STUDY PROTOCOL
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Title: Peer partners to improve physical activity in older Latinx adults with Parkinson's disease

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Protocol

Principal Investigator: **Cristina Colón-Semenza, PT, MPT, PhD**
Assistant Professor
Board-Certified Specialist in Neurologic Physical Therapy
University of Connecticut
College of Agriculture, Health, and Natural Resources
Dept of Kinesiology-Doctor of Physical Therapy Program
Storrs, CT

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OAIC Cores: **RC1, RC2, RC3.**

Background: The combination of physical activity and social support may improve disease management for people with Parkinson disease (PD) from under-represented groups (URG). Although pharmacological management is the standard treatment for this progressive neurological disease of older adults, physical activity and exercise are now critical components of effective disease management and likely slows the disease progression.[1–5] It is projected that the prevalence of PD in the US will exceed 1 million people by

2030 with the incidence highest amongst Hispanics.[6,7] Despite the critical importance of exercise in the management of PD, the majority of Hispanics with PD do not believe that exercise is an important factor for disease management and engage in physical therapy at lower rates than Caucasians[8,9], a pattern which mirrors physical activity disparities in older Hispanic vs. non-Hispanic whites.[10] Cultural as well as disease-related barriers compound the problem of inactivity and may contribute to delayed access of healthcare for PD [11] inhibiting optimal disease management. Although very little is known about how to increase physical activity in minority populations, older adults from URG have identified lack of time, inadequate social support, lack of motivation, physical ailments, and chronic health conditions as barriers to physical activity.[12,13] Facilitators of physical activity noted by older adults from URG include: receiving positive messages about physical activity from a trustworthy and reliable source; making physical activity enjoyable; peer social interaction, social support, and competition.[12,14] Simply put, peer support is an obvious facilitator of physical activity. Peers (defined here as Hispanic/Latinx individuals with PD) can help address these barriers by sharing knowledge, resources, and friendly competition.[15–17]

A previous investigation of the use of peer coaching through mobile health technology for people with PD resulted in initial indications of intervention effectiveness.[17] However, the sample of individuals involved in this study lacked ethnic diversity. This project will advance this research by culturally and linguistically tailoring this peer support intervention for older Hispanic individuals living with PD. Current evidence (unpublished) indicates that the family has significant influence on physical activity levels of people with PD who are Hispanic and therefore family involvement will be incorporated into the intervention.

The number of individuals living with PD in the most populous nations is expected to increase to approximately 9 million by 2030.[18] Developing strategies to support older individuals who are faced with a chronic health condition as well as cultural and structural barriers to physical activity and exercise must be prioritized to maximize best outcomes for quality of life. A peer-supported physical activity intervention using a culturally and linguistically tailored program could increase physical activity and improve disease self-management for Hispanic individuals living with PD. Engaging with a trusted peer who is also living with the same disease may provide access to health information as well as vicarious experiences, mastery experiences, and social persuasion to effect behavior change. Our approach offers a novel, scalable, and generalizable means to increase physical activity and enhance disease self-management. This work has the potential to impact under-served individuals world-wide living with PD and, potentially, millions more with other chronic progressive conditions.

Hypotheses or Research Question, Aims and Objectives:

- Hypothesis/Question: Is a peer partner training program and a peer-supported, mobile health, physical activity intervention feasible in Latinx people with PD?
    - Exploratory hypothesis: A peer partner training program and a peer-supported, mobile health, physical activity intervention will increase physical activity, motivation, quality of life and self-efficacy for physical activity in participants. This intervention will be most beneficial to those that are classified as sedentary (< 5,000 steps/day) at baseline.
- Aims / objectives
    - **Aim 1: To culturally adapt and determine feasibility of the *peer partner training program*.** We will examine (1A) acceptability (1B) appropriateness (1C) feasibility and (1D) cultural

relevance through self-report surveys and qualitative interviews with study participants. (1E) We will examine knowledge acquisition with a pre and post knowledge quiz. (1F) We will examine training engagement with attendance at the 2 virtual training sessions.

- **Aim 2: To determine the feasibility of a *peer-supported mobile health physical activity intervention (Compañeros con Parkinson's)* for exercise in Latinx people with PD.** We will examine: (2A) intervention engagement, as measured by attendance at exercise classes and with the number of peer contacts (2B) acceptability, (2C) appropriateness, (2D) feasibility and (2E) cultural relevance through self-report surveys and qualitative interviews with study participants.

