STUDY PROTOCOL

Pilot Feasibility Study of Rehabilitation Therapy Content and Effort Logging

NCT Number:	NCT_____ (to be assigned)
Protocol ID:	2025-02397
Document Date:	14 April 2026 (Version 3)
Sponsor-Investigator:	Dr. Diego Paez-Granados
Institution:	SCAI-Lab, D-HEST, ETH Zurich

ETH zürich

Pilot Feasibility Study of Rehabilitation Therapy Content and Effort Logging

Study Type:	Other Clinical Trial according to ClinO, Chapter 4
Risk Categorisation:	Risk category A according to ClinO, Art. 61
Study Registration:	Swiss Clinical Trials Portal Human Research Switzerland (HumRes)
Sponsor/ Principal Investigator:	Dr. Diego Paez-Granados SCAI-Lab, D-HEST, Swiss Paraplegic Research (SPF) Gloriastrasse 37/ 39 8092 Zürich, Switzerland
Investigated Intervention:	Participants wear two non-invasive, CE-marked wrist sensors (Corsano Cardiowatch 287-2) during routine neurorehabilitation sessions. Therapists may activate an audio recording system to capture verbal instructions, and a video camera is used to document therapy-related movement. All systems serve documentation and data collection purposes only. They do not alter therapy, introduce new procedures, or influence clinical decisions.
Protocol ID	2025-02397
Version and Date:	Version 3 (dated 14/04/2026)

CONFIDENTIALITY STATEMENT

e.g. “The information contained in this document is confidential and the property of ETH (or “the sponsor”). The information may not - in full or in part - be transmitted, reproduced, published, or disclosed to others than the applicable Competent Ethics Committee(s) and Regulatory Authority(ies) without prior written authorisation from the sponsor except to the extent necessary to obtain informed consent from those who will participate in the study.

PROTOCOL SIGNATURE FORM

Study Title	Pilot Feasibility Study of Rehabilitation Therapy Content and Effort Logging
Study ID	2025-02397

The Sponsor has approved the protocol version 3 (dated 14/04/2026) and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki, and ICH-GCP guidelines as well as the local legally applicable requirements.

Sponsor:

Name: Dr. Diego Paez-Granados

Date: 20.04.2026 Signature: 

Table of Contents

Table of Contents 4
GLOSSARY OF ABBREVATIONS 5
1 STUDY SYNOPSIS 6
Secondary Endpoints: 7
2 BACKGROUND and rationale 10
3 Study OBJECTIVES and Design 11
3.1 Hypothesis and primary objective 11
3.2 Primary and secondary endpoints 11
Secondary Endpoints: 11
3.3 Study design 12
3.4. Study intervention 12
3.5. Patient and public involvement 13
4 Study POPULATION and Study procedures 13
4.1 Inclusion and exclusion criteria, justification of study population 13
4.2 Recruitment, screening and informed consent procedure 14
4.3 Study procedures 15
4.4 Withdrawal and discontinuation 17
5 STATISTICS AND METHODOLOGY 17
5.1. Statistical analysis plan and sample size calculation 17
5.2. Handling of missing data and drop-outs 18
6 Regulatory Aspects AND SAFETY 18
6.1 Local regulations / Declaration of Helsinki 19
6.2 (Serious) Adverse Events and notification of safety and protective measures 19
6.3 Periodic reporting of safety and general progress of the clinical trial. 20
6.4 Radiation 21
6.5 Pregnancy 21
6.6 Amendments 21
6.7 Notification and reporting upon completion, discontinuation or interruption and resumption of the study 21
6.8 Insurance 22
7 FURTHER Aspects 22
7.1 Overall ethical considerations 22
7.2 Risk-benefit assessment 22
8 Quality CONTROL AND Data protection 24
8.1 Quality measures 24
8.2 Data recording and source data 24
8.3 Confidentiality and coding 25
8.4 Retention and destruction of study data and biological material 26
9 Monitoring and Registration 27
10. Funding / Publication / declaration of Interest 27
11. REFERENCES 28

GLOSSARY OF ABBREVATIONS

AE	*Adverse Event*
BASEC	*Business Administration System for Ethical Committees*
CRF	*Case Report Form*
CTCAE	*Common Terminology Criteria for Adverse Events*
FADP	*Federal Act on Data Protection (in German: DSG, in French: LPD, in Italian: LPD)*
eCRF	*electronic Case Report Form*
FOPH	*Federal Office of Public Health*
GCP	*Good Clinical Practice*
HRA	*Human Research Act (in German: HFG, in French: LRH, in Italian: LRUm)*
ICH	*International Conference on Harmonisation*
ClinO	*Ordinance on Clinical Trials in Human Research (in German: KlinV, in French: OClin, in Italian: OSRUm)*
SAE	*Serious Adverse Event*
IMU	*Inertial Measurement Unit*
EDA	*Electrodermal Activity*
PPG	*Photoplethysmography*
HR	*Heart Rate*
HRV	*Heart Rate Variability*
AI	*Artificial Intelligence*
ALS	*Amyotrophic Lateral Sclerosis*
SCI	*Spinal Cord Injury*
CP	*Cerebral Palsy*
PPG	*Photoplethysmography*
RR	*Respiration Rate*

