Cost-effectiveness of specialized nursing interventions for patients with Parkinson*s disease

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We aim to study the cost-effectiveness of specialized nursing care provided by a Parkinson Disease Nurse Specialist (PDNS) as compared to no PDNS care for patients with Parkinson's disease in all disease stages.We will also perform a subgroup...

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

Summary

ID

NL-OMON46561

Source
ToetsingOnline

Brief title
Cost-effectiveness of Parkinson's disease nursing care (PDNS)

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease and Parkinson's

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Zambon

Intervention

Keyword: Cost-effectiveness, Multidisciplinary care, Non-pharmacological treatment, Parkinson's disease, Parkinson's disease nurse specialist

Outcome measures

Primary outcome

The co-primary outcome measures are:

- Quality of life measured with the Parkinson's Disease Questionnaire (PDQ-39).

- Motor symptoms measured with the Movement Disorders Society-sponsored revision of the Unified Parkinson*s Disease Rating Scale part III (MDS-UPDRS part III)

Secondary outcome

Secondary patient-related outcome measures are:

- Longitudinal PD symptoms measured with the Movement Disorders Society-sponsored revision of the Unified Parkinson*s Disease Rating Scale Part I, II, IV

- Mobility measured with the Timed Up and Go Test (TUG)

- Bradykinesia measured with the Pegboard Test

- Non-motor symptoms (anxiety and depression) measured with the Hamilton Anxiety and Depression Scale (HADS)

- Non motor symptoms (e.g. sleep. cognition, urinary tract problems and constipation) measured with the Scales for Outcomes in Parkinson's Disease - Autonomic questionnaire (SCOPA-AUT)

- Health-related quality of life measured with the EuroQoL5D (EQ5D)

- Experienced quality of care measured with the Consumer Quality Index (CQI)

- Self-management measured with the Patient Activation Measure (PAM)

- Medication adherence measured with the Morisky Medication Adherence Scale (MMAS)

Secondary caregiver-related outcome measures are:

- Health-related quality of life measured with the EuroQoL5D (EQ5D)

- Caregiver burden measured with the Zarith Caregiver Burden Index (ZBI)

- Caregiver quality of life measured with the CarerQol-7D

- Skills of proactive coping measured with the Utrechtse Proactieve Coping Competentielijst (UPCC)

To measure healthcare consumption and costs:

- Medical consumption of the patient measured with the Medical Consumption Questionnaire.

- Productivity loss of working patients measured with the Productivity Cost Questionnaire.

- Medical consumption and productivity loss related to caregiver burden measured with a cost questionnaire specifically aimed at caregivers

Study description

Background summary

Despite optimal medical management with medication or brain surgery, most patients with Parkinson*s disease (PD) experience progressive disability that increasingly influences their quality of life. This creates tremendous challenges in advanced disease stages, and even early in the course of PD. There is increasing evidence that non-pharmacological management offers symptomatic relief of symptoms that are otherwise difficult to treat. For this an integral, multidisciplinary approach is needed, in which, among others, the Parkinson's Disease Nurse Specialist (PDNS) plays an essential role. The PDNS was introduced to bridge the gap between medical management and the unique personal needs of patients. The recent Dutch guideline on PDNS care (2015) clearly describes the roles of a PDNS, including diagnostic strategies (e.g. detection of urinary retention or orthostatic hypotension) and therapeutic interventions (e.g. optimising medication compliance, or strategies to alleviate orthostatic intervention). Also, the PDNS assists patients and carers in their selfmanagement, need of support, information, access to services and coordination of care.

The Dutch Multidisciplinary Guideline for PD recommends that each PD patient should have access to PDNS care. Based on this recommendation, almost all Dutch hospitals now offer PDNS treatment to their patients. However, many hospitals lack the nursing capacity that is needed to offer PDNS care to all patients, creating an undesirable inequality in access to care. Consequently, care delivery remains suboptimal, fragmented and ineffective for many patients, presumably leading to unnecessary disability and avoidable costs.

Crucially, this situation offers a unique opportunity to now, for the first time, study the cost-effectiveness of PDNS intervention. Indeed, existing evidence indicates that PDNS care may improve patient wellbeing, physical functioning and general health status, and reduce anxiety and depression. Also, scenario analyses (performed to estimate the potential cost-effectiveness of PDNS intervention) showed that PDNS treatment can be cost-effective, provided the patients* quality of life improves. Furthermore, expert opinion dictates that all PD patients can benefit from PDNS intervention, including those with early-stage disease where e.g. delivery of information, advice about exercise, education about medication compliance, and support in self-management are critical. However, there is little evidence to show that quality of life actually improves after PDNS intervention.

