Case management after acquired brain injury

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It is hypothesizes that case management after brain injury will be more effective in improving psychosocial well-being, preventing escalation of problems etc. (see primary and secondary outcomes for study parameters) than care as usual. Additionally…

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26595

Bron
Nationaal Trial Register

Verkorte titel
Case management after brain injury

Aandoening

Acquired brain injury

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Stichting In-Tussen/Ministerie van Volksgezondheid, Welzijn en Sport (VWS)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The Hospital Anxiety and Depression Scale (HADS38) will be administered to assess

symptoms of anxiety and depression. The scale consists of 14 items and two subscales (anxiety and depression). Scores >7 on a subscale suggest the presence of an anxiety disorder or depression. The psychometric quality of the scale is sufficient40.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.

Objective: The objectives are to evaluate 1) the effectiveness, 2) the feasibility of case management after brain injury and 3) cost-effectiveness of case management after brain injury compared to usual care.

Study design: This is a randomized controlled trial with repeated measures in patients with brain injury, taking place between September 2019 and December 2021 in three regions in the Netherlands. A group of brain injury patients and caregivers will receive monitoring and case management at discharge from the hospital, compared to the usual care in those regions.

Study population: Adults with acquired brain injury who were living in the community prior to the injury and with sufficient command of the Dutch language. Primary adult caregivers of eligible patients with sufficient command of the Dutch language. Health care professionals involved in caring for adult patients with brain injury.

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 patients in the intervention group will be entered into a digital monitoring system, which will be managed by the case managers. 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.

Main study parameters: 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 the Hospital Anxiety and Depression Scale (HADS)), care needs (Longer-term Unmet Needs after Stroke (LUNS)). 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)). Feasibility will be evaluated using qualitative methods, assessing fidelity, dose delivered, dose received, reach, recruitment and context. Cost-effectiveness will be determined by the EQ-5D-5L and service use (care consumption list).

Doel van het onderzoek

It is hypothesizes that case management after brain injury will be more effective in improving psychosocial well-being, preventing escalation of problems etc. (see primary and secondary outcomes for study parameters) than care as usual. Additionally, it is hypothesized that case management after acquired brain injury is cost-effective and feasible.

Onderzoeksopzet

T0 (baseline), T1 (6 months), T2 (12 months), T3 (18 months). For patients included in 2019, there will be T4 (24 months)

Onderzoeksproduct en/of interventie

Case management
The aim of case management for brain injury is to support patients' and caregivers' self-management of the consequences of brain injury and psychosocial well-being, to prevent (escalation of) problems and to facilitate timely access to appropriate services. Case management involves monitoring, identification, assessment, information, provision of support, referral and coordination.

Care as usual
The usual care differs depending on the regional structures and collaborations. In all regions, some form of care after brain injury is available for people who suffered from a stroke, but no structural care is provided for other types of brain injury. In addition, the care for stroke patients has a limited duration of 1 year. In contrast, case management provides care for a broad range of types of brain injury and has no fixed duration; intensity of case management fluctuates over time, following patient and caregiver needs.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, patients must meet all of the following criteria:
 Acquired brain injury objectified by medical specialist
 Aged 18 years or older
 Living in the community prior to the injury
 Discharged home or to temporary care facility after hospital
 Sufficient command of the Dutch language
 Access to a computer and the internet
 Willing and able to give informed consent

Primary caregivers (the informal caregiver who takes primary responsibility to care for the person with brain injury) of eligible patients are eligible when they are aged 18 years or older, have sufficient command of the Dutch language, have access to a computer and internet and are willing and able to give informed consent. Primary caregivers can only participate if the person with brain injury is participating. If the patient does not have a primary caregiver or if the caregiver is not willing to participate, this will not be an exclusion criterion for the patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential participant 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-10-2019
Aantal proefpersonen:	86
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8104
Ander register	METC azM/UM : METC 19-040

Resultaten