1 STUDY SYNOPSIS

Sponsor / Sponsor-Investigator	Dr. Diego Paez-Granados SCAI-Lab, D-HEST Swiss Paraplegic Research (SPF) Gloriastrasse 37/ 39 8092 Zürich, Switzerland
Study Title	Pilot Feasibility Study of Rehabilitation Therapy Content and Effort Logging
Short Title / Study ID	2025-02397
Protocol Version and Date	Version 3 (dated 14/04/2026)
Study Registration	Swiss Clinical Trials Portal Human Research Switzerland (HumRes)
Study Category and Rationale	Risk category A according to the Clinical Trials Ordinance (ClinO), Art. 61. In accordance with ClinO Art. 2, the study procedures involve only minimal risks and burdens. The study uses exclusively non-invasive, CE-marked wearable sensors strictly within their intended purpose for physiological monitoring. In addition, video recording of therapy-related movement and therapist-controlled audio recording of session instructions are performed for documentation and research analysis. All procedures are comparable to everyday clinical documentation practices and do not involve invasive measures or additional medical interventions. Participants receive routine rehabilitation therapy without modification. Wearable sensors, video recording and audio recording are used for data capture and do not influence therapy content, intensity, or clinical decision-making. The voice-based documentation system supports structured session documentation by therapists and affects only the documentation workflow. It does not provide diagnostic or therapeutic recommendations. The video recording serves exclusively to document movement during therapy sessions for research purposes. No investigational medical device is being tested, and no device is used outside its intended purpose. All study data, including wearable, audio and video recordings, are stored and processed locally on the institution's controlled ETH Zurich infrastructure. No manufacturer cloud services or third-party data processing are involved.

Background and Rationale	Rehabilitation therapy documentation is often incomplete and varies between therapists, limiting continuity of care and objective assessment of therapy intensity. Adults with neurological conditions such as stroke, cerebral palsy, Parkinson's disease, SCI and ALS frequently participate in structured therapy sessions where movement, effort, and activity type are clinically relevant but rarely measured objectively. Wearable sensors in combination with video and audio inputs offer a non-invasive way to capture motion and physiological effort during routine therapy, enabling feasibility testing of automated therapy logging. Sex and gender dimensions were assessed following the recommendations in "Sex and gender in research involving humans according to the HRA" (swissethics). For this feasibility study, sex and gender are not expected to influence the ability to capture wearable or voice-based data, as no biological or social mechanisms differing between sexes are being tested. Therefore, sex and gender considerations are not relevant for the study objectives.
Risk / Benefit Assessment	Potential risks are limited to minor physical inconvenience from wearing sensors (e.g. temporary skin irritation) and to data protection risks associated with recording and storing information. These risks are minimized through non-invasive device use and secure local data storage on the institution's controlled server without manufacturer cloud or third-party processing. Participants receive no direct medical benefit. Potential societal benefits include improved standardization and efficiency of rehabilitation therapy documentation and enhanced objective understanding of therapy content and effort.
Objective(s)	The primary objective is to evaluate the feasibility of structured rehabilitation therapy session logging using multimodal data sources (wearable sensor data and therapist documentation) during routine care in patients with neurological conditions. The secondary objective is to explore descriptive associations between therapist-reported effort, patient self-reported effort, and wearable-derived measures of activity and physiological load.
Endpoint(s)	Primary Endpoint: Feasibility of multimodal therapy session logging defined by: ○ Portable PPG derived HR, RR, Skin Temp, electrodermal activity. ○ Video-based motion estimation ○ Voice recording system for therapist Secondary Endpoints: ● Therapist-reported effort ● Patient-reported effort

	● Wearable derived measures of activity and effort from (PPG, HR, RR, RR-intervals, temperature, acceleration, angular velocity) ● Emography, electrodermal activity
Study Design	This study is an exploratory, monocentric, non-randomised, one-arm, open-label feasibility clinical trial assessing the ability to capture data during routine rehabilitation therapy.
Inclusion- / Exclusion Criteria	The study will include 20 adults undergoing routine neurorehabilitation for conditions such as stroke, cerebral palsy, Parkinson's disease, SCI or ALS. Key inclusion criteria are: age ≥18 years, ability to participate in therapy sessions of at least 30 minutes and capacity to give informed consent. Exclusion criteria include unstable medical conditions, severe cognitive impairment preventing participation, relevant skin issues preventing sensor placement, implanted cardiac devices that interfere with biosignal sensors, or concurrent participation in another interventional clinical trial.
Number of Participants with Rationale	The study will include 20 participants in a single-arm design. This sample size is appropriate for a feasibility clinical trial, allowing assessment of data quality, sensor practicality and workflow integration across different therapy types while remaining manageable within one clinical site. No group allocation is required, as all participants undergo the same observational procedures.
Study Intervention	The study consists of data collection, including movement data, physiological signals and therapist verbal cues, and includes brief five-minute baseline and recovery resting periods. Participants wear non-invasive, CE-marked wearable sensors during a routine rehabilitation session. During therapy, video recording is performed to document therapy-related movement. A therapist-controlled audio recording captures therapist instructions and task descriptions only. No therapeutic procedures are altered, and no clinical decisions are influenced by the study procedures.
Control Intervention	No control group
Study procedures	Participants are screened and provide written informed consent. Each participant completes three routine rehabilitation sessions at the clinic. At each session, wearable sensors are placed on the wrists followed by a five-minute baseline resting measurement. The therapist activates a voice recorder that captures therapist instructions only. Therapy proceeds as usual while motion and physiological signals are recorded. After each session, a five-minute recovery measurement is taken, sensors are removed and short effort questionnaires are completed. All data are coded and securely transferred for analysis.