- **Exploratory Aim: To determine the effects of the peer-supported mobile health physical activity intervention on physical activity** (objectively measured physical activity through the activity monitor)**, motivation** (Behavioral Regulation in Exercise Questionnaire)**, quality of life (**Parkinson Disease Questionnaire-39 (PDQ-39))**, depression (Geriatric Depression Scale (GDS)), apathy (Lille Apathy Rating Scale (LARS)) and self-efficacy for physical activity** (Self-Efficacy for Physical Activity (SEPA)).

Study Design: This is a prospective feasibility trial, single group pre-posttest design.

Sample size and justification
This study aims to enroll 20 participants. For this feasibility study, the sample size is comparable to other feasibility trials in populations of individuals with Parkinson disease (Lima & Rodrigues-de-Paula, 2013; Ellis et al., 2013, Colón-Semenza et al., 2018)[17,19,20]. This sample size will allow for a comparison in feasibility, acceptability, and appropriateness within and across groups. This sample will allow for identifying trends and preliminary efficacy for this intervention. This study will help to inform an appropriate sample size to adequately power larger samples in future studies.

SELECTION AND ENROLLMENT OF PARTICIPANTS
Characteristics of the Study Population: We will recruit 20 Hispanic male, female or non-binary adults age 50+ with Parkinson's Disease. Participants must have the ability to speak, read and write in Spanish or English.

We will use the Recruitment and Community Engagement Core of the UConn Center on Aging. The Core provides a centralized infrastructure for the recruitment of older research volunteers from the community. Recruitment of subjects will be carried out by several mechanisms, Including:

A) Referral from UConn Health physician and outpatient clinics treating patients with Parkinson's disease, the geriatric medicine clinic at UConn Health, and other providers in the community. Potential participants will be notified about the study through their healthcare team (medical doctors, nurses, therapists, social workers, administrative staff, etc.) or by a member of the research team. All individuals that attend an appointment at the Parkinson's Disease and Movement Disorders Center at UConn Health that have Parkinson's disease and are eligible candidates will be informed of the study (provided with a recruitment flyer). Recruitment flyers will also be provided to healthcare providers in other movement disorders centers, neurology clinics, primary care facilities and community health centers.

B) Additionally, recruitment flyers will be distributed by fitness professionals and support group leaders. A physical recruitment flyer will either be given to individuals or sent virtually through email or text messaging. Interested individuals may learn about the study through newsletters from organizations for people with Parkinson disease (e.g., American Parkinson Disease Association), clinical trials websites (clinicaltrials.gov, Fox Trial Finder), recruitment flyer postings in senior centers, churches, community centers, etc., events for people with Parkinson disease (e.g., fundraisers or educational events), word of mouth, or social media posts. Recruitment flyers will be shared on social media sites, national non-profit organizations' newsletters, and national websites that will expose our study to individuals across the US and its territories.

C) Additional recruitment methods will include community talks where participation in the research study will be offered; distribution of flyers to include community housing, churches, organizations, medical clinics, and community centers; and advertising in newspapers/newsletters or on the radio.

D) Educational events will be held at interested senior centers, support groups, or online webinars during which the recruitment flyer will be shared.

E) Mailing labels will be generated for patients seen by Dr. Rodrigues between January 2022 and January 2023 with ICD code of G20 and who identified as Hispanic/Latino. A letter from Dr. Rodrigues' office will be included in this mailing. Other patients within the UConn Health Center system that also have the ICD code of G20 but are not patients of Dr. Rodrigues will receive a mailing notifying them of the study from their treating physician's office. Interested participants will be interviewed for eligibility and those who offer written, informed consent will be enrolled.

F) We will also work with Clinical Research IT at UConn Health to identify eligible individuals seen at UConn Health and make them aware through their MyChart account that they may be eligible for participation in the study

Phone Screen
We will conduct a telephone screening to provide interested persons with more information about the study involvement and conduct a pre-consent telephone eligibility screening to see if they qualify.

