A feasibility study of a SDM intervention for the decision making process 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…

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

Summary

ID

NL-OMON21200

Source
NTR

Condition

- Movement disorders (incl parkinsonism)

Health condition

Advanced Parkinson's disease

Parkinson

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Institute for Health Sciences, Department of Neurology
Source(s) of monetary or material Support: Abbvie

Apotheekzorg
Medtronic

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

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.

Secondary outcome

1) acceptability is tested by:

a)structured questionnaires for patients on items as readibility, comprehensiveness, layout and amount of information

b) semi structured interviews with patients, neurologists and PD nurse specialists with items on perceived satisfaction, and perceived strengths and weakneses of the intervention

2) level of implementation is tested by:

a) field notes to what extent the intervention was implemented as planned and training was provided as planned

b) analysis of audiotapes consultations, logging data of navigation behaviour website, hard copies of value elicitation tool summary: evaluation if all elements of intervention are actually used

c) Analysis of audiotapes consultations, logging data of navigation behaviour website to analyse if patients engage in all elements of the intervention

d) semi structured interviews on the operceived interaction with the different elements of the intervention

e) Analysis of audiotapes consultations, logging data of navigation behaviour website to analyse which professionals and patients in the intervention group actually used the intervention

3) small-scale efficacy testing:level of SDM

a) patient and neurologist/PD nurse specialist perceived level of SDM: SDMQ-9,SDM-Q-9-doc, CollaboRATE, actual decision role(CPS)

b) researcher observed level of SDM: analysis of audiotaped consultations using OPTION-5

3) small-scale efficacy testing:decision quality

a) level of informed choice: measuring knowledge of patients on the advanced treatments in questionnaires at start and end of decision-making process

b) decisional conflict in decision-making: structured questionnaires for patients and neurologists/PD nurse specialists using Decisional conflict Scale and PDPAI

4) feasibility of study procedures:

a) field notes on study inclusion rate, drop-out rates

b) semi structured interviews with neurologists and PD nurse specialists with items such as barriers to recruitment

c) analysis of outcome measures from the small scale efficacy testingwith evaluation of conflicting data on outcome measures

d) semistructured interviews with patients and professionals with items on acceptability of the logistics of the study procedures

5) contextual factors:

a) structured questionnaires for patients:desired role(CPS desired), treatment preference, pre-knowledge, health literacy skills(FCHHL), mood(HADS)

b) cognitive tests for patients: MOCA, BSAT, Verbal fluency, Stroop Color Word test, National Adult Reading Test, Raven Advanced Progressive Matrices, MMSE

c) structured questionnaires for neurologists and PD nurse specialists with items on role in decision-making(CPS), treatment preference, and level of experience with treatments

d) field notes for example on national consensu of treatment of advanced PD, organizational structure for this specific decision in participating centers

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

Decision support intervention

Contacts

Public
F. Nijhuis
Canisius Wilhelmina Hospital Nijmegen, Dep. of Neurology

[default]
The Netherlands
0031-243658335
Scientific

F. Nijhuis
Canisius Wilhelmina Hospital Nijmegen, Dep. of Neurology

[default]
The Netherlands
0031-243658335

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2015
Enrollment:	40
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-12-2014
Application type:	First submission
Review commission:	METC Oost-Nederland p/a Radboudumc, huispost 628, Postbus 9101 6500 HB Nijmegen 024 361 3154 commissiemensgebondenonderzoek@radboudumc.nl

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	NL6471
NTR-old	NTR6649
Other	: 2014-1489 IRB Arnhem-Nijmegen

Study results

Summary results
not applicable