Plan Overview

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Title: Feasibility testing a double-blinded randomised cross-over trial as an independent evaluation of use of the Exopulse Mollii electrostimulation suit for people with ataxia and hereditary spastic paraplegia (Short title = Mollii Suit Feasibility Study)

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Template: Health Research Board DMP Template

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Project abstract:

Background:
Hereditary ataxias and hereditary spastic paraplegia (HSP) are rare, progressive neurological disorders associated with impaired balance, mobility, functional independence, fatigue, and reduced quality of life. Current treatment is largely symptomatic, and there is limited high-quality evidence supporting rehabilitation or neuromodulation interventions. The Exopulse Mollii® suit is a CE-marked wearable neuromodulation device that delivers low-frequency electrical stimulation through integrated textile electrodes. Although emerging evidence suggests potential benefits in neurological conditions characterised by spasticity and motor impairment, no randomised controlled trials have evaluated the device in hereditary ataxia or HSP.

Aim:
To determine the feasibility, acceptability and safety of delivering a remotely administered, home-based, double-blind, randomised sham-controlled crossover trial of the Exopulse Mollii® suit in people with hereditary ataxia and HSP and to evaluate the suitability of candidate outcome measures for a future definitive trial.

Methods:
The SUIT Study is a Phase 2a feasibility randomised crossover trial recruiting 48 participants (24 with hereditary ataxia and 24 with HSP). Participants will be randomised to receive either active stimulation followed by sham stimulation, or sham stimulation followed by active stimulation, with each intervention block lasting four weeks and separated by a four-week washout period. All participants will be followed for a further two weeks. Intervention delivery is home-based, with an initial in-person fitting visit and subsequent remote assessments undertaken by blinded assessors. Feasibility outcomes include recruitment, retention, adherence, assessment completion, acceptability, burden, safety and successful blinding. Secondary and exploratory outcomes include functional independence (mFIM), ataxia severity (SARA/Bal-SARA), spasticity, upper limb function, fatigue, quality of life, and remote inertial sensor-based measures of balance, movement and tone. Qualitative interviews and participant diaries will explore user experiences and perceptions of meaningful change.

Analysis:
As a feasibility study, analyses will focus on descriptive evaluation of progression criteria relating to recruitment, retention, adherence, data completeness and safety. Quantitative findings will be integrated with thematic analysis of qualitative data to inform intervention refinement, outcome selection and trial design for a future definitive effectiveness study.

Discussion:
This study addresses an important evidence gap regarding independent evaluation of the Exopulse Mollii® suit in hereditary ataxia and HSP. Findings will determine whether progression to a larger definitive trial is justified and will provide essential information regarding trial delivery, outcome selection, safety, and participant acceptability in geographically dispersed rare disease populations.

ID: 216472

Start date: 05-04-2027

End date: 31-07-2028

Last modified: 25-11-2026

Grant number / URL: https://www.ataxia.org.uk/research-project/feasibility-testing-a-double-blinded-randomised-cross-over-trial-as-an-independent-evaluation-of-use-of-the-exopulse-mollii-electrostimulation-suit-for-people-with-ataxia/

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Feasibility testing a double-blinded randomised cross-over trial as an independent evaluation of use of the Exopulse Mollii electrostimulation suit for people with ataxia and hereditary spastic paraplegia (Short title = Mollii Suit Feasibility Study)

Data description and collection or re-use of existing data

How will new data be collected or produced and/or how will existing data be re-used?

New data will be generated as part of the Mollii Suit Feasibility Study, a remotely delivered, double-blind randomised sham-controlled crossover feasibility trial involving people with hereditary ataxia and hereditary spastic paraplegia (HSP). Data collection will include demographic and screening information, participant-reported outcome measures, clinical assessment data, adverse event reporting, qualitative interview data, participant diaries, and wearable sensor-derived movement data.

Clinical and functional outcome measures will include the Motor Functional Independence Measure (mFIM), Scale for the Assessment and Rating of Ataxia (SARA/Bal-SARA), Modified Ashworth Scale, selected components of the Action Research Arm Test (ARAT), Fatigue Severity Scale (FSS), EQ-5D, and qualitative end-of-study interviews.

Instrumented movement data will be collected using Movella XSens inertial measurement sensors during assessments of sitting and standing balance, upper-limb reaching performance and Wartenberg pendulum testing. Data will be captured using the manufacturer's software and exported to secure University of Plymouth OneDrive storage for subsequent processing and analysis using Microsoft Excel and University-licensed MathWorks MATLAB software.

Assessment recordings will be stored within a secure University of Plymouth Panopto workspace with access restricted to authorised members of the research team (Chief Investigator, Co-Investigator and Research Associate) for the purposes of monitoring assessment fidelity and evaluating the success of blinding procedures.

Questionnaire, assessment and trial management data will be recorded using electronic Case Report Forms (eCRFs) and secure University of Plymouth Microsoft 365 systems, including Forms, Teams and OneDrive. Quantitative analyses will be undertaken using IBM SPSS Statistics or Mathworks Matlab.

Qualitative interviews will be automatically transcribed within Microsoft Teams and checked for accuracy against the original recording. Transcripts will be pseudonymised through removal of direct personal identifiers and stored as participant-coded Microsoft Word documents within University of Plymouth OneDrive. Thematic analysis will take place in University of Plymouth licenced NVivo software. Audio and video recordings will be retained only for the minimum period necessary to complete transcription, quality assurance and blinding assessments, after which they will be securely deleted in accordance with the University of Plymouth Research Data Management Policy and study-specific retention procedures.

The study does not rely on the re-use of existing research datasets. Existing NHS records may be consulted only for the purposes of confirming eligibility where participants provide permission and are known to specialist clinics. These records will not be incorporated into the research dataset beyond eligibility verification.

