Plan Overview

A Data Management Plan created using DeiC DMP

Title: Intensive gait-assisted versus intensive step-assisted training after traumatic brain injury – a randomised cross-over feasibility trial.

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Funder: Danish Victims Fund

Template: DCC Template

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Project abstract:

Background: Early mobilisation after acquired brain injury is recommended to prevent secondary bedrest complications and induce positive neuroplastic changes in the central nervous system. Assistive technologies relieve therapists and increase intensity for patients with neurological injuries and physical limitations. However, only a few studies have investigated robot-assisted gait training in patients with moderate to severe traumatic brain injury. We aim to investigate the feasibility and safety of two procedures on intensive gait training and intensive stepping training, in patients with moderate to severe traumatic brain injury and disorders of consciousness.
Methods: A randomised cross-over feasibility trial including adults with moderate to severe traumatic brain injury. Patients are allocated to a protocol with either five days of intensive gait training followed by intensive stepping training or vice versa. The feasibility outcomes are inclusion rate, intervention completion rate, and safety measures. Exploratory outcomes are physiological, behavioural, and functional changes. Data recorded via the technologies will be used to describe intervention practices.
Discussion: The potential to increase intensity without increasing the demand for staff resources are of outmost importance. However, due to the expensive equipment and requirements for the operator, it seems necessary to investigate if a protocol with intensive gait training should be prioritised in the early rehabilitation stages from a scientific, and patient-centred perspective.

ID: 6447

Start date: 01-04-2024

End date: 31-03-2026

Last modified: 10-04-2024

Grant number / **URL:** 21-610-00138

Intensive gait-assisted versus intensive step-assisted training after traumatic brain injury – a randomised cross-over feasibility trial.

Data Collection

What data will you collect or create?

The project collects data during rehabilitation; at admission, screening, and enrolment and during the intervention period for 26 days (inclusive close out and follow up).
Patient data:
Contact information and demographics
Physiological data, clinician assessed
Clinical assessments scales, clinician assessed
Adverse events and reactions, from intervention start to follow up. Assessed during intervention and from the patient chart.
Accelerometery data from activity sensors
Training data from the investigated technology
Patient video recordings from two training sessions per participant.
The following data is created:
Physical activity intensity during intervention (training sessions). This is calculated from the patients age, weight, height, average heart rate and activity time.
Physical activity levels/categories during the two weeks of intervention between 7am and 10 pm. The data is created based on the accelerometery data.

How will the data be collected or created?

To ensure consistency and quality of the data collection I will make Standard Operation Procedures (SOP) for the data collection and the tools used (REDCap, paper data collection charts, video recordings). I will also test my data collection chart in a healthy participant.
The pre-planned REDCap project consists of separate data management instruments for *Contact information and demographics, baseline data, intervention data, cross over data, close out and follow up data*. The instruments will be verified by an experienced statistician and REDCap user (Markus Harboe Olsen) (in progress).
Demographics are collected directly from the patient chart into the REDCap instrument designed for this purpose.
Baseline, cross-over, close out, and follow up assessments (clinical assessment scales) are collected from the patient chart or bedside test. If collected from the patient chart, data are entered directly into REDCap. If collected at the bedside, a de-identified data collection chart is used. If it is not possible to enter the data into REDCap immediately after collection, it is kept in a locked cabinet, then destroyed when entered.
Physiological data are collected via CE approved hospital equipment during interventions and charted into a de-identified data collection chart. If it is not possible to enter the data into REDCap immediately after collection, it is kept in a locked cabinet, then destroyed when entered.
Adverse events and reactions are collected bedside during the interventions and between interventions from the patient chart. Data will be entered directly into REDCap after collection/registration.
Accelerometery data from activity sensors are uploaded to a cloud via Bluetooth (www.sens.dk) and data is de-identified. The data is then downloaded and analysed in a statistical programme and collapsed into physical activity levels.
Training technology data is automatically stored in the technology (.xlsx, csv). It is downloaded per participant to the PIs PC and, uploaded to REDCap and then deleted.
Video recordings from two training sessions per participant are stored in a locked cabinet until analyses. A detailed analysis plan will be uploaded beforehand.

Documentation and Metadata

What documentation and metadata will accompany the data?

N.A

Ethics and Legal Compliance

How will you manage any ethical issues?

The ethical committee has approved disclosure of patient information to the trial under the Danish Health Law (Sundhedsloven) §46 stk.1. “Team for Journaldata” has approved access the medical journals of eligible patients under §46 stk. 5 and that information is disclosed to the trial. All patient-related data and information will be handled according to the Danish law for the protection of personal data (“Databeskyttelsesforordningen” and “Databeskyttelsesloven”) and the Danish health law (“Sundhedsloven”). Consent to participate in the study also grants primary investigator, sponsor and controlling authorities access to the medical record to perform quality control or access health status of patients.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

NA

Storage and Backup

How will the data be stored and backed up during the research?

Data is stored in the REDCap depository hosted by Capital Region Denmark, Copenhagen. If data in paper form is not entered into REDCap immediately after collecting it, it is secured in a locked cabinet. Video recordings are kept in a locked cabinet. See also “**How will the data be collected or created?**”

How will you manage access and security?

The PI (VW) and MHO have access to REDCap. The cabinet is only accessed by the PI.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

NA

What is the long-term preservation plan for the dataset?

Data will be kept until the analysis has been completed and published. After, the fully anonymised data set is preserved in an onlie data-repository.

Data Sharing

How will you share the data?

If possible – due to the participants all data will be public available either as a supplementary data set or via a data depository site
If not - data will be available upon request eg. for meta research .

Are any restrictions on data sharing required?

N.A

Responsibilities and Resources

Who will be responsible for data management?

The PI (VW) is responsible.

What resources will you require to deliver your plan?

Access to REDCap, L.drev, locked cabinet, all of which I have.
I will collect, analyse, and report data according to a pre-planned trial protocol, SOPs, and a statistical analyses plan (SAP). The trial is registered at clinicaltrials.gov. The trial protocol is published, preferably as open access or at least in the Open Science Framework www.osf.io. The SAP is made public available in the Open Science Framework www.osf.io. Any differences between protocol and final manuscript will be disclosed and all results, negative, inconclusive or positive, will be published.