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Research paper

ReadySteady intervention to promote physical activity in older adults with Parkinson's disease: Study design and methods

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ABSTRACT

The main motor impairments of gait and balance experienced by people with Parkinson's disease (PD) contribute to a sedentary lifestyle, resulting in poor physical conditioning, loss of functional independence, and reduced quality of life. Despite the known benefits of physical activity in PD, the majority of older adults with PD are insufficiently active. Few studies incorporate behavioral change approaches to promoting physical activity in PD. The main goal of this research is to foster community mobility in older adults with PD by promoting physical activity and improving gait patterns using a theory-based behavioral change intervention. The *ReadySteady* intervention combines wellness motivation theory with polestriding physical activity, which has been shown to be beneficial for people with PD. The intervention will be tested using a randomized controlled design, including inactive older adults diagnosed with PD. Participants will be randomly assigned the 12-week *ReadySteady* intervention, 12-week polestriding, and education intervention, or 12-week education intervention. Thirty-six older adults with PD will participate in each of the interventions. Level of physical activity, clinical scores, quantitative measures of gait and balance control, and motivational variables for each intervention will be measured at three time points: pre-intervention, post-intervention (12 weeks), and follow-up (24 weeks). If the intervention is beneficial, it may serve as a sustainable addition to current practice in health promotion efforts serving the PD population.

1. Introduction

Parkinson's disease (PD) is a chronic, progressive neurological disorder causing both motor and non-motor symptoms. Gait and postural impairments contribute to a sedentary lifestyle, which worsens as the disease progresses [1], resulting in poor physical conditioning, loss of functional independence, and reduced quality of life [2]. People with PD are about one-third less active compared to age-matched persons without PD, this is evident even in early stages of PD [3], and levels of physical activity decrease as a function of disease severity [1]. When comparing healthy older adults to those with PD, people with PD exhibited longer periods of sedentary behavior, poorer physical conditioning, and reduced daily energy expenditure [4,5].

Dopamine function, which plays a critical role in motivated behavior [6] is affected in PD thus compromising reward processing in people with PD [7,8]. As PD progresses, it affects the dopaminergic neurons projecting to ventral striatum which is associated with motivational functions [9]. This may have implications for patients' well-being and compliance with treatment options such as participation in treatments and inclination to practice physical activity [10]. One of the main reasons provided by people with PD who do not participate in any regular physical activity (compared to people with PD who engage in regular physical activity) is lack of motivation [11]. Therefore, it is crucial to utilize programs that can motivate people to engage in physical activity.

Among the many motor symptoms of PD, gait and balance impairments are typically expressed as reduced step length, gait speed, stability [12,13], movements in the upper limbs, and trunk [14–17] and automatic postural responses to perturbations [18], and stooped posture [12,19,20]. In addition, stooped posture also increases vulnerability to falls [21], and is an independent risk factor for falls in PD [22]. Gait and balance impairments in PD do not respond well to current pharmacological and surgical treatments; therefore, the need for non-pharmacological interventions is essential.

Regular physical activity is advocated as an important adjunct in the

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treatment of PD [23,24]. A review of 33 randomized controlled trials with about 1500 persons with PD reported that regular physical activity significantly improves gait velocity, balance, daily activities, and functional mobility [25]. Regarding mobility, physical activity has improved gait efficiency and gait initiation [26–29]. Moreover, cadence and gait velocity [30–32], balance, and fall risk [33–39] have been improved. Physical activity also improves non-motor symptoms including cognitive impairment [40–43], depression [44–46], and sleep difficulty [47].

Despite the extensive literature on physical activity in PD, approaches fostering initiation and maintenance of physical activity in this vulnerable population are limited, and few studies have tested interventions consistent with behavioral change. The ParkFit trial, a 2-year, multicenter, randomized controlled trial comparing physical therapy with an emphasis on behavior change (ParkFit program), with matched physical therapy emphasizing safety (ParkSafe program), reported no significant improvement in the primary outcome measure of the level of physical activity measured by a self-report questionnaire [48]. Ellis and colleagues [49] evaluated a single group non-randomized clinical trial using a virtual exercise coach to promote daily walking, reporting improved adherence to walking, and improved walking speed. In these studies, theoretical perspectives and key barriers were not clearly articulated or evaluated, and limited rationale for intervention dose and type of activity were provided [48,49]. Furthermore, these studies did not evaluate the quality of movements such as gait and balance impairments observed in PD.

Some of the main barriers to physical activity in people with PD are identified as low-outcome expectations from physical activity, fear of falling, and motivation to exercise [50] In addition to motivation to exercise [51], self-capacity, a primary positive correlate of physical activity, is reduced in PD [50,52]. Given this, it may be beneficial to implement an intervention that can address these barriers and lead to improvements in engagement in physical activity.

