INFORMATION SHEET

INTENSIVE RUNNING EXERCISE IMPROVES PARKINSON'S MOTOR AND NON-MOTOR SYMPTOMS

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DESCRIPTION

You are invited to participate in a study to investigate the effect of regular vigorous aerobic exercise training of running on motor and non-motor symptoms, and quality-of-life of Parkinson's patients. Please carefully read the contents of this information sheet before you decide whether or not to participate in the study. Please ensure that you understand the benefits and risks of participating in this study before providing informed consent. The purpose of the study, the procedures, risks, alternative treatments, and data confidentiality will be discussed below. If there is anything in this information leaflet which is unclear to you, or which you need more information on, please consult the doctor in charge.

BACKGROUND INFORMATION

The mainstay of treatment for Parkinson's disease (PD) is medication, and in some cases, surgery. However, they only provide symptomatic control but not a cure. Parkinson's disease does not directly cause muscle weakness; yet compromises co-ordination, causing inadequate exercise and psychological burdens, and would subsequently result in significant deterioration in muscle strength.

A growing volume of evidence showed that physical therapy and exercise brought a positive effect on Parkinson's disease. Flexibility training (stretching) is shown to be beneficial to patients with Parkinson's disease at all stages, in terms of improved range of movement in joints and spinal stability. It is regarded as the first and essential step in every patient's exercise program to combat muscle rigidity and subsequent impaired balance or agility.

As for aerobic endurance training, studies have demonstrated short term, and to a lesser extent, long term benefits in various outcome measures. To achieve positive effects, a threshold of intensity of exercise is required. A 12-week supervised progressive strength training and aerobic endurance training program is suggested. Aerobic endurance training would increase walking capacity up to 16 months. While extended progressive strength training improved muscle strength for up to 24 months.

PURPOSE OF THE STUDY

In this study, we would like to examine the effect of regular vigorous aerobic exercise training of running on motor and non-motor symptoms, and quality-of-life of Parkinson's patients.

PARTICIPANTS

30 patients with Parkinson's disease, from 40 to 60 years of age, will participate in this research study. Participants should be able to walk independently without walking aids for a distance of 30 meters. Patients with concurrent neuro-degenerative diseases, physical disability, ischemic heart disease or musculoskeletal and cardiopulmonary disorder that affect gait and balance performance will be excluded. Patients who have regular running practice in the past 6 months will be excluded in this study.

STUDY PROCEDURES

The study is a randomized controlled, single-blinded study. You will be randomly assigned to the intervention (progressive aerobic track running) arm or the control group (stretching). You are unaware of the allocation possibilities before the recruitment.

If you are in the supervised progressive aerobic track running program, you will be engaged in regular supervised warm-up stretching for 30 minutes followed by track running training for 60 minutes for 2 sessions per week, for 24 weeks in total. The training will be performed in Shatin playground under supervision of licensed coaches.

If you are in the control group, you will be assigned with a 60 minutes of physical stretching training session under the supervision of a physiotherapist at indoor gymnasium once every week for 24 weeks.

You 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 treatment period and up to 6-month follow-up after training completion. You will be encouraged to record any adverse events related to the intervention such as pain, injury, muscle soreness etc.

RISKS

You will be supervised by licensed coaches or physiotherapists. Potential adverse events include fall, injury, muscle soreness due to either training programs. Medical interventions may be required, depending on the severity of the events.

BENEFITS

There is no guarantee that you will receive direct benefit from this research. However, information obtained from this clinical research will contribute to a better understanding of the optimal training content for patients with Parkinson's disease.

ALTERNATIVES TO PARTICIPATING

If you decide not to participate in this research study, you will continue to receive appropriate treatments according to the standard practice of your hospital. You may discuss these alternatives with your doctor.

PARTICIPATION AND TERMINATION

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled to. Your refusal to participate or request to withdraw before completion of the study will have no influence on your future medical care. You do not need to justify for your refusal or withdrawal.

COSTS

You will not be charged any fees and no incentives will be offered.

CONFIDENTIALITY

All information which is collected about you during the course of the research will be kept strictly confidential. Any information you provide the hospital with will have your name and address removed. The data will be kept for three years after study closure.

CONTACT FOR FURTHER DETAILS:

For any inquiry, the Principal Investigator, Dr. Chan Tat Ming Danny, of Division of Neurosurgery, Department of Surgery, The Chinese University of Hong Kong, can be reached at phone number (852) 3505 1316/ 3505 1625 during office hours.

If you have question regarding your right as a clinical research study subject, you may contact the following party for further information:

The Joint CUHK-NTEC Clinical Research Ethics Committee
Address: 8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong

Tel: (852) 3505 3935

NTEC-CUHK Cluster REC/IRB as one of the authorized parties to access the subjects' records related to study for ethics review purpose.

INTENSIVE RUNNING EXERCISE IMPROVES

PARKINSON'S MOTOR AND NON-MOTOR SYMPTOMS
INFORMED CONSENT FORM

Affix Patient Label   ***(Optional)***

I have read, or have had read to me the Plain Language Statement above in my first language, and I understand the Patient Information Sheet. I have had the opportunity to ask questions and my questions have been answered. I hereby give my informed consent to be a participant in this study entitled with Intensive running exercise improves Parkinson's motor and non-motor symptoms. I have been given a copy of the Patient Information Sheet and the signed informed consent form. I am aware that I will receive a copy of this fully signed Informed Consent.

I also realize that the information obtained from this study, will be held in both computerized and manual filing systems, although these will not identify me by name.

I understand that I am free to withdraw from the study:

- at any time
- without having to give a reason for withdrawing
- and without affecting my future medical care

Name of Patient	Signature of Patient	Date
Name of Witness	Signature of Witness	Date
Name of Investigator	Signature of Investigator	Date

Reminder: A copy of this signed consent form must be given to the patient.

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