RUTGERS
School of Health Professions

Judith Deutsch

IMMERSIVE VIRTUAL REALITY BICYCLING FOR PERSONS WITH PARKINSON'S DISEASE

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

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INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  Enhancing Exercise Intensity, Motivation and Enjoyment for Persons with PD (VCycle-Competition)

- **Principal Investigator Name**
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- **Principal Investigator Div. & Dept.**
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- **Protocol Version and Date:**
  [v5 1.18.23]

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1.0 Research Design

1.1 Purpose/Specific Aims

The short-term goal of this project is to gain insight into specific strategies of VR-based rehabilitation to increase motivation and intensity for persons with PD during a cycling task. **The long-term goal of this study is to determine the essential elements in designing a training circuit for persons with PD to promote mobility and fitness resulting increased activity and participation.** The short-term goals will be achieved through two primary aims that build upon the parent grant (1-2) and further refined through a mechanistic aim about the role of attention in explaining behavior in the VE (3).

We aim to build upon our work in PD and that of others in persons post stroke by using augmented visual feedback and competition to increase exercise intensity and motivation while cycling in a virtual environment.

Aim 1: Determine the effect of visual feedback and competition (self or others) during virtual bicycling on neuromuscular (cycling cadence) and cardiovascular (% max heart rate) intensity

Hypothesis: Competition will produce higher neuromuscular and cardiovascular intensity compared to feedback.

Aim 2: Determine the effect of visual-feedback and competition (self or others) during virtual bicycling on the user experience of motivation & enjoyment (Intrinsic Motivation Inventory: IMI) & perception of exercise intensity (Borg Scale)

Hypotheses: Competition will elicit a higher motivation and enjoyment compared to visual feedback. Competition will result in lower perceived exertion compared to visual feedback.

Aim 3: Determine if attention differs (dwell time percentage) in augmented visual feedback bicycling compared to competition (self or others) virtual bicycling

Hypothesis: Attention will be higher during competition virtual bicycling when compared to augmented bicycling.

A. Objectives (see above)

B. Hypotheses / Research Question(s) (see above)

1.2 Research Significance (Briefly describe the following in 500 words or less)

Parkinson's Disease (PD) is a neurodegenerative condition that affects over 10 million individuals worldwide. [1] In addition to pharmacotherapy, intense (cardiovascular and neuromuscular) exercise is recommended for persons with PD. Studies investigating the positive neuroplastic effects of intense exercise in animals [2] have been extended to humans regarding improved brain connectivity and upregulation of brain-derived neurotrophic factor. [3, 4] In addition to neuroplastic effects, exercise has been shown to have positive clinical benefits in reducing PD severity and improving motor and cognitive

function in persons with PD. [4-6] Specifically, bicycling has been shown to improve balance and mobility and reduce both motor symptoms, and disease severity for persons with PD. [7-10] In achieving and adhering to the intensity of bicycling required to benefit from the training, factors such as the user experience of exercise, specifically motivation, [11] enjoyment, and perceived exertion need to be considered. This is important as adherence to routine exercise is challenging for persons with PD. [12, 13] One method that may enhance exercise intensity for persons with PD is bicycling augmented with a virtual environment (VE). VEs serve as an interactive context to engage the participant in the exercise task. [14] This is because VEs provide visual feedback and cueing that may drive the intensity of the exercise. Specifically, we have shown that neuromuscular cycling intensity (cadence) was increased with visual feedback in short bouts of bicycling in a VE (see Pilot Data). [15] To maintain engagement for longer bouts, competition may provide an additive effect to visual feedback in the VE.

While motor and cognitive outcomes have been documented for persons with PD interacting with virtual environments, [16, 17] less is known about visual attention of persons with PD during motor tasks in VEs. Though visual attention has been studied in persons with PD, [18] only a few studies have investigated visual attention in VEs. [19] To address this knowledge gap, we will be the first lab to investigate eye movements as a surrogate of attention in persons with PD during virtual reality (VR) bicycling to study a mechanistic explanation for behavioral changes.