The incorporation of polestriding exercise to an intervention may at least address the barriers such as low-outcome expectations from exercise and fear of falling in people with PD. Polestriding is an outdoor, non-competitive form of physical activity that involves brisk walking with specially designed poles. It involves walking upright and looking forward with the poles used bilaterally in a movement similar to cross-country skiing. Furthermore, the placement of poles provides additional points of support thus increasing stability, which may directly address the fear of falling and lowered confidence in outdoor walking.

Moreover, proper polestriding involves deliberate arm swings, which may promote longer steps [53], and provides external cues from the landing of the poles for each step [54], which may encourage greater regularity in step/stride times. Polestriding requires greater activation of arm and trunk muscles and partially unloads the lower extremities [55]. These lead to greater energy expenditure (20–40% more than the normal walking) and improvement in the range of motion in the upper body and back joints.

Our recent study [56] involving a 12-week polestriding intervention in people with mild to moderate PD significantly improved various indices of gait that are specifically affected in PD, including step length, stride length, and speed [14,57,58]. Regarding gait rhythmicity, which is affected in PD and shown to be associated with risk of falls [17,60], polestriding reduced step time variability and stride time variability. In addition, polestriding reduced disease severity as measured by the Hoehn and Yahr (HY) scale, Unified Parkinson's Disease Rating Scale (UPDRS) motor score, and components of UPDRS score related to gait, balance, and axial difficulties. The improvements in the HY scale and the UPDRS gait and balance sub-scores were sustained even 12 weeks after the intervention ended. Other studies in PD involving polestriding have shown improvements in quality of life [54,61], disease severity [61,62], and balance and gait parameters [53,62], including stride length, sit-to-stand performance [63], leg muscle strength [62], and non-motor symptoms [62]. Thus, the demonstration of consistent improvements due to polestriding in people with PD can address the barrier on low outcome expectations of participation in the exercise program.

The other main barrier in PD, the issue of lack of motivation, can be targeted by an intervention that can help in the process of people with PD moving beyond the present toward valued goals and health outcomes. The wellness motivation theory (WMT) is built upon the concept where health behavior change is conceptualized as a growth-oriented process consistent with an individual's unique strengths, values, and goals [64], mediated by behavior change process variables (self--knowledge, motivation appraisal, and self-regulation), and social contextual resources (social support and environmental resources).

Interventions based on WMT have been successfully implemented to increase physical activity in community-dwelling older adults with various health issues. A WMT-based intervention improved functional balance using fall-reducing physical activities in community-dwelling older adults [65]. Similarly, a WMT-based intervention increased mobility and physical activity in older Korean Americans, and improved self-regulation, self-efficacy, readiness, and social support from family and friends for physical activity [66]. In a study [67] involving people in cardiac rehabilitation, researchers explored the relationship between environmental resources (a component of the wellness motivation intervention) and level of physical activity. Changes in physical activity levels differed by the level of perceived environmental resources. In another study, the application of WMT-based intervention significantly increased levels of physical activity and quantity of vegetable servings to reduce stroke risk factors in older adults [68].

Thus, we propose a novel *ReadySteady* intervention to address the main barriers, such as lack of motivation, low-outcome expectations, and fear of falling in people with PD. The *ReadySteady* intervention is guided by WMT [69,70] and operationalized in light of the principles and practices for polestriding in older adults with PD. While WMT-based intervention has not been tested in older adults with PD, it is likely that physical support in the form of polestriding, and motivational support through WMT can promote physical activity and improve gait patterns in PD. The purpose of this paper is to describe the design of the *ReadySteady* trial, which aims to evaluate the efficacy of an individualized behavior change intervention fostering community mobility in older adults with PD, by providing motivational and physical support for regular physical activity.

2. Methods

2.1. Trial design

The benefits of the *ReadySteady* intervention will be investigated using a randomized controlled, longitudinal study design with evaluation at T1-pre; T2-post (12 weeks); T3-follow-up (24 weeks) (Fig. 1). Three study interventions will be investigated: (1) *ReadySteady* (RS) Intervention (Group 1), Polestriding and Education intervention (PEI) (Group 2), and Education intervention (EI) (Group 3). The PEI and EI groups will serve as control interventions to understand the effects of the main intervention, *ReadySteady* intervention.

Group 1: Those in the *ReadySteady intervention* will participate in weekly sessions providing polestriding and motivational support for 12 weeks. *ReadySteady* intervention duration is based on previous research [65,68,71] testing a theory-based motivational intervention for 8–12 weeks to promote physical activity in older adults, and polestriding intervention shown to be effective in PD [56].