Community-recognised and clinically validated outcome measures will be used throughout the study. These include established neurological rehabilitation measures such as the mFIM, SARA/Bal-SARA, ARAT, FSS and EQ-5D. Standard operating procedures, assessor training and predefined assessment protocols will be used to maximise consistency, reproducibility and data quality across study sites and time points. Data provenance will be maintained through the use of unique participant study identification numbers, electronic case report forms, version-controlled study documentation and audit trails within University of Plymouth systems. All datasets will be labelled with participant ID, assessment timepoint, date of collection, assessor identity and file version where applicable. A separate encrypted participant identification log linking personal identifiers to study IDs will be stored securely and accessible only to authorised study personnel.

What data (for example the kind, formats, and volumes), will be collected or produced?

Consent forms and participant contact information will be collected and shared with the authorised Remotion Industries representative, Richard Welch, solely for the purposes of arranging home visits, fitting, training and assessment associated with delivery of the Mollii Suit intervention. Data sharing will be limited to the minimum information necessary to undertake these activities and will be conducted in accordance with the study privacy notice, participant consent and applicable data protection legislation.

This data will be collected in online forms:

Mollii Suit Feasibility Study - Consent sheet – Fill in form https://forms.cloud.microsoft/e/Csw5QBiMGM

Mollii Suit Feasibility Study - Consent sheet (SUPPORTER) – Fill in form https://forms.cloud.microsoft/e/fNKZRZLn8L

Key Contacts Mollii Suit Feasibility Study_372009 (Version 1.0, Date 24/11/2026) – Fill in form https://forms.cloud.microsoft/e/mQY9zmxWRi

Adopting a two-step consent process, wet signatures will be added to online prepared and printed consent taken verbally. Wet signatures will be added on the home visit witnessed by the Remotion representative. Hard copies of the now paper consent forms will be securely stored with patient records at Remotion Industries. These will be posted to the chief investigator at the study end date by signed Royal Mail delivery.

The study will generate both quantitative and qualitative data.

Quantitative data will include participant demographics, eligibility screening information, intervention adherence records, adverse events, and outcomes from validated clinical and participant-reported measures including the Motor Functional Independence Measure (mFIM), Scale for the Assessment and Rating of Ataxia (SARA/Bal-SARA), Modified Ashworth Scale, selected components of the Action Research Arm Test (ARAT), Fatigue Severity Scale (FSS), EQ-5D and participant diary data.

This data is pseudonymous and is collected in the following online forms:

Suit parameter selection: Remotion Stimulation Parameter Log_Mollii Suit Feasibility Study_372009 – Fill in form https://forms.cloud.microsoft/e/Y7ZjNyfVtu

Standard Operating Procedure Log: Process data (anonymous but including screening, time and date scheduling, equipment logging, adverse event reporting, withdrawal requests): SOP Mollii Suit Feasibility Study_372009 (Version 1.0, Date: 25/11/2026) – Fill in form https://forms.cloud.microsoft/e/ssSKiHSBb8

Assessment data: Assessment Form_Mollii Suit Feasibility Study_372009 (Version 1.0, Date: 24/11/2026) – Fill in form https://forms.cloud.microsoft/e/Rqd7JgB066

Daily diary data: Daily Diary_Mollii Suit Feasibility Study (Version 1.0, Date: 24/11/2026) – Fill in form https://forms.cloud.microsoft/e/BUzt8SAsB9

Supporter feedback (end-exit): Supporter Feedback Survey_Mollii Suit Feasibility Suit_372009 – Fill in form https://forms.cloud.microsoft/e/dAPtisSj54

Instrumented movement assessments will generate inertial sensor data relating to balance, postural sway, upper limb movement and Wartenberg pendulum testing as .csv exports from the Movella cloud App (copies will exist on participant's own Movella App and .csv files stored in the phone's files directory if selected). CSV files will be downloaded to the OneDrive research data asset account of Dr Lisa Bunn for onward analysis.

Qualitative data will include semi-structured end-of-study interviews exploring participant experiences, acceptability, perceived benefits, challenges associated with intervention use and recommendations for future research. Interview transcripts will be pseudonymised prior to analysis.

Data will be stored in a range of formats according to their purpose:

Data type	Format(s)
Electronic forms (see above list)	XLSX, CSV [Microsoft Forms]
Electronic forms as consent sheets and key contact information	Individual responses (consents and key contacts per person) exported as .PDF and sent by email from mollii@plymouth.ac.uk to richardwelch@remotion.co.uk [Microsoft Forms]
Statistical analysis datasets (imported from assessment forms, daily diaries and sensor data)	XLSX, CSV, MAT, SAV [SPSS, MATLAB]
Supporter surveys	XLSX [Microsoft 365, Excel]
Sensor data	Proprietary Movella XSens formats and CSV exports* [MATLAB]
Qualitative transcripts	DOCX [Nvivo]
Study documentation and SOPs	XLSX, CSV [Microsoft 365 Excel]
Participant daily diaries	XLSX, CSV [Microsoft 365 Excel]
Audio/video recordings	MP4 [Teams, Panopto]
Email correspondence and scheduling appointments	Contained within Outlook mollii@plymouth.ac.uk email and calendar account
Hard copy consent forms with wet signatures	Held in Remotion patient records until trial completion when sent to Dr Lisa Bunn to securely store at the University of Plymouth
Remotion assessment notes	Clinical and operational records maintained independently by Remotion Industries for routine service delivery purposes are not part of the research dataset and will not routinely be transferred to the research team.

