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

Published: 08-09-2023
Last updated: 24-06-2025

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

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment started |
| **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:** Collectebussenfonds

## Intervention

- Other intervention

**Keyword:** Acquired brain injury, Aftercare, Implementation, Rehabilitation

**Explanation**

N.a.

## Outcome measures

**Primary outcome**

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

**Secondary outcome**

Secondary, it is examined whether the patient-reported outcomes (physical<br>activity, fatigue, anxiety, depression, cognitive complaints, coping, community<br>integration, HRQoL, physical fitness, health care use, return to work), which<br>are collected using validated questionnaires before and 3, 6 and 12 months<br>after discharge from 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 in- and/or 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 in- and/or 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 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 in- and/or 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

### Scientific

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# Trial sites

## Trial sites in the Netherlands

Rijndam Revalidatie
Target size: 60

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Elderly (65 years and older)
Adults (18-64 years)

## Inclusion criteria

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

## Exclusion criteria

- Life expectancy < 1 year
- Incapacitated persons.

# Study design

## Design

| | |
|---|---|
| Study phase: | N/A |
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Other type of control |
| Primary purpose: | Health services research |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment started |
| Start date (anticipated): | 12-04-2024 |
| Enrollment: | 60 |
| Duration: | 12 months (per patient) |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Product type: | N.a. |

## IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
N.a.

# 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) |
| Approved WMO Date: | 11-06-2025 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC |

# 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 | NL85316.078.23 |
| ClinicalTrials.gov | NCT06058351 |
| CCMO | NL85316.078.23 |
| Research portal | NL-005771 |