The relationship between neurocognition, coping and outcome in acquired brain injury during rehabilitation: the COGCO-R study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29123

Source
Nationaal Trial Register

Brief title
COGCO-R Study

Health condition

Acquired brain injury, Neurocognition, Coping, Rehabilitation, Participation, Quality of Life

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: No funding sources

Intervention

Outcome measures

Primary outcome

Performance on a neurocognitive battery of computerised cognitive tests (reaction times,

accuracy, task performance analysis).
Coping is measured with the Utrecht Coping List (UCL), a self-report questionnaire measuring coping styles.
Participation is measured with the USER-Participation (USER-P), a self-report questionnaire measuring objective and subjective participation.
Quality of Life is measured with the Quality of Life after Brain Injury (QOLIBRI), an internationally validated self-report questionnaire measuring disease specific health-related quality of life in patients with brain injury.

Secondary outcome

Not applicable

Study description

Background summary

Rationale:
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.

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 cohort study design.

Study population:
Patients (aged 18+ years) with ABI (time since injury < three months) referred for multidisciplinary rehabilitation.

Main study parameters/endpoints:
1. Neurocognitive functioning (Emma Toolbox for Neurocognitive Functioning).
2. Coping (Utrecht Coping Lijst: UCL).
3. Participation (Utrechtse Schaal voor de Evaluatie van Revalidatie - Participatie: USER-P).
4. Quality of life (Quality of Life after Brain Injury: QOLIBRI).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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 comprise administration of a neurocognitive test battery (75 minutes) and completion of three self-report questionnaires. The first assessment will include one additional demographics and medical history questionnaire. Duration is estimated at 115 minutes for assessment T1 (maximum duration: 130 minutes), and 105 minutes (maximum duration 120 minutes) for assessment T2, summing up to a total estimated assessment time of 220 minutes (maximum: 230 minutes) over a period of 6 months. Risk of participation is considered negligible.

Study objective

Exploration

Study design

Assessment times are at the start of rehabilitation and six months later.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

This study will recruit patients with ABI who are referred and included for multidisciplinary ABI-rehabilitation at Libra Revalidatie & Audiologie between April 2021 and October 2021. In order to be eligible to participate in this study, a subject must meet all of the following 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

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-09-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	13-09-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52156
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9725
CCMO	NL76395.018.21
OMON	NL-OMON52156

Study results