Feasibility and acceptability of a physical activity behavior change intervention for Parkinson's disease

NCT03696589

Study Protocol

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Participants

Participants were recruited from a purposive convenience sample. Study recruitment fliers were distributed to local neurologists and therapists who work with PwPD, support groups, and within the Neurological Institute at the Columbia University Medical Center. Flyers were also distributed at the 2018 PD Unity Walk in Central Park, NYC, where the Columbia Movement Disorder Division had an official booth. At the booth, the investigator took down names and contacts of individuals who expressed an interest in the study and then contacted them after the event to see if they wanted to participate and be screened for qualification. Potential participants who met the inclusion/exclusion criteria were also contacted from the NRL PD registry. The NRL PD registry contained contact information of PwPD who consented to be contacted for new PD-related studies at NRL. Finally, the study was registered on clinicaltrials.gov (Clinical Trials Registration NCT03696589) which led to it being posted on the Michael J Fox (MJF) Trial Finder. Participants were not excluded based on gender, class, or race. This study took place in the Neurorehabilitation Research Lab (NRL) at Teachers College, Columbia University.

Participants were included if they were: 1) between the ages of 18 and 85 years of age; 2) had a neurologist confirmed clinical diagnosis for Parkinson's disease H&Y stage I or II [1]; 3) able to ambulate indoor and outdoor without assistance or the use of an assistive device; 4) successful completion of the Physical Activity Readiness Questionnaire (PAR-Q)[2] safety screen or medical clearance from their general practitioner. The age group was limited, given the research questions to be addressed. The incidence and prevalence of PD are 1.5–2 times greater in males than in females,[3] thus we anticipated there would be a greater enrolment of men than women

Participants were excluded if they (1) had a musculoskeletal injury that would prevent them from participating in an exercise program; (2) had another neurological disease or disorder such as stroke; or (3) if they were already engaging in aerobic exercise for at least 30 minutes for five or more days per week.

Study Design

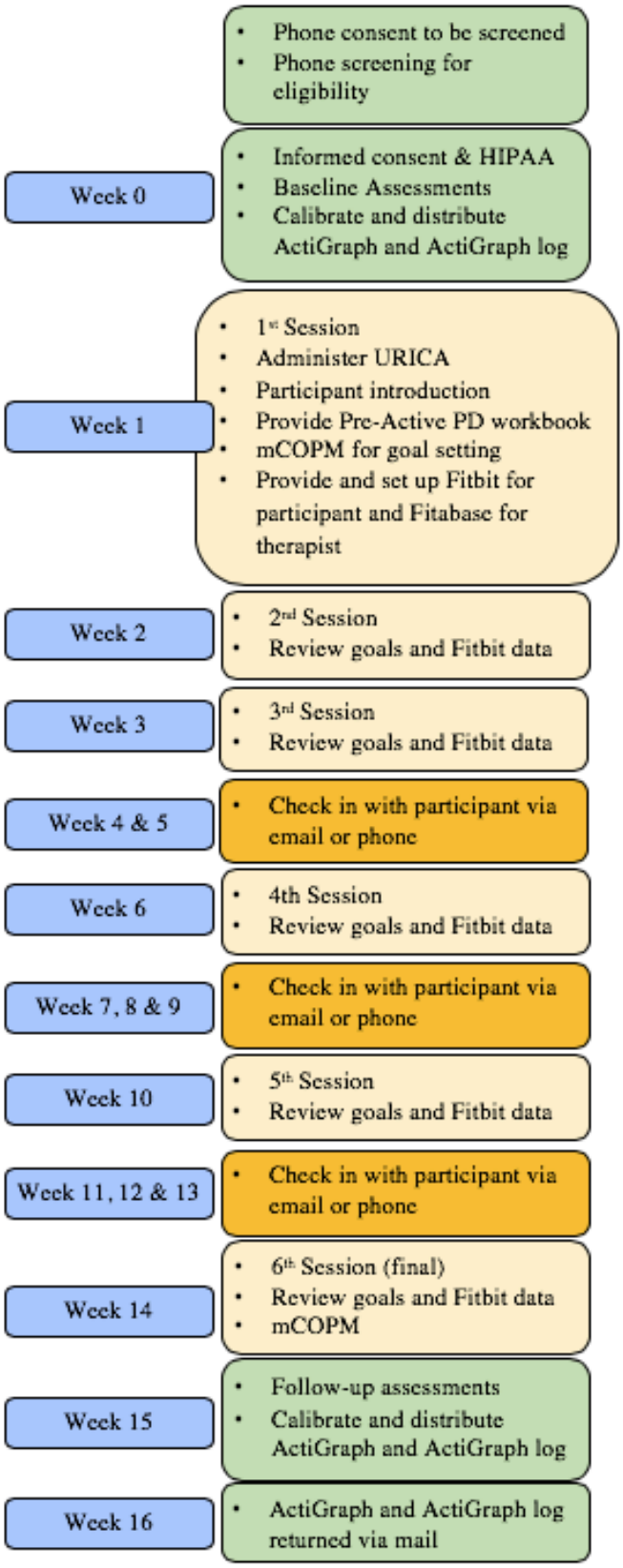
A feasibility design was used to assess if the Pre-Active PD intervention can work in regards to acceptability and implementation[4] and to investigate the effect estimates in regards to PA levels, self-efficacy, motivation, and self-perception of performance. Given the stage of the presently proposed question, an open pre-post cohort design was selected. The selected cohort is adults with early stage PD (H&Y I-II). An open cohort was selected to present less obstacles for attaining the desired sample size for the study. The design was prospective, which allowed the investigators to obtain baseline exposure data in real time and then follow the participants to measure the occurrence of the health outcome.[4] In addition, there was a retrospective element to the design: the inclusion of post-intervention questionnaires designed to assess retrospective acceptability of the intervention.