Open and widely used file formats (CSV, PDF and DOCX) will be used wherever practicable to maximise interoperability, accessibility and long-term preservation. Proprietary formats (e.g. MATLAB MAT files, SPSS SAV files and native Movella XSens files) are required for efficient processing and analysis but key analytical datasets will be retained in CSV format to support future accessibility and potential reuse. Format choices reflect established practice within neurological rehabilitation research, staff expertise and compatibility with University of Plymouth licensed software systems.

The study aims to recruit approximately 48 participants, retaining 40 to completion and is expected to generate a relatively modest data volume. Storage limits are within available staff allocation within the OneDrive system. Video recordings will be deleted following completion of transcription, quality assurance and blinding assessments in accordance with the study protocol and University retention policy. Total study data are anticipated to occupy less than 100 GB of storage, with the largest component being temporary video recordings used for interview transcription and blinding assessment procedures.

Data likely to have value for future research include de-identified participant-level outcome data, metadata describing assessment procedures, analysis code and study documentation. Subject to participant consent, ethical approvals, sponsor requirements and data protection legislation, these materials may be shared through an appropriate controlled-access repository following study completion. Individual-level interview recordings, identifiable data and participant identification logs will not be shared because disclosure could compromise participant confidentiality and because the participant population comprises individuals with rare neurological conditions, increasing the risk of re-identification even following anonymisation.

Research outcome datasets will be stored separately from participant identifiers, with linkage maintained through a secure participant identification log accessible only to authorised study personnel. Specifically, this form will be the sole form to connect participant codes with a name: Mollii Suit Feasibility Study - Consent sheet – Fill in form https://forms.cloud.microsoft/e/Csw5QBiMGM Mollii Suit Feasibility Study - Consent sheet – Fill in form https://forms.cloud.microsoft/e/Csw5QBiMGM

Documentation and data quality

What metadata and documentation (for example the methodology of data collection and way of organising data) will accompany data?

Metadata is largely planned aprior with the use of Microsoft Forms as our principal data input method. Supporting documentation will be created throughout the study to ensure that datasets can be understood, interpreted and, where appropriate, reused by other researchers.

Each dataset will be accompanied by descriptive metadata including:

- Study title and protocol version.
- Dataset title and description.
- Data collection date and study timepoint.
- Variable names, definitions and permitted values.
- Units of measurement.
- Outcome measure scoring procedures.
- Data collection method and instrument used.
- Software used for data capture, processing and analysis.
- File format and version information.
- Dataset creator and date of creation.
- Version history.

Data will be organised within a secure University of Plymouth OneDrive environment using a predefined folder structure, with separate directories for:

- Study management documentation.
- Consent and participant administration records.
- Quantitative assessment data.
- Wearable sensor data.
- Qualitative interview data.
- Statistical analysis datasets.
- Study outputs and dissemination materials.
- Individual participant case reports generated from study assessment data to support end-of-study feedback discussions following unblinding.

Research outcome data will be stored separately from participant identifiers, with linkage maintained through a secure participant identification log accessible only to authorised study personnel.

A standard file naming convention will be used throughout the project. File names will incorporate participant study ID, assessment timepoint, data type and date of collection where appropriate (e.g., CP017_T2_SensorData_20270315.csv). Identifiable information will not be included within research dataset filenames. The prefix PP in our study logs refers to recruitment/screening flow data relating to potential participants. CP stands for consented participant.

Version control will be maintained through systematic file version numbering and dated study documentation. Master datasets will be stored separately from working analysis files to preserve data integrity and facilitate audit and reproducibility. Changes to study documents, databases and analysis scripts will be documented through version-controlled file histories within University of Plymouth Microsoft 365 systems.

Supporting documentation required for interpretation and reuse of the data will include:

- Participant Handbook.
- Study protocol.
- Statistical Analysis Plan.
- Standard Operating Procedures.
- Data dictionary/codebook describing variables and coding structures.
- Remotion stimulation parameter log.
- Assessment form and scoring procedures.
- Remotion home visit checklist.
- Daily diary.
- Supporter feedback survey.
- Sensor processing and analysis workflows.
- Qualitative coding framework and methodology description.

Quantitative datasets will include variable labels, coding instructions, units of measurement and details of any derived variables. Analysis scripts developed in MATLAB, SPSS syntax files and NVivo project documentation will be retained where appropriate to support transparency and reproducibility.

A metadata register will be maintained describing each Microsoft Form used within the study, including purpose, version number, variables collected, date of implementation and any subsequent amendments.

No disciplinary metadata standard is currently established for the combination of clinical feasibility outcomes, wearable sensor

assessments and qualitative interview data collected within this study. Therefore, metadata will follow recognised research data management good practice and repository requirements at the point of archiving. Documentation will be produced in open and widely accessible formats (PDF, CSV and TXT where appropriate) to maximise long-term accessibility and reuse.

Metadata will therefore follow University of Plymouth Research Data Management guidance and repository-specific requirements at the point of archiving. Remotion Industries will maintain paper source documentation for operational and clinical purposes alongside study-specific electronic data capture forms. These records will be managed in accordance with Remotion Industries' information governance procedures.

What data quality control measures will be used?

Multiple quality control measures will be implemented throughout the study to ensure the accuracy, consistency, completeness and reliability of the data collected.

Research data will be entered directly into Microsoft Forms at the point of collection to minimise transcription errors associated with manual data entry. Remotion representatives may choose to use printed paper versions of the assessment form in addition to their own documentation on home visits. The chief investigator will prompt the representative if this is not uploaded to the digital data collection form within 72 hours of the visit to complete this task.

Forms incorporate predefined response options, mandatory fields, standardised variable naming conventions and restricted response formats and have been extensively piloted with test case scenarios. Automated date and time stamping will support auditability and quality assurance but date of collection is also in some key parts of the forms where reporting may be delayed to an actual activity that has taken place (e.g. Remotion upload of assessment from the home visit).

