Distinguishing awareness deficits after acquired brain injury: Validation of a clinical assessment tool in a Dutch sample.

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1) Main Objective: To investigate the validity, reliability and feasibility of the Clinician*s Rating Scale for evaluating impaired self-awareness and denial of disability after brain injury (CRS-ISA-DD) for use in the Dutch clinical practice.2)...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43799

Source
ToetsingOnline

Brief title
Distinguishing awareness deficits

Condition

- Other condition

Synonym
traumatic brain injury

Health condition

niet-aangeboren hersenletsel

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Assessment, Awareness, Brain Injuries

Outcome measures

Primary outcome

Convergent validity: correlation between the CRS-ISA-DD and tools that measure similar constructs (Patient Competency Rating Scale, COPE Inventory and responses to Thematic Apperception Test pictures); inter-rater reliability: correlations between scores on the CRS-ISA-DD of two independent raters; internal consistency: Cronbach*s alpha of the CRS-ISA scale and the CRS-DD scale; feasibility: means and frequencies on a feasibility questionnaire.

Secondary outcome

Correlations between impaired awareness of deficits (PCRS, COPE Inventory, Thematic Apperception Test, CRS-ISA-DD) and neurological data (MRI scan data, fingertapping, ZOO test, verbal fluency) and psychological data (Hospital Anxiety Depression Scale).

Study description

Background summary

Impaired awareness of deficits is common after acquired brain injury. It refers to the inability to appraise one*s strengths and weaknesses and the implications for daily life activities at present and in the future.

In clinical practice two different types of patients with impaired awareness of deficits after acquired brain injury are recognized. Some patients overestimate their competencies. This is thought to be a direct result of an underlying neurological deficit and is called impaired self-awareness (ISA). Other patients however deny their impairments to protect themselves from emotional distress. This is thought to be the result of an underlying psychological mechanism and is called defensive coping (DC). These two groups require different rehabilitation programs. Intervention techniques helpful for patients with impaired self-awareness who overestimate their competencies are not effective for patients with defensive coping who deny their impairments. For optimal treatment it is therefore important to distinguish between these types of awareness deficits.
Up until now there is no gold standard measurement tool that is specifically designed to make this distinction in the Dutch clinical practice. Also, the relationship between impaired awareness of deficits and possible underlying neurological and psychological mechanisms is unclear.

Study objective

1) Main Objective: To investigate the validity, reliability and feasibility of the Clinician*s Rating Scale for evaluating impaired self-awareness and denial of disability after brain injury (CRS-ISA-DD) for use in the Dutch clinical practice.
2) Secondary objective: To explore the relationship between impaired awareness of deficits and neurological (incidence of brain lesions, severity of brain injury, executive functioning) and psychological (anxiety) correlates.

Study design

Cross sectional observational cohort study.

Study burden and risks

Patients are assessed once. The assessment protocol takes approximately 150 minutes. Patients will be assessed at home or at the university lab. There are no direct benefits associated with participation. Participants will be asked to talk about possible changes in their daily life functioning due to the brain injury. This may be confronting (but not new) for some patients. These issues have also been discussed during rehabilitation in the rehabilitation center.

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

Patients will be male or female and will be 18 years or older. Patients will be eligible for inclusion in the study if they have had a traumatic brain injury; if they have moderate to severe brain injury; if they are at least 6 months post injury and maximally 5 years post injury; if they were discharged home after rehabilitation; if a significant other is willing to participate; and if informed consent is signed.
Significant others (male or female) will be eligible for participation if they are 18 years or older.

Exclusion criteria

Patients will be excluded from participation if they had a premorbid psychiatric disorder for which treatment was necessary; if no data of a post-injury MRI scan is available; if they do not want feedback of their memory and speed of processing test results; if they do not wish to be contacted in case severe abnormalities are found; if they are unable to complete the interview and assessment due to language and communication problems; and if it is indicated in the file that the patient does not want to participate in scientific research.
Significant others will be excluded if they are unable to complete the interview and

assessment due to language and communication problems.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-07-2013
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	13-05-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	06-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL42752.068.12