

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20765

Source

Nationaal Trial Register

Brief title

EXAMPLE Part II

Health condition

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

Sponsors and support

Primary sponsor: -

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

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 (button test 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).

Secondary outcome

N/A

Study description

Background summary

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 framework, 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), button test, 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 or 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.

Study objective

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2006
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date: 07-02-2006

Application type: First submission

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	NL553
NTR-old	NTR609
Other	: 2006-01
ISRCTN	ISRCTN29920470

Study results

Summary results

Peer reviewed SCI-journals 2007-2009.