All study personnel will receive protocol-specific training prior to participant recruitment. Standard Operating Procedures (SOPs), assessor guidance documents, scripted assessment procedures and standardised data collection forms will be used to promote consistency across all assessment timepoints and participants. The same assessment procedures will be used throughout the study unless protocol amendments are formally approved.

Clinical outcome measures selected for the study are established and validated instruments widely used within neurological rehabilitation research, including the Motor Functional Independence Measure (mFIM), Scale for the Assessment and Rating of Ataxia (SARA/Bal-SARA), Action Research Arm Test (grasp sub-scale) (ARAT), Modified Ashworth Scale, Fatigue Severity Scale (FSS) and EQ-5D. Established scoring guidance will be followed for all outcome measures.

The intervention delivery process will be standardised through use of the Remotion stimulation parameter log, home visit checklist and intervention training procedures.

Wearable sensor assessments using Movella XSens technology will follow predefined assessment protocols (instrumented parts of the SARA and Wartenburg's Pendulum Test and ARAT-grasp), with positioning guidance and analysis workflows to maximise measurement consistency and reproducibility.

Data quality checks will be conducted throughout the study. These will include routine reviews for completeness, missing values, implausible responses, protocol deviations and inconsistencies between datasets. Queries identified during quality review will be documented and resolved where appropriate.

Source datasets (Microsoft Forms exports) will be retained separately from cleaned and analysis-ready datasets to provide a complete audit trail.

Assessment recordings will be reviewed by authorised members (Dr Lisa Bunn or Prof Jon Marsden) of the research team to monitor assessment fidelity and evaluate the effectiveness of participant and assessor blinding procedures. Qualitative interview transcripts generated through Microsoft Teams transcription will be checked against the original recordings before analysis. Any transcription errors, omissions or personally identifiable information will be corrected or removed prior to coding.

Data minimisation principles will be applied throughout the study, collecting only information necessary to address the research objectives and regulatory requirements. Research datasets will be pseudonymised using unique participant study identification numbers. Participant identifiers will be stored separately from research data within a restricted-access identification log. Pseudonymisation procedures will reduce disclosure risk while preserving sufficient information to permit longitudinal analysis across multiple study timepoints.

Version control procedures will be used for study documents, analysis scripts, data dictionaries and derived datasets. Analysis workflows developed in MATLAB, SPSS and NVivo will be retained where appropriate to support transparency, reproducibility and verification of findings.

Given the feasibility nature of the study, data quality monitoring will focus on ensuring completeness, acceptability and usability of study processes while also informing refinements required for a future definitive trial.

Storage and backup during the research process

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

Primary Research Storage

Data and metadata generated during the study will be stored primarily within secure University of Plymouth information systems. University-managed Microsoft 365 services (OneDrive, Teams, Outlook and Forms) will serve as the principal research data environment. All elements have been created in the domain of Lisa Bunn (chief investigator). These systems are institutionally managed, access-controlled and subject to University backup, security and disaster recovery procedures.

The primary storage location for research data will be a dedicated University of Plymouth OneDrive study directory maintained by the Chief Investigator (Lisa Bunn). Research data, metadata, analysis files, study documentation and supporting materials will be organised within a predefined folder structure with access restricted to authorised study personnel (General | Mollii Suit Feasibility Study - A Microsoft Teams site owned by Lisa Bunn) . Data access permissions will be limited to co-investigators and the research associate and reviewed periodically and amended as required throughout the study.

Data Collection Systems

Microsoft Forms will act as the master data collection platform for study questionnaires, assessment forms, participant diaries, supporter feedback and study process logs. Data submitted through Forms are stored within the University's Microsoft 365 environment and can be exported directly to analysis datasets without manual transcription. Source data exports will be retained separately from cleaned and analysis-ready datasets to preserve a complete audit trail.

Consent Documentation and Identifiable Participant Information

Personally identifiable information, including participant contact details and consent documentation, will be stored separately from research outcome data. A participant identification log linking participant identities to study IDs will be maintained in a restricted-access location and accessible only to authorised members of the study team (Dr Lisa Bunn, Prof Jon Marsden, Gabriela Gonzalez Chan as the Research Associate).

Consent documentation and key contact information required for home visit scheduling will be transmitted via authorised University of Plymouth and Remotion Industries email accounts and retained only by personnel directly involved in participant scheduling and intervention delivery. Data sharing will be limited to the minimum information necessary to facilitate study procedures.

Signed consent documentation generated through the study consent process will be maintained securely by Remotion Industries during the study period. Original signed consent forms will be transferred securely to the Chief Investigator at study completion and retained in accordance with University of Plymouth research governance and retention requirements.

Assessment Recordings and Qualitative Data

Assessment recordings and interview recordings will initially be captured within Microsoft Teams and subsequently transferred to a secure University of Plymouth Panopto workspace (to avoid risk of automatic deletion of recordings after 90 days, now a standard for all Teams recordings at the University of Plymouth). Access will be restricted to authorised members of the research team for quality assurance, blinding assessment and transcription purposes.

Audio and video recordings will be retained only for the minimum period necessary to complete transcription, quality assurance and blinding checks, after which they will be securely deleted in accordance with the study protocol and University retention procedures.

Qualitative interview transcripts, once pseudonymised, will be stored within the study OneDrive environment and analysed using University-licensed NVivo software.

Sensor and Device Data

Wearable sensor data collected using Movella XSens technology will initially be processed through the manufacturer's cloud-based platform before export to University-managed OneDrive storage.

Temporary copies of sensor data may exist within the participant's Movella application and on data collection devices during transfer and processing. These files will not constitute the primary research record. Downloaded CSV files and processed datasets will be stored within secure University systems, with local copies deleted following successful transfer and verification and participant trial completion.

