

Intensive running exercise improves Parkinson's motor and non-motor symptoms.

Protocol version 1.0

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Objectives

The objectives of this study are to investigate the effect of regular vigorous aerobic exercise training of running on motor and non-motor symptoms, and quality-of-life of people with Parkinson's disease.

Background and purpose

There is a growing volume of evidences support the positive effect of exercise and physical therapy to Parkinson's disease. Various exercise types have shown different positive effects. Gait training for 4 weeks showed a moderate improvement in balancing while balance training of 8 to 26 weeks decreased fall rate. Cued exercise would mildly increase the speed of the gait. Complementary exercises, such as Tai Chi and dancing, have shown improvement in balancing of the patients.

One of the main complaints of Parkinson's disease is rigidity. It is because of the musculoskeletal impairments which compromise the flexibility and stability of both axial structure (spine) and the extremities. Truncal stiffness and rigidity results in a stooped posture, which further undermines one's balance and agility. Flexibility training (stretching) is shown to be beneficial to all stages of patients with Parkinson's disease, in terms of improved both range of movement in joints and spinal stability.¹ It is recommended that regular stretching should be the first step in one's exercise program to combat the muscle rigidity.² High quality clinical trial and meta-analysis have demonstrated short term, and to a lesser extent, long term benefits in various outcome measures. To achieve positive effects, supervised progressive strength and aerobic endurance training program of 12 weeks was required. Extended progressive strength training improved muscle strength for up to 24 months. While aerobic endurance training would increase walking capacity up to 16 months.³

There are data suggested a threshold of intensity of exercise to be reached for the positive effect. This overall body of evidence suggests that regular vigorous exercise should be accorded a central place in the treatment of Parkinson's disease.

However, there was no evidence about regular intensive exercise of running in Parkinson's disease. And most of the studies were not randomized with a control group.

Study design

Prospective randomized controlled, single-blind study

Inclusion criteria

1. Patient with idiopathic Parkinson's disease, aging from 40 years to 60 years old.
2. Patient should be able to walk independently without walking aids for a distance of 30 meters.

Exclusion criteria

1. Previous history of other neuro-degenerative diseases
2. Presence of ischemic heart disease or musculoskeletal and cardiopulmonary diseases
3. Presence of physical disability
4. History of regular running practice in the past 6 months.

Method

This is a prospective randomized controlled single-blinded study. 30 patients will be included and randomized to intervention arm or control arm in a ratio of 2 to 1. Informed consent will be signed after the patient is fully informed about the procedures and prior to the baseline assessments.

Intervention arm

- Number of participants: 20
- Venue: Shatin playground
- Supervisors: licensed coaches (2 to 4 per session)
- Training session:
 - 30 minutes of warm-up stretching
 - 60 minutes supervised progressive aerobic endurance track running ⁴
- Targeted intensity:
 - 60-75% of maximum heart rate ($HR_{max} = 220 - \text{age}$) OR
 - 40-50% heart rate reserve ($HRR = HR_{max} - HR_{rest}$)
- Frequency and training period: 2 sessions per week, for 24 weeks

Control arm

- Number of participants: 10
- Venue: Indoor gymnasium
- Supervisor: a physiotherapist
- Training session: 60 minutes of physical stretching
- Frequency and training period: 1 session per week, for 24 weeks

Each participant in either group will be given a diary to record the number of self-practice sessions to measure the exercise compliance; as well as the fall incidence during the whole training period and up to 6-month follow-up after training completion. They will also record any adverse events related to the training such as pain, injury, muscle soreness etc. Compliance and drop-out rate can also be monitored using the diary. The diary will be collected at the end of each month.

Primary outcomes

Unified Parkinson's disease rating scale overall score, Unified Parkinson's disease rating scale UPDRS part III motor score and Parkinson's disease questionnaire with 39 questions for quality of life score, at completion of the training and 6 months after.

Secondary outcomes

- Endurance: 6-minute walking test; Gait: fastest walking speed; Balance: minibest test
- Non-motor symptoms including depression and mood
- Adverse events: fall incidence (6 months prior to the training, throughout training and follow-up period), injury, muscle soreness and whether medical intervention is required.

The assessment will be taken by two blinded assessors (one occupational therapist and a registered research nurse) at baseline, at completion of the training and 6 months after, at Prince of Wales Hospital.

Data safekeeping methods and duration

The diary will be transcribed into an encrypted, password-protecting spread sheet. No Hong Kong Identity Card numbers or other personal identifiers of the participants will be recorded in the spread sheet. Only one softcopy will be available in a designated computer in PI's institution. The data will be kept for three years after study closure.

Ethical conduct of the study

The study will be conducted in accordance with the protocol and ethical principles that have their origin in the Declaration of Helsinki and all applicable local regulations.

Reference:

1. Gallo PM, Garber CE. PARKINSON ' S DISEASE A Comprehensive Approach to Exercise. *ACSM's Heal Fit J.* 2011;15(4):8-17.
2. Ciani H. Parkinson's Disease: Fitness Counts. *Natl Park Found.* 2016.
http://www.parkinson.org/sites/default/files/Fitness_Counts.pdf.
3. Mak MK, Wong-Yu IS, Shen X, Chung CL. Long-term effects of exercise and physical therapy in people with Parkinson disease. *Nat Rev Neurol.* 2017;13(11):689-703.
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4. Ehrman JK, editor. *ACSM's Guidelines for Exercise Testing and Prescription*, 6th ed. Baltimore: Lippincott Williams & Wilkins; 2010: 448–462.