Cohort study on the effects of aging in acquired brain injury patients

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Primairy objective:Explore the prevalence of the ABI-effect, by mapping the participation level. Secundary objective:Substatiate the occurence of the ABI-effect, by mapping cognitive functions of patients and compare these to healthy controls....

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

Summary

ID

NL-OMON52212

Source
ToetsingOnline

Brief title
BRAIN-ReADAPT study

Condition

- Other condition
- Structural brain disorders

Synonym
acquired brain injury

Health condition

niet-aangeboren hersenletsel (traumatisch hersenletsel, CVA en SAB)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Zon MW

Intervention

Keyword: acquired brain injury, aging, disability, participation

Outcome measures

Primary outcome

Cohort study:

The percentage of patients experiencing the ABI-effect. Also, a 95% confidence interval of this prevalence will be calculated.

Case-control study:

The significant difference in cognitive functions between the patient groep and the healthy controls.

Secondary outcome

Cohort study:

- The degree of decline in participation
- The different areas in which decline in participation is experienced.
- Scores on questionnaires
- Need of care for patients

Case-control study:

- Comparison of scores in two points in time (first and second NPA)
- Performance on neuropsychological tests in different cognitive domains

Study description

Background summary

In the Netherlands an estimated 650.000 people live with the daily consequences of an Acquired Brain Injury (ABI). A substantial amount of these patients acquired their brain injury (traumatic brain injury, subarachnoïd hemmorhage or cebrovascular accident) at a relatively young age: between 18 and 50 years old. The chain-of-care for ABI aims for recovery in the subacute phase, usually within a period of one year after injury. After an adaptation period, the patients reach a new balance, with stabilization of complaints and reintegration, sometimes with the necessity of modifications. The group of patients who acquired a brain injury at a young age, have to face the effects of aging like decreased cognitive functions, which can cause the participation level to drop. This is called the ABI-effect in the current study. At this moment, insufficient information is available about the functioning of people who suffered ABI multiple years ago and have established a new balance, and now make the transition to an older phase of live.

Study objective

Primairy objective:
Explore the prevalence of the ABI-effect, by mapping the participation level.

Secundary objective:
Substatiate the occurence of the ABI-effect, by mapping cognitive functions of patients and compare these to healthy controls.

Tertiary objective:
Gain insight in the need of care for patients, to enhance regular care after ABI.

Study design

A prospective cohort study (questionnaires), with an embedded case control study (neuropsychological assessments) in which the data is gathered whitin a timeframe of 3 years.

Study burden and risks

The risks for measurements (neuropsychological tests and questionnaires) used in this study are negligible.

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

- acute acquired brain injury (ABI) (traumatic brain injury, subarachnoidal hemorrhage, cerebrovascular accident
- ABI more than 5 years ago
- ABI at the age of 25 years or older
- current age between 50- 67 years
- able to complete questionnaires independently
- for case-control study: results of an earlier neuropsychological assessment, that has been done in the non-acute but confined phase after ABI; between 3 and 12 months after injury must be availabe.

Exclusion criteria

- second ABI for which patient was admitted
- psychiatric disease for which the patient is treated
- alcohol and drug abuse
- language barriers or illiteracy limiting filling out questionnaires

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2022
Enrollment:	715
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-07-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL79072.042.21