

Care for Late Stage Parkinsonism

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

Summary

ID

NL-OMON41035

Source

ToetsingOnline

Brief title

CLaSP

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

Intervention

Keyword: Care models, Cohort study, Disease progression, Parkinson's disease

Outcome measures

Primary outcome

UPDRS-ADL disability measure

Secondary outcome

Quality of life:

- Patients* and carers* quality of life
- Patients* and carers* satisfaction with care
- Meaning in Life

Other palliative care aspects

- Symptom burden in late stage Parkinsonism
- Carer burden
- Palliative care status
- Nutritional status/BMI
- Nursing home placement/institutionalisation
- Place of death
- Mortality

Health care utilization

Process evaluation:

* Sampling quality: Proportion of eligible patients participating in the study, i.e. reach.

* Intervention quality:

-To what extent is the CLaSP-intervention implemented, ie. level of implementation?

-What are the barriers and facilitators to implementation?

* Reach: During patient recruitment, the researcher documents:

-Number of potential participants, identified in databases and other sources, receiving a invitation letter for participation.

-Number of potential participants agreeing to participate, before screening on eligibility

-Number of participant fulfilling inclusion criteria and included in the study

-Number of participant not fulfilling inclusion criteria and reasons for exclusion

Study description

Background summary

Parkinson's disease (PD) affects approximately 1% of the population over 65 in Western countries. Its prevalence is predicted to rise with the increase in the ageing population. Health and social care needs will therefore also rise. Health-care interventions for Parkinsonism are primarily directed towards patients in the early stages of the disease, with a range of pharmacological options and some non-pharmacological interventions including physiotherapy. As the disease progresses, however, patients become more disabled and management becomes more difficult. Complex drug treatment combinations often become necessary to manage different motor and non-motor symptoms. Treatment options in addition to oral antiparkinsonian medications include deep brain stimulation, and two types of medication that are administered by continuous pump infusion (apomorphine, levodopa/carbidopa intestinal gel) and require specialist input, but these are suitable for and administered to only a minority of patients. In the national guidelines for PD (e.g. NICE in the UK or guidelines of the German

Neurological Society) the treatment and care of this special population is inadequately addressed. Many patients become immobile with declining response to medications, falls, communication problems and high rates of non-motor symptoms, such as behavioural and psychological symptoms (e.g. dementia, depression, psychosis), autonomic failure, sleep disturbances and pain. Thus, there is increased need for non-pharmacological intervention in addition to the ongoing therapeutic adjustments of complex medication regimes. Mean time from disease onset to the late disease stages in PD is estimated to be 14 years, with considerable variation, but once milestones of this late stage are reached, including falls, psychosis, or dementia, the prognosis is poor with an average time to death of less than 5 years.

Study objective

This project will investigate what the needs of patients with late stage parkinsonism, their families and of their carers are, what services and support they receive, and the extent to which their needs are met in different health-care systems. This will be done through in-depth cross-sectional and longitudinal assessments of a multicentred cohort study of patients, and through interrogation of national or regional databases, where available. In order to inform guidelines and provide the starting point for future randomised controlled trials of therapeutic interventions in these patients, we will i) undertake a review of the literature on effective treatments of late stage Parkinsonism, ii) examine the outcome associated with different care models, and iii) investigate the impact of a specialist assessment with management suggestions, provision of guidance and access to telephone assistance on patient-reported outcomes, carer burden and use of health-care resources. At the conclusion of the study, we will produce a platform for assessment as well as good practice guidelines for health and social care practitioners based on the results.

Research questions are:

- What is the impact of late stage Parkinsonism on patients and their carers and families and what are their medical and social needs, costs and use of health-care resources?
- How appropriate and valid are the existing assessment tools in this population?
- How do disability and disease severity milestones (psychosis, dementia, falls, wheelchair-bound, institutionalisation) progress over 12 months in these patients?
- What are the health-care and social determinants of outcome once disease variables are accounted for?
- What is the impact of different health-care pathways?
- What are management strategies that have been shown to be effective in late stage Parkinsonism?
- What is the impact of a specialist review with management recommendations,

provision of guidance and access to telephone assistance?