Study Duration and Schedule	Planned 01/04/2026 of First-Participant-In Planned 31/12/2026 of Last-Participant-Out
Investigator(s)	Dr. Diego Paez-Granados SCAI-Lab, D-HEST ETH Zurich, Swiss Paraplegic Research (SPF) Gloriastrasse 37/ 39 8092 Zürich, Switzerland
Study Center(s)	Nextherapy AG Uraniastrasse 9, 8001 Zurich, Switzerland Multergasse 47, 9000, Saint Gallen, Switzerland
Statistical Considerations:	The analysis focuses on feasibility outcomes, data completeness, sensor signal quality, and agreement between wearable-derived effort indicators and therapist-reported effort. Descriptive statistics and correlation analyses will be used; no hypothesis testing is planned. The sample size of 20 participants is appropriate for a feasibility study and allows assessment of data capture reliability across three sessions per participant. Following the recommendations “sex and gender in research involving humans according to the HRA” (swissethics), sex and gender are not expected to influence these feasibility measures and are therefore not considered analytically relevant.
Data privacy	Privacy of data is guaranteed through pseudonymization and secure storage on access-restricted ETH servers. Each participant receives a study code and the key linking codes to personal information is stored separately and accessible only to the project lead. No names or identifiers appear in the recorded data. All data are transferred via encrypted connections, handled only by authorised study staff, and stored in compliance with Swiss data protection requirements. No biological material is collected
Ethical consideration	The study provides scientific value by testing whether wearable and voice-based data can be captured reliably during routine neurorehabilitation. The methodology is appropriate because it is fully observational and does not alter therapy. Risks are minimal and comparable to everyday activities, while potential benefits relate to improved future documentation. No vulnerable populations are included.
GCP Statement	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP, the HRA as well as other locally relevant legal and regulatory requirements. A clinical trial covered by ClinO Chapter 4 may be conducted in accordance with other rules than ICH-GCP guidelines, provided that such rules are recognised in the specialty in question and the protection of participants and data quality, and security are guaranteed (ClinO Art. 5, Abs 2). If the clinical trial is not conducted according to ICH-GCP guidelines, the paragraph above must be adapted accordingly.

2 BACKGROUND AND RATIONALE

Rehabilitation therapy documentation is predominantly manual and therapist dependent, with variation in structure, timing and level of detail across practitioners. While such documentation supports clinical communication and continuity of care, it does not systematically capture the temporal structure and quantitative characteristics of therapy sessions. Wearable physiological sensors provide objective signals that can complement therapist documentation. Photoplethysmography (PPG)-based heart rate monitoring has demonstrated acceptable agreement with electrocardiography under resting and low to moderate movement conditions (Shcherbina et al., 2017; Bent et al., 2020). Electrodermal activity reflects sympathetic nervous system activation and has been widely used as an index of psychophysiological arousal (Boucsein, 2012). In rehabilitation research, wearable devices have been applied to quantify activity levels and movement intensity in ecological environments (Porciuncula et al., 2018; Wei and Wu, 2023). These physiological signals do not encode task identity or movement quality directly but provide continuous measures of physiological load during therapy sessions.

Video-based markerless motion analysis represents a complementary behavioural measurement approach. Deep learning-based human pose estimation methods allow extraction of joint trajectories from standard RGB video without physical markers (Cao et al., 2017). Such approaches have been applied in clinical and movement analysis contexts to quantify gross motor behaviour outside laboratory-based multi-camera systems. Single-camera setups enable capture of task structure, body segment involvement and observable repetition patterns within routine environments. Although not equivalent to laboratory-grade three-dimensional motion capture systems, single-camera video allows structured observation of therapy activities under real-world clinical conditions.

Speech-based documentation tools allow structured capture of session information during therapy. Therapist-controlled audio recording enables real-time verbal annotation of task descriptions, assistance levels and qualitative observations that would otherwise be documented retrospectively. Natural language processing methods can convert spoken descriptions into structured documentation fields (Ermolina and Tiberius, 2021). From a measurement perspective, audio data represent an additional contextual layer rather than an autonomous decision system.

Multimodal measurement approaches combining physiological and behavioural data streams have demonstrated improved contextual modelling performance compared with single-modality systems in activity recognition research (Sevil et al., 2020). Integrating synchronised wrist-worn physiological data, single-camera video recording and therapist-controlled audio documentation enables temporal alignment of observable behaviour, physiological response and documented session content within a unified therapy log.

The central research question of this study is whether a multimodal therapy logging system combining wrist-worn physiological sensor data, single-camera video recording and therapist-controlled voice documentation can be feasibly integrated into routine neurorehabilitation to generate structured, time-resolved documentation of therapy content without disrupting clinical workflows. The intended intervention consists of equipping participants with non-invasive CE-marked wristband sensors and recording therapy sessions

using a camera and therapist-controlled audio recording during three routine sessions, including short baseline and recovery measurements and brief effort questionnaires.

This feasibility clinical trial aims to evaluate practicality, data quality and agreement between multimodal automated logs and therapist documentation in routine practice. Equivalent knowledge cannot be derived from existing documentation because current records do not contain synchronised physiological and behavioural measurements and structured time-resolved representations of session content.

The study is classified as Risk Category A according to ClinO Art. 61. All procedures are non-invasive and comparable to routine therapy conditions. The wearable devices are external CE-marked sensors used according to their intended purpose. Audio and video recording are therapist-controlled, locally stored and can be paused or terminated at any time. According to ClinO Art. 2 these procedures are associated with minimal risks and burdens comparable to everyday activities. Participation is voluntary and coded data is stored on secure ETH infrastructure.

Sex and gender dimensions were assessed in accordance with the recommendations on sex and gender in research involving humans under the HRA. For this feasibility study sex and gender are not expected to influence feasibility outcomes or data agreement metrics and no sex-stratified analyses are planned.

3 Study OBJECTIVES and Design

3.1 Hypothesis and primary objective

Hypothesis: Exploratory study. No hypothesis will be tested.