Procedures

Participants were consented to be screened over the phone and then screened for eligibility using the inclusion/exclusion criteria and PAR-Q. Participants were then scheduled individually to come to the NRL for their baseline assessments. Informed consent, baseline assessments and ActiGraph administration were carried out at week 0 by a trained research assistant. The ActiGraph was worn for seven consecutive days and then returned to NRL. The

intervention was delivered by an occupational therapist. The first one-to-one session occurred on week 1, and subsequent sessions followed on week 2, 3, 6, 10, and 14. On the alternate weeks when there were no sessions, the participants were contacted via phone or email for check-ins. At week 15, the follow-up assessments and another ActiGraph were administered by the research assistant,. At week 16 the ActiGraph was returned via mail. See figure below for study schema diagram.

Figure. Study schema diagram



Intervention. The Pre-Active PD intervention underpinnings and components were described in detail in chapter one (see figure II for Logic Model). The intervention was delivered by the investigator who is a licensed occupational therapist with experience working with PwPD, PA coaching, and MI. For the intervention sessions, participants had the option of doing them in person at NRL or remotely via a secured web-based server, Zoom. One week following baseline measures, participants received their first of six one-to-one sessions that occurred over the following 14 weeks (week 1, 2, 3, 6, 10, and 14). The therapist checked-in with the participant via phone or email to provide additional support and feedback on the weeks when the participant did not have one-to-one sessions (week 4, 5, 7, 8, 9, 11, 12, and 13).

At the first session, the therapist used the University of Rhode Island Change Assessment – Exercise 2 (URICA-E2)[5–7] to determine which stage of change the participant was beginning with in regards to PA. After the stage of change was identified**,** the therapist introduced the Pre-Active PD workbook and gave an overview of the program and timeline. The therapist used the MI techniques (described in chapter one) in alignment with the SDT in in order to facilitate progression through the TTM stages for PA behavior change. [8–10]

Towards the end of the first session, the therapist employed the mCOPM and helped the participant identify 3-4 PA goals. The goals were related to frequency, duration, and intensity of selected exercises. Finally, the therapist asked the participant if they wanted to use the Fitbit (Charge 2 model) to monitor their PA. If the participant said yes, the therapist provided a pre-charged Fitbit device with charger. The therapist showed the participant how to download the Fitbit app, create a Fitbit account, sync the device to their smart phone, and explained how to use it. Before concluding, the therapist scheduled their next session for the following week and asked if they wanted to do it in person at NRL or remotely via Zoom.