Group 2: Persons assigned to the Polestriding and Education Intervention (PEI) will participate in weekly educational sessions (education about symptoms and difficulties in PD without the motivational behavior change component) for 12 weeks. They will not receive content specific to motivation or feedback on their level of physical activity. Participants in the PEI intervention, based on the knowledge on the benefits of polestriding in PD and access to the poles, may choose to polestride regularly. However, they will not be instructed explicitly to perform physical activity, including polestriding, throughout the study

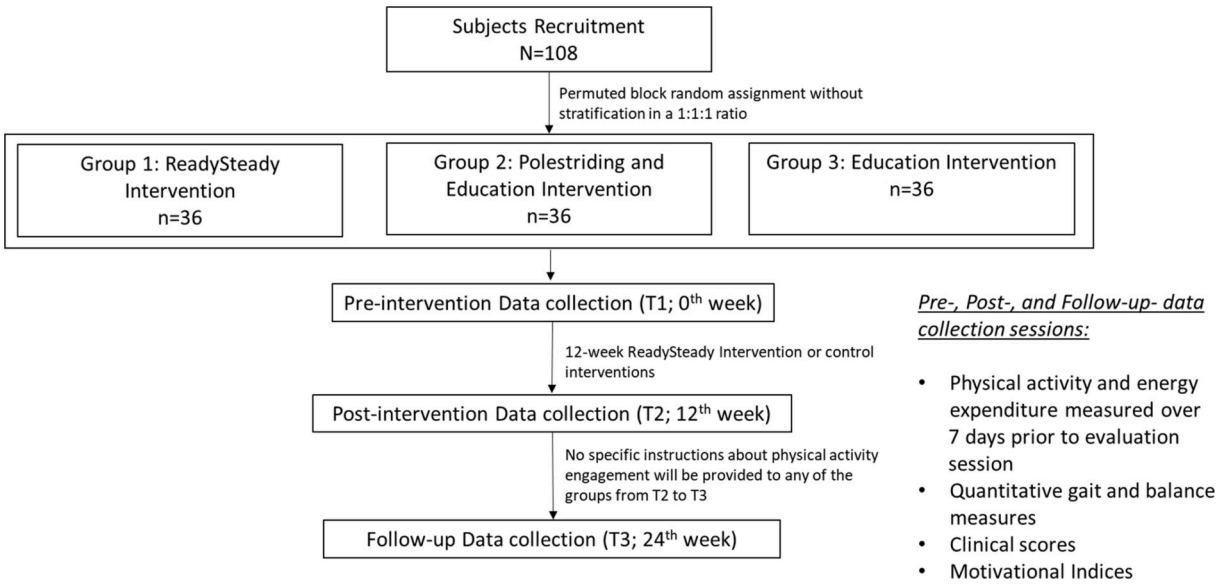

Fig. 1. Flowchart for study design.

period. The participants in the *ReadySteady* intervention and Polestriding and Education intervention will be provided with poles for polestriding along with initial training for proper polestriding.

Group 3: The subjects in the Education Intervention (EI) group, will participate in the weekly educational sessions about PD (similar to the PEI group); however, they will not receive any content specific to motivation, a pair of poles and education on polestriding, or feedback on their level of physical activity. Moreover, they will be asked not to change their usual exercise routine, if any, during the entire study period.

Maximum efforts will be taken to provide an equal amount of contact between the research team and participants of all the groups, including 12-week study interventions and evaluation sessions. To improve effectiveness, the motivational part of the *ReadySteady* Intervention (Group 1) and educational sessions (Group 2 and Group 3) will be conducted in a small of group of participants (groups of about 5 participants).

Each participant will be provided an iPod Touch device, onto which we will load the *ReadySteady* Mobile application and which we will use to obtain physical activity measures such as intensity, duration, and frequency of physical activity, the metabolic equivalent of task (MET) of physical activity, and energy expenditure, from a built-in accelerometer. The participants will be asked to wear the device on a belt clip during the day and charge it every night throughout the 24-week study period. The *ReadySteady* Mobile app has the capability to provide daily motivation messages based on the degree of physical activity achieved on each day (further details are provided in the *ReadySteady* Mobile App section). It should be noted that the *ReadySteady* Mobile app will be configured to provide motivational messages and feedback only to participants in the *ReadySteady* intervention group. For the PEI and EI groups, the *ReadySteady* Mobile app will only collect the accelerometer data. Accelerometer data from the iPod devices will also be downloaded during weekly sessions and biweekly during week 13–24 to obtain the above-mentioned physical activity measures.