Primary Objective: The primary objective is to evaluate the feasibility of structured rehabilitation therapy session logging using multimodal data sources (wearable sensor data, vocal interface for therapist documentation and motion capture) during routine care in patients with neurological conditions.

The secondary objective is to explore descriptive associations between therapist-reported effort, patient self-reported effort, and wearable-derived measures of activity and physiological load.

3.2 Primary and secondary endpoints

Primary Endpoint: Feasibility of multimodal therapy session logging defined by:

- Portable PPG derived HR, RR, Skin Temp, electrodermal activity.
- Video-based motion estimation
- Voice recording system for therapist

Secondary Endpoints:

- Therapist-reported effort
- Patient-reported effort

- Wearable derived measures of activity and effort from (PPG, HR, RR, RR-intervals, temperature, acceleration, angular velocity)
- Emography, electrodermal activity

3.3 Study design

This is an exploratory, non-randomised, one-arm, open-label feasibility clinical trial conducted monocentrically at Nextherapy AG. The aim is to assess whether data (wearable sensors, therapist voice recordings and a motion capture) can be captured reliably during routine neurorehabilitation. All participants undergo the same observational procedure during three therapy sessions; therefore, randomisation, blinding, or control groups are not applicable. Potential issues include occasional sensor signal loss or variable session content, which are inherent to feasibility studies. Bias is minimised through standardised sensor placement, fixed baseline and recovery periods, consistent handling of the voice recorder and and video camera set up, and the use of validated effort questionnaires. Data is coded and processed with predefined procedures to avoid selective analysis.

3.4. Study intervention

Patient-Related Procedures

Participants continue routine neurorehabilitation therapy without modification. As part of the study, they wear non-invasive, CE-marked wearable sensors used strictly within their intended purpose for physiological and movement monitoring (two Corsano wrist-worn devices). At each of the three therapy sessions:

- A five-minute baseline resting measurement is recorded prior to therapy.
- Wearable sensors and a video camera record movement and physiological parameters during routine therapy.
- A five-minute recovery measurement is recorded after therapy.
- Sensors are then removed.
- Participants complete a brief self-reported effort questionnaire.

The wearable sensors are used solely for observational data collection. No therapy content, intensity, or clinical decision-making is influenced by sensor output.

Therapist-Related Procedures

Therapists conduct rehabilitation sessions according to standard clinical practice and remain fully responsible for all therapeutic decisions. The study does not modify therapy content,

session structure or clinical reasoning. During each therapy session, the therapist activates a therapist-controlled voice recording system for documentation purposes. In addition, a video camera records the therapy session from a predefined position to capture observable movement behaviour and task execution. Video recording is used for structured analysis of therapy content and does not provide real-time feedback or therapeutic guidance. The voice and video recording systems serve to support structured session logging. They do not provide diagnostic or therapeutic recommendations and do not influence treatment decisions or session content. No automated output is available to the therapist during the session.

3.5. Patient and public involvement

No formal patient or public involvement process was conducted in the design of this feasibility study. Informal feedback from therapists and patients at Nextherapy AG regarding documentation burden and the relevance of objective therapy information informed the choice of research question and the focus on data capture feasibility. No PPI contributors are included in ongoing study procedures or decision-making.

4 Study POPULATION and Study procedures

4.1 Inclusion and exclusion criteria, justification of study population

We will recruit 20 adult individuals undergoing neurorehabilitation following stroke, cerebral palsy, Parkinson's disease, SCI or amyotrophic lateral sclerosis (ALS) at Nextherapy AG. Nextherapy is a specialised rehabilitation centre offering interdisciplinary therapy for neurological conditions and provides access to eligible participants and a clinical environment for data collection. The study population reflects the clinical group in which objective quantification of therapy intensity and effort is most relevant.

The sample size of 20 participants is appropriate for a feasibility study and ensures sufficient variability across therapy types and effort levels while remaining manageable within a single centre. According to ClinO Art. 4a, the selection criteria allow an appropriate representation of adults of different ages and genders who attend neurorehabilitation at the study site.

Sex and gender considerations were evaluated according to the swissethics recommendations "Sex and gender in research involving humans according to the HRA." A balanced distribution of male and female participants will be pursued through consecutive recruitment of eligible patients. Sex or gender are not expected to influence the feasibility outcomes (data completeness, sensor quality), and no sex-specific biological or social mechanisms are investigated. Therefore, no sex- or gender-stratified analyses are planned.

Inclusion criteria:

- Signed informed consent form
- Age ≥18 years
- Clinical diagnosis of a neurological motor impairment (stroke, cerebral palsy, Parkinson's

disease, ALS)
• Ability to participate in a therapy session of at least 30 minutes

Exclusion criteria:
• Acute infection or unstable medical condition
• Severe cognitive or communicative impairment preventing consent or participation
• Skin conditions preventing sensor placement
• Implanted cardiac devices that may interfere with PPG or EDA recordings

Justification for inclusion and exclusion criteria:
The inclusion criteria ensure that the study population represents adults for whom objective therapy documentation is clinically meaningful. Exclusion criteria ensure participant safety and prevent technical interference with sensor measurements. Individuals unable to provide informed consent or follow therapy instructions are excluded to maintain data quality. Minors and adults incapable of judgement are not included, as comparable findings can be obtained safely and effectively from adults capable of consent.

4.2 Recruitment, screening and informed consent procedure

The investigators will explain to each participant the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant will be informed that the participation in the study is voluntary and that he or she may withdraw from the study at any time and that withdrawal of consent will not affect his or her subsequent medical assistance and treatment.

