

Evaluating the clinical and cost-effectiveness of a combined person-centred intervention of Advance Care Planning (ACP) and care coordination for people with Parkinson's disease and their family caregiver(s)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26859

Source

Nationaal Trial Register

Brief title

PD_Pal

Health condition

Parkinson's disease and Parkinsonisms

Sponsors and support

Primary sponsor: Radboud university medical center, Nijmegen, the Netherlands

Source(s) of monetary or material Support: H2020

Intervention

Outcome measures

Primary outcome

% patients with documented ACP arrangements

Secondary outcome

- patient's symptom burden
- FC's burden
- patients and their FC experienced quality of life
- care coordination
- quality of (palliative) care
- cost effectiveness of the intervention

Study description

Background summary

To determine the effectiveness of a community-based outpatient palliative care intervention for people with Parkinson's disease and their Family Caregiver (FC) compared to care as usual on Advanced Care Planning (ACP) documentation in the patient's central file, on patient's clinical outcomes, on caregiver burden and on costs and service utilization. To test the feasibility of the community-based outpatient palliative care intervention for people with Parkinson's disease and their FC in six European countries.

Study objective

none

Study design

The active intervention period is 6 months, with a follow-up assessment after 12 months.

Intervention

The intervention consists of a specifically trained (neurology) nurse who provide and coordinate transmural, integrated and proactive palliative care, including Advance Care Planning (ACP)

Contacts

Public

Radboud university medical center
Marieke Groot

0031646570487

Scientific

Radboud university medical center
Marieke Groot

0031646570487

Eligibility criteria

Inclusion criteria

- Capable to participate;
- Able to provide informed consent;
- Meeting the MDS clinical diagnostic criteria for PD, including Parkinsonisms (Postuma et al., 2015);
- H&Y ≥ 3 ;
- Progressive deterioration in physical and/or cognitive function despite optimal therapy, according to the primary physician; and
- Availability of a family caregiver or informal caregiver.

Exclusion criteria

- Inability to communicate independently, with or without supportive communication tools.
- Presence of additional chronic medical illnesses which may require palliative services (e.g. metastatic cancer).
- Already receiving palliative care or hospice services.
- Already participating in a clinical study for palliative care.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	176
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	01-10-2019
Application type:	First submission

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
NTR-new	NL8180
Other	METC Radboudumc : SEP-210512305

Study results