Therefore, here we will study the cost-effectiveness of treatment by a PDNS. We expect that the results will show higher quality of life of patients with PD and reduced caregiver burden, hopefully leading to broad implementation of PDNS

care and consequently equal access to care for all patients with PD.

Study objective

We aim to study the cost-effectiveness of specialized nursing care provided by a Parkinson Disease Nurse Specialist (PDNS) as compared to no PDNS care for patients with Parkinson's disease in all disease stages.

We will also perform a subgroup analysis to gain more insight into the exact interventions used per disease stage and the effects of PDNS care in these different groups of patients:
- Disease duration of <5 years (early, relatively uncomplicated phase)
- Disease duration of 5-10 years (phase of response fluctuations)
- Disease duration of >10 years (complicated phase)

Our expectation is that offering more patients access to a PDNS will, in line with literature, lead to higher quality of life with equal costs. Increasing direct medical costs (for nurse staffing) will be offset by a reduced number of visits to the neurologist and telephone consultations with the general practitioner. These short-term goals are the focus of the present project proposal. In addition to these short-term effects, we also expect that long-term benefits may arise, including a reduction in the number of nursing home admissions. If such effects can indeed be demonstrated, then this will reduce total costs substantially. However, this latter hypothesis related to the long-term benefits will not be tested in the present study.

Study design

We will perform an 18-month Randomized Controlled Trial (RCT) in eight regional community hospitals in the Netherlands. We consider this a monocenter study, because all research activities are carried out by a researcher from the Radboudumc. The neurologists in the community hospitals only refer patients for inclusion and are not included in the research team.

We have selected hospitals where, due to lack of sufficient PDNS staff, only a proportion of PD patients currently has access to PDNS care:
- Maasziekenhuis Pantein in Boxmeer
- Gelre Ziekenhuis in Zutphen
- BovenIJ Ziekenhuis in Amsterdam
- Careyn/St. Antonius Ziekenhuis in Utrecht
- Waterlandziekenhuis in Purmerend
- Rode Kruis Ziekenhuis in Beverwijk
- TweeSteden/Elisabeth Ziekenhuis in Tilburg
- Maxima Medisch Centrum in Eindhoven

This gives us a unique opportunity to identify patients who currently have no

access to PDNS care, and to randomize them within hospitals, and at the patient level, between PDNS care versus no nursing care. A total of 240 patients (and their caregivers) will be included, which means 30 patients in each hospital. Eligible patients will be allocated randomly using a computerized sequence, in a 1:1 ratio, to either PDNS care or no nursing intervention. A blinded researcher from the Radboudumc will perform an assessment of PD motor symptoms (Movement Disorders Society-sponsored revision of the Unified Parkinson*s Disease Rating Scale), mobility (Timed up and Go Test) and bradykinesia (Pegboard Test) at three time points: at baseline, prior to randomization (t0), after 12 months (t1) and after 18 months (t2). Caregivers will be asked whether they also agree to fill out questionnaires. Subsequently, patients and their caregivers will complete online questionnaires (e.g. about non-motor symptoms and caregiver burden) at home at t0, t1 and t2. Furthermore, patients and their caregivers will complete a short questionnaire about healthcare utilization and healthcare costs every three months.

Importantly, for the purpose of this study, we will implement an increase in nursing staff capacity of the existing nurses in the participating hospitals. This will allow us to study the real impact of current usual care (this could not be achieved by adding a new set of specifically trained research nurses to the existing PDNS staff). These PDNSs are all graduated nurses (education level according to the European Qualifications Framework 6 or 7) with a certificate in Parkinson*s Nursing. Furthermore, they have achieved a standard of competences as described in the PD guideline.