After the participant left, their Fitbit account was set up with Fitabase program a web-based platform that integrates FitBit data from users (Small Steps Lab, Inc; San Diego, CA, USA). During the intervention, participants' PA behaviors were monitored remotely through the Fitabase platform, whereby the therapist could view summaries of the participants' PA levels, and heart rate zones throughout the day. For each of the remaining five sessions, the goals were revisited, the Fitbit data was reviewed, and discussion ensued regarding participants' successes or struggles, and themes from the Pre-Active PD workbook.

Assessments

Demographic data and assessments were collected to illustrate the participant characteristics at baseline. Feasibility was assessed at follow-up in regards to the domains of acceptability and implementation (see table 1). Additional outcomes measures were administered at baseline and follow-up to assess effect estimates in the areas of self-efficacy, motivation, PA levels, and self-perception of performance and satisfaction (see table 2).

Participant Characteristics. At baseline, demographic data were recorded for each participant including age, gender, H&Y score, height, weight, date of diagnoses or onset of symptoms, and most affected side. In addition, the Montreal Cognitive Assessment (MoCA)[11] was administered at baseline. The MoCA is a 30-point cognitive screening instrument. A score of less than or equal to 26 is indicative of cognitive impairment.[12] The MoCA was used to assess presence and severity of cognitive impairment.

The University of Rhode Island continuous measure (URICA-E2)[13] was administered by the therapist at the beginning of the first session to assess the participants' readiness to change

with regard to exercise behavior, based on the TTM stages of behavior change. The URICA-E2 is a 24-item, 5-point Likert-sale, questionnaire. Each item has a statement that reflects an intention toward exercise, with responses ranging from one "strongly disagree" to five "strongly agree". Internal consistency of this questionnaire was 0.80 to 0.93. [6]

Feasibility. Feasibility was assessed in regards to acceptability and implementation fidelity. Table 1 includes a summary of the feasibility measures, variable names, and the corresponding feasibility domain.

Table 1. Feasibility measures

Feasibility Domain	Outcome Measures	Variable Name	When
Acceptability	Participant completion of ≥ 75% of sessions 1, 2 & 3	Adherence	Post follow-up
Acceptability	> 75% of participants retained at follow-up	Retention	Post follow-up
Acceptability	Fitbit Wear-time, or written logs	PA log	During intervention
Acceptability	Theoretical framework of acceptability questionnaire	TFAQ	1x Follow-up
Acceptability	Perceived Autonomy Support Healthcare Climate Questionnaire (Williams, Freedman, & Deci, 1998)	PAS-HCCQ	1x Follow-up
Implementation	Rating Tool to Assess Fidelity of Intervention Delivery [14]	Fidelity	Post follow-up

Adherence and Retention. Adherence was defined as the participant's commitment to the Pre-Active PD program through continued participation. Participation in the one-to-one coaching sessions along with the Fitbit data provided insight to the level of adherence. An adherence rate of ≥ 75% of the participants completing session 1-3 and a retention rate of > 75% retained at follow-up were deemed appropriate to suggest feasibility of this intervention. This threshold for adherence was set relative to the number of visits required to discuss all content of the workbook, as modeled in the Engage-HD study.[15] In addition, PA logs (i.e. Fitbit wear-time or written log) were also selected as it is recognized as a valid and acceptable method for measuring adherence. [16] The minimum threshold for adherence to PA logs was defined as valid data reported for at least four days or more in over half the weeks during the intervention for any one of the components.

TFA Questionnaire (TFAQ). Informed by the Theoretical Framework of Acceptability (TFA),[17] the TFA Questionnaire (TFAQ) was designed to inductively evaluate the retrospective acceptability of the Pre-Active PD intervention for patients with early stage PD by the present investigator. The TFAQ was not tested for reliability or validity. The TFAQ was designed to gather the participants' thoughts and feedback regarding the intervention delivery and workbook post-intervention, and was administered once at the 15-week assessment. The TFAQ part I included 25-items, where participants were asked to rate each statement on a Likert scale from 1