Participants will also be asked to maintain diaries on physical activity and falls. They will be given activity journals and asked to identify the time and duration they engaged in meaningful activities for health or well being (walking, jogging, running, other exercises such as stretching, bicycling, weight lifting, yard activities, etc.), and any falls experienced, each day. A research staff member will contact the subjects every couple of days to remind them about keeping the diary. Moreover, any falls can be detected from the accelerometer data of iPod device. All participants in the *ReadySteady* intervention and PEI group will also be asked to maintain information on polestriding activity; dairy details will be collected once a week.

The following **hypotheses** will be investigated (see Table 1 for summary of hypotheses, endpoints, and instruments):

H1. *The ReadySteady intervention will increase the amount of time spent on physical activity and improve gait in people with PD (pre-vs. post-intervention):* Improvements in physical activity will be indicated by the amount of time spent (duration) in physical activity. Improvements in gait will be indicated by an increase in gait speed.

H2. *The ReadySteady intervention will experience greater benefits than the*

Table 1
Summary of hypotheses, endpoints, and instruments/comparisons that will be used to obtain endpoints.

Hypothesis	Endpoints (comparison of pre and post time points)	Instruments/Comparisons to Obtain Endpoints
H1: The *ReadySteady* intervention will increase the amount of time spent on physical activity and improve gait in people with PD (pre- vs. post-intervention)	Changes expected during post-*ReadySteady* intervention compared to that of pre-*ReadySteady* intervention: • increase in the amount of time spent on physical activity • increase in gait speed	• The amount of time spent on physical activity will be measured by the *ReadySteady* Mobile App using the data from the built-in accelerometer of the iPod device. • Gait speed will be obtained from the APDM Mobility Lab system.
H2: The *ReadySteady* intervention will experience greater benefits than the other groups (PEI and EI)	For physical activity and gait measures: • ΔRS > ΔPEI; • ΔRS > ΔEI ΔRS, ΔPEI, and ΔEI: changes (differences between pre- and post-measurements) due to the *ReadySteady* intervention (RS), Polestriding and Education intervention (PEI), and Education intervention (EI), respectively.	For each measure, differences (Δ) will be calculated by subtracting the pre- from the post-intervention measurements.

other groups (PEI and EI). The changes between pre and post time points in the measures described in H1 will be compared across the three groups.

2.2. Participants

The research will focus on people with postural instability and gait disorder (PIGD) symptoms, as they may benefit the most from physical activity that includes polestriding, which has been shown to improve gait and balance in PD. Eligibility for participation includes: (1) age between 50 and 75 years, (2) idiopathic PD, according to UK brain bank criteria [72], (3) Unified Parkinson's Disease Rating Scale (UPDRS) walking score>=1 during "medication-on" state, (4) Hoehn & Yahr (HY) stage score of 2–3 in "medication-on" state, (5) stable dose of PD medication for the four weeks prior to the study and do not anticipate a change in the PD medications or dosage of PD medication during the study period, (6) ability and willingness to perform the intervention and evaluations, and (7) lead a sedentary lifestyle, defined as < 3 times a week vigorous-intensity physical activity for < 60 min or < 3 times a week moderate-intensity physical activity for < 150 min [73]. Subjects with any of the following conditions will be excluded: (1) presence of dementia, according to Emre criteria [74], (2) regular use of assistive gait device such as a walker or cane (3), presence of significant on/off motor fluctuations (>25% throughout the day), frequent falls (UPDRS fall score > 1), dyskinesia (>50% of day or UPDRS dyskinesia score > 1), or freezing leading to falls or balance impairment, which in the opinion of the medical monitor can affect the subjects' safety or compliance with the study protocols, (4) recent history of unstable heart or lung disease, evidence of current pregnancy, untreated chemical addiction or abuse, uncontrolled psychiatric illness, major neurological (except PD, e.g., stroke), or metabolic (e.g., diabetes) problems, (5) presence of postural hypotension, cardiovascular disorders, musculoskeletal disorders, or vestibular dysfunction limiting locomotion or balance, (6) current or recent (within 6 months) participation in any other study to promote physical activity or improve gait or posture, (7) medication schedule that results in having to take a dose of medication during the data collection session (to avoid confounding factors of fluctuations in medication effects), or (8) lack of approval from subjects' PCP or cardiologist to participate in the study.

2.3. Recruitment

Persons with mild to moderate PD, including all races and genders, will be recruited. Given the statistics on PD, we may have a higher representation of males but will seek an equal distribution of males and females. The incidence of PD increases with age, rising after the age of 55 years, with a sharp increase after 60 years. Based on this information, we will recruit adults between the ages of 50 and 75 years. We will limit recruitment to mild to moderate PD, as even those in their early stages of PD exhibit a sedentary lifestyle and experience gait difficulties [75,76].