The ultimate goal of this research is to improve the well-being of persons with PD by making intense exercise more practical and enjoyable for them. It is significant that we bring inter-disciplinary expertise in understanding virtual environments and the demands of implementing the technology in clinical practice. By developing and validating virtual reality simulations that are enjoyable, motivating, and facilitate intense exercise, we aim to remove barriers associated with exercise for persons with PD and improve activity and participation as well as promote a healthy lifestyle. Being a valuable adjuvant to pharmacotherapy in addressing the motor and nonmotor symptoms of PD, intense exercise measured by neuromusculoskeletal and cardiovascular criteria may ultimately have beneficial therapeutic effects in decreasing disease severity and improving well-being.

1.3 Research Design and Methods

This is a controlled study within subject design. It is a single cohort.

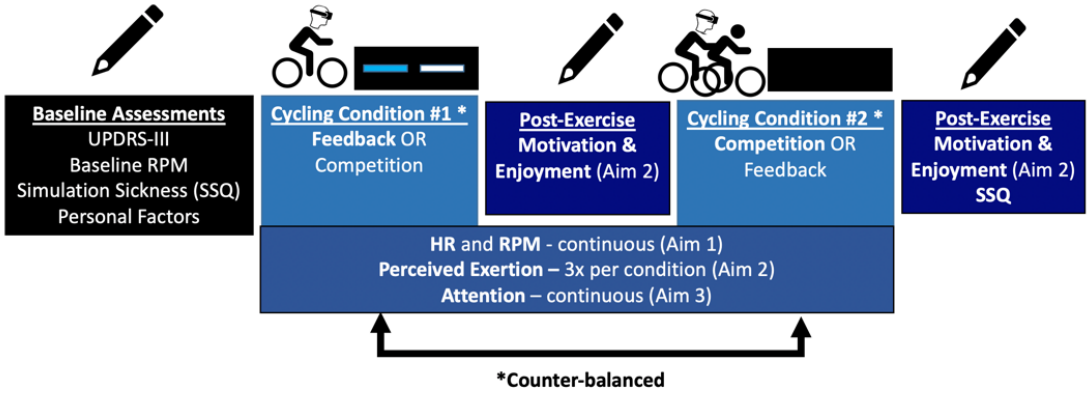

Figure 1: An overview of the study protocol in a single session. There are three trials competition (self or others) and feedback.

A. Research Procedures

After phone screening and in-person consent, participants will complete baseline assessments related to personal factors, clinical ratings of PD, and baseline simulation sickness. Then participants will familiarize themselves with three different bicycling conditions. After familiarization, participants will complete each bicycling condition in a counter-balanced random order. Each condition will last 8 minutes (~24 minutes of exercise total) and will be preceded by a baseline cadence assessment. **For the visual feedback condition,** the cyclist will be instructed to cycle at a target cadence that will turn the road markers blue. **For the competition conditions,** the participant will be instructed to cycle fast enough to pass a virtual cyclist in the simulation that is pedaling at the target cadence. **Measurements** of cardiovascular (HR) and neuromuscular (cycling cadence) intensity and visual attention (eye-tracking data) will be recorded continuously during both cycling conditions. Ratings of perceived exertion (RPE) will be collected at the beginning, midpoint, and end of each condition. At the end of each cycling bout, motivation & enjoyment and simulation sickness will be assessed. Open ended questions about the experience in each condition will conclude the session. **Participant safety** will be carefully monitored. If the intensity of the exercise is too high, the cyclists may overexert themselves risking adverse cardiovascular events. Therefore, different termination criteria will be implemented to ensure the safety of the patient. Participants will also be supervised at all times for safety on the bike. They will also be monitored for signs of cybersickness (dizziness, sweating) and be given an opportunity to stop at any time.

B. Data Points

See outcome table below (*Table 1)*.