Intervention

The PDNS intervention will be performed according to the Dutch Guideline on PDNS care (2015). The intervention is not standardized, but tailored to the patients* and caregivers* needs. This includes the following aspects:

1. Assessment of individual care needs of PD patients and their caregivers. The PDNS performs a specific nursing assessment related to the medical, physical, psychological and social domains.
2. Development of a patient-centered treatment plan that supports patients and caregivers in self-management. The PDNS composes a multidisciplinary care plan, based on the results of the assessments, and as prioritized by the patient and caregiver themselves (shared decision making).
3. Specific nursing interventions. The nursing intervention varies across different disease stages and are always tailored to the specific problems and needs of individual patients and their caregivers. The PD nursing guideline describes specific interventions for the following problems: mental functions, fatigue, sleep, urogenital functions, sexuality, medication adherence, orthostatic hypotension, caregiver burden, coping, mobility, self-management, and dietary issues. Three general important PDNS nursing interventions include providing information and education, disease management (e.g. monitoring treatment effects, considering advanced treatment options such

as Deep Brain Stimulation) and monitoring (e.g. screening for motor- and non-motor symptoms, caregiver burden).
4. Collaboration with other healthcare professionals. The PDNS stimulates and supports multidisciplinary collaboration between healthcare professionals based on the individual patient-centered plan.

Patients have regular contact with their PDNS about the progress and realization of their personal goals, mostly by telephone, but also during face-to-face contacts and sometimes during additional home visits. The optimal frequency of contact varies, depending on the disease stage and individual needs and preferences.

The control group will continue usual care that is otherwise comparable, but without a nursing intervention. Specifically, there are no restrictions to any other medical treatments or contact with other healthcare professionals. Comparable care can be achieved by randomizing comparable patients within hospitals, so that other important elements (including in particular the treating neurologist) remain identical between the two intervention arms.

Study burden and risks

The burden for patients is limited and consists of the following:
-Three visits to the researcher during the research period (in the patient's own hospital), taking approximately 60 minutes each visit
- Completing questionnaires at home three times during the study period (baseline, after 12 months and after 18 months), taking approximately 60 minutes each time. For caregivers this will take approximately 30 minutes each time. This can be done online or on paper.
- Completing a questionnaire about healthcare utilization and costs every three months during the study period. This questionnaire will take approximately 30 minutes to complete for patients, and 20 minutes for caregivers.

The vast majority of the questionnaires can be completed at home, online or on paper.

The intervention evaluated in this study is non invasive and of very low risk, which therefore causes the risks associated with this study to be negligible. The risk not associated with the intervention itself, but rather with the organization of PDNS care in the Netherlands, consists of the following: during the study, each hospital receives budget to increase their PDNS capacity to provide care to 15 patients in the intervention group. However, when the study is finished, there is a chance that PDNS care for these patients will be cancelled because the extra nursing capacity is no longer paid by the study. Each hospital will, in the end, make its own decisions regarding the continuation of care for the patients participating in the study. The 15 patients in the control group will not be allowed to receive PDNS care during the study period.

However, PDNS care is currently only partially implemented in the Netherlands, and therefore not 'usual care'. The 240 patients included in this study do not receive PDNS care at the moment, mainly due to a lack of scientific evidence of its cost-effectiveness. With positive results, it is more likely that PDNS care will be further implemented for all PD patients. In addition, it is possible that, in the case of positive patient experiences, participating hospitals will increase their own budget for increasing PDNS capacity. Furthermore, besides PDNS care, there are no restrictions to other medical treatments for the patients in the control group, and they can visit all other available healthcare providers (such as physiotherapists or psychologists).

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

1. Patients with idiopathic Parkinson's disease:
- that have sufficient knowledge of the Dutch language;
- that were 18 years old at the time of diagnosis;
- in all disease stages, regardless of disease severity or disease duration;
- who are currently not treated by a Parkinson's disease nurse specialist and who have not been treated by a Parkinson's disease nurse specialist in the past two years;
- who have a score of >=18 on the Mini-Mental State Examination (MMSE) and >=12 on the Frontal Assessment Battery (FAB).

Exclusion criteria

1. Patients with a type of atypical parkinsonism caused by medication (e.g. neuroleptics), a metabolic disorder (e.g. Wilson's disease), encephalitis or a neurodegenerative disorder (e.g. MSA, PSP).
2. Patients with Parkinson's disease that live in a nursing home or another type of residential care facility (because the Parkinson's disease nurse specialist is not operational there).
3. Any other medical or psychiatric disorder that, in the opinion of the researcher, may compromise participation in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2018
Enrollment:	240

Type:	Anticipated

Ethics review

Approved WMO Date:	05-07-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-05-2019
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	NL65468.091.18