The participant will be informed that his or her medical records may be examined by authorised individuals other than their treating physician.

All participants for the study will be provided a participant information sheet and a consent form describing the study and providing sufficient information for participants to make an informed decision about their participation in the study.

The formal consent of a participant, using the approved consent form, will be obtained before the participant is submitted to any study procedure.

The consent form will be signed and dated by the investigator or his designee at the same time as the participant sign. A copy of the signed informed consent will be given to the study participant. The consent form will be retained as part of the study records.

Recruitment will take place at Nextherapy AG. Therapists at Nextherapy will identify potential participants among adults undergoing routine neurorehabilitation for stroke, cerebral palsy, Parkinson’s disease, SCI or ALS, and inform them about the opportunity to participate. Recruitment is consecutive and ongoing within daily clinical practice. Flyers may be used on-site at the clinic; They will be submitted to the Ethics Committee via BASEC for approval before distribution.

Interested individuals will receive verbal and written information about the study from the ETH research team. Participants may contact the study team directly via email or telephone to ask questions or express interest. Participation is entirely voluntary, and declining or withdrawing consent will have no impact on current or future treatment.

Potential participants will receive the study information sheet and the informed consent form (ICF) in written form (email or print) at least 24 hours before the first study session, allowing adequate time for consideration. Screening will be performed to verify that inclusion and exclusion criteria are met. Written informed consent will be obtained prior to any study procedure.

On study days, participants attend their usual therapy session. Before sensors are applied, the investigator or delegated study staff will review the procedures again, answer questions, and confirm consent. Participants will be informed when wearable sensors are placed and when voice recording of therapist instructions is active. Each participant will be assigned a unique coded study ID. The code key linking personal information to study IDs is stored separately and securely by the principal investigator. No identifying information is stored with the sensor or audio recordings.

The investigator or the sponsor notifies the Ethics Committee of the first study participant, in accordance with art 62 lit. c ClinO, resp. art 38 ClinO. If the first participating person is not included in the trial within two years following the issuance of the authorization, the trial is considered interrupted (art. 23a ClinO). The clinical trial may not be commenced until an application for an extension of the time limit has been approved. The application for the extension is submitted to the CEC as a substantial amendment.

4.3 Study procedures

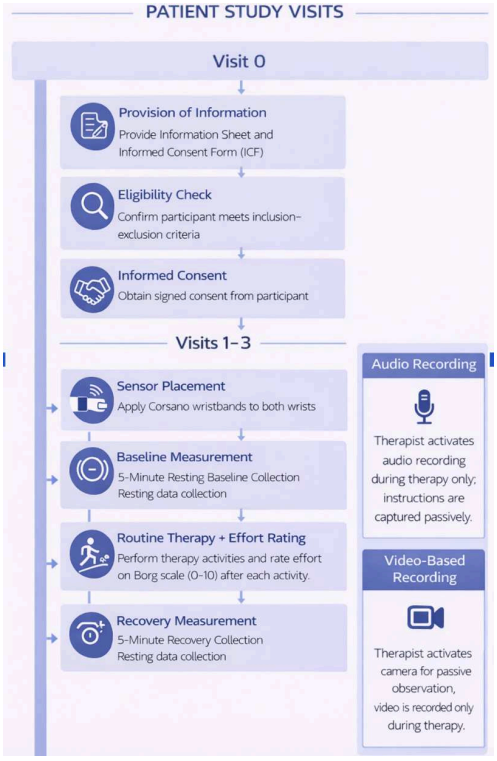


Figure 1:Study Procedure

Sensor set up

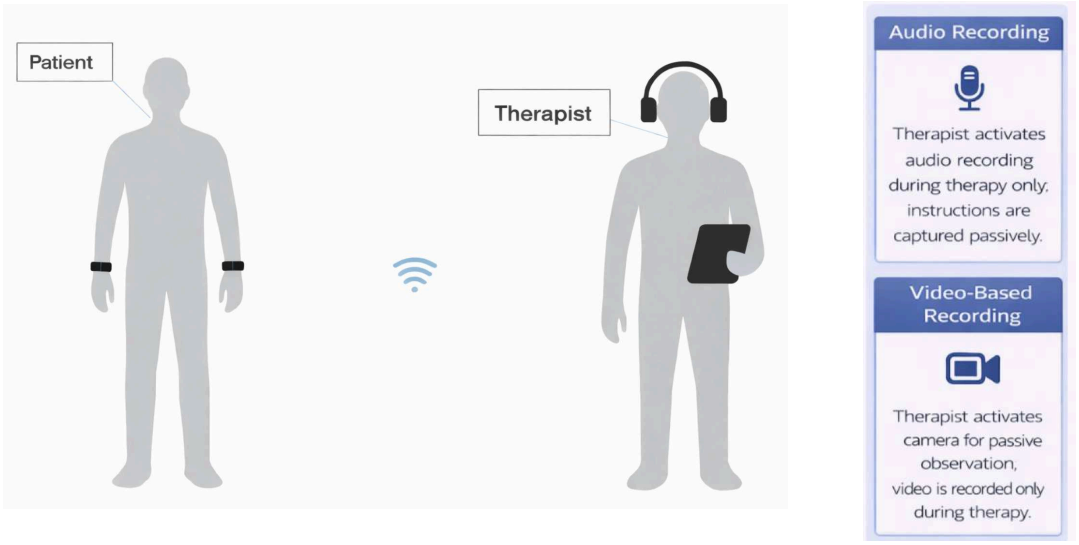


Figure 2: Study Set up

1. Cardiowatch Bracelet 287-2 (Crosano, Hague, Netherlands): heart rate and respiratory rate intervals (PPG and ECG based), breaths per minute, activity, core body temperature, oxygen saturation, electrodermal activity and acceleration. https://corsano.com/products/bracelet-2/
2. Headphones: Headphones: DT 990 PRO, 250 OHM https://www.beyerdynamic.ch/p/dt-990-pro

