The relationship between neurocognition, coping and outcome in acquired brain injury during rehabilitation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52156

Source
ToetsingOnline

Brief title
COGCO-R

Condition

- Central nervous system vascular disorders

Synonym
cerebral haemorrhage, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Amsterdam UMC en Libra Revalidatie & Audiologie

Intervention

Keyword: acquired brain injury, coping, neurocognition, outcome

Outcome measures

Primary outcome

The primary study paramenters are:

1. Neurocognitive functioning

2. Coping

3. Participation

4. Quality of life

Secondary outcome

Not applicable.

Study description

Background summary

Acquired Brain Injury (ABI) can severely impact every-day functioning through physical, neurocognitive, emotional and behavioural disturbances, thereby affecting participation and the quality of life of these patients on the long term. ABI rehabilitation programmes help to improve function and decrease disability in patients, but there are great differences in long-term outcome between patients. The underlying causes of these differences remain largely unclear, although neurocognitive functioning and coping are considered important factors influencing ABI outcome after rehabilitation. The current study aims to explore the roles of neurocognitive functioning and coping in participation and quality of life during rehabilitation after ABI. This study will contribute to our knowledge of factors influencing outcome of ABI, thereby exposing targets to improve rehabilitation programmes.

Study objective

This study aims to:
1. Determine the role of early neurocognitive functioning in the outcome from ABI in rehabilitation, as defined by the level of neurocognitive functioning, participation and quality of life at six months after start of the rehabilitation trajectory.
2. Determine the modulating role of coping in the relation between neurocognitive functioning and outcome of rehabilitation after ABI, as defined by participation and quality of life at six months after start of rehabilitation trajectory.

Study design

A longitudinal observational study design.

Study burden and risks

There will be two assessments for participating subjects. The first assessment (T1) will be during the first two weeks of the rehabilitation programme and the second assessment (T2) will be six months later. The assessments both comprise administration of a neurocognitive test battery (75 minutes) and completion of three self-report questionnaires. At assessment T1 participants will also be asked to fill out a demographics and medical history questionnaire. Duration of assessment T1 is estimated at 115 minutes (maximum duration: 130 minutes) and duration of assessment T2 is estimated at 105 minutes (maximum duration 120 minutes), summing up to a total estimated assessment time of 220 minutes (maximum: 250 minutes) over a period of 6 months. Risk of participation is considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

The subject is at least 18 years old.
The subject has acquired brain injury, which is acquired less than three months ago.
The subject has given verbal and written consent.

Exclusion criteria

The subject is unable to comprehend task instructions or fill in the questionnaires, due to a language barrier or a severe form of aphasia.
The subject is unable to complete the neuropsychological assessment, due to disturbances in consciousness, severe fatigue, severe motor disability that interferes with outcome assessment at time of assessment or inability to comprehend testing instruction at time of assessment other than aphasia.
The subject is diagnosed with a degenerative disorder, like Parkinson's disease or Multiple Sclerosis.

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):	23-09-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2021
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

ID: 29123
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76395.018.21
OMON	NL-OMON29123