginning, middle (2 months) and end (4 months) of the study, for a total of $30.
Staff and Health Coaches will receive $100 at the end of each month as compensation for their time, for a total of $500.
The pilot study center will receive $500 for costs related to the pilot study, including: new equipment, printing expenses, participant prizes and celebrations.

PEP4PA Main Study:
Participants in the study will receive $10 upon completion of study assessments at the beginning, 6, and 18 month time points and $20 at the 12 and 24 month time points. Participants will receive $10 for attending the group orientation at the beginning of the study, for a total of $80. Participants will not be paid if they are unable to wear the devices as instructed at baseline.
Health Coaches (intervention sites only) will receive $100 at the end of each month as compensation for their time. At sites randomized to receive financial support in months 18-24, health coaches will receive a total of $2,400. At sites randomized to no longer receive financial support, health coaches and staff will receive $1800 total. Health coaches will also receive $10 upon completion of study assessments at the beginning, 6, and 18 month time points and $20 at the 12 and 24 month time points. Health coaches will also receive $10 for completing the supplemental survey at the beginning of the program for a total of $80.

Study sites (intervention sites only) will receive $250 every 6 months for costs related to the improvement of programs or equipment offered at participating centers. These expenses may be used to purchase PA equipment, pay for participants to be transported to offsite locations for group walks, or to cover fitness instruction costs, for example. Intervention sites randomized to receive funding in months 18 - 24 will receive a total of $1000 and sites randomized to not receive funding in the final 6 months will receive $750 total. An additional $250 every 6 months will be given to the intervention sites to be utilized by the Health Coaches for expenses related to the study like prizes for participant achievement, monthly celebrations, or food for group meetings. Intervention sites randomized to receive funding in months 18 - 24 will receive a total of $1000 and sites randomized to not receive funding in the final 6 months will receive $750 total. Sites will receive $600 every 6 months for staff costs related to the intervention as a staff person will be designated to assist with the intervention. Intervention sites randomized to receive funding in months 18 - 24 will receive a total of $2400 and sites randomized to not receive funding in the final 6 months will receive $1800 total for staff costs.

Payment to participants will be made in cash. Payment to study sites, peer health coaches will be made via a preprinted check (Scrip) that can be cashed at any bank. Participants in the physical activity intervention will be able to keep their pedometer.

21. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

All members of the research team listed below will be trained and certified in HIPAA and CITI policies for research subjects.

Gregory Aarons, PhD, Co-Investigator, Dr. Aarons is a Professor in the Department Psychiatry, School of Medicine at the University of California, San Diego. He is the Director of the Child and Adolescent Services Research Center (CASRC). His expertise is in the areas of dissemination and implementation research, organizational psychology, and health services research in public sector services for youths and adults in primary care settings for adults and older adults. Dr. Aarons' most recent work focuses on organizational factors that influence effective dissemination and implementation of evidence-based practices in multiple settings including primary care, social service, mental health, and alcohol/drug settings. Dr.

Aarons is the PI of three currently funded NIMH R01 grants. He is or has been a co-investigator on a number of other studies examining EBP implementation in primary care and community service settings. Dr. Aarons leads the UCSD School of Medicine Implementation Science Seminar. He is an Associate Editor of the journal *Implementation Science* and has been an invited keynote speaker at the first two meetings of the NIH Conference on the Science of Dissemination and Implementation and he served as a Scientific Advisor for the latest (3rd annual) DI conference.

Veronica Cardenas, PhD, Co-Investigator, Dr. Cardenas is an Assistant Clinical Professor in the Department of Psychology at the University of California, San Diego, who completed her postdoctoral training in Clinical Geropsychology. Her research focuses on physical and mental health interventions in Latino, older adults. She has experience with interventions that include the use of *promotores*, similar to the peer leader model proposed in PEP4PA. She is Co- Investigator on a San Diego County grant evaluating the implementation of a Spanish language treatment intervention in older adult Latinos diagnosed with diabetes and depression, that includes physical activity. Dr Cardenas is bilingual and bicultural Dr. Cardenas will provide input into intervention design to ensure cultural relevancy. She will also provide case management supervision for the in person counselors, help with training and intervention delivery in the Spanish speaking Centers, and will help train Spanish speaking measurement assistants.

