Visual problems in Parkinson disease frequently overlooked: study protocol for a multicenter observational, cross-sectional study

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Routinely asking patients about visual problems by using a simple screening questionnaire could be an easy solution leading to tailored treatment to prevent complications, to restore mobility, to ascertain independence, and to improve quality of...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23926

Bron
NTR

Verkorte titel
VIP

Aandoening

Parkinson's disease
visual disorders
visual impairment
Screening questionnaire
ophthalmology
non-motor symptoms

De ziekte van Parkinson
Oogheelkunde, oogproblemen
Niet motore symptomen
Vragenlijst

Ondersteuning

Primaire sponsor: RadboudUMC
Overige ondersteuning: Stichting Parkinson fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- validation of screening questionnaire regarding visual problems. We use in depth ophthalmological assessment as gold standard

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Visual disorders are common in Parkinson's disease (PD). However, the exact frequency and severity of visual problems are not known. Good visual functioning is crucial for patients with PD, because of their need to compensate visually for motor deficits and postural instability . Awareness, early detection and, when possible treatment of visual problems can lead to increased quality of life. Here, we describe the study design of an observational, multi-center, cross sectional study aiming to (1) validate a screening questionnaire to identify PD patients who should be referred to an ophthalmologist for further assessment; to (2) study the prevalence of visual disorders in PD, and to (3) study the severity and clinical impact of different types of visual disorders.

Methods: This study consists of two phases. In phase one, 750 PD patients and 250 healthy controls will be asked to fill out a newly developed screening questionnaire on visual problems. In phase two, a subgroup of responders (n=100) (with the highest and lowest scores on the screening questionnaire) is invited for an extensive neurological and ophthalmological assessment. The in depth ophthalmologic examination will serve as the ¡°gold standard¡± for validating the screening questionnaire. Moreover, these assessments will be used to study associations between visual disorders and clinical presentation in order to gain more insight in it's clinical impact.

Discussion: Our study will create awareness of ophthalmologic problems in PD, and offers a solid starting point for a careful approach to his subject. In clinical practice, the association

between ophthalmologic symptoms and PD is far from obvious to both patients and clinicians. Consequently, patients may not adequately report ophthalmic problems themselves, while clinicians may miss many ophthalmologic disorders that can often be treated. Routinely asking patients about visual problems by using a simple screening questionnaire could be an easy solution leading to tailored treatment to prevent complications, to restore mobility, to ascertain independence, and to improve quality of life.

Doel van het onderzoek

Routinely asking patients about visual problems by using a simple screening questionnaire could be an easy solution leading to tailored treatment to prevent complications, to restore mobility, to ascertain independence, and to improve quality of life.

Onderzoeksopzet

- phase 1: 750 PD patients screening questionnaire, 250 controls. (ending 31-07-2018)

- Phase 2: 100 PD patients selected for in depth ophthalmological assessment (ending april 2019)

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

phase 1: Parkinson's disease or control (no inclusion criteria for screening questionnaire)

phase 2:

Diagnosis of PD according to the UKPSDBB criteria

The patient must be able and willing to give written informed consent

The patient must be willing to participate in all study related activities and visits

Age of onset Parkinson's disease > 30 years

Stable doses of Parkinson medications ≥ 4 weeks

Current age≥ 60 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Hoehn and Yahr's Parkinson's staging score ≥ 4

Secondary cause of parkinsonism as detected by history

(e.g. drug-induced parkinsonism)

Secondary cause of parkinsonism as detected by investigation

(e.g. vascular parkinsonism as detected by neuroimaging)

Dementia according to DSM-IV

Major depressive disorder according to DSM-IV

Psychotic disorder(s) according to DSM-IV

Prior brain surgery (except deep brain stimulation)

Previous eye surgery (except phacoemulsification for cataract and artificial lenses)

Blindness in 1 eye

Medication that influences normal visual function other than PD medication. (Detailed information see Appendix 1)

Systemic diseases that may cause eye problems (HIV, DM type I, type II if the patient had ophthalmologic therapy and/or abnormalities at last screening.)

Neurodegenerative diseases other than Parkinson's disease.

History of lesions near the optic chiasm or occipital cortex.

Migraine

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42851
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7421
NTR-old	NTR7663
CCMO	NL58535.091.16
OMON	NL-OMON42851

Resultaten