Inclusion Criteria
Idiopathic Parkinson disease, able to walk without the assistance of another person for 10 minutes, ≥ 29 on Telephone Interview for Cognitive Status (TICS), has a close friend/family member over the age of 18 that would support the participant during the intervention, ≥ 50 years of age, Hispanic, willing to use an activity tracker, on a stable course of PD medications without any plans for change over the next 3 months, able to speak, read and write in Spanish or English, currently live in the United States or US Territory (*Puerto Rico, U.S. Virgin Islands, Guam).*

Exclusion Criteria
Unstable cardiopulmonary, orthopedic, psychological or metabolic condition, Atypical Parkinsonism Disorders, a fall in the last 6 months (that was unrelated to an external force), currently engaging in 150 minutes of mod-vigorous physical activity/week

Study Enrollment Procedures

A HIPAA waiver will be obtained from the IRB to collect personal information over the telephone. Following a phone screen, participants will be sent a link, through email or text message, to an online consent form or receive the consent form via standard mail. (see below for additional details on the consent process)

Study Procedures: All study procedures will be conducted in the preferred language of the participant (English or Spanish). All participant-facing written and spoken study materials will be available in English or Spanish. Study materials will be translated and back translated by study staff members. Participants will be able to self-select which language to set on their phone or tablet. Their preferred language will automatically be programmed for the application used in the study.

- Screening Procedures: Interested individuals will call or email the lab. A research assistant (bilingual) will respond to their interest by telephone call or email and will establish a mutually agreeable date and time for the telephone screening. The telephone screening will assess basic information (age, ethnicity, verbal confirmation of physician diagnosis of Parkinson's disease and ability to walk for 10 minutes without the assistance of another person) and includes a screening of cognition (Telephone Interview for Cognitive Status (TICS)) and Physical Activity Readiness (PAR-Q). Additionally, individuals will be asked about their medical history, current medications, willingness to wear an activity monitor and use the FitBit app, ability to speak, read and write in Spanish or English, current involvement in exercise and the availability of a family member (≥ 18 years of age) to support their participation in the study. (approximately 30-40 minutes)

  Those that are:

  - ≥ 50 years of age
  - Hispanic/Latinx
  - Diagnosed with idiopathic Parkinson's disease (by self or family-report)
  - Indicates that there is a close friend/family member ≥ 18 years of age that can support their participation in the study
  - self-report the ability to walk 10 minutes without the assistance of another person
  - score ≥ 29 on the TICS
  - are willing to wear an activity monitor and use a FitBit and the FitBit application
  - able to speak, read, and write in Spanish or English
  - on a stable course of PD medications without any plans for change in the next 3 months

  will be invited to participate in the study.

IRB Review
IRB NUMBER: 23-117S-2
IRB APPROVAL DATE: 07/31/2023

- Study Procedures: Once interested individuals have passed the telephone screening, they will be sent a link, through email or text message, to an online consent form or receive the consent form via standard mail. (Consent procedures are detailed further below)

- After consent has been obtained, participants will complete the following through an interview with the research assistant by telephone or via a virtual meeting platform (e.g., WebEx). Participants will select their preferred language to complete the interview.

1. Additional **demographic** information. This will include work status (full-time, part-time, unemployed, retired, disability), occupation, country of origin, preferred language, community (urban, rural, suburban), years since diagnosis, previous exerciser/preference for type of exercise. (approximately 10-15 minutes).

2. **Behavioral Regulation in Exercise Questionnaire-2**[21–23]**:** This is the most commonly used measure of motivators for exercise. It is a 19-item survey that evaluates the stages of motivation to exercise. This includes amotivation, external regulation, introjected regulation, identified regulation, and intrinsic regulation. (approximately 10 minutes to complete)
3. **Parkinson Disease Questionnaire-39 (PDQ-39)**[24]: This 39-item self-report survey will assess quality of life. This covers an assessment of mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. (approximately 10 minutes to complete)

4. **Self-Efficacy for Physical Activity (SEPA)**[25,26]**:** This is a 5-item self-report measure that assesses self-efficacy for physical activity. It has been validated in a population of Latina women. It has acceptable internal consistency and concurrent and predictive validity. (approx. 2-3 minutes to complete)

5. **Physical Activity Scale Elderly (PASE):**[27] This is a 10-item questionnaire that asks questions related to leisure time, household and work or volunteer related physical activity for older adults. Reliability is reported at 0.84 and validity was established by correlation with health status and physiologic measures.[27] (approx. 15 minutes)

