A feasibility study to test if an intervention can improve shared decision-making in advanced Parkinson's disease

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The study will address the feasibility of the shared decision-making (SDM) intervention by (1) analysing the acceptability of the intervention by users (i.e. professionals and patients); (2) assessing the level of implementation; (3) testing…

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Bewegingsstoornissen (incl. parkinsonisme)
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21200

Bron
Nationaal Trial Register

Aandoening

- Bewegingsstoornissen (incl. parkinsonisme)

Aandoening

Advanced Parkinson's disease

Parkinson

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Radboud Institute for Health Sciences, Department of Neurology
Overige ondersteuning: Abbvie
Apotheekzorg
Medtronic

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

This feasibility study will focus on four aspects, being acceptability, level of implementation, small-scale efficacy testing, and evaluation of study procedures, each with their own relevant outcome measures (see secondary outcomes for more detail)

In order to increase cross-validation of the data contextual factors will also be measured.

Toelichting onderzoek

Achtergrond van het onderzoek

In advanced stages of Parkinson’s disease (PD), patients and neurologists regularly face complex treatment decisions. Shared decision-making (SDM) can support the process where evidence, the clinician’s expertise and the patient’s preferences jointly contribute to reach an optimal decision.

The aim of the study is to test the feasibility of the SDM intervention by (1) analysing the acceptability of the intervention by users (i.e. professionals and patients); (2) assessing the level of implementation; (3) testing efficacy on a small-scale; and (4) evaluating the study procedures.

Using an uncontrolled before-after mixed methods design, patients in the pre-intervention group will receive information and decisional support as usual. Patients in the post-intervention group will receive the SDM intervention, consisting of an Option Grid TM patient decision aid and a website with supplementary information plus a value clarification tool for both patients and professionals. An Option Grid is a one-page, evidence-based summary of

available options, listing the frequently asked questions that patients consider when making treatment decisions. A value clarification tool helps patients identify which option he/she prefers based on attributes in the treatment decision context. Neurologists and PD nurse specialists will receive a 1-hour instruction on SDM and how to use the SDM intervention.

Through purposive sampling, neurologists and PD nurse specialists will be recruited from both specialised neurology clinics and community-based hospitals. Included professionals will invite consecutive patients who are eligible for the advanced therapies.

Data will be collected using questionnaires, interviews, audio observations of the consultations, and tracking users' logging behaviour of the website. Data will be analysed using a mixed methods design.

The mixed methods design will create a deeper understanding of how the SDM intervention affects the interactions between professionals (neurologist and/ or PD nurse specialist) and the patient, when an advanced treatment is chosen. The results of the study will inform the design of an RCT to test the effectiveness of the SDM intervention.

Doel van het onderzoek

The study will address the feasibility of the shared decision-making (SDM) intervention by (1) analysing the acceptability of the intervention by users (i.e. professionals and patients); (2) assessing the level of implementation; (3) testing efficacy on a small-scale; and (4) evaluating the study procedures.

Onderzoeksopzet

Demographic data professionals and patients: at moment of inclusion

acceptability: at end of post-intervention phase with patients from intervention group and professionals

level of implementation: continuous from the introduction of the intervention to the end of the post-intervention phase

Small scale efficacy testing, level of SDM: during the decision-making process in both the pre-intervention phase and the post-intervention phase

Small scale efficacy testing, decision quality: at time of inclusion of the patients and at the end of the decision process in both the pre-intervention phase and post-intervention phase

feasibility of study procedures: throughout the study

contextual factors: throughout the study

Onderzoeksproduct en/of interventie

It is a before- after design.

For the pre-intervention group, patients will receive information and decision support as usual. The decision process of an individual patient ends when a preliminary choice for a treatment has been made and the screening for definite treatment eligibility is initiated.

Once 20 patients in the pre-intervention group have finished their decision process, the professionals will be introduced to the shared decision-making (SDM) intervention.

The SDM intervention consists of an Option Grid, online supplementary information with a value clarification tool and a one-hour training for professionals. An Option Grid is a one-page, evidence-based summary of available options presented in a tabulated format, listing the frequently asked questions (FAQs) that patients consider when making treatment decisions. An Option Grid is used in the clinical encounters and stimulates the discussion on the treatment options. A value clarification tool helps patients think about which attributes of options matters to him/ her most in order to identify which option he/she prefers.

After the introduction of the intervention to the professionals, the 20 patients for the post-intervention group will be included and enter the decision process using the SDM intervention

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Five hospitals will participate and are selected from our previous studies. Specialised neurology centers and community based hospitals will be represented, because they have differential access to advanced PD treatments. Neurologists in these hospitals will be eligible if they (1) consider at least five PD patients per year for advanced treatment; and (2) collaborate with a PD nurse specialist in the same hospital. We aim for a total of five to ten neurologists, each participating centre may provide more than one neurologist. Moreover, we aim to include professionals with different levels of expertise on the advanced treatment options. Patients may be included if they: 1) are diagnosed with advanced PD and are considered for advanced treatment, judged by their own neurologist; and 2) are eligible for all three treatments at the beginning of the decision-making process.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for patients are: Current or previous advanced treatment for Parkinson's Disease

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geen controle groep
Doel:	Anders

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-12-2014
Soort:	Eerste indiening
Toetsingscommissie:	METC Oost-Nederland

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6471
NTR-old	NTR6649

Register	ID
Ander register	: 2014-1489 IRB Arnhem-Nijmegen

Resultaten

Samenvatting resultaten
not applicable