The study participants will be recruited from the Lonnie and Muhammad Ali Movement Disorder Center at St. Joseph's Hospital and Medical Center, which is directed by HAS (one of the study investigators). The center has seen about 2500 patients with PD in the last two years and sees about 650 new patients with PD every year; it will provide a sufficient resource for subject recruitment given the eligibility criteria. HAS will screen the potential study participants for the screening criteria mentioned above. This will include obtaining clinical scores such as UPDRS, HY, Emre criteria, Scales for Outcomes of Parkinson' Disease–Cognition (SCOPA-Cog), Non-motor symptoms scale (NMSS), Mini-Balance Evaluation Systems Test (Mini-BESTest), and Parkinson's disease questionnaire-39 (PDQ-39).

2.4. Randomization and blinding

Eligible participants will be randomly assigned to one of the three interventions in a ratio of 1:1:1, without stratification, with the use of permuted-block randomization, to achieve an equal number of participants in each group. Data collectors will be blinded to group allocation, with the importance of blinding to the type of intervention emphasized. Participants will be asked not to reveal their group status during data collection.

2.5. Intervention implementation

2.5.1. Motivational part of the ReadySteady intervention

The motivational part of the *ReadySteady* intervention will be conducted at ASU by an Interventionist whom JF (one of the investigators) will train for 40 h over 2 weeks. The Interventionist will keep a log of each session, including the duration and content of contacts with participants. The PI and Dr. Fleury will meet with the Interventionist weekly for debriefing to allow communication of feedback from the Interventionist regarding the implementation of the intervention.

In WMT-based *ReadySteady* intervention, health behavior change is conceptualized as a growth-oriented process mediated by behavior change process variables (self-knowledge, motivation appraisal, and self-regulation) and social contextual resources (social support and community resources).

Older adults with PD may not believe that there is potential for improvement through physical activity; they may believe that lack of functional independence is inevitable. Due to gait and balance difficulties, there may be a fear of falling or fear of being vulnerable. There may be lack confidence about being active or concern that participating in physical activity programs may threaten their independence and autonomy [77–80]. Self-knowledge and self-capacity will be fostered through acknowledging valued goals, promoting positive outcome expectations, reflecting on personal strengths, and recognizing the potential for growth in PD.

Motivation appraisal reflects intention formation for goal-directed behavior related to personal beliefs and values, information, resources, and goals [69,70]. In older adults with PD, motivation appraisal will be fostered through analyzing concerns about physical activities proven to improve mobility, exploring ways to overcome problems that create barriers, linking personal beliefs and values to goals for physical activity, and developing skills to achieve goals for physical activity.

Like many older adults [70,81], persons with PD may not monitor their behavior in light of goals for functional independence. Self-regulation will be fostered through problem-solving strategies specific to individual concerns, self-monitoring physical activity behavior, developing resources central to goal achievement, and planning for and evaluating responses to social contextual changes.

Social contextual resources reflect the individual in a mutual process with one's environment. Decreased or lack of social support has been associated with a risk of dependency and a reduced level of function. This is important, as social connectedness is disrupted in PD by several factors such as progressive physical disability, mood disturbances, shrinking of social activities, and secluding oneself [82]. Moreover, deficits in social perception are observed in PD [83]. Social support will be fostered in PD through identifying support resources, reaching out and communicating, offering positive feedback to others, involving others in their efforts to be active, and acknowledging and encouraging the open expression of feelings.

Contextual resources include community resources used to support behavioral changes, including physical activity. Approaches in people with PD will include identifying opportunities to remain active in the community; connecting to community organizations that provide services; and identifying safe, low-cost places to engage in physical activity.

2.5.2. Physical activity (polestriding) part of the ReadySteady intervention

The physical activity part of the *ReadySteady* intervention, which will include polestriding, will be individualized according to participant ability. A pair of Exerstrider™ poles, along with lessons for the proper

way of polestriding [56] will be provided to the participants of this intervention as part of the weekly session for the first 2 weeks. During each intervention session, the subjects will be asked to polestride at their self-selected brisk pace for 40 min under the supervision of an instructor who has extensive experience in providing exercise training to individuals with PD. Subjects who are unable to exercise continuously for 40 min will be allowed intermittent training until the target duration is reached (the protocol will allow for short breaks up to 2 min). The exercise duration will be progressed as tolerated for each subject up to 5 min per 2 weeks until subjects reach the target of 40 min duration. All sessions include 5-minute warm-up and cool-down periods. During each session of training, heart rate (using heart rate monitor watch), session duration, distance walked and the number of steps taken (measured with a pedometer) will be recorded.

