Keck School of Medicine of USC

SMARTfit Training for Parkinson's Disease

Please note that Smart Patients does not conduct clinical trials. If you would like to enroll in a trial or if you need more information, please contact the trial team directly.

Overview

Conditions	Parkinson disease, exercise training, cognitive change
Treatments	smartfit training, conventional physical training
Sponsor	University of Southern California
Collaborator	University of California, Irvine
Start date	May 2018
End date	August 2019
Trial size	12 participants
Trial identifier	NCT03921359, HS-17-00928

Summary

This pilot study aims to investigate the effects of 8-week SMARTfit training versus conventional physical training on motor function, cognition and brain functional connectivity in individuals with PD. The investigators hypothesize that clinical and physical performance will improve after SMARTfit training more than after conventional physical training.

Recruiting in the following locations…

Overall contact – Yu-Chen Chung, PT, PhD - Email

Location	Institution	Status
Los Angeles, CA	USC Center for Neurorestoration	Recruiting

Study Design

Allocation	Randomized
Intervention model	Crossover assignment
Primary purpose	Treatment
Masking	None (open label)

Arm

Conventional physical training (Experimental)

Participants assigned to this arm will receive the conventional physical training.

SMARTfit training

For SMARTfit training, participants receive three 1-hour training sessions per week for 8 weeks. During each week, participants will receive physical training focused on six tasks, which are the functional tasks individuals with PD commonly have difficulty with. The six tasks are paired into 3 pairs: (1) sit-to-stand and multi-plane locomotor tasks, (2) gait and reach & grasp, and (3) floor-to-stand; stand-to-floor and single limb standing. Participants will focus on practicing one pair of tasks during each session. There is an additional cognition component that can be manipulated using features provided by SMARTfit.

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Primary Outcomes

Measure
Pre-post training change in Modified Physical Performance Test score (mPPT) time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)

Secondary Outcomes

Measure
Pre-post training change in MDS-UPDRS score time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)
Pre-post training change in Self-Efficacy for Exercise scale (SEES) time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)
Pre-post training change in trail-making test (TMT) time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)
Pre-post training change in Parkinson's Disease-Cognitive Rating Scale (PDCRS) time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)
Pre-post training change in Quotient system test time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)
Pre-post training change in functional connectivity time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)
Pre-post training change in EEG delta (2.5-4 Hz) bandpower time frame: pre-assessment 1 (baseline), post-assessment 1 (8 weeks), pre-assessment 2 (after 2-month washout period after post-assessment 1, 16 weeks), post-assessment 2 (24 weeks)

Eligibility Criteria

All participants from 50 years up to 85 years old

Inclusion Criteria:

1. 50-85 years of age
2. Diagnosis of idiopathic Parkinson's disease using the UK Brain Bank criteria (as determined by the study movement disorders neurologist) with Hoehn and Yahr stage 1-2
3. No contraindications to exercise including untreated cardiovascular disease or stroke
4. Medically stable and optimized on their medications
5. Able to ambulate independently with or without device
6. No other neurologic, neuromuscular, or orthopedic disease
7. No serious cognitive deficits and able to participate in the informed consent process
8. With medical clearance from primary care physician to participate in the physical therapy intervention
9. No contraindications for MRI

Exclusion Criteria:

1. Severe cardiac disease (New York Heart Association classification II-IV)
2. Systolic blood pressure reduction of greater than 20 mmHg with standing
3. A history of poorly controlled or brittle diabetes
4. A history of lower limb amputation
5. Been prescribed any new dopamine replacement medications or new mood stabilizer medications.
6. Presence of a lower limb non-healing ulcer
7. Montreal cognitive assessment score of less than 21
8. The presence of any medical condition which the investigator believes might present an unacceptable health risk to the subject should they participate in the study
9. Electrically, magnetically, or mechanically activated implant (such as cardiac
1. pacemakers or intracerebral vascular clip)
10. Metal in any part of the body including metal injury to the eye
11. History of brain lesions (such as stroke), seizures, or unexplained spells of loss of
2. consciousness
12. Pregnant or breast-feeding
13. With other neurologic, neuromuscular, or orthopedic disease that would interfere with ability to participate in exercise training
14. Currently participating in other studies

Additional Information

Official title	Effect of SMARTfit Training on Motor, Cognitive Functions and Brain Connectivity in Individuals with Parkinson's Disease: a Pilot Study
Principal investigator	Charles Liu, MD, PhD
Description	Although Parkinson's disease (PD) has been mainly viewed as a movement disorder, the pathophysiology of declined motor function incorporates impairments of multiple systems, including sensory, motor and cognitive pathways. Specifically, it has been demonstrated that cognitive function may play an essential role in motor function for individuals with PD. Cognitive dysfunction involving set-shifting and attentional control has been found to be associated with movement slowness in performing a finger sequence task and freezing of gait. Furthermore, a recent rodent model indicates that cognitive dysfunction may occur prior to the onset of motor symptoms. Similarly, human studies show that 25-30% individuals with PD exhibit cognitive impairments at the time of diagnosis. The overall evidence suggests that cognitive dysfunction may contribute to degraded motor function in PD. Interestingly, several studies demonstrate that aerobic exercise and resistance training can improve cognitive function in individuals with PD, indicating a tight interplay between motor and cognitive function. Targeting cognitive function by incorporating cognitive training into physical rehabilitation may be important for people with PD. Although there is mounting evidence for the benefits of physical exercise in PD, few studies investigate whether combining cognitive training with physical exercise can provide additional benefits than physical exercise alone. Thus, the purpose of this pilot study is to investigate the effect of SMARTfit training, a novel technology that provides an opportunity to combine physical training with cognitive training, in individuals with PD. The hypothesis is that SMARTfit training will promote greater motor and cognition improvements than conventional physical training. To test the above hypothesis, ten individuals with mild PD will receive both SMARTfit training and conventional physical training in a counterbalanced order with a washout period. For each training program, participants will receive a 1-hour training session 3 times per week for 8 weeks. The changes in disease biomarkers before and after training will also be explored.