Analysis Data and Documentation

Analysis datasets and derived outputs generated using Microsoft Excel, MathWorks MATLAB, IBM SPSS Statistics and NVivo, licenced by the University, will be stored within the secure University of Plymouth environment.

Version-controlled copies of analysis scripts, codebooks, data dictionaries, study documentation and methodological guidance will be retained throughout the study to support transparency, reproducibility and auditability.

Backup and Recovery

The study will utilise University of Plymouth managed Microsoft 365 systems, which provide institutional backup, redundancy and disaster recovery arrangements. Research data will therefore exist across multiple managed locations throughout the study lifecycle, including Microsoft Forms, OneDrive, Teams and associated institutional backup systems.

Source data will be retained separately from cleaned and analysis-ready datasets to preserve audit trails and facilitate recovery where necessary. No research data will be routinely stored on personal laptops, personal cloud storage platforms, USB devices or other unmanaged storage media.

Where temporary local storage is unavoidable during data collection or transfer (under exceptional circumstances e.g. Microsoft outage and a phone call came in about an adverse event that needed logging), data will be transferred to University-managed systems at the earliest opportunity and local copies removed once successful transfer has been confirmed.

Security and Access Control

Access to research data will be controlled through University authentication processes, password-protected systems and role-based permissions. Research outcome data will be stored separately from identifiable participant information wherever possible.

These arrangements provide secure storage, controlled access, institutional backup and resilience against accidental loss, corruption or unauthorised access throughout the study lifecycle.

How will data security and protection of sensitive data be taken care of during the research?

Identified Risks

The study involves collection of identifiable personal data, special category health data, assessment recordings, interview recordings and participant contact information from individuals with hereditary ataxia and hereditary spastic paraplegia. The

principal risks are:

- Unauthorised access to identifiable participant data.
- Accidental disclosure of health information.
- Re-identification of participants from research datasets.
- Data loss resulting from technical failure or accidental deletion.
- Data transfer risks associated with collaboration between the University of Plymouth and Remotion Industries.
- Disclosure of participant allocation during this double-blind sham-controlled feasibility study.

Given the rare disease populations involved, particular care will be taken to minimise the risk of participant re-identification from shared datasets or dissemination outputs.

Management of Sensitive and Identifiable Data

The study will operate according to the principles of UK GDPR, the Data Protection Act 2018 and University of Plymouth information governance policies.

Only the minimum amount of personal information required to conduct the study will be collected. Identifiable information will be stored separately from research outcome data wherever possible.

Participants will be assigned unique study identification numbers. Research datasets used for analysis will be pseudonymised, with direct identifiers removed. A separate participant identification log linking participant identities to study IDs will be maintained in a restricted-access location and accessible only to authorised study personnel.

Interview transcripts will be reviewed and pseudonymised before analysis. Names, locations and other directly identifying information disclosed during interviews will be removed.

Access Control

Access to study data will be restricted according to role and study responsibility.

The following personnel will have access to identifiable participant information where required for study delivery:

- Dr Lisa Bunn (Chief Investigator).
- Prof Jon Marsden (Co-Investigator).
- The study Research Associate.
- Richard Welch and authorised personnel at Remotion Industries where participant contact details are required for intervention scheduling, suit fitting, home visits or related study procedures.

Access will be granted on a least-privilege basis, providing individuals only with the information necessary to fulfil their study responsibilities.

Research datasets, analysis files and study documentation stored within University of Plymouth systems will be protected through institutional authentication, password protection and role-based access controls.

Collaborative Working with Remotion Industries

As part of study delivery, consent documentation and participant contact information will be shared with authorised personnel at Remotion Industries to facilitate home visits, intervention fitting and assessment procedures.

Information sharing will be limited to the minimum information necessary to support study activities. Research outcome datasets will remain under the control of the University of Plymouth and will not routinely include direct participant identifiers.

Remotion Industries will maintain its own secure operational records and paper source documents in accordance with its information governance procedures. These records will not form part of the routinely shared research dataset.

Data Recovery and Continuity

The study will primarily utilise University of Plymouth managed Microsoft 365 systems, including OneDrive, Teams, Outlook and Forms. These systems benefit from institutional backup, redundancy and disaster recovery arrangements.

Where accidental deletion, corruption or technical failure occurs, recovery procedures available through University-managed systems will be utilised. Source datasets will be retained separately from cleaned and analysis-ready datasets to support recovery, verification and reconstruction if required.

Retention of source data, audit trails, version histories and analysis scripts will further support recovery and reproducibility in the event of an incident.

Secure Handling of Recordings and Sensor Data

Assessment recordings and interview recordings will be stored within secure University of Plymouth Teams and Panopto environments with restricted access permissions.

Audio and video recordings will be retained only for the minimum period necessary to complete transcription, blinding assessment and quality assurance activities before secure deletion in accordance with study procedures.

Wearable sensor data collected using Movella XSens systems will be transferred to University-managed storage as soon as practicable following collection. Downloaded datasets stored within University systems will be considered the primary research record.

Institutional Policies and Regulatory Compliance

The study will comply with:

- UK General Data Protection Regulation (UK GDPR).
- Data Protection Act 2018.
- University of Plymouth Research Data Management Policy.
- University of Plymouth Information Security and Information Governance policies.
- University of Plymouth Ethics and Research Governance procedures.
- Sponsor (University of Plymouth) and NHS research governance requirements (IRAS HRA application).

All members of the research team will complete required research governance, data protection and information security training before undertaking study activities. Access permissions will be reviewed periodically throughout the study to ensure ongoing compliance with study requirements and institutional policy.

Legal and ethical requirements, codes of conduct

If personal data are processed, how will compliance with legislation on personal data and on security be ensured?