Study design

A longitudinal, multicentric, observational study in six European countries with different health-care and social care models. In each country, 120 patients will be included, with two assessments (baseline and 6 months).

We will undertake an observational analysis of the data from the cohort study, plus an open-label trial on the impact of specialist review with management recommendations, guidance and availability of telephone assistance on outcome at baseline and 8 weeks following the intervention. Eligible patients will be randomised either receive recommendations by the research teams to their primary health care team or continuing routine care management. There will be a 3:1 allocation to intervention with a quarter of randomly selected individuals not receiving the intervention, except where it is felt to be an urgent medical need, e.g. contraindicated medications. We hypothesise that this specialist input in the late stage of Parkinsonism provides better outcomes than standard care.

The evaluation of the impact of the specialist review and management suggestion takes place, 6 months after randomization.

The European protocol includes two additional assessments (at 12 and 18 months after inclusion). Both assessments are optional and will not be done in the Netherlands.

Intervention

Management suggestions to the primary clinician involved in the care for the patient, made by the senior physician/researcher at baseline following the medical assessment, taking into account current and previous disease factors, review of medications and current medical and social care arrangements. The decision on implementation of any recommendations given will remain with the primary health care team.

The suggestions may include recommendations on medication changes and referrals for assessment by health-care services such as physiotherapist or other medical specialties, and social care services. For physiotherapy, occupational therapy and speech & language therapy guidelines are available with indications for referral plus evidence-based treatment suggestions. There will also be access to telephone assistance by the study team over an 8 week period for patient, carer and primary care physician.

Study burden and risks

Participation in the study begins by giving a written informed consent. Next, two assessments are foreseen (T1 in month 1 , T2 in month 6). These assessments entail:

- Questionnaire for the patient, to be completed at home, 15 minutes each time, 2 times during the study period (T1 , T2)
- Questionnaire for carers, to be completed at home, 15 minutes each time, 2 times during the study period (T1 , T2)
- Medical assessment, consisting of an interview and observations by a physician/researcher at the patient's home; 200-240 minutes each time, 2 times during the study period (T1 , T2)
- semi-structured interview with the patient and caregiver, at the patient's home about care needs, 30 minutes; 1x during the study period (T1, optional).
- semi-structured interview with the patient and caregiver, at the patient's home about received treatment recommendations; 15 minutes (T2, only for trial participant in intervention group)

In particular, the medical assessment may be exhausting to the patient or carer. Therefore it can be interrupted at any time if it is too heavy a burden for the patient. The physician/researcher will later come back to finish the assessment. In case the assessor is unsure about a particular assessment, the patient will be asked for written consent to make a video recording. This video will be presented to a second independent assessor for a second opinion. Both assessors will work towards a consensus-based rating.

Depending on the recommendations, interventions can be implemented for those patients assigned to the intervention group. These interventions will only be started after consent of the patient is obtained. The interventions include both pharmacological interventions, and non -pharmacological interventions, such as physical therapy, speech therapy or social work. The recommendations aim to provide the best management for the patient.

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

Diagnosed with Parkinson's disease AND;- Hoehn and Yahr stages IV or V during 'On' phase;
OR

- Significant levels of disability (Schwab and England stage 50% or less) in *On* and a
disease duration of at least 7 years

Exclusion criteria

Hoehn and Yahr stages I-III

Symptomatic Parkinsonism

Patients with Parkinsonism with a clear history of dementia occurring before the onset of
Parkinsonism

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2015
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO	
Date:	10-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	02-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	23-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	21-07-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	10-12-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	13-04-2016

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	28-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	12-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	15-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	12-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	01-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	22-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	18-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	14-05-2018
Application type:	Amendment
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	NL47805.091.14