C. Duration for Study and Each Subject

The study will be conducted over 20 months. Participants will attend one data collection session, lasting approximately three hours.

D. Endpoints

See Section 1.10 for the Data Monitoring timeline

1.4 Preliminary Data

In the parent study, data have already been collected from 22 participants with PD bicycling in a fully-immersive VE using visual feedback. Participants tolerated the HMD well, showing no significant difference in simulation sickness scores post-trial compared to baseline. Participants also reported moderate-high scores for several constructs of the IMI at the end of the 5-minute bout, including interest & enjoyment, perceived competence, and value & usefulness. Participants also bicycled at a moderate-high intensity, indicated by an average % HR Max of >55% and a bicycling cadence that was >30% faster than their comfortable baseline cadences.

There are many parallels between the parent study and this project. In particular, we have demonstrated our ability to recruit, screen, and clinically test persons with PD. Furthermore, we have collected time series of heart rate and bicycling cadence data during exercise for persons with PD.

1.5 Sample Size Justification

Power analyses- Sample size for **Aim 1**: An a priori power analysis was powered upon preliminary cycling cadence data published from the lab. [15] The power analysis conducted in G*Power, [20] determined that 19 participants would be required to reach a power level of 0.80 (Cohen's D =0.7, moderate effect size). **Aim 2:** An a priori power analysis powered on motivation and enjoyment (Intrinsic Motivation Inventory) [21] with an effect size of 0.75 determined that 16 participants would be required. This effect size was adapted from Cikajilo & Potisk 2019, who investigated a fine motor upper extremity task for persons with PD in a fully-immersive environment. We used their reported average effect size of the different IMI subscales. [22] **Aim 3:** There are no pilot data (collected by our team or published by others) for this aim. An effect size will be calculated from these data to power future studies. Considering all the sample size calculations and accounting for a 20% attrition rate, 24 participants will be required for this study.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables
Cycling Mode (Visual feedback versus competition against self and others)

B. Dependent Variables or Outcome Measures
See table below (*Table 1)*:

Neuromuscular Exercise Intensity	
Cycling cadence	Measured by the Wahoo sensor on the bicycle crank. Referenced to the self-selected cadence to measure the % increase as well as the absolute value (Aim 1)
Cardiovascular Exercise Intensity	
Heart Rate (HR) % of maximum	Collected with Garmin or Polar HR monitor worn on the forearm. Referenced to age maximum and interpreted as a percent (Aim 1)
Blood pressure (BP)	Collected manually with upright Braum mercury sphygmomanometer (Aim 1)
Perceived Effort	
Rating of perceived exertion (RPE)	The Borg Scale of perceived Exertion will be used to collect this information. The lowest measure on the scale is 6: no exertion at all, and the highest is 20: maximal exertion (Aim 2)
Open Ended Questions	Ranking of 3 conditions and interview for qualitative data (Aim 2)
Motivation	
Intrinsic Motivation Inventory (IMI)	Customized motivation inventory capturing 4 constructs including: interest & enjoyment, perceived competence, effort & importance, value & usefulness. Participants will complete the IMI after each condition. The IMI has been validated for older adults (Aim 2)
Open Ended Questions	Ranking of 3 conditions and interview for qualitative data (Aim 2)

Attention	
Eye-Tracking Data	Collected continuously at 30-50 Hz with HTC Vive Pro Eye, using built-in Tobii infrared eye-trackers. Data will be collected and analyzed from 1 minute until the end of the bicycling bout to account for acclimation to the VE
Participant Characteristics	
UPDRS Motor Score Section III	To quantify motor involvement & disease severity
Physical Activity Scale for the Elderly (PASE)	To measure participants physical activity at time of testing (can be used to classify individuals as high and low exercisers. Used and validated to measures activity in persons with PD May be used as a co-variate
Simulator Sickness Questionnaire (SSQ)	To measure adverse events in the immersive virtual environment. Has been used to measure simulator sickness in persons with PD
Multi-Dimensional Competitive Orientation Inventory (mCOI)	To measure participant competitiveness (can be used to classify individuals as competitive or non-competitive). May be used as a covariate