6. **Geriatric Depression Scale-15 (GDS-15):**[28,29] This is a 15-item self-report measure of depression in older adults. It has demonstrated sensitivity (81.8%) and specificity (93.4%) in people with Parkinson's disease.[30] (approx. 5 minutes to complete)

7. **Patient Health Questionnaire-8 (PHQ-8):**[31] This is an 8-question self-report screening tool for depression and depression severity. It that has strong sensitivity (90.9%) and specificity (89.3%) in people with Parkinson's disease.[30] (approx. 5 minutes to complete)

8. **Lille Apathy Rating Scale (LARS):**[32] This is a 33-item structured interview that was designed to assess apathy in Parkinson's disease. It is suggested scale for use in people with PD by the Movement Disorder Society.[33] (approx. 15-20 minutes to complete)

9. **Sallis Support Support Scale for Exercise Survey:**[34] This is a survey with 5 items focused on perceptions of social support from friends and 15 items for family regarding exercise behavior. It

has reported reliability of 0.86-0.90 and internal consistency of 0.86-0.89.[35] (approx. 10 minutes to complete)

10. Participants will be sent a research-grade activity monitor, **Actigraph GT9X** device, in the standard mail at their residence. After receiving the device, participants will engage in a telephone or virtual meeting with a research assistant to learn how to use the device. (approximately 30-40 minutes)

    a. Participants will be asked to wear the activity monitor for 10 days prior to beginning the study. They will be asked to continuously wear the device on their wrist for the 10 days. Participants will return the device in a pre-paid envelope. (10 days) The same procedure will occur at the conclusion of the intervention for a post-intervention assessment. (10 days)

Orientation Session

All participants will participate in a virtual meeting with a research assistant that will welcome them to the study, review and reinforce the procedures and the technology that will be used. A review of WebEx, accessing the website and training videos, completing online surveys, and how to contact the research staff. Participants will then be administered a knowledge quiz by a research assistant. Finally, participants will be given the link and a the password to access the peer partner training videos on a website.

Peer partner training

There are a total of 11 videos (5-8 minutes in length) that participants will be asked to watch over a 2-week period. The total amount of time spent watching videos will be 55- 88 minutes. Participants can choose to complete watching these videos on their own schedule, in their self-selected environment. The videos will be available in Spanish and English.

The initial videos will cover topics on basic information about PD and exercise:

a. What is Parkinson's disease?

b. How can exercise help people with Parkinson's disease?

c. What is the best type of exercise for people with Parkinson's disease?

d. What is peer support?

e. How can I help someone else living with Parkinson's disease?

There will then be a synchronous virtual meeting that is led by the research team to review the content of the first 6 videos. (approximately 30 - 45 minutes)

The additional 6 videos will cover the following topics related to peer and social support:

f. Active listening

g. Creating SMART goals for exercise

h. Checking in: getting feedback on exercise goals

i. Identifying facilitators for exercise

j. Problem-solving and overcoming barriers to exercise

k. Family and community support for exercise

There will then be a second synchronous virtual meeting, led by the research team, to review the content of the last 6 videos to ensure comprehension and baseline knowledge. (approximately 30 - 45 minutes)

There will be a final synchronous meeting to review check-off sheets that will guide weekly discussions and a knowledge check will be completed through a brief quiz. (approximately 30 - 45 minutes)

Peer-supported mobile health physical activity intervention (*Compañeros con Parkinson's*)

All participants will be peer partners (supporters). Individuals will be matched with a peer of the same gender. Attempts will be made to match those with additional similar traits, such as age, physical activity level, work status, and country of origin. Participants in each matched pair will support one another as they both strive to improve their physical activity.

After participants have completed the training, they will receive a commercially available activity tracker (Fitbit Inspire 2) and instructions on its use. They will wear this activity tracker for the duration of the 8-week period except for showering/bathing. Peers will download the FitBit application on their smart phone or tablet. Participants will be asked to log in to the FitBit app daily to sync their data with the app. If they do not have a smartphone or tablet, one will be provided to them, along with a data plan for the duration of the study. They can choose to have assistance with downloading the app from a research assistant. They can receive basic training on its use with the support of a research assistant via a telephone call or virtual meeting.