2.6. ReadySteady mobile app

The *ReadySteady* mobile application provides motivational messages in response to levels of physical activity. The application was developed on the iOS platform to monitor activity levels using the built-in accelerometer of an iPod Touch device. The application has the ability to evaluate the intensity, duration, and frequency of physical activity and energy expenditure to provide real-time motivational feedback reinforcing physical activity behavior. Pilot experiments assessing the validity of activity measurement showed that the system accurately measures sedentary, light, moderate, and vigorous activities [64,65,84]. Output includes real-time activity metaphors, motivational messages, and trended history feedback. The metaphorical representation consists of a view of a garden from a window, with the garden blooming with flowers as the user becomes more active. The sun also serves as a meter, filling as the user gets closer to completing his or her goal. When a user completes the daily goal, a final state is reached (a bird is depicted in the garden). In addition to the pictorial representation, users are provided numeric feedback on their progress, including trended history. Motivational messages were developed based on the WMT; while all messages are designed to provide encouragement, the message changes in tone as the user comes closer to reaching his or her goal. For example, “Every bit helps” is a message that appears when the user has completed less than 25% of their daily goal. Messages such as “Energy, attitude, and persistence conquer all” appears when the users have met their daily goal [64].

Since people experiencing mild to moderate PD with UPDRS walking item score>=1 during medication-on state and leading a sedentary lifestyle will be recruited for the study, a combination of light and moderate activity of 100 min per day will be set as a daily goal. The *ReadySteady Mobile* app considers stretching exercises, housework, yard work, and walking as light and moderate level activities depending on the intensity of these activities, and standing, rocking, and driving a vehicle, are considered as no activity. The messages and pictorial representations, which are based on the minutes spent on activities, will be provided every 3 h and when 25%, 50%, 75%, and 100% of the daily goal is reached (between 6 a.m. and 9 p.m. to avoid bothering the subject at night times). Also, the participants will have the option to view the number of minutes spent on activities for the previous 7-day period.

2.7. The Polestriding and Education intervention (PEI)

Participants in the PEI will be provided weekly educational sessions about symptoms and difficulties in PD for 12 weeks. Specifically, educational sessions will focus on selected topics from PD Expert Briefings of the Parkinson’s Disease Foundation such as (1) Nutrition, (2) Cognitive Issues, (3) Anxiety, (4) Dementia, (5) Apathy or Depression, (6) Medication Management, (7) Sexuality and Intimacy, (8) Swallowing and Dental challenges, (9) Managing motor symptoms, (10) Under-recognized non-motor symptoms, (11) Fatigue and Sleep Disorders, and (12) Gait, Balance, and Falls.

Also, a pair of Exerstrider™ poles will be provided along with lessons in proper polestriding [56] (that includes practicing polestriding) as part of weekly sessions for the first two weeks; proper polestriding will be evaluated initially, and every four weeks during the weekly sessions. However, the participants in this group will not be provided with any content specific to motivation or feedback on their level of physical activity. Moreover, they will not be instructed explicitly to perform physical activity, including polestriding, throughout the study period. However, they may choose to polestride regularly based on the knowledge on the benefits of polestriding in PD and access to the poles.

2.8. Education intervention (EI)

The EI consists of the same weekly educational sessions on health issues in PD for 12 weeks as that of PEI (described above). However, they will neither be provided any content specific to motivation nor a pair of poles and education on polestriding. Moreover, they will be asked not to change their usual physical activity routine, if any, during the entire study period.

2.9. Evaluation design

Data collectors will be blinded to group allocation. Participants will engage in *pre-intervention* data collection sessions (T1, 0^{th} week), *post-intervention* sessions (T2, 12th week), and *follow-up* sessions (T3, 24th week). During the period from T2 to T3, no specific instructions about physical activity engagement will be provided to any of the groups. At each time point (T1-T3), participants in all three groups will participate in two experimental sessions: the *Gait, Balance, and Motivation Evaluation Session* and the *Clinical Evaluation Session*. The sessions will be conducted during the medication-on condition (when the medication best controls symptoms of PD, usually 60–90 min after the subjects’ usual dose of anti-parkinsonian medication). Moreover, for each subject, maximum efforts will be made to conduct the sessions during the same time of the day to facilitate a better comparison of performances among T1, T2, and T3. One of the primary outcomes, the time spent in physical exercise, will be obtained from an iPod Touch device during a 7-day period at T1, T2, and T3, which will be utilized to compare the groups. During these three 7-day periods (prior to T1, T2, and T3), no feedback on their physical activity or motivation messages will be provided to any of the groups. The gait speed will be the primary outcome related to gait. The secondary outcomes will be other gait measures such as step length and variability in step time and length, and clinical scores such as the Unified Parkinson’s Disease Rating Scale (UPDRS), Mini-BESTest, Parkinson’s Disease Questionnaire (PDQ) −39, Non-motor symptoms scale (NMSS) and limits of stability.

