A Study Assessing The Effect Of A Structured Medication Review On Quality Of Life In Patients With Parkinson*s Disease*

Published: 08-05-2014
Last updated: 15-05-2024

The aim of this study is to assess whether a structured medication review in primary care improves medication adherence and leads to positive patient outcomes in patients with PD. The expectation is that the results of this study might be used to...

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

Summary

ID

NL-OMON44681

Source
ToetsingOnline

Brief title
Medication Review in Parkinson

Condition

- Movement disorders (incl parkinsonism)

Synonym
Movement Disorders, Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Subsidieaanvraag is ingediend bij de KNMP

Intervention

Keyword: Medication, Parkinson's Disease, Polypharmacy, Therapy adherence

Outcome measures

Primary outcome

The primary objective of the study is to assess whether a structured medication review leads to better quality of life in patients with PD. Disease-specific quality of life will be measured, using the PDQ-39.

Secondary outcome

The secondary objectives of the study are measurements of activities in daily life and physical disability, non-motor symptoms, cost-effectiveness and health status, and personal carers* quality of life, by comparing the results of PD patients who receive a medication review with PD patients who will not receive a medication review.

- The effects on activities in daily life and the level of physical disability will be measured, using the ALDS.
- The effects on non-motor symptoms will be measured, using the NMSQuest.
- Cost-effectiveness and the experience of health status will be measured, using the EQ-5D and the VAS.
- The effects on quality of life for personal or home caregivers of patients with PD will be measured, using the PDQ carer questionnaire.
- A better insight in the process of performing a medication review will be obtained from the perspective of community pharmacists, analysing probable

bottlenecks and mapping which method of working is the most sufficient.

Study description

Background summary

Parkinson*s Disease (PD) is a progressive, neurodegenerative disease resulting from degeneration of dopaminergic neurons within the substantia nigra, which leads to a shortage of dopamine in the striatum. Patients with PD need to take a variety of anti-Parkinson medications in order to manage the symptoms of the disease. Next to this, possible other medications might be prescribed due to comorbidity. Since all these medications need to be taken at different doses and at different times of a day, this can lead to complicated medication schedules. Due to these multiple drug regimens, decreased medication adherence occurs, which means that a considerable amount of patients with PD do not fully benefit from their medical treatment. A potential intervention to enhance medication adherence is by performing a structured medication review.

Study objective

The aim of this study is to assess whether a structured medication review in primary care improves medication adherence and leads to positive patient outcomes in patients with PD. The expectation is that the results of this study might be used to improve daily treatment of patients with PD.

Study design

The study will be designed as a randomized controlled trial (RCT) with a follow-up of six months. Half of the randomly assigned patients will receive the intervention, while the other half will not receive the intervention and receives usual care. Measurements at baseline will be done before the intervention. The follow-up measurements will take place after three months and six months to compare possible differences in outcomes between the intervention group and the control group.

Intervention

As intervention, community pharmacists will perform the structured medication reviews as one-time assessment at the start of the study within the intervention group. Measurements at baseline will be done before the intervention. The follow-up measurements will take place after three months and six months.

Study burden and risks

The intervention is a useful tool that does not cause a burden for participants and is not associated with risks. During the study, solely patients with PD in the intervention group might benefit from the investigation. Patients in the control group will not receive the intervention and will not benefit.

Contacts

Public
Medisch Spectrum Twente

Haaksbergerstraat 55
Enschede 7513 ER
NL
Scientific
Medisch Spectrum Twente

Haaksbergerstraat 55
Enschede 7513 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Diagnosed with PD according to the UK-brain banking criteria
* * Eighteen years of age
* * Four different medications daily

* * Four medication intake moments daily
* Expressing motor symptoms or non-motor symptoms
* Living independent or semi-independent in the region of Enschede
* Be able to read and write the Dutch language

Exclusion criteria

* Unable to take own medications, excluding PD patients with personal or family home caregivers
* Received a medication review within a year before the study
* Received a Deep Brain Stimulator within a year before the study
* Receiving continuous duodopa gastro-intestinal gel therapy or will receive this within three months

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2014
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO

Date:	08-05-2014
Application type:	First submission

Review commission:	METC Twente (Enschede)
Approved WMO Date:	17-11-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	23-04-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	01-06-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-07-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21486
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL48661.044.14
OMON	NL-OMON21486