Table 1: **Primary Outcome Measures are bolded**

1.7 Drugs/Devices/Biologics
NA

1.8 Specimen Collection
NA

1.9 Data Collection

A. Primary Data Collection
- **Location**: Rutgers Sites: SSB 912, 224, and 210
- Non-Rutgers Sites: New York Institute of Technology
  - Northern Boulevard, PO Box 8000, Old Westbury, NY
    - Riland Building, Academic Health Care Center Biomechanics Lab
- **Process of Data Collection**:
  The data collection procedures are described in detail in the screening document and the data collection document that were uploaded with this IRB proposal.

Protocol: See Figure 1 above.

Screening: Prior to the cycling session, participants will be screened over the phone for exercise readiness using the Physical Activity Readiness for Everyone scale (PAR-Q+). [23] A positive response to 2 or more of the questions will prompt a request for medical clearance for the

participant. As depression is prevalent in the PD population and is associated with disability, [24] participants will also be screen using the short form of the Geriatric Depression Scale (GDS-15), [25] which has been validated in persons with PD. [26] Participants with a score of 9 or more on the GDS-15 (indicating moderate depression) will be excluded. Once cleared, participants will be asked to take their medications as normal. Testing will be scheduled at peak medication, approximately 2 hours after administration.

Baseline Assessments: Participants will complete a questionnaire about personal factors including age, gender, previous VR use and competitiveness. Competitiveness will be measured with a validated 12-item inventory. [27] Disease severity will be assessed with the motor subscale of the UPDRS (UPDRS-III). [28] The simulation sickness questionnaire (SSQ) will be collected at baseline and at the end of the final trial to monitor cybersickness. [29]

Familiarization: Participants will don the HMD and bicycle in the three different conditions until they execute each cycling task correctly and are accustomed to the HMD and understand the Borg Scale. After familiarization, there will be a brief period of rest to restore HR to baseline.

Cycling Conditions

Baseline cycling cadence will be established for each condition. Participants will cycle at a comfortable pace that can be maintained for 30 minutes. This comfortable baseline pace will be used to set the target cadence (rate at which the visual markers are presented or rate of the virtual competitive cyclist) for participants during the given trial. The target cadence will be set at a pace that is 25% higher than comfortable baseline pace. [10, 15]

Visual Feedback Condition: The cyclist will be instructed to cycle at a pace that will turn the road markers blue. If the cyclist pedals at a speed that is below the target cadence, the markers will remain white. If the cyclist cycles at a pace that is above the target cadence the markers will turn from white to blue, serving as visual feedback for the user to maintain the pace. If the cyclist pedals too fast (threshold set at 40% greater than the comfortable baseline RPM), the road markers will turn from blue to red, serving as visual feedback for the user to slow down. The participant will also receive summary information at fixed time intervals about how well they are maintaining their cadence in the target range. Explicit instructions will be provided to the user before the trial begins.

Competition Condition (Other): The virtual cyclist will be referred to as a virtual agent, since the cyclist is not being controlled by another human being. [30] Once the 8-minute trial begins, the participant will be instructed to cycle fast enough to pass the virtual agent travelling at their target cadence. If the cyclist passes the virtual agent, another agent will appear further ahead on the road (travelling at the target cadence) in order to maintain the competitive effect of this cycling task. The goal of the activity is to pass as many virtual agents as possible can within the 8-minute condition.

Competition Condition (Self): This condition is similar to the other competition condition. However, participants will be instructed that the virtual agent represents their best time. Therefore, the condition is framed as self-competition as the goal is to perform better than their best time by passing as many other virtual agents as possible. Since the conditions are counter-balanced, if this condition occurs first, participants will be informed that the other virtual agents are modelled after an estimation of their best time using data from familiarization. Importantly, the timescale of visual information presentation will be identical across the three cycling conditions (all responding instantaneously to deviations from the target intensity).