Loki Natarajan, PhD, Co-Investigator, Dr. Natarajan conducts methodological research in biostatistics, primarily in the area of survival analysis. She is interested in modeling survival distributions in research situations where there are time dependent effects and wherein the proportional hazards model is not applicable. Dr. Natarajan is also a co-Investigator on Dr. Kerr's improving sedentary behavior classification grant (1st percentile score). Dr. Natarajan will provide statistical advice on design and analysis issues, generate randomization allocation sequences perform statistical analyses and develop statistical methodology where needed. will be the lead statistician and be responsible for, supervising data analysis, and developing and implementing novel

Sarah Linke, PhD, MPH, Co-Investigator. Dr. Linke is an Assistant Clinical Professor with the Department of Family Medicine and Public Health. Her research examines the role of exercise and other healthy lifestyle behaviors in the prevention and treatment of physical and mental health problems. . She led the traditional exercise arm of a pilot study examining tai chi vs. traditional exercise on physical and mental health outcomes among heart failure patients with depressive symptoms. She designed and implemented an Internet-based exercise intervention for smoking cessation, which formed the basis of her dissertation. She has worked on multiple exercise-related research studies, papers, and projects with Dr. Bess Marcus, who served as her research mentor at Brown University and my primary postdoctoral fellowship mentor at UCSD. She led a team of researchers at UCSD and the VASDHS investigating the effects of exercise-based programs on individuals at-risk for and diagnosed with SUDs, including a pilot study with Veterans in outpatient alcohol & drug treatment. Her position includes a blend of clinical, research, and teaching responsibilities, and one of her main goals is to increase collaborations between the researchers and clinicians in the Department.

Dori Rosenberg, PhD, MPH is an Associate Investigator at Kaiser Permanente Washington Health Reearch Institute and an Affiliate Assistant Professor in the Department of Health Services at the University of Washington's School of Public Health. Her background is in behavioral science through her advanced degrees in clinical psychology and public health. She has specific expertise in promoting physical activity and sedentary behavior change among various populations including youth, older adults, and people with chronic medical conditions. Dr. Rosenberg is a consultant and has helped develop all intervention protocols and measurement assessments for the PEP4PA study. Dr. Rosenberg is primarily responsible for providing advice on counseling techniques and handling challenging cases.

Yuyan Shi, PhD, Co-Investigator, Dr. Shi is an Assistant Professor in the Division of Health Policy, Department of Family and Preventive Medicine, at the University of California San Diego (UCSD). Her research has focused on policy and economic evaluation of lifestyle interventions. Trained as a policy analyst and a health economist, Dr. Shi specializes in research design and data analysis using large population surveys and large medical claims, cost-benefit analysis, cost-utility analysis, and cost-effectiveness of treatments and interventions to promote physical activity, smoking cessation and decrease alcohol misuse. The proposed research is an extension of her prior work on economic evaluation of physical activity interventions, where a method was developed to frame the relative magnitudes of effectiveness and costs of different community-based programs in terms of a single common metric Dr. Shi will lead the two secondary aims in the proposed

research. Specifically, she will design the cost effectiveness analysis, provide advice on data collection, conduct the data analysis, and interpret the results of cost-effectiveness evaluation.

Linda Hill, MD, MPH is a board-certified public health & general preventive medicine doctor and a clinical Professor in the Department of Family Medicine and Public Health at the University of California, San Diego and an Associate Professor of Health Promotion in the Graduate School of Public Health at San Diego State University. Dr. Hill has directed two community health centers (CHC) in San Diego, providing direct patient care in addition to programmatic responsibilities. She continues her 30-year practice at one of these CHCs. She will supervise Jonathan Unkhart as the safety monitor for the PEP4PA intervention, responding to all adverse event reports.