2.9.1. Gait, balance, and Motivation Evaluation Session

Gait will be evaluated during overground walking using the APDM Mobility Lab system [85–88] (APDM, OR), which uses wearable sensors. Participants will wear the lightweight wearable sensors at ankles, wrists, center of back at about 5th lumbar vertebra, and sternum. Each set of sensors consists of accelerometers, gyroscopes, and magnetometers. The sensors are lightweight and are not expected to affect walking patterns. Participants will be asked to perform three trials of standard 3-m Timed Up and Go (TUG) test, which is correlated to the level of functional mobility [89]. TUG measures the time taken for the following task: getting up from the chair, stand up, walk 3 m, turn around, walk back, and sit down. Gait will be evaluated during 2-trials of 40 m each, with turns at 20 m. This approach will provide longer walking segments to obtain reliable gait indices, including variability measures [90]. Gait indices including step length, step time, gait speed, variabilities in step time and step length, the range of arm swing, single and double support duration, gait asymmetry, and bilateral coordination will be obtained from 40-m walking trials. From TUG trials, information on time to stand

up, sit down, turn, and the number of steps during turning will be obtained.

Participant limits of stability (LoS), and the ability to stand on one leg will be measured. The LoS measures the maximum angle of sway (maximum excursion) a person can achieve in various directions from vertical without losing balance and without lifting their leg from the standing force platform. Another indicator of LoS is direction control, which assesses whether the subject moved (swayed) in the intended target direction, calculated as the ratio of movement in the intended direction to the extraneous movement, will also be measured. Three trials will be performed in each of the direction (front, back, and sideways). The LoS and direction control will be calculated using the center-of-pressure signals obtained from the force platform during these tasks. Higher values of maximum excursion and direction control indicate better balance control. Also, balance control will also be evaluated using Mini-Balance Evaluation Systems Test (Mini-BESTest), which has been shown to detect even subtle balance deficits in people with PD [91–93], evaluating different aspects of balance such as anticipatory control, reactive postural control, sensory orientation, and dynamic gait.

Motivational processes and resources, including social support, community resources, self-knowledge, motivational appraisal, and self-regulation, will be assessed using scales whose validity and internal consistency have been established in older adult populations. Social support will be measured using the Social Support and Exercise Survey (SSES), which reflects the level of support people believe that they receive for physical activity from friends and family [94]. Community resources will be measured using the Perceived Environmental Support Scale [95]. Self-knowledge will be evaluated using a measure of Self-Capacity [96,97], which reflects the dimensions of personal growth, purpose in life, and self-acceptance. The Index of Readiness (IR) will be used to measure motivation appraisal, which informs aspects of behavioral change, including reevaluation, acknowledgment of barriers, and goal commitment [98]. Self-regulation will be evaluated using the Index of Self-Regulation (ISR), which represents self-monitoring, assessing participation in the behavior, and integration of the behavior into everyday life [99].

2.9.2. Clinical Evaluation Session

Participants in each of the interventions will undergo clinical evaluation at T1, T2, and T3 in their "medication-on" condition. Clinical scores to assess disease severity, including motor and non-motor symptoms, quality of life, and cognition will be assessed. Quality of life will be evaluated using self-reported PDQ-39 [100,101], which consists of 39 questions to assess eight domains of life, such as Mobility, Activities of Daily Living, Emotional Well-Being, Stigma, Social Support, Cognition, Communication, and Bodily Discomfort. Disease severity will be measured using UPDRS [102], the most widely applied rating scale for PD that will include an examination of Part I – mentation, behavior, and mood; Part II – activities of daily living; and Part III – motor examination.

Scales for Outcomes of Parkinson' Disease–Cognition (SCOPA-Cog) [103] will be used to evaluate cognition. SCOPA-Cog is a PD-specific scale that tests the non-verbal and verbal memory, learning, attention, and executive function, including complex motor planning, working memory, and verbal fluency, and has undergone extensive clinimetric testing [104]. To assess non-motor symptoms, Non-Motor Symptoms Scale (NMSS), a validated scale in PD [105] will be utilized. NMSS assesses nine aspects of non-motor difficulties: cardiovascular, sleep/fatigue, mood/apathy, perceptual problems/hallucinations, attention/memory, gastrointestinal, urinary, sexual function, and miscellaneous.