Measurements: Measures of cardiovascular (HR) and neuromuscular (cycling cadence) intensity and visual attention (eye-tracking data) will be recorded continuously during both cycling conditions. Rating of perceived exertion (RPE) will be collected at the beginning, midpoint, and end of each condition. Each condition will last 10 minutes [10] and will be followed by assessment of motivation and enjoyment using the Intrinsic Motivation Inventory (IMI) [21, 31] and simulation sickness using the SSQ. (*Figure 1*)

Participant Safety: will be carefully monitored. If the intensity of the exercise is too high, the cyclists may overexert themselves risking adverse cardiovascular events. Therefore, different termination criteria will be implemented to ensure the safety of the patient (i.e. if RPE > 16 and HR > 80% MaxHR, the experiment will be terminated). These criteria are based on ACSM guidelines for exercise termination. [32]

- **Timing and Frequency**: Data will be collected in a single session lasting ~3 hours.
- **Procedures for Audio/Visual Recording**: Participants will be recorded during the debriefing at the conclusion of each data collection session. These data will subsequently be used to analyze the qualitative data. The consent language was incorporated into the consent form.
  Study Instruments:
  Data are collected with known validated instruments (see outcomes table).
- **Ethnographic Studies, Interviews, Or Observation**: The semi-structured interviews will be audio-recorded and transcribed. The data will be loaded into NVivo 12 (QSR International) for content analysis. Since the interviews will verify and add depth to the survey findings, we will use a combination of conventional and directed content analysis. [33] These content analysis procedures include coding transcripts to identify key concepts as initial coding categories, developing operational definitions for each concept, and then identifying and labeling patterns and themes. We will verify categories, operational definitions, and themes through team coding and discussion.
- **Subject Identifiers**: All paper instruments will be assigned a code.

B. Secondary Data Collection
NA

1.10 Timetable/Schedule of Events

Months	2	4	6	8	10	12	14	16	18	20
IRB										

Recruitment										
Data Collection										
Data Monitoring										
Data Analysis										
Data Interpretation & Writing										

2.0 Project Management

2.1 Research Staff and Qualifications

Dr. Deutsch: Project PI and Manager, has history of running clinical studies and supervising personnel across skill sets at multiple sites.
Dr. Gallagher: Project PI (external NYIT site, has history of running clinical studies and supervising personnel across skill sets)
Dr. Donoghue: Project PI (external NYIT site, has history of running clinical studies and supervising personnel across skill sets)
Dr. Parrott: Director of MIST has extensive experience with study design and analysis. Has collaborated previously with the team
Dr. Daneault: Consultant, expertise in PD research, has history of data collection and analysis for persons with PD
John Palmieri: MD PhD student has experience with technology development and support and data collection. Will continue to develop skills with analysis during this project.

2.2 Research Staff Training

Dr. Deutsch will be responsible for training support staff site.

2.3 Other Resources

Rutgers has sites and adequate facilities to run the study. These are detailed in the facilities section of the funded NIH grant application. The Rutgers facilities also have medical support in the event that a referral is required. NYIT also has medical support resources if needed.

2.4 Research Sites

Rutgers SHP Rivers Lab (SSB 912), CP (SSB 224), and Motion Analysis Lab (SSB 210)
Non-Rutgers Sites: New York Institute of Technology

- Northern Boulevard, PO Box 8000, Old Westbury, NY
  - Riland Building, Academic Health Care Center Biomechanics Lab

3.0 Multi Center Research

Yes, an email was sent to the IRB Reliance Administrator. See other sections and forms attached to eIRB protocol (HRP-1812a, HRP-830, and HRP-811) for more details on multi center research.