(strongly disagree) to 5 (strongly agree), with higher numbers indicating greater acceptability. Part I quantitatively measured 4 of the 7 theoretical constructs from the TFA: (1) *affective attitude* (how the participant feels about the intervention; items 1-4), (2) *intervention coherence* (the extent to which the participant understands the intervention and how it works; items 5-10), (3) *perceived effectiveness* (the extent to which the intervention is perceived as likely to achieve its purpose; items 11-18), and (4) *self-efficacy* (the participant's confidence that they can perform the behaviors required to participate in the intervention; items 19-25). Specific questions for each TFA domain were constructed with respect to the therapist (items 1-3, 10, and 15-17), workbook (items 4-8 and 11), and intervention as a whole (items 9, and 12-14). Acceptability was indicated by a total score higher than 75 from the sum of items 1-25 on the TFAQ-part I. The intervention components were also analyzed in separate aggregates in the domains of therapist, workbook, and overall impression. Part II of the TFAQ was optional and included open-ended questions to gather qualitative data from the participant's experience and feedback for the Pre-Active PD intervention. Acceptability was indicated by a total score higher than 75 from the sum of items 1-25 on the TFAQ-part I.

Perceived Autonomy Support Health Care Climate Questionnaire (PAS-HCCQ). The PAS-HCCQ is a 15 item questionnaire[18] designed to assess constructs encompassed within SDT as it applies to health-care behavior.[19]. The PAS-HCCQ items were marked by a high internal consistency (Cronbach's alpha = .96).[20] The scores indicate the degree to which the therapist was perceived to be autonomy supportive. Each item is rated on a 7-point Likert-type scale ranging from 1 (strongly disagree) to 7 (strongly agree). Scores were calculated by averaging the individual item scores. As per instructions, before averaging the item scores, the score of item 13 must be "reversed" by subtract the score on this item response from 8. For example, the score of 3, when reversed would become 5. Higher average scores represent a higher level of perceived autonomy support.[18]

Implementation Fidelity. An intervention fidelity rating tool[14] was used to assess the extent to which the therapist promoted the components of SDT (autonomy, relatedness, competence, and general impression). Four items were rated on a 0-4 Likert scale, and then summed to produce a total score range of 0-16, with the higher scores indicating higher intervention fidelity. A licensed occupational therapist, who was not involved in the intervention delivery or the administration of the other assessments, was instructed on how to use the measure. The assessor viewed and rated 12 sessions (one from each participant), that had been previously recorded via Zoom. In addition to the ratings, the assessor identified quotes from the therapist and participant that illustrated promotion of autonomy, relatedness, and competence.

Efficacy outcome measures.

Efficacy of the intervention was assessed in regards to effect estimates comparing pre and post intervention for physical activity, self-efficacy, motivation and self-performance of performance and satisfaction on goals. In addition to measures of feasibility and acceptability, there were two primary efficacy outcomes: 1) change from baseline in moderate vigorous physical activity using Actigraph, and 2) change from baseline in the relative autonomy index (RAI) of the behavioral regulation in exercise questionnaire (BREQ-2). Table 2 includes a summary of the efficacy outcome measures.

Table 2. Efficacy Outcome Measures

Effect Estimate Domain	Outcome Measures	Variable Name	When
Physical Activity	Brunel Lifestyle Physical Activity Questionnaire [21]	Brunel-PAQ	2x, Baseline and follow-up
Physical Activity	Wearable activity monitor	ActiGraph	2x, Worn 7 consecutive days pre and post intervention
Self-efficacy	The Exercise Self-Efficacy Scale [22]	Norman-SES	2x, Baseline and follow-up
Motivation	The Behavioral Regulation In Exercise Questionnaire [23]	BREQ-2	2x, Baseline and follow-up
Self-perception of Performance & Satisfaction	Modified Canadian Occupational Performance Measure [24]	mCOPM	2x, First and last session

Physical Activity Levels. The Brunel-PAQ is a 10-item questionnaire that measures both pre-planned and un-planned lifestyle PA [21] The Brunel-PAQ was designed to provide an online behavioral assessment to be used in conjunction with a 12-week personalized fitness program delivered through the internet, and was found to be a valid and reliable instrument. [25]. The Cronbach alpha coefficient for criterion validity of the behavioral intention items was $\alpha = .93$[25]. Internal consistency (Cronbach's alpha) estimates for the Brunel-PAQ subscales were $\alpha = .90$ for *Planned PA* $\alpha = .90$, and $\alpha = .68$ for *Unplanned PA.* [25] The BRUNEL-PAQ defined planned PA for participants as: "any activity that is scheduled into your daily routine, which may enhance your health, fitness, or wellbeing.".[25] Examples were provided, including brisk walking, gardening, cycling, team games, etc.

