ABI-aftercare in motion: Multidisciplinary aftercare in the home environment in patients with acquired brain injury

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To improve aftercare for patients with ABI receiving outpatient rehabilitation, aimed at promoting an active lifestyle to prevent persistent complaints after ABI and poor HR-QoL.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56555

Source
ToetsingOnline

Brief title
ABI-motion

Condition

- Structural brain disorders

Synonym
acquired brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: Acquired brain injury, Aftercare, Implementation, Rehabilitation

Outcome measures

Primary outcome

The proportion of participants with ABI participating in the community buddy program (target 60%) and feasibility (rating of satisfaction) of the program will be calculated. In addition, it is investigated whether the program promotes an active lifestyle by exploring objectively measured physical activity, physical fitness and cognitive functioning of the intervention and control group.

Secondary outcome

Secondary, it is examined whether the patient-reported outcomes (physical activity, fatigue, anxiety, depression, cognitive complaints, coping, community integration, HRQoL, physical fitness, health care use, return to work), which are collected using validated questionnaires before and 3, 6 and 12 months after discharge from outpatient rehabilitation, change over time.

Study description

Background summary

Many people with acquired brain injury (ABI) experience difficulties in reintegration into their social life after discharge from the rehabilitation center. It is also known that people with ABI do not meet the Dutch physical activity guidelines; they have lower physical activity levels than healthy people and they have difficulty maintaining their physical fitness level reached during rehabilitation. An inactive lifestyle may lead to persistent complaints, such as fatigue, anxiety or depression, and may result in a poor

health-related quality of life (HR-QoL).

Study objective

To improve aftercare for patients with ABI receiving outpatient rehabilitation, aimed at promoting an active lifestyle to prevent persistent complaints after ABI and poor HR-QoL.

Study design

Care improvement study using a prospective mono-center cohort with a pre-post implementation study design. Implementation of an aftercare program that strengthens the cooperation between rehabilitation center and local patient support organisations in the community. The aftercare program integrates standard outpatient rehabilitation and community services, including: 1) standard brain education regarding long-term consequences of ABI, physical activity guidelines, and patient support organizations in the area, including a new, to be developped during the study, information leaflet; 2) new: introduction of the patient to a buddy from a patient support organisation during outpatient rehabilitation; 3) optional existing buddy support program (max 8 hrs) in the community towards an active lifestyle after rehabilitation discharge; 4) follow-up by the rehabilitation physician (standard care).

Study burden and risks

The implementation of the ABI-motion aftercare program involves integration of standard outpatient rehabilitation and existing aftercare initiatives. Participation in the ABI-motion program requires a certain time investment from patients. The buddy program provides a maximum of 8 hours support towards an active lifestyle. Participants with a contra-indication for moderate to vigorous exercise will be guided towards light activities, such as walking. Participation is voluntary. The total duration of the four patient measurements will be 6 hours, in which patients are tested (3 visits) and (online) questionnaires are completed (4 times), which may lead to temporary fatigue. Regular breaks are provided. Optional focus groups will be organized to evaluate the aftercare program, which will take 2 hours in total. Patients are asked to wear a Geneactiv wristwatch and to keep an electronic diary during a week along the baseline, 6 and 12 months visits to measure activity level over time in the home environment. Burden of wearing small activity monitors in daily life is low, based on experience in previous studies (e.g. MEC-2016-072). We expect that patients will benefit from the ABI-motion aftercare program, if they succeed in adopting an active lifestyle, in multiple aspects, including reduction of persistent complaints after ABI and improvement of HRQoL, and that the benefits of participation will outweigh the burden.

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

- Age at least 18 years
- Diagnosed with acquired brain injury (ABI)
- Follows an outpatient rehabilitation program for ABI in Rijndam Rehabilitation

Exclusion criteria

- Life expectancy < 1 year
- Incapacitated persons.

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):	12-04-2024
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-08-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT06058351
CCMO	NL85316.078.23