Schedule of assessments

Study phase **Timing**	**Procedures**
Screening	- Provision of information sheet and ICF - Eligibility check before therapy - Informed consent
Therapy session 1-3	- Baseline resting measurement (5 min) - Sensor placement (Corsano ×2, AX6 ×3) - Routine therapy/assessments with continuous sensor, video and voice - Effort questionnaire after each activity - Recovery resting measurement (5 min)

Recruitment is performed consecutively within routine clinical practice at Nextherapy AG Zurich and St. Gallen, it takes place before participation, usually within one week before the first session. Each participant completes three therapy sessions within a two-week period. No follow-up visits are required after the third session.

The planned intervention consists of non-invasive data collection during routine physiotherapy or occupational therapy. Procedures include a five-minute baseline resting measurement before therapy, continuous recording of sensor and video data during the therapy session and therapist-voice recording capturing instructions and task descriptions. After each activity performed during therapy, participants complete a brief effort questionnaire. Following the session, a five-minute recovery resting measurement is recorded. No additional examinations, diagnostic tests or biological sampling are performed, and no materials are stored or analysed.

Expected sources of bias include variability in therapy content between sessions, occasional sensor signal loss due to movement or displacement, and potential behavioural changes because participants and therapists are aware of the recording. These are minimised through standardised sensor placement, fixed baseline and recovery durations, identical procedures across all three sessions, therapist instruction to deliver therapy as usual, and predefined data-processing pipelines ensuring uniform handling of all recordings.

4.4 Withdrawal and discontinuation

Participants may be withdrawn from the study at any time upon their own request, without providing a reason and without consequences for their ongoing or future treatment. Withdrawal of informed consent automatically leads to discontinuation of all further study procedures. Participants may also be withdrawn if new information arises indicating that continued participation is not in their best interest (e.g. acute illness, medical instability, or safety concerns), or if they are no longer able to participate in routine therapy.

In the event of premature withdrawal or withdrawal of consent, no further study procedures will be carried out. Because the study consists only of observational data collection during routine therapy, no final examinations are required. Participants will be asked whether previously collected data may be retained. If they request data deletion, all pseudonymised wearable and audio recordings linked to their study ID will be irreversibly deleted. The code key used to link personal information to study IDs will also be updated to reflect the withdrawal.

If a participant consents to retention of data already collected prior to withdrawal, these data will remain coded and used in accordance with the original informed consent. No biological material is collected in this study; therefore, no sample-related procedures apply.

5 STATISTICS AND METHODOLOGY

5.1. Statistical analysis plan and sample size calculation

This feasibility study does not aim to test a clinical hypothesis and therefore does not include formal hypothesis testing, power calculations, or confirmatory statistical analyses. The main objective is to assess data completeness, signal quality, and the practical feasibility of combining wearable sensor data with therapist voice recordings during routine

neurorehabilitation. As such, no null or alternative hypotheses are defined, and no inferential significance level is applied.

The planned sample size of 20 participants is justified by the exploratory design and the need to capture variation in therapy content and effort levels across three sessions per participant. This number is sufficient to assess feasibility outcomes while remaining manageable within a monocentric clinical setting.

The analysis population consists of all participants who complete at least one recorded therapy session and one therapy assessment. For participants with partial data, all available data will be included in descriptive analyses. No interim analyses or stopping rules are foreseen, as the study involves minimal risk and generates only observational data.

Statistical analyses will be descriptive and include:

- data completeness metrics
- descriptive comparisons of sensor activity/effort estimates with therapist documentation
- correlation analyses between therapy scores and wearable-based signals (IMU, HR, EDA, and video-based markers)

No adjustments for multiple testing are required, as no confirmatory endpoints or hypothesis tests are planned. Sex and gender are not expected to influence feasibility outcomes, and no sex- or gender-stratified analyses will be conducted; this has been assessed according to the swissethics recommendations “Sex and gender in research involving humans according to the HRA.”

Statistical analyses will be performed using Python (version 3.10) and standard scientific libraries (e.g. pandas, NumPy, SciPy). Any deviations from the statistical plan will be documented and justified in the final study report.

5.2. Handling of missing data and drop-outs

Because this is a feasibility study, analyses will focus on descriptive summaries of data completeness and signal quality. Missing data will be handled using a complete-case approach; no imputations or replacements (e.g. last observation carried forward or multiple imputation) will be performed. For participants with partial data, all available recordings from completed sessions will be included in the analysis.

Dropouts will not be replaced unless fewer than 10 complete datasets of at least two recorded sessions per participant. In this case, recruitment may continue until the target sample of up to 20 participants is reached. Participants who withdraw from the study will not contribute additional data after the withdrawal date. Data collected before withdrawal will be retained or deleted according to the participant’s preference stated at the time of withdrawal.

6 Regulatory Aspects AND SAFETY

The Sponsor of this clinical trial is Dr. Diego Paez-Granados (ETH Zurich), acting as Sponsor-Investigator in accordance with the Human Research Act. The Sponsor assumes full responsibility for the design, management, regulatory compliance, safety oversight, data management, reporting, and financing of the study.

ETH Zurich provides the institutional infrastructure for study conduct, including secure data storage (Leonhard Med server), IT infrastructure, and institutional liability insurance coverage for potential study-related harm in accordance with KlinV.

