Effectiveness of an Active Lifestyle Promotion Program for Patients with Parkinson*s disease; The ParkFit study

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First aim of the study is to investigate whether a physical activity promotion program will result in a improvement in physical activity in sedentary patients with PD. Furthermore, the related health benefits will be analysed.

Ethical review	-
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON32044

Source
ToetsingOnline

Brief title
Not applicable

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMw & Michael J Fox Foundation

Intervention

Keyword: Health benefits, Parkinson's disease, Physical Activity Promoting program

Outcome measures

Primary outcome

Primary Outcome: Level of Physical Activity

- Level of physical activity: LASA Physical Activity Questionnaire (LAPAQ)

Secondary outcome

Secundary outcomes:

- Functional Fitness: 6 minute walk test

- Quality of Life (Parkinson's Disease Quality of Life Questionnaire (PDQ39))

- walkingtime: Patient activity monitor

Tertiary outcomes:

- Functioning and mobility (Timed up and Go test (TUG) & Activities of Daily Living Scale (ALDS))

- Disease progression (Unified Parkinson's Disease Rating Scale (UPDRS), motor part)

- Depression and mood (Beck Depression Inventory (BDI) & Hospital Anxiety and Depression Scale (HADS))

- Constipation (Patient Assessment of Constipation Symptoms (PAC-SYM))

- Sleep disturbances (Pittsburgh Sleep Quality Index)

- Cognitive changes (Mizes Anorectic Cognition questionnaire (MAC))

- Number of falls (Computerized phonecall-system)

- Fatigue: Checklist Individual Strength (CIS)

Study description

Background summary

Patients with Parkinson*s disease (PD) are heavily inclined towards a sedentary lifestyle. This is caused by a combination of physical impairments and cognitive dysfunction. However, regular physical activity in PD is highly desirable, for two reasons. First, physical activity has positive generic effects in preventing complications such as cardiovascular diseases, type II diabetes mellitus, osteoporosis and certain cases of cancer. Second, physical activity has additional disease-specific merits in PD such as depression, sleep disturbances and constipation. These effects lead to raised quality of life. Furthermore, animal studies suggest that physical activity could slow down disease progression.
The first aim of the ParkFit-study is to investigate if a exercise-program results in a meaningful improvement in physical activity levels during two years in patients with PD with a sedentary lifestyle. Second, the disease-specific health benefits of improved physical activity will be determined.
During a period of two years, patients are referred to a physical therapist with specific exercise in PD. These physical therapists are educated and trained in the past two years (The ParkNet trial). In the ParkFit-study, physical therapists will be specifically trained as a ParkFit-therapist. Next to sport-specific information, special attention will be given to motivational interviewing and the coaching of sedentary patients.
A PD-specific physical promotion program will be developed as a principle for the intervention. Signing a Health Contract will be added to the intervention. The contract includes motivation strategies, goal setting, social support, memory techniques and problem solving techniques. Besides, each patient receives a pedometer as a motivational and feedback tool.
Weekly participation in a Parkinson exercise group is also part of the intervention. These exercise groups are formed in order to experience effects of physical activity in a controlled and supervised situation.
Seven hundred patients with PD will be enrolled in the study. Patients will be randomly assigned to the experimental group or the control group. In the control group, patients will receive ParkinsonNet physical therapy. After 6, 12 and 24 months the effects will be measured by standardized questionnaires and a test for physical fitness.
In order to try to investigate genetic variations in responsible growth factors for neuroplasticity, patients have to give one blood sample.

Study objective

First aim of the study is to investigate whether a physical activity promotion program will result in a improvement in physical activity in sedentary patients with PD. Furthermore, the related health benefits will be analysed.

Study design

Multicentre randomised controlled trial

Intervention

The intervention has four key elements:
- Personal Activity Coach (the ParkFit-therapist) for counseling and motivating the patient
- Health Contract between coach and patient which leads to a Personal Activity Plan
- Exercise group sessions
Year 1
Month 1-3: two times per week exercise group
Month 4-12: one time per week exercise group
Year 2
Month 1-3: two times per week exercise group
Month 4-12: one time per week exercise group
- Pedometer as an individual motivational and feedback tool

Study burden and risks

During the study, measurements will take place at baseline, and after 6, 12 and 24 months. Measurements will be performed in a local hospital or sports hall. For the once-only venapuncture, patients can visit the polyclinic of the participating hospital in the patients' neighbourhood.

In the experimental group, physical therapists with specific expertise in activity coaching and in PD will take care over the patients. However, also in daily life patients will be supported towards an active lifestyle which is not possible without investing in time and energy. The sport exercise group is time consuming but we are convinced that offering sport groups will be very motivating and supporting. Next to exercise, attention will be paid to motivational strategies and patients can motivate and help each other.
The risks of an improved level of physical activity are at first an increased risk of (sport-)injuries. Furthermore, patients who are more physically active are in a higher risk of falling. However, these possible risks are minimal and in our opinion no contra-indication for participating in the study, for example because of the intensive counseling. The risks to and burdens for the patients are also extensively described in the research protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Idiopathic Parkinson's disease
- Hoehn and Yahr stage I-IV
- Age between 40 and 75 years old
- Physically inactive according to the Dutch Norm of Healthy Daily Exercise

Exclusion criteria

- Wheel chair bounded
- Severe respons fluctuations
- Severe co-morbidity

- Severe cognitive decline, defined as Mini Mental State Examination > 24

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	700
Type:	Anticipated

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL21917.091.08