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Upon IRB approval, 35 persons with PD will be recruited from outpatient Parkinson's groups at Kessler Institute and from the JFK Outpatient Clinic and Atlantic Health. We will also post the study on websites such as FoxTrialFinder. At NYIT, participants will be recruited from the NYIT College of Osteopathic Medicine (NYITCOM) Parkinson's Program. We will make every effort to recruit individuals that represent the ethnic and gender distribution of the populations we are examining.

B. Recruitment Details

Participants will be recruited from the sites indicated above through paper ads, social media posts. Emails may be sent to persons who have previously indicated an interest in our studies. A short description of the study will be in the body of the text with the approved ad attached. A similar process will be used to post on the site.

C. Subject Screening

Participants will be screened for eligibility. The screening includes readiness for activity using the PARQ+ 2021 and for moderate depression using the Geriatric Depression Scale. The full screening document is uploaded.

- **Inclusion Criteria**
  - Diagnosis of Parkinson's disease following the UK Brain Bank Diagnostic Criteria,
  - Hoehn and Yahr stages II-III, [34]
  - 45-80 years old,
  - Able to ride a stationary upright bicycle,
  - Able to sign informed consent.
- **Exclusion Criteria**
  - Have a recent history of severe heart disease, severe lung disease, uncontrolled diabetes, traumatic brain injury or neurological disorder other than Parkinson Disease,
  - Are unable to follow directions or sign a consent form,
  - Do not have adequate vision or hearing ability to see or hear a television,
  - Have unstable medical condition or musculoskeletal disorder such as severe arthritis, recent knee surgery, hip surgery, or any other condition that the investigators determine would impair the ability to ride the bicycle,
  - Have any other medical condition that prevents bicycling,
  - Have moderate depression (score of 9 or more on GDS screening tool).

D. Privacy Protections

PHI (participant name, address, date of birth) will be kept in a separate document. Participant's age and health condition is part of the recruitment. It will only be included with the single data set that is used to generate the study codes.

4.2 Obtaining Identifiable Information About Non-Subjects:

NA

4.3 Number of Subjects

A. Total Number of Subjects

35 participants will be screened. The study is powered to enroll 24 participants allowing for a 20% attrition rate.

B. Total Number of Subjects If Multicenter Study

18 participants will be screened for collection at the NYIT site. At NYIT, 12 of the 24 participants will be enrolled.

C. Feasibility

At Rutgers there are other active research programs in the same department that have been recruiting participants. There is dedicated parking for participants.

At the NYIT site, there is a boxing program for individuals with Parkinson Disease and other active research programs recruiting participants. There is also adequate parking for participants.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  At Rutgers, consent will take place in the SSB 224 and 210. At NYIT, consent will take place in the Riland Building, Academic Health Care Center Biomechanics Lab
- **Ongoing Consent**
  The study consists of one session. During the session, participants will be reminded that they may withdraw from the study at any time.
- **Individual Roles for Researchers Involved in Consent**
  Consent will be obtained at Rutgers by Dr. Deutsch and John Palmieri (MD PhD student). Consent will be obtained at NYIT by Dr. Donoghue, Dr. Gallagher, and John Palmieri.
- **Consent Discussion Duration**
  Consenting will require 15 minutes.
- **Coercion or Undue Influence**
  The procedures will be explained, and participants will be told that they may choose not to participate.
- **Subject Understanding**

Participants will be informed about the nature and purpose of the research and given an explanation of procedures. After reading the consent form, participants will be asked to describe the elements of the study in their own words. If a participant shows a clear understanding of the study, they will be permitted to sign the consent form. An experimenter knowledgeable about the research project will be available at all times to answer any questions a participant may have. Participants will be told that they are free to withdraw at any point during testing.

- **Protecting Privacy**

Participant's name and health condition is part of the consent form. It will only be included with the single data set that is used to generate the study codes.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
- **Destruction of Identifiers:** NA
- **Use of Deception/Concealment:** NA
  a. **Minimal Risk Justification:** Study is conducted on a bicycle with monitoring of HR exercise intensity and symptoms throughout.
  b. **Alternatives**
  Participants will not be told the hypothesis of the study as doing so may influence their effort and self-reported ratings throughout the session. There are no alternatives. Information will not be withheld from participants, as questions that participants may have will be addressed at the end of the protocol.
  c. **Subject Debriefing:** Participants will be debriefed at the end of each session.

