# A pilot study to investigate the feasibility of an intervention based on the Arm Activity Tracker in stroke patients.

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The primary objective of this pilot study is to investigate the feasibility of an intervention based on the Arm Activity Tracker that aims to increase arm use during daily life conditions in stroke patients. Secondary objective is to obtain...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50142

**Source**
ToetsingOnline

**Brief title**
Feasibility of the Arm Activity Tracker.

### Condition

- Other condition

**Synonym**
CVA, stroke

**Health condition**

CVA / beroerte

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** feedback, rehabilitation, stroke, technology

## Outcome measures

### Primary outcome

The main study parameter is feasibility of the intervention based on the Arm Activity Tracker. The following feasibility parameters will be evaluated: 1) technical and operational feasibility of the device, 2) user acceptance, 3) adherence during the intervention.

Amendment:

- We will extend the evaluation of the feasibility parameter *user acceptance* by also determining how contextual, social and personal factors influence the user acceptance.

### Secondary outcome

Secondary study parameter is the difference in objectively measured arm use in daily life between the intervention condition and control condition.

Amendment:

- We will extend the secondary study parameter by also investigating the

patient characteristics that have an impact on the changes observed in the

objectively measured arm use in daily life.

# Study description

### Background summary

People that have suffered from a stroke frequently have an impaired function of the affected arm in daily life. Studies showed that a high intensity of arm exercise and high levels of arm use in daily life contribute to better arm functioning. However, currently there are no feasible and effective therapies available for stimulating arm use in daily life outside supervised therapy sessions. Therefore, we designed and developed an Arm Activity Tracker that provides objective feedback to stimulate people with a stroke to use the arm outside supervised therapy more frequently and intensively.

### Study objective

The primary objective of this pilot study is to investigate the feasibility of an intervention based on the Arm Activity Tracker that aims to increase arm use during daily life conditions in stroke patients. Secondary objective is to obtain preliminary estimates of the effectiveness of the intervention in increasing arm use for planning a larger randomized controlled trial. Since the Arm Activity Tracker has been designed and developed in a user-centered design and development process, we hypothesize that the intervention is feasible for application in a clinical setting.

Amendment:

To get more in-depth information, we will extend both objectives. We will extend the primary objective by also investigating how the context, social and personal factors influence the user interaction and use of the Arm Activity Tracker. We will extend the secondary objective by also determining the patient demographics for which the device is best suited.

### Study design

Randomized cross-over within-subjects design with an intervention and control condition. The order of the conditions will be balanced across participants.

Amendment:

To obtain the information for the extended aims, the control intervention is not needed. Instead, the study will be performed as a non-controlled explorative study.

**Intervention**

In the intervention condition participants will wear the system for two weeks while receiving direct feedback on arm use from the device and coaching on objectively measured arm use from a therapist. In the control condition participants will wear the system (to measure arm use) for two weeks without direct feedback from the device and without coaching on objectively measured arm use from a therapist. Before the intervention and control condition participants will wear the system for one week to measure baseline arm use level.

Amendment:
For the extended aims, we will skip the control condition.

**Study burden and risks**

It is important that the study is performed in stroke patients since the Arm Activity Tracker is specifically developed for people with a stroke. During the study we will ask patients to wear the Arm Activity Tracker during daily life activities. The activities that will be performed by the stroke patients are normal daily activities. Patients do not need to change their usual daily activities when participating in the study. Hence, for participants risks are not increased and the burden for participants is minimal.

# 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

- People that suffered from an ischemic or hemorrhagic unilateral stroke more than one week ago and less than six months ago.
- The stroke resulted in new reduced upper limb function on one side.
- Age: 18 years or older.
- Subjects have to be able to lift the paretic arm against gravity.
- Inpatient in rehabilitation institute.
- Participants have to be able to do on/off the devices on both wrists independently or with the assistance of a caregiver.
- Participants need to be able to provide informed consent as documented by signature.
- The patient is planned to stay in the rehabilitation institute for at least five weeks from the start of the study

Amendment:
To evaluate the extended aims, we aim to include 12 additional participants with same characteristics but that are:
-Getting outpatient treatment in a rehabilitation institute or planned to received outpatient treatment in a rehabilitation institute, for at least five weeks from the moment of inclusion.

## Exclusion criteria

- Severely reduced upper limb function which results in inability to lift the affected hand off the lap when sitting.
- Upper limb complications (e.g. frozen shoulder, severe upper limb pain).
- Participants cannot comply with the study as a result of significant cognitive, communication or visual impairment.

- Severely impaired sensation resulting in inability to sense vibro-tactile triggers from the arm activity tracker.
- Severely impaired vision which results in inability to read messages from the display of the hand activity tracker.
- Comprehensive aphasia which results in inability to read and/or understand messages from the display of the hand activity tracker.
- Potential non-compliance, such as known intolerance to the device material, major comorbidities (e.g. cardiopulmonary disease, orthopaedic disorders of the upper limb).
- Major depression.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 29-03-2021 |
| Enrollment: | 32 |
| Type: | Actual |

## Medical products/devices used

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| Generic name: | Arm Activity Tracker |
| Registration: | No |

# Ethics review

Approved WMO

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| Date: | 06-05-2020 |

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| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 10-11-2023 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 21-10-2024 |
| 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 |
|---|---|
| CCMO | NL71693.078.19 |