Nextherapy AG Zurich and St. Gallen serves exclusively as the clinical study site where data collection takes place during routine rehabilitation therapy. Nextherapy supports participant recruitment and allows study procedures within its clinical setting but does not assume sponsor responsibilities, financial responsibility, insurance obligations, or regulatory management duties.

6.1 Local regulations / Declaration of Helsinki

This study is conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP the HRA as well as other locally relevant legal and regulatory requirements.

6.2 (Serious) Adverse Events and notification of safety and protective measures

An Adverse Event (AE) is any untoward medical occurrence in a patient or a clinical investigation participant which does not necessarily have a causal relationship with the trial procedure. An AE can therefore be any unfavourable or unintended finding, symptom, or disease temporally associated with a trial procedure, whether or not related to it.

A Serious Adverse Event (SAE) (ClinO, Art. 63) is any untoward medical occurrence that

- Results in death or is life-threatening,
- Requires in-patient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability or incapacity, or
- Causes a congenital anomaly or birth defect

Both Investigator and Sponsor make a causality assessment of the event to the trial intervention, (see table below based on the terms given in ICH E2A guidelines). Any event assessed as possibly, probably or definitely related is classified as related to the trial intervention.

Relationship	Description
Definitely	Temporal relationship Improvement after dechallenge* Recurrence after rechallenge (or other proof of drug cause)
Probably	Temporal relationship Improvement after dechallenge No other cause evident

Possibly	Temporal relationship Other cause possible
Unlikely	Any assessable reaction that does not fulfil the above conditions
Not related	Causal relationship can be ruled out
*Improvement after dechallenge only taken into consideration, if applicable to reaction	

Both Investigator and Sponsor make a severity assessment of the event as mild, moderate or severe. Mild means the complication is tolerable, moderate means it interferes with daily activities and severe means it renders daily activities impossible.

Reporting of SAEs (see ClinO, Art. 63)

All SAEs are documented and reported immediately (within a maximum of 24 hours) to the Sponsor of the study.

If it cannot be excluded that the SAE occurring in Switzerland is attributable to the intervention under investigation (i.e., the SAE is definitely, probably, or possibly related to the intervention), the Investigator reports it to the Ethics Committee via BASEC within 15 days.

Follow up of (Serious) Adverse Events

Given that the study involves only non-invasive wearable sensors used according to their CE-marked intended purpose, no serious adverse events are expected. If an adverse event or serious adverse event is reported by a participant during participation (e.g. skin irritation at sensor sites, discomfort, or any unexpected medical issue), the participant will be followed until the event has resolved or stabilised. Follow-up will be conducted by the investigator or delegated study staff, who will document the course, outcome, and any actions taken.

If a participant terminates the study prematurely due to an ongoing adverse event, they will be contacted as needed to assess the status of the event until resolution or stabilisation. No study-specific examinations are required for follow-up, as no investigational treatment or invasive procedure is involved. All (S)AEs will be handled in accordance with applicable reporting requirements.

Notification of safety and protective measures (see ClinO, Art 62, b)

If immediate safety and protective measures have to be taken during the conduct of the study, the investigator notifies the Ethics committee of these measures, and of the circumstances necessitating them, within 7 days.

6.3 Periodic reporting of safety and general progress of the clinical trial.

Once a year, the investigator submits to the Ethics Committee a list of the safety events including the severity of the events, their causality to the intervention and the safety of the study participants. The investigator also informs the Ethics Committee about the general progress of the clinical trial (ClinO, Art. 43).

6.4 Radiation

No procedures involving ionising radiation, radiopharmaceuticals, or radiation-emitting medical devices are used in this study. All wearable sensors employed (Corsano wrist devices) are non-ionising and CE-marked and are used according to their intended purpose. Therefore, no review by the Federal Office of Public Health (FOPH) under Art. 36a ClinO is required.

6.5 Pregnancy

Pregnancy reporting is not required in this study, as the intervention consists solely of non-invasive wearable sensors, video and audio recording, without exposure to any medication, radiation, or procedures that could pose risk to pregnant individuals. If a participant becomes pregnant during the study, she may continue participation if she wishes, as no procedures are contraindicated in pregnancy. Pregnancies will not be systematically monitored or followed up and no pregnancy outcome data will be collected.

6.6 Amendments

Substantial changes to the study setup and study organization, the protocol and relevant study documents are submitted to the Ethics Committee for approval before implementation. Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of participants may proceed without prior approval of the Ethics Committee. Such deviations shall be documented and reported to the Ethics Committee as soon as possible.

A list of all non-substantial amendments will be submitted once a year to the competent EC together with the safety report / general study progress report.

6.7 Notification and reporting upon completion, discontinuation or interruption and resumption of the study

Upon regular study completion, the Ethics Committee is notified via BASEC within 30 days (ClinO, Art. 38).

The Sponsor may terminate the study prematurely according to certain circumstances, e.g.

- Ethical concerns,
- Insufficient participant recruitment,
- When the safety of the participants is doubtful or at risk (e.g. when the benefit-risk assessment is no longer positive),
- Alterations in accepted clinical practice that make the continuation of the study unwise, or
- Early evidence of harm or benefit of the experimental intervention

The investigator reports the premature termination, interruption or resumption of the study, including reasons thereof, to the Ethics Committee within 15 days. An interruption lasting more than two years is considered a premature termination (Article 38 ClinO).

Completion, discontinuation or interruption of the clinical trial will be notified to the Ethics Committee using the templates provided on www.swissethics.ch.