Question not answered.

How will other legal issues, such as intellectual property rights and ownership, be managed? What legislation is applicable?

This study involves the collection and processing of personally identifiable information and special category health data. All data processing activities will be conducted in accordance with the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, University of Plymouth Research Governance procedures, Research Data Management policies and any sponsor requirements applicable to the study (https://www.plymouth.ac.uk/research/governance).

Lawful Collection and Informed Consent

Participants will receive a Participant Information Sheet explaining how their information will be collected, used, stored, shared and retained during and after the study. Written informed consent will be obtained before study participation commences.

The consent process explicitly explains:

- What personal information will be collected.
- Which organisations will access participant data.
- Why contact information must be shared with Remotion Industries for intervention delivery.
- How research data will be stored and protected.
- How study findings may be published.
- Whether de-identified data may be shared for future research purposes.

Any future preservation or sharing of research data will be undertaken only where consistent with the participant consent provided and the approvals granted for the study.

Data Minimisation

Only information necessary to achieve the study objectives and fulfil regulatory requirements will be collected.

Personal information is limited to data required for:

- Eligibility screening.
- Informed consent.
- Participant contact.
- Intervention delivery and assessment.
- Safety monitoring.
- Study administration.

Research outcome datasets will contain only the information required to answer the research questions.

Pseudonymisation

Participants will be assigned a unique study identification number at expression of interest stage (e.g. PP01 = potential participant 01), and once consented (e.g. PP01 converts to CP01 = consented participant).

Research datasets used for analysis will be pseudonymised through the removal of direct identifiers. Participant names, addresses, contact details and other directly identifying information will not be included within analytical datasets.

A separate participant identification log linking participant identities with study identifiers will be maintained (Mollii Suit Feasibility Study - Consent sheet). Access to this log will be restricted to authorised members of the research team and stored separately from research datasets.

Pseudonymisation will permit longitudinal analysis across multiple study timepoints while reducing the risk of participant identification.

Anonymisation and Data Sharing

Where data are retained for archiving, dissemination or future sharing, consideration will be given to further anonymisation of datasets wherever feasible.

Due to the rarity of hereditary ataxia and hereditary spastic paraplegia, complete anonymisation may not always be achievable because combinations of demographic and clinical characteristics could increase re-identification risk. Prior to any data sharing activity, datasets will be reviewed to identify and suppress variables carrying unacceptable disclosure risks.

Identifiable data, participant contact details, consent forms, participant identification logs, interview recordings and other data that could reasonably permit identification of an individual will not be shared outside approved study governance arrangements.

Encryption and Secure Systems

The study will utilise secure University of Plymouth information systems including Microsoft 365, OneDrive, Teams, Outlook and Panopto.

These systems employ institutional security controls including:

- User authentication.
- Password protection.
- Role-based permissions.
- Encrypted data transfer (using the standard employee Authenticator App).
- Managed backup and recovery systems.
- Institutional monitoring and security management.

Where sensitive information is transferred between collaborating organisations, access will be restricted to authorised personnel and limited to the minimum information required for study delivery.

Controlled Access

Access to personal data will be managed according to study role and responsibility.

Authorised access to identifiable information will be restricted to:

- The Chief Investigator.
- Delegated members of the research team.
- The study Research Associate.
- Authorised personnel at Remotion Industries where contact information is required for participant scheduling, home visits, suit fitting and intervention delivery.

Permissions will be granted on a least-privilege basis and reviewed throughout the study.

Research outcome datasets will be accessible only to authorised study personnel involved in analysis, monitoring, quality assurance and reporting activities.

Retention, Archiving and Destruction

Personal data will be retained only for as long as required by the study protocol, sponsor requirements, University retention schedules and applicable legislation.

Audio and video recordings will be securely deleted following completion of quality assurance, transcription and blinding assessment activities. At study completion, research datasets and supporting documentation will be archived in accordance with University of Plymouth governance requirements.

Any future access to archived data will be managed through appropriate governance and approval procedures to ensure continued compliance with participant consent and data protection legislation.

What ethical issues and codes of conduct are there, and how will they be taken into account?

The study will be conducted in accordance with the Declaration of Helsinki, Good Clinical Practice (GCP), the UK Policy Framework for Health and Social Care Research, University of Plymouth Research Ethics procedures, UK GDPR and the Data Protection Act 2018. Ethical approval will be obtained before participant recruitment begins.

The study involves people with hereditary ataxia and hereditary spastic paraplegia, which are rare neurological conditions. Particular consideration has therefore been given to participant confidentiality and the risk of re-identification. Research datasets will be pseudonymised, stored separately from participant identifiers and accessed only by authorised personnel. Any future data sharing will be limited to appropriately de-identified datasets and governed by participant consent, ethical approvals and applicable legislation.

The study utilises home visits, remote assessments, audio/video recordings and collaboration with Remotion Industries. Participant information shared with external partners will be limited to the minimum necessary to support intervention delivery, home visit scheduling and safety monitoring. Audio and video recordings will be retained only for quality assurance, blinding assessment and transcription purposes before secure deletion.

The informed consent process provides participants with clear information regarding study procedures, data collection, data sharing, confidentiality and withdrawal rights. Participants may withdraw at any time without affecting their usual care.

All study personnel will operate within institutional governance frameworks and complete relevant training in research ethics, data protection, information governance and Good Clinical Practice. Participant welfare, confidentiality and data security will be monitored throughout the study and any incidents managed in accordance with University, sponsor and regulatory procedures

Data sharing and long-term preservation

How and when will data be shared? Are there possible restrictions to data sharing or embargo reasons?

The study team is committed to making research outputs as open and accessible as possible whilst protecting participant confidentiality and complying with legal, ethical and contractual obligations.

