Case management after acquired brain injury

Published: 18-09-2019
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The primary objective is to evaluate the (cost)effectiveness and feasibility of case management after brain injury.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49157

Source
ToetsingOnline

Brief title
Case management brain injury

Condition

- Other condition

Synonym
ABI, acquired brain injury

Health condition

niet aangeboren hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: stichting In-Tussen/ministerie van VWS

Intervention

Keyword: brain injury, case management, effectiveness, feasibility

Outcome measures

Primary outcome

Hospital Anxiety and Depression Scale (HADS)

Secondary outcome

The effectiveness will be evaluated by assessment of self-management (Patient Activation Measure (PAM)), psychosocial well-being (Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P) restriction subscale, the Life Satisfaction Questionnaire (LiSat) and care needs (Longer-term Unmet Needs after Stroke (LUNS)) and service use (care consumption list). Caregiver outcomes include self-efficacy (Carer Self-Efficacy Scale (CSES)), caregiver burden (Caregiver Strain Index (CSI)), psychosocial well-being (LiSat, HADS), caregiver needs (Family Needs Questionnaire (FNQ)).

The feasibility will be evaluated using registration by caseamangers and patients/caregivers.

The costeneffectiveness is measured with a specific costquestionnaire and the EQ-5D-5L.

Study description

Background summary

In the Netherlands, approximately 650.000 people live with the consequences of brain injury, affecting their participation and well-being. There are sufficient services available to support people with learning how to live with the consequences of brain injury. However, referral to such services is minimal and patients/caregivers cannot find them on their own. Continuity of care is currently lacking, hindering timely access to the appropriate services.

Study objective

The primary objective is to evaluate the (cost)effectiveness and feasibility of case management after brain injury.

Study design

This is a randomized controlled study with repeated measures in patients with brain injury, taking place between September 2019 and September 2020 in three regions in the Netherlands. A group of brain injury patients and caregivers will receive case management at discharge from the hospital, to explore the (cost)effectiveness and feasibility of case management for brain injury compared to the usual care

Intervention

The aim of case management after brain injury is to support patients* and caregivers* self-management of the consequences of brain injury, to improve/maintain psychosocial well-being, to prevent (escalation of) problems and to facilitate timely access to appropriate services. The early inclusion group will be entered into a digital monitoring system. When needs are identified through the monitoring tool, the case manager gets in touch with the patient/caregiver; the form and intensity of case management depend on their individual needs, varying from providing information via telephone or email to multiple contact moments, support in finding/accessing care services, etc. Since the late inclusion group enters the study because they have a need for help, they will be contacted by the case manager right away (i.e. not entered in the monitoring tool first). Case management has no fixed frequency nor duration.

Study burden and risks

There are no risks related to participation. Participants will fill out questionnaires every six months for a duration of 18-24 months. Patients receiving case management are expected to benefit from the monitoring of needs and problems and getting support by the case manager.
Amendment: patients were informed they would receive questionnaires up to 18 months after baseline when they started after December 2019. Due to the coronacrisis the subsiding party has extended the study period until December

2022. This provides us with the opportunity to assess all participants until 24 months after baseline. After T3, we will approach all participants who indicated that they agree to be approached for future research on the original consent form of the study. We will send them information on the extension and the additional assessment at T4 (see appendix E1-3) and ask them to provide written consent (see appendix E2-3). Those who fill out this consent form will receive the questionnaires at T4

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

Inclusion criteria for patients:
* Acquired brain injury objectified by medical specialist (see appendix for diagnosis and medical codes)

* Aged 18 years or older
* Living in the community prior to the injury
* Discharged home after hospital/rehabilitation
* Sufficient command of the Dutch language
* Access to a computer and the internet (monitoring tool and questionnaires)
* Willing and able to give informed consent

Exclusion criteria

A potential subject will be excluded from participation in this study when they have degenerative disorders (e.g. Parkinson*s disease, dementia) because of the progressive course of the disease. Patients with a diagnosis related to neuro-oncology will be excluded as well, since an intensive care trajectory is already in place for these patients.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2019
Enrollment:	209
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-06-2020
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	NL70449.068.19
Other	NL7691