Katie Crist, MPH, MPH - will be responsible for overall project management, supporting Dr. Natarajan with meeting organization, Co-Investigator communication, staff training, supervising and scheduling all Research Assistant activities, and supervising and ensuring quality control for data collection, coding, processing and analysis, overseeing IRB submission and adherence and will direct all recruitment and measurement activities on the project. They will manage English and Spanish speaking staff, recruitment script development and translation, and any community recruitment events.

Khalisa Bolling, MPH Health Educator, was the health educator on the MIPARC study, delivering both the pedometer and successful aging program. She also led intervention sessions in the MIPASC pilot study. She has developed the peer Health Coach trainings and will deliver to all intervention sites. She will liaise with Drs. Rosenberg and Castro for feedback on case management.

Marta Jankowska PhD, MS - Dr. Jankowska has worked on numerous projects relating the environment to health outcomes. She will prepare all dynamic and static GPS and GIS variables for analyses. She will be responsible for developing new methods in GIS related to GPS data and testing these techniques to predict behavior.

Kelsie Full, MPH is a doctoral student working with Dr. Natarajan. She will be responsible for ensuring data completeness, that all data is entered into the study databases and perform standard data cleaning and quality control procedures. Ms. Full will assist with the preparation of datasets for statistical analysis. She will also analyze study sleep data.

Suneeta Godbole, MPH, Fatima Tuz Zahra, John Bellettiere, Susan Pinheiro, Chenyu Liu and Chase Reuter- will be responsible for data cleaning, quality control checking, processing and will support Dr. Natarajan with statistical analyses as appropriate in later years.

Brittany Lewars, , Dana Song, Vivian Trang, Jaclyn Calkins, Shady Faltaou, Victoria Neumann, Ellie Klee, will serve as site liaisons and recruitment and measurement research assistants.They will be responsible for conducting in-person eligibility screening and obtaining informed consent, performing physical and cognitive functioning assessments, collecting blood pressure, written survey and interview data with English and Spanish speaking participants. They will also process activity data from accelerometer and GPS devices and enter measurement data.

Michelle Black is a UCSD-SDSU PhD student that will assist with study activities. She performed telephone counseling and cognitive assessments in the MIPARC intervention. She will be trained in all informed consent and data collection procedures and will assist with IRB administrative duties.

Jonathan Unkart MD, is a physician and post-doctoral fellow in the Preventive Medicine Residency at UCSD. He is interested in assessing falls risk, medication use and health care utilization in this population. He will serve as the safety monitor for the PEP4PA intervention, responding to all adverse event reports.

David Wing and Michael Higgins, MS are experts in physical activity measurement and members of the EPARC lab. They will be responsible for initializing and downloading devices and training staff and students in study measures.

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24. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

N/A

25. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER

N/A

26. IMPACT ON STAFF

None

27. CONFLICT OF INTEREST

None

28. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

N/A

29. OTHER APPROVALS/REGULATED MATERIALS

N/A

30. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

Participants in this study are older adults who may be at risk for diminished decisional capacity. A criteria for entry into the study is no cognitive, visual or hearing impairments that will affect independent participation in the study. We will be sure to carefully check this and other entry criteria with participants. To mitigate against the risk of enrolling participants without obtaining informed consent, we will administer the generic 3-item interviewer rated test of decisional capacity after the informed consent form is read to participants. The test items correspond to the key elements of the study design and procedures as well as participant rights. Because participants are NOT being recruited with a primary condition of cognitive impairment, a longer test was not considered necessary. If participants appear capable of participating in the study but did not fully understand the consent process we will repeat the information and test. Screening for participation will be conducted in person to better assess hearing impairments.

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