Effectiveness of occupational therapy in Parkinson*s disease: a nationwide, randomized controlled trial.

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The primary objective is to evaluate the effectiveness of occupational therapy in improving daily functioning of patients with Parkinson's Disease and reducing caregivers* burden.

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

Summary

ID

NL-OMON33392

Source
ToetsingOnline

Brief title
The OTiP trial

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's, Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds NutsOhra

Intervention

Keyword: Economic Evaluation, Effectiveness, Occupational Therapy, Parkinson's Disease

Outcome measures

Primary outcome

The primary outcome/endpoint for the patient is the quality and level of independence in daily functioning, assessed with the Assessment of Motor and Process Skills (AMPS) and the Amsterdam Medical Centre Linear Disability Score (ALDS). The primary outcome/ endpoint for the caregivers is their self perceived burden of care as assessed with the Zarit Burden Inventory (ZBI). The primary analysis will be the changes between baseline and 3 months after start of the intervention.

Secondary outcome

Secondary outcomes/endpoints are: self perceived performance in daily activities (patient and caregiver), participation and autonomy (patient), quality of life (patient and caregiver), and objective burden of care (caregiver).

Study description

Background summary

Parkinson*s disease (PD) is a complex disabling condition progressively affecting activities, social participation and quality of life of patients and their caregivers. Occupational Therapy (OT) aims to optimize functional performance and engagement in meaningful activities.
Under auspices of the Dutch Association of Occupational Therapy, Parkinson Centre Nijmegen recently developed an evidence based Guideline for OT in PD. This guideline highlights the urgent need for high quality intervention studies

to investigate the effectiveness of OT in PD.

Study objective

The primary objective is to evaluate the effectiveness of occupational therapy in improving daily functioning of patients with Parkinson's Disease and reducing caregivers* burden.

Study design

A multicentre assessor blind, randomized controlled trial.

Intervention

Patients in the experimental group will receive 10 weeks (max 16 sessions) of occupational therapy according to a treatment protocol, which is based on the evidence based guideline *Occupational Therapy in Parkinson*s Disease* and refined for this study. The intervention will be provided by occupational therapists with expertise in the area of Parkinson*s Disease (ParkinsonNet therapists). Patients and their caregivers in the control group will have no occupational therapy intervention until their last measurement has taken place (6 months).

Study burden and risks

All participants receive occupational therapy addressing their individual needs in the area of daily activities within or after the study.
There are four moments of assessments for all participants: at baseline (two visits) and 3 and 6 months after start of the intervention. The outcome measurements are non-invasive and will take place at the patient*s home. The total time for investment voor the measurements will be 7.5 hrs for the patient and 2.5 hours for the caregiver. The intervention (experimental group) will take a maximum of 16 hours over a period of 10 weeks.
There are no foreseeable risks associated with participation in the study.

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

Inclusion criteria patients
1 Idiopathic Parkinson's Disease according to accepted criteria.
2 Need for assistance in daily activities
3 Home dwelling;Inclusion criteria caregivers
1 Providing informal support minimal two times a week to a patient who participates in the study
2 Available to take part in the intervention.

Exclusion criteria

1 Co morbidity with symptoms that precludes active partcipation in the intervention (e.g psychosis, severe cardiac failure). Or limitations in activities are dominated by the co morbid condition rather than by Parkinson*s Disease.
2 Current participation in other allied health research (IMPACT, PARKFIT, ERGODIM)
3 Having received occupational therapy in the last 12 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2009
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL27905.091.09