Peers will become "FitBit Friends/*Amigos*" through the FitBit application. Peer pairs will be able to see each other's accumulated steps over the week and communicate as a pair. This will connect 2 participants into a peer pair. Peer pairs can provide social support to each other through the app with comments and emojis. Participants will be asked to open the FitBit app daily to sync their data with the app. Additionally, peer pairs will establish a weekly meeting schedule by telephone or virtual meeting platform. Weekly meetings will be guided by check-off sheets to ensure critical content is covered and discussion of goal status is completed. Participants will be encouraged to participate in a weekly bilingual virtual exercise class that is synchronous.

In addition, all participants will join a FitBit closed group of *all* participants in the study. This group will be created by the research team and is not publicly available to others. It will be moderated by a research assistant and daily informational and motivational content will be posted. Participants can provide social support to each other in the group through the app with comments and emojis.

Weekly Meeting Calls Topics of Discussion (approx. 15- 30-minute discussions, 1x/week for 8 weeks)

1. Getting acquainted and building rapport; identifying core values; becoming "FitBit friends/*amigos*"
2. Establishing SMART goal (short-term/weekly and overall/8 week) and tying in with core values
3. Action Plan (Goal Check)
4. Benefits of Exercise (Goal check)
5. Feedback on Goals (Goal Check)
6. Facilitators/Barriers of Exercise (Goal check)
7. Family Support for Exercise/ Local and National Exercise Resources (Goal check)
8. Re-establishing goals/Sustaining exercise/Wrap up (Goal check)

A research assistant will call participants each week to determine if the weekly peer interaction call has been completed, to assist with any barriers to peer connection, and to assess technology needs. The research assistant will also assess for adverse events during this call. The RA will be guided by the adverse events form.

Support for an increase in physical activity

To support an increase in physical activity, participants will have access to a weekly virtual synchronous bilingual exercise class that is geared towards the needs of people with PD. The class will have 3 areas of focus: aerobic exercise, resistance exercise (using body weight), and balance, breathing, and stretching exercise. The first 3 weeks will focus on aerobic exercise, the second 3 weeks on resistance training and the last 2 weeks will focus on balance, breathing and stretching exercise. All exercise classes will be tailored to the needs of people with PD and designed by a physical therapist with a specialization in neurologic physical therapy (PI-CCS) and a fitness instructor with a certificate from the American Parkinson Disease Association for Fitness Professionals. The instructor will provide modifications of the exercises so that individuals can participate at the level that is suited to their status.

Outside of the exercise class, participants will be encouraged to increase their walking and general physical activity. For example, peer pairs may develop a goal to increase their steps by 1,000 steps/day and may develop a plan to march in place during commercials when watching their favorite television show.

Post-assessment

Baseline measures will be repeated at the conclusion of the intervention as presented above. They will include:

a. **Physical Activity Scale for the Elderly**
b. **Behavioral Regulation in Exercise Questionnaire-2**[21–23]
c. **Parkinson Disease Questionnaire-39 (PDQ-39)**[24]
d. **Self-Efficacy for Physical Activity (SEPA)**[25,26]

e. GDS-15

f. LARS

Participants will receive a phone call to complete the aforementioned assessments.

In addition, the following surveys, **Acceptability of Intervention Measure (AIM), Intervention Appropriateness measure (IAM), and Feasibility of Intervention Measure (FIM)** will be completed via ReDCAP**. (**If individuals are unable to complete the survey online, they will receive a physical copy of these surveys through standard mail with a self-addressed envelope to return to the research team.) Each measure has 4 items that assess acceptability, appropriateness, and feasibility, respectively. They are constructed at a 5th grade reading level with a Likert scale that ranges from completely agree to completely disagree. Validity (α from 0.85-0.91) and reliability (0.73-0.88) were high for all three scales.[25] (approximately 15 minutes to complete all 3 surveys)

Participants will be asked to again wear the **Actigraph GTX9** for 10 days post-intervention, following the procedures noted for baseline assessment.