C. Documentation of Consent

- **Documenting Consent**
  Participants will sign the consent form. Forms will be scanned and saved.
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
  NA

4.5 Special Consent/Populations

A. Enrolling Minors-Subjects Who Are Not Yet Adults: NA

B. Enrolling Wards of the State: NA

C. Enrolling Non-English-Speaking Subjects. It is anticipated that most subjects will be English speaking, however the study team at Rutgers is fluent in Spanish and able to instruct and consent participants. However, all study protocols are in English so the likelihood of enrolling a person that is not conversant in English is highly unlikely.

- **Process for Non-English-Speaking Subjects**
  The study team is fluent in Spanish and is able to translate the consent form orally.
- **Short Form Consent for Non-English Speakers**
  Not currently planned.

D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)
NA

E. Special Consent Considerations
NA

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
Participants may incur travel expenses to and from the site. There are no other expenses to participate in this study.

B. Compensation/Incentives
Participants will be compensated 30 dollars at the end of the session.

C. Compensation Documentation
Participants will be compensated 30 dollars for the session. Documentation at Rutgers will record the payment was received.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  The training studies are non-invasive and pose minimal risk to the participants. They may experience occasional fatigue of the lower extremities. We are using one virtual reality simulation that will be displayed through a head mounted display. This may pose a small risk for nausea or dizziness or present with sweatiness and fatigue.
- **Risk of Harm from an Intervention on a Subject with an Existing Condition: NA**
  We are aware that participants with PD in the study are more likely than the other participants to have health conditions that make them more vulnerable to adverse medical events directly related to the potential symptoms of nausea or dizziness. Certain other conditions, though not necessarily caused by PD, are much more common in people with PD than in the general population, including depression, sexual dysfunction, and fatigue. For this reason, we have included a screen for depression. Persons with PD who present with moderate depression will be excluded. They will be referred to behavioral services for support.
- **Other Foreseeable Risks of Harm:** NA
- **Observation and Sensitive Information:** NA

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects: NA

C. Risks of Harm to Non-Subjects: NA

D. Assessment of Social Behavior Considerations: NA

E. Minimizing Risks of Harm

It is unlikely that they will lose their balance on the bicycle. A physical therapist will closely monitor the participant's balance. We are using virtual reality simulations that will be displayed through a head mounted display. This may pose a small risk for nausea or dizziness or present with sweatiness and fatigue. These symptoms will be monitored, and we are prepared to stop data collection to allow participants to return to their baseline physiology. Importantly, it will be clearly explained to participants that they may discontinue bicycling at any point in which they experience nausea or dizziness or feel hot. Ample time will be given to participants between cycling bouts in the event that they develop symptoms. They will be offered an opportunity to sit comfortably with low lighting and given something to drink.

- **Certificate of Confidentiality**
  To be issued automatically because this is a NIH funded study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For

example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

- **Provisions to Protect the Privacy Interests of Subjects**
  Participant's privacy will be carefully guarded. The person performing the consent will explain all procedures and personnel involved in data collection.

F. Potential Direct Benefits to Subjects

Participants are informed that they may receive no direct benefit from taking part in this study. However, investigators may learn better ways to implement rehabilitation and improve fitness for persons with PD.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

PHI (name: for tracking reimbursement with gift cards) This will be kept in a separate document. Participants age and health condition is part of the data set. It will only be included with the single data set that is used to generate the study codes.

