Plan Overview

A Data Management Plan created using DMPonline

Title: Internet-based Vestibular Rehabilitation Versus Standard Care After Acute Onset Vertigo

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Project abstract:

Acute onset vertigo is common and entails much suffering with persisting symptoms at 3 months after onset in up to half of those afflicted. Vestibular rehabilitation to aid recovery is not readily available. The purpose of this study was to investigate the effects on vertigo symptoms of a 6-week online vestibular rehabilitation tool compared with standard care (written instructions leaflet) after acute onset vertigo.

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Internet-based Vestibular Rehabilitation Versus Standard Care After Acute Onset Vertigo

General Information

Project Title

Internet-based Vestibular Rehabilitation Versus Standard Care After Acute Onset Vertigo

Project Leader

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Registration number/corresponding, date and version of the data management plan

8-Dec-2025

Version

Version 1.0

Date

8-Dec-2025

Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

Data were collected using an eCRF (REDCap) during the course of the clinical randomized controlled study. Only newly generated data were used in the study. Randomization were done in the eCRF.
At site, data were collected directly from study participant, from measurements and from medical records. All study site data collection were performed through REDCap apart from site specific screening lists and subject identification lists which were kept, managed, and stored in the investigation site file at the study site, in a manner that enabled correct reporting, interpretation, and

verification. Primary data collection were also done on paper before data entry into the eCRF, for example the EQ-5D-3L questionnaires or when worksheets were needed. A list specifying where source data were located was established at each study site before study start.

All activity in the eCRF system were logged and time stamped.

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

Clinical and technical parameters relating to balance system function from n=184 study participants during 3 visits and 2 telephone contacts over the course of 12 months. Data pertains to health variables, images of testing set up, videos of eye-motor function.

Subjects who participated in the study were coded with a specific study identification number. All subjects were registered in a subject identification list that connects the subject's name and personal number with a study identification number

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

Health data were collected during the research project and stored in eCRF REDCap and may be exported in structured data sheets (.csv). Images (.jpg), ErgoExposure data (.zip) and videos (.avi) are uploaded and stored in the eCRF. An annotated CRF (Codebook) listing the instruments and variables included in the study with their generic names, labels and attributes is stored in the trial master file.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

The eCRF is tested, validated and approved before the eCRF went into production and the first study participant was included in the study, to ensure compliance with the protocol, logical order of variables and functionality. All sites were monitored by an external monitoring organization during the course of the project. The monitoring includes source data verification and remedy of missing data. Monitor locked individual instruments continuously throughout the study after each monitoring visit.

Study data were reviewed for completeness by the data monitoring unit through eCRF review every sixth months and missing data queries sent out to the local PIs. After the last participant underwent the 12 months follow-up phone call any remaining queries were resolved and closed, followed by database lock.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

REDCap is a web-based data collection tool provided by Umeå University to collect clinical research data. Data is stored on a secure dedicated server with firewall at Umeå University. The server is maintained by the central IT-unit at Umeå University and backed-up daily.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

The traffic between the web browser and REDCap is encrypted. Individual login with UmU-id and multi factor authentication (MFA) is needed for access to the eCRF. Only personnel directly involved in data collection and/or management are granted access to the project and user privileges are adjusted according to the role in the study. An index of persons with access is displayed on the project dashboard within the eCRF.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

The clinical investigation was conducted in accordance with the clinical investigation plan, the ethical principles of the Declaration of Helsinki, the principles of ISO 14155:2020 and current national and international regulations governing this clinical investigation.

Before data was handled by any other organization, appropriate agreements and/or other documentation were established, to ensure that the data processing is performed in accordance with the provisions of the General Data Protection Regulation (EU ordinance 2016/679, GDPR) and other relevant legislation, before any data transfer takes place. The study datafiles were after export from the eCRF be archived on a secure local server at Umeå University (Skyddade document) which can only be accessed by invited UmU-id users using their password and MFA. Participating researchers who need access to datafiles are invited to the secure server by having their UmU-id added by the project sponsor Jonatan Salzer. Any copies of files used during the analyses are manually registered in a log-file on the secure server and deleted locally after use, and uploaded to the server after use. Access for other than participating researchers may be made possible after request, which will be assessed according to a legally compliant procedure.

All information processed by the sponsor will be pseudonymized and identified with a study-ID.

Intellectual property rights: As the data contains sensitive and personal data it will not be made openly available (does not require any use-information through licenses).

How is correct data handling according to ethical aspects safeguarded?

The clinical investigation was conducted in accordance with the clinical investigation plan and the ethical principles of the Declaration of Helsinki. The study has been reviewed and approved by the Swedish ethical review authority (2021-01766)

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

The clinical investigation was registered in a publicly accessible database (https://clinicaltrials.gov/study/NCT05056324) before the start of recruitment activities and the content are be updated throughout the conduct of the clinical investigation and the results will be entered at completion of the clinical investigation.

A clinical investigation report will be prepared within one year of the end of the clinical investigation or within three months of the early termination or temporary halt, irrespective of the results. An easily understandable summary will also be prepared. The clinical investigation report and summary will be submitted to the Swedish Medical Products Agency.

The sponsor will, together with the local PIs, prepare and submit a scientific report of the clinical investigation results for publication in a scientific journal within two years of the end of the clinical study.

Data access and reuse will be embargoed until all pre-planned analyses have been performed and reports published by the study group. These analyses will be performed in an as timely manner as possible and care will be taken nog to delay any analyses and publications. An upper limit of 10 years embargo from database lock will be applied.

A metadata description was published in DORIS (the *SND Data Organisation and Information System*) at the Swedish National Data Service (SND): https://doi.org/10.71540/jvqj-vp44. The availability level for data was set at: "Available upon request" and the project sponsor Jonatan Salzer is set as the contact person.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

The PIs and sponsor will maintain the essential clinical investigation documents in the investigation site files archive and sponsor files archive, respectively. The sponsor shall keep all documentation and data for at least 10 years after the rehabilitation tool removal from the market. After this the prefect of the department (Clinical Science) will be responsible for making a deletion decision. This decision will be in written and archived. The site PIs will archive all local study documentation for at least 10 years or as long as stipulated by the local institution.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

No

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

The metadata description and information to data access has been published using the Catalogue of the Swedish National Dataservice (SND). The publication of the description in SNDs catalogue is identified with a DOI (https://doi.org/10.71540/jvqj-vp44), which makes the data findable and give

access information which makes the dataset as fair as possible.

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

During the research project sponsor Jonatan Salzer and data manager Gabriel Granåsen are responsible for data management. At Umeå University the department of Clinical Science is in charge of archiving the research data after the project has been finished.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

The use of the REDCap eCRF data collection and archiving resource is associated with a running cost for the individual research group. This running cost is financed by the institution in case of research group failure. At Umeå University archiving costs are under the responsibility of the institution, as mentioned above.