2.10. Sample size calculation

One hundred and eight people with *mild to moderate PD* will be enrolled and randomly assigned to the *ReadySteady* intervention (n = 36), the Polestriding and Education intervention (n = 36), or the Education intervention (n = 36). This sample size will accommodate approximately 20% attrition, although less than 10% attrition was observed in a large study evaluating a behavior change intervention in PD [48], and in our recent study [56] of polestriding. We expect 86 participants to provide complete data through the follow-up at the 24th week. Power calculations were conducted using repeated-measures ANOVA that forms the primary method of analysis for Hypotheses 1–2 using G*Power 3.1.7.1 [106]. A conservative effect size value of d = 0.57 was chosen based on the effect sizes for the primary outcomes of clinical interest; effect sizes for gait speed and time spent on very active physical movements were approximately, 0.57, and 0.94, respectively [56,107]. The power to detect an effect size of 0.57 with an N = 108 is 0.80, given a correlation of 0.8 over time and an alpha level of 0.05. This will provide adequate power to detect an intervention effect using repeated measures ANOVA to examine Hypotheses 1–2.

2.11. Outcome analysis

To test the impact of the *ReadySteady* intervention on physical activity and gait (H1), generalized linear mixed models will be used to analyze group change over time. Group membership, time, and the interaction of group and time will be used as the predictors, and the primary outcome variables will be time spent on physical activity and gait speed. The analysis will test a planned contrast to look at change over time for people with PD (e.g., pre vs. post). Finally, to test whether *ReadySteady* intervention is superior to PEI and EI, the differences (between T1 and T2) due to *ReadySteady* intervention will be compared against corresponding differences due to PEI and EI (H2). The Dunnett's *t*-test will be used for post-hoc pairwise comparisons. Also, any differences in age, gender, disease severity, and level of physical activity during baseline (evaluated at T1) will be addressed as covariates in the statistical analysis. And, any changes in medication change/dosage throughout participation will be incorporated as a covariate during statistical analyses. A statistically significant interaction will be followed up with tests of the simple effects. Since the proposed study will be the first one to investigate the effects of *ReadySteady* intervention in people with PD, the possible benefits of this intervention on many secondary gait measures, balance control, disease severity, and energy expenditure will also be explored. In addition, the correlations between changes (pre vs. post) in cognition and motivation-related measures and benefits in physical activity and gait patterns will be obtained.

To address missing data, if any, intention-to-treat analysis (using multiple imputation techniques) will be performed. Furthermore, a complete case analysis will be conducted, and the results of the two analysis (intention-to-treat analysis and complete case analysis) will be compared to make sure that the conclusions obtained from both the methods are the same [108].

3. Discussion

The *ReadySteady* intervention builds on literature regarding the benefits of physical exercise in PD, extending knowledge in evaluating the efficacy of individualized intervention fostering community mobility in older adults with PD, using physical and motivational support. While few studies have incorporated approaches to behavioral change promoting physical exercise in people with PD, *ReadySteady* intervention is guided by wellness motivation theory [69,70], operationalized in light of the principles and practices for polestriding in older adults with PD.

The *ReadySteady* intervention acknowledges barriers to physical exercise identified in PD, including fear of falling and low outcome expectations, which may promote incorporating physical activity into a daily routine in the community setting. While interventions addressing behavior change aim to improve walking and physical activity in general, they do not address key barriers to community walking in older adults with PD or evaluate the quality of movements.

Attempting to improve physical activity in older adults with PD without addressing the fear of falls or improving the quality of movements such as gait patterns may result in a cycle of increased fear of falls and low outcome expectations. The use of polestriding in the proposed intervention provides the individual with a means of physical support and sensory feedback while encouraging improved and healthy gait patterns. Approaches to behavior change in older adults with PD are needed, which acknowledge the patterning of health behavior in mutual process with the environment [109], and motivation as moving beyond the present toward valued goals and health outcomes [69]. From this perspective, motivational approaches to promoting physical activity reflect the unique strengths of each older adult, with behavior change as a growth-oriented process. Thus, individualized interventions fostering community mobility and focused on physical and motivational support are essential to the initiation and maintenance of physical activity in PD.

The use of WMT-based behavior change is innovative, as no studies have evaluated the effects of WMT-based behavior change to promote physical exercise in PD. Intervention approaches to developing self-knowledge, motivation appraisal, self-regulation, and social support and community resources have not been applied to increase physical activity in PD. Further, the proposed intervention dose is consistent with the WMT theory, allowing a theoretical understanding of the process of behavioral change over 12 weeks, a higher dosage than tested in other trials.

Declaration of competing interest

The authors have no conflicts of interest/financial disclosures to report.

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