Patients with Chronic Idiopathic Axonal Polyneuropathy (CIAP): Relationships in the Disablement Process.

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A specific set of variables of impairments are related/ predictive of functional limitations and disabilities. A specific set of variables of functional limitations are related/ predictive of disabilities. Psychological variables (defined by TPB,...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20765

Bron
NTR

Verkorte titel
EXAMPLE Part II

Aandoening

framework 'the disablement process' (DP) (or it's equivalent 'the International classification of Functioning, Disability and Health)

Ondersteuning

Primaire sponsor: -
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Parameters of four domains of the Disablement Process will be measured:
Impairment: muscle strength (hand-held dynamometry), balance (Berg Balance Scale), sensory function (sensory modality score), pain (McGill pain questionnaire), fatigue (Fatigue Severity Scale).
Functional limitations: walking (modified Shuttle Walk Test), physical functioning (Physical Functioning Performance 10 Test), hand functioning (buttontest and Disabilities of the Arm, Shoulder, and Hand questionnaire), physical activity (DigiWalker Stepcounter), problematic activities (McMaster-Toronto Arthritis patient function preference questionnaire),
Disability: autonomy and participation (Impact on Participation and Autonomy questionnaire and Rankin score).
Intra-individual risk factor: cognitions; intentions and perceptions of control (TPB questionnaire), emotions (Hospital anxiety and depression scale).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Patients with CIAP do report more functional limitations and disability than a reference population of healthy adults. Rehabilitation for this group of patients is recommended but determinants and effects of such interventions are not investigated yet. Factors which can be changed and thereby possibly used in rehabilitation interventions need to be identified. As a theoretical frame work, the disablement process which represents a series of related concepts that describe the consequences or impact of a health condition (and is synonymous to the International Classification of Functioning(ICF)) is used. While performing activities (functional limitations) can be seen as behaviour as such psychological factors (intentions and control cognitions) which predict behaviour are incorporated into the model (intrapersonal factors).
Objective: Aims of this longitudinal multidisciplinary study are to describe the health status of patients with CIAP over time using the framework ‘the disablement process (DP)’ and to identify factors that decrease/ minimise functional limitations and disabilities which can be used in rehabilitation intervention tailored to the needs of this particular patient group.
Study population: A group of 90 newly diagnosed patients with CIAP, registered at the clinic of UMCU will be invited to participate in this research project.
Study parameters: Measures of four domains of the ‘disablement process’: ‘impairment’ (handheld dynamometer for muscle strength, Berg balance scale, Sensory modality score, McGill pain questionnaire and the Fatigue Severity scale functional limitations), ‘functional limitation’ (Shuttle walking test (SWT), Digiwalker Stepcounter to assess physical activity during the day, The Physical functional performance 10 test (PFP-10), buttontest, Mactar, The disabilities of the arm, shoulder and Hand questionnaire (DASH)), ‘disability’ (The Impact on participation and autonomy questionnaire (IPA)) and ‘intra-individual/ risk factors’ (emotions; Hospital anxiety and depression scale and control cognitions and intentions) will be taken, as well as ‘quality of life’ assessment with help of the MOS 36-Item Short-Form Health Survey and the InQoL .
These measures are taken at four measurements points, T0 baseline, T1 is 6 months after T0,

T2 is one year after T0 and T3 is five years after T0. Inclusion of patients in this study is planned in October 2005, the last inclusion will be in September 2007. Because CIAP is a slowly progressive disease, there will be a follow- up five years after baseline.
Nature and extent of the burden and risk: The patient will be asked four times to spend half a day at completing questionnaires and performing several physical tests in a period of five years (three times in the first year at one time after five years). The estimated extra risk for the patient while participating in this study is very low. The patient is only asked to complete questionnaires and to perform functional tests which can confront him of her with the consequences of his/ her disease which may be experienced as a psychological burden.
Analysis: To describe the health status of patients with CIAP over time descriptive statistics will be used. Multiple linear regression analysis will be used to assess concurrent and predictive relationships between the domains of the disablement process. Mediation analyses using the methodology of Baron and Kenny will be performed to assess if psychological factors mediate the relationship between impairment and functional limitations.

Doel van het onderzoek

A specific set of variables of impairments are related/ predictive of functional limitations and disabilities.
A specific set of variables of functional limitations are related/ predictive of disabilities.
Psychological variables (defined by TPB, anxiety and depression) add to impairment variables in the prediction of functional limitation (in self-report and performance measures).
These psychological variables mediate the relation between impairment and functional limitations

Onderzoeksproduct en/of interventie

None: longitudinal study with one patientgroup with CIAP in which the healthstatus will be monitored.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with CIAP, diagnosed on established criteria;
2. Dutch written and spoken language;
3. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Relevant co-morbidity, expected to influence the test results;
2. Anticipated health risks during performance-based testing.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-02-2006
Soort:	Eerste indiening

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	NL553
NTR-old	NTR609
Ander register	: 2006-01
ISRCTN	ISRCTN29920470

Resultaten

Samenvatting resultaten
Peer reviewed SCI-journals 2007-2009.