Responses to each item in the PA subscale were provided on a five-point categorical Likert-type scale (continuous closed numerical scale). For example, answer options for question one included: (1) never, (2) 1–2 times, (3) 3–4 times, (4) 5–6 times, (5) 7 or more times. Participants were asked to base their responses on what a typical week is like for them. The

planned PA subscale includes six items that were designed to measure the intensity, frequency, and duration of the identified activity. The unplanned PA subscale did not assess frequency because of its highly transient nature making it difficult to obtain validity.

The ActiGraph™ GT9X quantitatively measured PA levels (step count, MVPA levels, and sedentary behavior) to assess change before and after the intervention. Actigraphy is a non-invasive way of monitoring human rest/activity cycles and has been used to study PA levels and patterns in PwPD who have mild to moderate severity. [26–28] The ActiGraph™ GT9X is a reliable assessment of steps for PwPD or altered gait in both clinical and research evaluations. [29] The ActiGraph™ is an inertial measurement unit (IMU) which includes an accelerometer, a gyroscope, and magnetometer sensors to capture position and rotation, and wear time sensor. Participants were instructed to wear the ActiGraph™ secured on their hip by an elastic clip-on waist band on their hip for 7 consecutive days prior to receiving the intervention, and again after their last session. In addition, participants were asked to keep a written log, using handouts provided, to record times when the ActiGraph™ was removed and put it back on. Participants were instructed to not wear the device in water, such as when bathing or during water sports.

Self-efficacy. Self-efficacy was measured by the Exercise Self-Efficacy Scale (Norman-SES).[22] The Norman-SES is an 18-item test that measures an individual's self-efficacy to participate in exercise when numerous barriers are present, including both social and physical barriers. The measure employs a 5-point Likert scale for confidence, from 1 "not at all confident" to 5 "completely confident", in the areas of negative affect ($\alpha = .853$), excuse making ($\alpha = .829$), must exercise alone ($\alpha = .869$), inconvenient to exercise ($\alpha = .773$), resistance from others ($\alpha = .853$), and bad weather ($\alpha = .837$). A score less than or equal to 54 indicated low self-efficacy (18 items x Likert score of 3 "neutral"), a score between 54 and 72 (18 items x Likert score of 4 "confident"), and a score between 72 and 90 (18 items x Likert score of 5 "completely confident") indicates high self-efficacy.

Motivation. The Behavioral Regulation in Exercise Questionnaire (BREQ-2) measures the stages of self-determination continuum with respect to motivation to exercise.[23] It is a 19-item questionnaire, with a 5 point Likert scale from 0 "not true for me" to 4 "very true for me" for statements regarding PA engagement. For example, "I don't see why I should have to exercise" (amotivation), "I exercise because other people say I should" (extrinsic), "I feel guilty when I don't exercise" (introjected), "I value the benefits of exercise" (identified) and "I exercise because it is fun" (intrinsic). Acceptable internal consistency was previously demonstrated for the 5 subcategories: amotivation (items 5, 9, 12 & 19), external regulation $\alpha = .81$ (items 1, 6, 11 & 16),, introjected regulation $\alpha = .79$ (items 2, 7 & 13),, identified regulation $\alpha = .78$ (items 3, 8, 14 & 17), and intrinsic motivation $\alpha = .93$ (items 4, 10, 15 & 18). [30] A composite score of intrinsic motivation and identified regulation subscales represented autonomous motivation ($\alpha = .90$). [30] A composite score of introjected regulation and external regulation represented controlled motivation ($\alpha = .78$). [30] The BREQ-2 was scored by calculating the mean scores for each set of items per domain as indicated by its scoring key.

Self-perception of Performance & Satisfaction. The Canadian Occupational Performance Measure (COPM)[24] is a tool used to detect change in participant's self-perception of occupational performance, in regards to performance and satisfaction, over time using two 10-point ordinal scales, with 10 being the best score. The COPM was designed to enable personalized health care and identify issues of personal importance to the client. The COPM is a tool for initiating conversation about performance issues in everyday living, which provides the basis for setting intervention goals. More specifically, the COPM helps the therapist to: (1)

identify problem areas in occupational performance; (2) provide a rating of the client's priorities in occupational performance; (3) evaluate performance and satisfaction relative to those problem areas; (4) provide the basis for goal setting; and (5) measure changes in client's perception of his/her occupational performance over the course of the intervention.