Study findings will be disseminated through conference presentations, peer-reviewed publications, reports and other research outputs. Metadata describing the study and resulting datasets will be retained to support discoverability and future reuse.

Following completion of the study and publication of the primary findings, suitably de-identified research datasets may be made available to other bona fide researchers upon reasonable request to the Chief Investigator, subject to appropriate governance, ethical approvals and data protection requirements. Supporting documentation including the study protocol, statistical analysis plan, data dictionary, analysis code and methodological documentation may also be shared where appropriate.

Due to the rare disease populations involved (hereditary ataxia and hereditary spastic paraplegia), fully open sharing of participant-level data may not always be possible because of the increased risk of participant re-identification. Prior to any data sharing, datasets will be reviewed and, where necessary, demographic or clinical variables will be removed, aggregated or otherwise modified to minimise disclosure risk.

The following data will not be shared:

- Participant names and contact information.
- Signed consent forms.
- Participant identification logs.
- Audio and video recordings.
- Interview transcripts containing potentially identifying information.
- Any data that could reasonably permit re-identification of a participant.

Access to any shared participant-level datasets may therefore be restricted through a managed access process and, where appropriate, a data sharing agreement.

The research team will retain exclusive use of the data until completion of the primary analyses, reporting of feasibility outcomes and publication of the principal study findings. Following publication, requests for access will be considered on a case-by-case basis.

Research data and supporting documentation will be retained in accordance with University of Plymouth research governance requirements and any applicable sponsor requirements. De-identified datasets, associated metadata and supporting documentation with potential long-term value will be preserved in an appropriate institutional or disciplinary repository where feasible. Data will be retained for a minimum period consistent with University policy and regulatory requirements, after which continued preservation will be reviewed based on scientific value, legal obligations and participant confidentiality considerations.

Any restrictions on data sharing will be limited to those necessary to comply with participant consent, protect confidentiality, maintain data security and meet legal, ethical or contractual obligations. The study team will seek to maximise the availability of de-identified research outputs wherever this can be achieved safely and responsibly.

How will data for preservation be selected, and where data will be preserved long-term (for example a data repository or archive)?

Data preservation decisions will be guided by scientific value, regulatory requirements, participant consent, confidentiality considerations and University of Plymouth research governance requirements.

The following records will be retained in accordance with University and sponsor retention requirements:

- Final de-identified research datasets.
- Study protocol and protocol amendments.
- Statistical Analysis Plan.
- Data dictionary and metadata documentation.
- Microsoft Forms structures and associated documentation.
- Analysis code and processing scripts (e.g. MATLAB and SPSS syntax).
- Standard Operating Procedures.
- Study reports and publications.
- Documentation required for audit, regulatory and governance purposes.

Data that contain direct participant identifiers, including participant identification logs, contact information and signed consent documentation, will be retained only for the period required by University, sponsor and legal requirements and will be securely destroyed when retention requirements have been met.

Audio and video recordings will not be preserved long-term. These recordings are collected to support assessment fidelity, blinding checks and qualitative transcription. Once these purposes have been been fulfilled and verified, recordings will be securely deleted in accordance with the study protocol and University procedures.

Selection for long-term preservation will focus on data that support verification of study findings, future secondary analyses, methodological transparency and research reproducibility. Preference will be given to preserving de-identified datasets, metadata, documentation and analysis workflows that can be understood and reused independently of the original research team.

Given the rarity of hereditary ataxia and hereditary spastic paraplegia, future preservation and sharing arrangements will be reviewed to minimise the risk of participant re-identification. Any datasets selected for long-term preservation will undergo disclosure risk assessment prior to deposit or release.

Where appropriate, de-identified datasets and accompanying documentation will be deposited within the University of Plymouth research repository, managed by the Associate Head of School for Research.

Where data cannot be shared openly because of confidentiality, ethical or legal restrictions, metadata describing the dataset and conditions for potential access will be retained to support discoverability. Requests for access to preserved datasets may be considered through a managed access process, subject to participant consent, ethical approvals, data protection requirements and any applicable data sharing agreements.

Potential future users of the preserved data may include researchers in neurological rehabilitation, rare neurological conditions, wearable technologies, neuromodulation, clinical trial methodology and patient-centred rehabilitation research. Preserved datasets may also support future grant applications, systematic reviews, methodological research and planning of a definitive trial evaluating the Exopulse Mollii® Suit.

What methods or software tools are needed to access and use data?

The study will prioritise the use of widely adopted and sustainable file formats to maximise long-term accessibility and reuse. Most preserved datasets and supporting documentation will be available in commonly used formats including CSV, XLSX, PDF and DOCX, which can be accessed using standard office software and are not dependent on specialist infrastructure.

Primary data collection will occur through Microsoft Forms, with exported datasets stored in CSV and XLSX formats. These formats can be imported into a wide range of statistical and database software packages and are expected to remain accessible over the long term.

Some analytical datasets and workflows may use specialist software including:

- Microsoft Excel
- IBM SPSS Statistics
- MathWorks MATLAB
- NVivo
- Movella XSens software

Where specialist software is used, key analytical datasets will additionally be retained in non-proprietary formats (e.g. CSV) wherever possible to support future accessibility and reuse without requiring access to the original software platform.

Supporting documentation, including the study protocol, statistical analysis plan, data dictionary, metadata documentation and analysis workflows, will be preserved alongside datasets to facilitate interpretation and secondary analysis by other researchers.

Subject to participant consent, ethical approvals and data protection requirements, data sharing will normally occur through a managed access process coordinated by the Chief Investigator and the University of Plymouth. If a suitable repository is identified at study completion, de-identified datasets, metadata and accompanying documentation may be deposited within an institutional or disciplinary repository. Where data cannot be shared openly owing to confidentiality, legal or ethical restrictions, metadata describing the dataset and conditions of access will be retained to support discoverability and appropriate future use.