Focus group

After the 8-week intervention period is completed, participants will participate in one of 2 focus groups (10 participants per group) with a semi-structured interview format to further discuss acceptability, appropriateness, and feasibility. In addition, participants will discuss the cultural relevance of the intervention. The focus group will be held on a virtual meeting platform. Participants will have the choice to participate with their camera on or off. The discussion will be moderated by a research assistant. (Approximately 60 minutes)

A device/tablet/data plan for 3 months will be provided to participants, if they do not have one, so that they can participate in the study. We will ask participants to return the device/tablet at the conclusion of the study. We will provide them with a stamped and self-addressed envelope for the return of the device.

Length of subject's participation in the study including number of visits, frequency of visits, and length of visits: Participant's participation in the study will be via remote interactions. The number, frequency and length of sessions are noted above.

CONSENT PROCESS:

The informed consent process will occur either electronically or by standard mail combined with phone calls with the study team. Consent will be initiated, questions answered, and the informed consent form signed before any other study procedures are performed. The informed consent form will be signed electronically through a ReDCAP forms or via standard mail (with a provided self-addressed/stamped return envelope).

Consent Procedure: (Approximate time = 30 minutes) Potential participants who express interest in participating in the study and clear pre-screening questions will be provided with the option to provide informed consent electronically or to receive a hard copy of the consent to sign once received via standard mail. If electronic consent is selected, the participant will choose a time to speak with an authorized consenter to review and submit the form together while on the telephone.

Electronic Informed Consent/ HIPAA Authorization A link by email to the electronic Informed Consent will be sent to individuals who choose the online e-Informed Consent process. The link will bring potential participants directly to the e-Consent form. Sections of the consent form will be presented in increments to encourage participants to read each section in detail. Participants will be able to scroll up and down through the form, allowing them to read and reread the information, as needed. They will be able to answer yes/no questions by selecting radial buttons, type in their name, enter the date of consent, and add their signature or initials through use of their mouse. All required fields will need to be completed before the form can be submitted. After the form is submitted, a read-only copy of the completed e-consent is displayed for the participant to review. Participants are able to certify that all the information is correct by checking a box and selecting submit or they are able to select "previous page" to go back and revise their consent. An authorized study consenter will be on the phone with potential participants to answer questions during the e-consent process. The HIPAA Authorization form will automatically display only if the e-consent was agreed to and signed. When consent is completed, an email will be sent from ReDCAP to the participant thanking them for joining the study. A copy of the completed Informed Consent and HIPAA Authorization forms will be sent separately to the participant by email from the study team. This process will be documented by the consenter using a Documentation of Consent Form at the time of e-documentation that will be stored in the ReDCAP research record under a unique Participant Identifier (PID).

Telephone/Mail: If the participant does not have the ability and/or access to complete the consent electronically, they will be mailed a copy of the informed consent form and a time will be set up once it has been received, to review the consent by telephone. Participants will mail back in a pre-paid, pre-addressed envelope the signed consent. Research staff will sign consent upon receiving by mail and send back to fully executed and signed consent to participants before engaging in the research activity.

Consent forms, HIPAA Authorization forms and any other paper documents that contain the participant's name or other direct identifiers will be stored separately from the research records in a locked file in the principal investigator's (CCS) office. Consent forms, HIPAA Authorization forms and any other documents containing participant identifiers that are completed online, will be stored in the study database in UConn Health ReDCAP with access restricted to the UConn Health study team."

- **Process for Obtaining Consent** Interested individuals will either call or email members of the research team to express their interest in the study. At that time, a phone screening will occur to determine eligibility. If the individual passes the telephone screening, they will be sent a link to an online consent form. Individuals will be given the opportunity to read the consent form on their own. In addition, a research assistant will read the consent form, section by section, in its entirety, to the individual and provide time for the individual to ask questions. Then they will be asked to provide consent through the online consent form.

- **Privacy of Subjects:** Private information will only be collected once individuals have completed the informed consent process. Potential participants' private information will be stored in a password protected cloud storage system (ReDCAP) on password protected computers.

Due to the nature of the intervention (peer support) participants will be sharing their information with a peer. Participants will be instructed to only use first names to maximize privacy; however, peers will know that they both have Parkinson's disease. Participants will be instructed to maintain confidentiality with all information that is gathered during the peer interaction. Participants will be instructed to conduct their virtual meetings in a private environment so that others in the area are not able to hear or see conversations/interactions.

Confidentiality of Data: Procedures are in place to ensure confidentiality of research data. Data will be kept confidential by being housed in a password-protected secured web application (ReDCAP) on a password protected computer. In addition, a numerical code will be created to separate identifiable data from study data. This code will be saved in a separate application (OneDrive) that is also secure and password protected.

