Validation of the Dutch Patient-Reported Spectacle Independence Questionnaire (PRSIQ)

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The PRSIQ-NL is a valid questionnaire to assess the need, use, and wear of spectacles to see at far, intermediate, and near in patients with cataract and healthy subjects.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21890

Bron
NTR

Verkorte titel
PRSIQ-NL

Aandoening

cataract

Ondersteuning

Primaire sponsor: Relationship between spectacle dependency, as assessed with PRSIQ-NL, and visual functioning, as assessed with Catquest-9SF-NL, after cataract surgery.
Overige ondersteuning: Wetenschapsfonds Amphia (Amphia en MSB-A)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Validation of the Dutch version of the PRSIQ by means of Rasch analysis and item response theory (IRT) analysis and test-retest reliability.

Toelichting onderzoek

Achtergrond van het onderzoek

Whether a patient will use spectacles after cataract surgery typically depends on the type of intraocular lens (IOL) implanted, any remaining refractive error, and personal preference of the patient. The Patient-Reported Spectacle Independence Questionnaire (PRSIQ) is a patient-reported outcome measure (PROM) that evaluates what patients say about their need for spectacles, what they use in daily life, and how they function without spectacles. More specifically, it contains a total of 11 questions on the need, use, and wear of spectacles to see at far, intermediate, and near. It is available in the English language and has been validated for use in the United States. Recently, we developed a formal Dutch translation of the questionnaire. Our main objective is to validate the Dutch translation of the PRSIQ and assess its test-retest reliability. Our secondary objective is to evaluate any differences in spectacle dependency between patients with different types of IOLs and healthy subjects of different ages. Our tertiairy objective is to assess the relationship between spectacle dependency and experienced visual functioning after cataract surgery, assessed with the Catquest-9SF-NL PROM.

Doel van het onderzoek

The PRSIQ-NL is a valid questionnaire to assess the need, use, and wear of spectacles to see at far, intermediate, and near in patients with cataract and healthy subjects.

Onderzoeksopzet

Preoperatively and postoperatively.

Onderzoeksproduct en/of interventie

Cataract patients will fill in the PRSIQ-NL questionnaire before and 3 months after surgery. Half of them will fill in a second PRSIQ-NL questionnaire, both preoperatively and postoperatively, to assess reproducibility. Healthy subjects will fill in on PRSIQ-NL questionnaire. Half of them will fill in a second PRSIQ-NL questionnaire to test reproducibility. In addition, automated refractometry will be performed in healthy subjects to assess their refractive error.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Cataract patients: age of at least 18 years, diagnosis of cataract in both eyes, having consented to and is planned to undergo cataract surgery in both eyes, expected best-corrected distance Snellen decimal visual acuity of 0.7 or better in each eye, planned for implantation in both eyes of a a) non-toric monofocal IOL with target emmetropia, b) non-toxic monofocal IOL with target mild myopia, c) toric monofocal IOL with target emmetropia, d) non-toric enhanced far-focus IOL, e) extended depth of focus IOL with target emmetropia or monovision, f) trifocal IOL with target emmetropia, willing and able to participate in both preoperatieve and postoperative examination, and agreeing to sign the consent form.
Healthy subjects: age of at least 18 years, no ocular or visual complaints (other than using spectacles or contact lenses), no significant history of ocular disease (including cataract, corneal disease, glaucoma, and posterior segment eye disease), no history of ocular surgery (including cataract surgery and corneal refractive surgery), willing and able to participate in examinations, and agreeing to sign the consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Cataract patients: insufficient understanding of the Dutch language to comply with study procedures, best-corrected distance Snellen decimal visual acuity of <0.7 in either eye after cataract surgery, any comorbidity (other than cataract) that may significantly affect visual

function, influence subjective ocular visual symptoms, or prolong visual recovery after surgery, such as significant macular degeneration, glaucoma, diabetic eye disease, ocular surface disease, corneal dystrophy, corneal opacification, significant vitreous opacities (such as asteroid hyalosis and clinically significant floaters), and history of cerebral vascular accident, a history of ocular surgery (e.g., corneal refractive surgery), an increased risk of complicated cataract surgery, such as lens subluxation or (phaco)iridodonesis, brunescens cataract, rubra cataract, ingrains cataract, or posterior pole cataract, history of ocular trauma, and a complication, either perioperatively or postoperatively, that significantly affects vision and has not resolved before 3 months after surgery.
Healthy subjects: insufficient understanding of the Dutch language to comply with study procedures.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8815
Ander register	MEC-U : Not yet appointed

Resultaten