How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?

The study has been registered with ClinicalTrials.gov and assigned a unique trial registration number. This identifier will be used consistently across study documentation, publications and dissemination activities to support discoverability and linkage between research outputs.

Datasets generated during the study will be managed using unique study identifiers, dataset version numbers and associated metadata documentation. Participant-level data will be identified internally through unique study participant identifiers (e.g. CP001, CP002) to support traceability whilst maintaining confidentiality.

The study will not make participant-level datasets publicly available through an open repository. This decision reflects the relatively small sample size and the involvement of participants with rare neurological conditions, where the risk of re-identification may remain even after de-identification procedures have been applied.

Metadata describing the study, methodology and available data resources may be made publicly available to support discoverability. Future peer-reviewed publications and conference outputs will contain aggregated, processed and anonymised results, together with supplementary materials where appropriate.

Requests for access to underlying research data will be considered on a case-by-case basis by the Chief Investigator and corresponding author, subject to participant consent, ethical approvals, data protection requirements and the proposed use of the data. Any approved sharing will occur under appropriate governance arrangements and data sharing agreements where required.

This approach aims to maximise transparency and scientific value whilst protecting participant confidentiality and meeting the ethical obligations associated with research involving rare neurological conditions.

Data management responsibilities and resources

Who (for example role, position, and institution) will be responsible for data management (i.e. the data steward)?

Overall responsibility for data management rests with Dr Lisa Bunn, Associate Professor of Neurological Rehabilitation, University of Plymouth and NIHR Senior Research Leader, as Chief Investigator. Dr Bunn is responsible for ensuring that data are collected, stored, processed, shared, archived and destroyed in accordance with the approved protocol, ethical approvals, University of Plymouth policies, UK GDPR and this Data Management Plan.

Specific responsibilities are as follows:

Role	Responsibility
Dr Lisa Bunn (Chief Investigator, University of Plymouth)	Overall data stewardship; implementation and review of the Data Management Plan; management of identifiable data; oversight of data quality; approval of data access requests; oversight of archiving, retention and destruction arrangements.
Research Associate (University of Plymouth)	Day-to-day data management activities including participant administration, monitoring data completeness, maintaining study records, quality checking, pseudonymisation, preparation of datasets for analysis and ensuring adherence to SOPs.
Prof Jon Marsden (Co-Investigator, University of Plymouth)	Support for study oversight, data quality assurance, assessment fidelity monitoring, blinding verification procedures and review of study conduct.
Richard Welch and authorised personnel at Remotion Industries	Collection and management of operational records required for suit fitting, participant scheduling, intervention delivery and home visits; secure handling of consent documentation and participant contact information required for study delivery.
University of Plymouth Information Technology Services (ITS)	Provision and maintenance of institutional data storage, security, backup and disaster recovery systems used by the study.

Sensitive and confidential information, including participant identifiers, consent documentation and contact details, will be managed under the direction of the Chief Investigator. Access will be restricted to authorised personnel and granted only where necessary for study delivery.

Responsibility for data quality will be shared between the Chief Investigator, Research Associate and Co-Investigator through routine monitoring of data completeness, protocol compliance, assessment fidelity and dataset verification.

Data management responsibilities across collaborating organisations will be coordinated by the Chief Investigator. Data shared between the University of Plymouth and Remotion Industries will be restricted to information necessary for delivery of study procedures and managed in accordance with approved study documentation, consent arrangements and applicable data protection legislation.

The Chief Investigator will be responsible for ensuring that this Data Management Plan is implemented, monitored and reviewed throughout the study. The DMP will be reviewed periodically and updated where required following protocol amendments, procedural changes, regulatory requirements or identification of new data management risks.

What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

The study has been designed to utilise existing University of Plymouth infrastructure and software licences wherever possible, thereby minimising additional costs associated with research data management.

Data collection, storage and management will be undertaken using University-supported systems including Microsoft 365 (Forms, OneDrive, Teams and Outlook), Panopto, Microsoft Excel, IBM SPSS Statistics, NVivo and MathWorks MATLAB. Costs associated with the use of these systems are covered through existing institutional licences and support arrangements.

Data management activities have been incorporated into the responsibilities of the Chief Investigator, Co-Investigator and Research Associate. Staff time has been allocated for:

- Development and maintenance of data collection systems.
- Monitoring data quality and completeness.
- Pseudonymisation and management of confidential information.
- Verification and cleaning of datasets.
- Production of metadata and supporting documentation.
- Data analysis and preparation of research outputs.
- Preparation of data and accompanying documentation for archiving and controlled sharing where appropriate.

The use of Microsoft Forms as the primary data capture tool reduces data entry burden and minimises the resources required for transcription and data cleaning. Standard Operating Procedures, predefined metadata structures, file naming conventions and version control processes further support efficient data management throughout the project lifecycle.

The study will support FAIR principles where this is compatible with participant confidentiality, ethical approvals and the rare disease context of the research. Data will be made findable through study registration, publication of research outputs and retention of appropriate metadata. Data will be accessible through managed access arrangements where appropriate, rather than unrestricted public release. Widely used formats including CSV, XLSX, PDF and DOCX will support interoperability and reuse. Accompanying documentation, data dictionaries, protocols and analysis documentation will be retained to maximise future interpretability and reuse.

At present, no additional costs are anticipated for long-term storage, archiving or repository deposit. Given the anticipated use of controlled-access data sharing rather than open publication of participant-level datasets, substantial repository charges are not expected.

The resources allocated are considered proportionate to the scale of this feasibility study and sufficient to support secure, well-documented and reusable research data throughout the lifecycle of the project.