METHOD(S) OF DATA ANALYSIS:
Content and thematic analysis of qualitative data; descriptive statistics to characterize the sample and measure feasibility.

- Aim 1 analysis
  - Scores equal to or greater than 75% on the Acceptability of Intervention Measure (AIM), Intervention Appropriateness measure (IAM), and Feasibility of Intervention Measure (FIM) are set to determine acceptability, appropriateness, and feasibility of the peer partner training.
  - Cultural relevance of the peer partner training will be determined through content analysis of focus group discussions
- Aim 2 analysis
  - Peer engagement will be successful if connecting ≥ 80% of the recommended times over the course of the intervention period.
  - Scores equal to or greater than 75% on the Acceptability of Intervention Measure (AIM), Intervention Appropriateness measure (IAM), and Feasibility of Intervention Measure (FIM) are set to determine acceptability, appropriateness and feasibility of the peer partner intervention.

- Exploratory aim analysis
  - Group means will be compared from baseline to post-intervention using paired t-tests to assess change in physical activity levels (Physical Activity Scale for the Elderly & objectively measured physical activity through the activity monitor), motivation (Behavioral Regulation in Exercise Questionnaire), quality of life (Parkinson Disease Questionnaire-39 (PDQ-39)), depression (GDS), apathy (LARS) and self-efficacy for physical activity (Self-Efficacy for Physical Activity (SEPA)).

Dissemination: The results of this research will be disseminated at a professional conference in a poster or platform presentation. After receiving feedback from this presentation, results will be disseminated in a peer-

reviewed scholarly journal. Additionally, if the results from this research are promising, it will be used to inform a randomized controlled trial of the intervention.

PROTECTION OF HUMAN SUBJECTS

Risks to Human Subjects:

Physical Risk

Exercise may cause minor and temporary muscle soreness or joint stiffness. The soreness typically begins 1-3 days after exercise begins, does not last more than 2-3 days and does not damage the muscle. Participants may also experience minor fatigue following an exercise session. Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. Participants may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue. In order to reduce this risk, participants will be instructed in proper technique and progression. Participants will be educated on signs and symptoms of when to stop exercise and get medical attention. Participants will be provided with exercises that are appropriate for their individual status.

Informational Risk

While we will protect the confidentiality of the information participants provide, confidentiality cannot be guaranteed. People outside of the research team will learn of participants study participation because of the group nature of the intervention (FitBit closed community group, group training sessions, group exercise class). Participants will be instructed to use first names only and will be educated on privacy and confidentiality in the orientation meeting. The data collected for this research study will be accessible only to authorized persons. A code that is housed on a password-protected computer, that identifies participants will be kept separate from the data. A certificate of confidentiality has also been obtained for this study.

Participants will be matched in pairs and will communicate in groups therefore there is a risk of loss of confidentiality. Participants will be educated on the importance of confidentiality and will be instructed to only use first names. Participants will be given the option to not use their camera for group engagement.

Data that is housed in the Actigraph might be subject to a loss of confidentiality. Only those that have the software to download the data from the device will be able to access the data on the device. The data on the activity monitor will be downloaded onto a UConn encrypted and password protected device and will only be accessible to trained research personnel.

The FitBit data will be housed on the FitBit device and might be subject to a loss of confidentiality. Only those that have the email and password for the FitBit account will have access to this data. This data will be downloaded to an encrypted and password protected UConn computer during the course of the study. Once the study is over the password will be changed so that only the individual has access to their FitBit data.

Participants will be matched with another person with PD and communicate with this person once per week during a virtual meeting. Participants will be FitBit friends and see each other's steps per week. There is a risk of conflicts between the peer partners. One person in the peer pair may drop out of the study. We will attempt to create a successful match by matching peers with others with similar characteristics (age, retired

vs working, stage of the disease, etc.). If there is a conflict between peer partners, a research assistant will be available to meet with the pairs to help resolve the conflict. If a peer partner drops out, we will attempt to reassign the participant to another partner.

Other risks

Survey administration may make participants feel uncomfortable answering some of the questions. Participants will be instructed that they can choose not to answer any questions that make them feel uncomfortable.

References:

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