Validity and Reliability of the Northwestern Ego Integrity Scale in patients with amyotrophic lateral sclerosis

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To evaluate measurement properties and feasibility of the self-report Northwestern Ego-Integrity Scale in patients with ALS (or its variants PMA and PLS)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44390

Source
ToetsingOnline

Brief title
Ego-Integrity in ALS

Condition

- Neuromuscular disorders

Synonym
Amyotrophic lateral sclerosis, motor neuron disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Despair, Ego-integrity, Motor Neuron Disease, Psychometrics

Outcome measures

Primary outcome

Ego-integrity as measured by the Northwestern Ego-Integrity Scale (NEIS). The NEIS is a self-reported, 15 item questionnaire measuring ego-integrity and despair, with higher mean scores indicating more despair and ego-integrity.

Secondary outcome

Psychological distress assessed with the Hospital Anxiety and Depression Scale (HADS): The HADS is a 14 items questionnaire which measures depression and anxiety. This questionnaire is specifically validated for patients with a (chronic) disease. The HADS consists of two subscales: HADS-D (7 items) measuring depression and HADS-A (7 items) measuring anxiety. Higher scores reflect more anxiety and/or depressive symptoms.

Illness cognitions assessed with the Dutch questionnaire "Ziekte Cognitie Lijst" (ZCL): The ZCL consists of 3 subscales: helplessness (6 items), acceptation (6 items) and disease benefits (6 items). The scores per scale range from 6-24.

Sense of hope assessed with the Dutch version of the Herth Hope Index (HHI), a short (12 item) questionnaire that assesses the cognitive, affective, behavioral, temporal, and contextual dimensions of hope.

Study description

Background summary

Receiving a diagnosis of MND is challenging for patients and their families and represents an existential shock. Most ALS-patients show resilience but in some patients the prospect of loss of physical abilities and early death can result in despair, depression and hopelessness. The Northwestern Ego-Integrity Scale was developed to measure ego-integrity and despair, and may be a valid instrument in patients with ALS.

Study objective

To evaluate measurement properties and feasibility of the self-report Northwestern Ego-Integrity Scale in patients with ALS (or its variants PMA and PLS)

Study design

To evaluate reliability, participants will fill in the Northwestern Ego-integrity Scale (NEIS) twice with one week in between. Test-retest reliability will be assessed by the intraclass correlation coefficient (ICC), and the measurement error (expressed as SEM and limits of agreement).Construct validity will be assessed by the degree to which the NEIS domain scores (ego-integrity and despair) are consistent with predefined hypotheses regarding relationships with other measures of related constructs (Anxiety, depression, hope, illness cognitions).

Study burden and risks

Participants will be asked to fill in questionnaires of which the NEIS is completed twice for reliability purpose. Two of these questionnaires (HADS and ZCL) are currently used in ALS-care practice. Patients will be able to complete the questionnaires at home. No significant physical or psychological discomfort can be expected. There are no risks associated with study participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis of ALS, Progressieve Spinal Muscular Atrophy (PMA) or Primary Lateral Sclerosis (PLS)
Currently under the care of a rehabilitation specialist
-No cognitive impairments as judged by the rehabilitation specialist of the patient
-Documented score on the ALSFRS-R
-Sufficient fluency in the Dutch language to complete study questionnaires
-Aged 18 years or older

Exclusion criteria

- If the patient has received the diagnosis less than 6 months ago
- Diagnosis of frontotemporal dementia
- Other life-threatening diagnosis or patients who are in the finale stage of the disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-09-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL62688.018.17