5.2 Family Educational Rights and Privacy Act (FERPA): NA

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations): NA

A. Special Populations

5.4 General Data Protection Regulation (GDPR): NA

5.5 NJ Access to Medical Research Act (Surrogate Consent): NA

6.0 Data Management Plan

6.1 Data Analysis

Power analysis was described under sample calculation

Aim / Dependent variable	Factor(s)	Test
Aim 1 – Exercise Intensity		
Cycling Cadence (baseline-adjusted)	condition (feedback & 2 competition conditions)	Repeated measures ANOVA (Rm-ANOVA)

		Post-hoc paired t-tests with appropriate Bonferroni corrections
Heart Rate (age-adjusted)	condition (feedback & 2 competition conditions)	Rm-ANOVA *Post-hoc* paired t-tests with appropriate Bonferroni corrections
AIM 2 – User Experience of Exercise		
Rating of Perceived Exertion (RPE)	condition (feedback & 2 competition conditions)	Rm-ANOVA *Post-hoc* paired t-tests with appropriate Bonferroni corrections
Motivation (custom IMI Scale) Interest/Enjoyment Perceived Competence Effort/Importance Value/Usefulness	condition (feedback & 2 competition conditions)	Rm-ANOVA *Post-hoc* paired t-tests with appropriate Bonferroni corrections
AIM 3 - Attention		
Eye-Tracking Data Dwell Time Percentage	condition (feedback & 2 competition conditions)	Rm-ANOVA *Post-hoc* paired t-tests with appropriate Bonferroni corrections

Bold = Primary comparison Co-variates (exercise readiness, competitiveness, and physical activity) may be included in an ANCOVA analysis. Analysis is simple to parse individual effects and then explore the moderating effects of the cycling condition. Due to the sample size, we will not attempt to impute for missing measures. Analyses will be carried out with all available data for each one of the planned comparisons.

6.2 Data Security

Participant coding will be generated at Rutgers and stored by the PI on a security encrypted computer. De-identified data collected at Rutgers (on paper will be scanned, or digitally) will be uploaded by the PI or her designee to shared Box Account for this project. All paper data will be stored in locked file cabinet and digital data on a password protected computer. Consent forms will also be scanned and uploaded to a separate folder from the de-identified data. By the conclusion of the study all data will be stored in Box at the Rutgers site. Identifiers connected to the data will be destroyed once all the publications from the project are complete and grants have been submitted to extend the work. The project PI will make that determination. Data will not be stored at NYIT.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

The PI will monitor ongoing data collection, check actual participant files for recording accuracy, and monitor data entry for accuracy, including random checks throughout the duration of the study.

The research team will periodically evaluate the data collected regarding harms and benefits to determine whether subjects remain safe. Specifically, we will review the response to exercise (% of max heart rate and rate of perceived exertion) and the reports on the SSQ Cybersickness Questionnaires for every participant. This will be done by the study team led by the PI. At monthly research study meetings, we will discuss these variables. Minutes from the monthly safety minutes will serve to document this process. Any follow-ups with specific participants will be added to the monthly documentation. Any adverse events will be reported immediately to the IRB at both Rutgers and NYIT. Rutgers and NYIT will have a health monitor to verify the adherence to safety. Data monitoring will be overseen by an independent statistician who will receive quarterly reports on data management.

B. Data/Safety Monitoring Board Details

Statistician (Chair)	Professor and Dean School of Public Health, Rutgers University
Health Monitor	Associate Professor and Physical Therapist, School of Health Professions Rutgers University, JFK Medical Center

6.4 Reporting Results

A. Individual Subjects' Results

There is no plan to share individual results.

B. Aggregate Results

Summary of study findings will be shared with participants once published.

C. Professional Reporting

Study results will be disseminated at the appropriate conferences and published in the appropriate journals.

D. Clinical Trials Registration, Results Reporting and Consent Posting

Study will be registered as a clinical trial upon IRB approval.

6.5 Secondary Use of the Data

NA

7.0 Research Repositories – Specimens and/or Data

Data will be stored for future research: (1) are the dependent variables from the study (2) to be stored in Synapse.Org.

8.0 Approvals/Authorizations

NA

9.0 Bibliography

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