The COPM has demonstrated strong content and concurrent validity[31] as well as test–retest reliability (intraclass correlation [ICC] .63 for performance, ICC .84 for satisfaction).[32] The COPM has been demonstrated to be more meaningful for identifying and prioritizing problems in meaningful areas when compared to self-evaluation lists. [24,33] Though it has not been specifically studied with respect to PwPD, it is assumed to be valid for PwPD and recommended by the ParkinsonNet/National Parkinson Foundation (NPF) in their Guidelines for Occupational Therapy in Parkinson's Disease Rehabilitation. [34]

For the Pre-Active PD intervention, the COPM was modified in a-similar manner as previous research.[35,36] For the purpose of the intervention, the occupational performance area focus was within the domain of active recreation or physical activity. Participants were asked to identify goals that they wanted to address over the duration of program, and each goal was rated for importance, performance, and satisfaction using the 10-point ordinal scale. The goals were then narrowed down to the 3 most important goals, similar to the Engage-HD intervention.[14] Participants had the option to modify or change their goals at each session as they progressed during the 4-month period. The original goals were revisited and scored again at the last session.

The mCOPM total scores were calculated by summing the scores of each goal (scores range from 1-10), then dividing by the number of goals (3 or 4), to give the average score. This was done for both performance and satisfaction ratings separately. The average score was calculated for both the first and final session. The post-pretest change score was calculated by subtracting the first session score from the last session score. To date, research suggests that a change of 2 or more points represents a clinically important change.[37,38]

Statistical Analysis

Descriptive statistics summarized the participant characteristics and the results of the outcome measures. IBM's Statistical Package for Social Sciences (SPSS) (version 26; SPSS Inc., Chicago, IL, USA) was used for inferential statistical analyses. Feasibility was evaluated in terms of acceptability and implementation. Percentages were reported for adherence and retention rates. Descriptive statistics were reported for the TFAQ-part I; the Perceived Autonomy Support Healthcare Climate Questionnaire (PAS-HCCQ)[18]; and fidelity rating tool[14].

Percentage of participants who selected Fitbit as their primary PA log was reported. Descriptive statistics were calculated for Fitbit data with regards to total percentage of time worn and daily step counts for the first and last 7 days. Data from the FitBit devices were synced with Fitabase program to provide sync events, wear time, number of steps per day, and moderate-vigorous activity. The data were downloaded into a .csv file for all participants for the duration of their intervention (16 weeks). Aggregate data were then calculated to provide mean and SD for all metrics

Descriptive statistics were calculated for the outcome measures for baseline and follow-up: PA levels (Brunel-PAQ and ActiGraph™), exercise self-efficacy (Norman-SES), motivation to exercise (BREQ-2), and self-perception of performance & satisfaction of goals (mCOPM). The mean difference between the baseline and follow-up was then calculated with a 95% confidence interval (CI). Effect sizes were calculated using Cohen's d[39], with $d = 0.2$ being considered a small effect size, $d = 0.5$ a medium effect size, and $d = 0.8$ a large effect size.

Descriptive statistics were calculated for participants in the different stages of exercise behavior change (URICA-E2) with regards to their changes in exercise self-efficacy (Norman-SES) and planned PA (Brunel-PAQ). Descriptive statistics were also calculated for changes in kinds of PAs enjoyed (Brunel-PAQ) from baseline to follow-up. ActiGraph™ findings were calculated with regards to percentage of time spent in sedentary activity, percentage of time in MVPA, and daily step count.

The accelerometry data were preprocessed as accelerometer data files (AGD files) using ActiLife software (ActiLife v6.13.2; Pensacola, FL, 2016) and then converted to CSV files with 60-second epochs. Participants with less than 4 days (and a minimum of 1 weekend day) of 10 hours per day of wear time were excluded from the results. Based on the results of earlier studies, 60 minutes of consecutive zero counts were classified as non-wear time. Non-wear time was excluded from calculations for each individual.

Correlation coefficients were calculated to determine the relationship between: post-pretest change scores of planned PA and self-efficacy; baseline self-efficacy scores and follow-up planned-PA times; and post-pretest change scores of planned PA and unplanned PA and BREQ-2 measures of amotivation, external regulation, introjected regulation, identified regulation, and intrinsic regulation.

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