At the end of the study, all health-related data (wearable sensor recordings, therapist-voice recordings, effort questionnaires) will remain pseudonymised. After completion of data analysis, the code key linking participant identities to study IDs will be destroyed, resulting in irreversible pseudonymization of the dataset. No biological materials are collected or stored in this study.

A final report is submitted to the Ethics Committee via BASEC within a year after completion or discontinuation of the study, unless a longer period is specified in the protocol (ClinO, Art. 38).

6.8 Insurance

The insurance (guarantee) must cover damage occurring up to 20 years after the end of the clinical trial. Refer to ClinO Art. 10 for exemptions from liability and to ClinO Art. 12 for exemptions from liability coverage requirements. In the event of study-related damage or injuries, the liability of the institution ETH provides compensation.

7 FURTHER ASPECTS

7.1 Overall ethical considerations

This study addresses a clear gap in current neurorehabilitation practice, where therapy content and effort are documented mainly through manual, heterogeneous notes. By evaluating the feasibility of combining wearable sensor data with therapist-voice information during routine therapy, the study has both scientific and social value: it may enable more objective, standardized documentation and more transparent monitoring of therapy dose in the future. The feasibility design with a small sample and three sessions per participant is appropriate to answer this question without exposing participants to unnecessary procedures.

The study population (adults with neurological motor impairment capable of providing informed consent and participating in standard therapy sessions) is well justified, as these patients are the primary group for whom objective therapy documentation is clinically relevant. Vulnerable populations such as minors or adults incapable of judgement are not included because equivalent findings can be obtained in adults capable of consent, reducing ethical complexity and risk. The study procedures are limited to non-invasive wearable sensors, brief resting measurements, and short effort questionnaires after therapy activities. Routine therapy is not modified, and no experimental treatments, invasive procedures or biological sampling are introduced. Overall, the burden on participants is low and comparable to everyday clinical conditions.

Data protection and privacy are central ethical aspects. Wearable signals, video data and therapist voice recordings are coded with study IDs; the code key is stored separately by the principal investigator. Voice recording is limited to therapist instructions during therapy sessions; participants are informed when recording is active and may request pauses or stop recording at any time. No genetic data are collected, and incidental clinical findings are not expected, as the study does not involve diagnostic imaging or laboratory investigations. Participation is entirely voluntary, and withdrawal is possible at any time without consequences for current or future treatment. Taken together, the minimal risks and low burden of the procedures are fairly balanced by the potential benefit of improving future documentation quality and enabling more data-driven rehabilitation planning, ensuring an acceptable overall ethical profile for this feasibility trial.

7.2 Risk-benefit assessment

The study involves minimal risks, as all procedures take place during routine neurorehabilitation sessions and consist exclusively of non-invasive, CE-marked wearable sensors used according to their intended purpose, therapist-controlled audio recording, and video recording for movement analysis. No therapeutic procedures are modified, and no additional exercises, physical load, invasive tests, or imaging procedures are introduced.

Potential physical risks are limited to mild discomfort from sensor placement, transient skin irritation, or minor pressure marks from wearable devices. These risks are mitigated through careful application by trained staff, short wearing durations confined to routine therapy sessions, and immediate removal upon participant request.

Video recording introduces an additional privacy-related consideration. The camera is used solely to capture therapy-related movement for research analysis and documentation purposes. It does not record outside the therapy session and is activated only during the defined measurement periods. Participants are clearly informed when video recording is active and may request pausing or discontinuation at any time without consequences. The presence of the camera may cause temporary awareness or mild discomfort related to being recorded; however, this is considered comparable to standard clinical documentation practices or educational recordings in rehabilitation settings.

Audio recording remains restricted to therapist instructions and task descriptions. Participants are not required to speak and may request pausing or stopping of audio recording at any time. No emotionally sensitive interviews, psychological interventions, or diagnostic assessments are conducted; therefore, the risk of psychological distress is negligible.

Data-related risks (e.g., unauthorized access, accidental disclosure, or re-identification) are addressed through strict pseudonymisation, separation of the identification key (in a printerd locked document at ETHZ) from research data, encrypted data transfer, and secure storage on access-restricted ETH Zürich server. Video and audio files are stored only in coded form and are accessible exclusively to authorised study personnel. No biological samples, genetic data, or sensitive diagnostic imaging data are collected.

There is no direct therapeutic benefit for participants, as the study is observational and does not influence treatment decisions or therapy content. The anticipated societal and scientific benefit lies in evaluating whether multimodal sensor-, audio-, and video-based documentation can be feasibly integrated into routine neurorehabilitation without disrupting workflows. If successful, the approach may improve transparency, standardisation, and objectivity of therapy documentation, support future clinical decision-making, enhance understanding of therapy dose and patient effort, and reduce documentation burden for therapists. These improvements may ultimately benefit future patients through more consistent and data-informed rehabilitation practice.

Overall, the physical, psychological, and data-related risks are minimal and appropriately mitigated. They remain proportionate to the potential future scientific and societal value of establishing a reliable multimodal therapy documentation framework, resulting in an ethically acceptable risk–benefit balance under ClinO Risk Category A.

8 QUALITY CONTROL AND DATA PROTECTION

8.1 Quality measures

All study personnel at ETH Zurich, will be informed of all study procedures, including eligibility assessment, informed consent, sensor placement, voice and camera recording procedures and data handling. The staff at Nextherapy AG will be informed of the study procedure and will be enabled to perform routine therapy without interruption from the study team.

Wearable sensor data, audio recordings and video recordings are captured directly in electronic form, eliminating manual transcription steps and reducing the risk of data-entry errors. Digital questionnaires are completed electronically and automatically stored under the coded study ID. The principal investigator will periodically review data quality and protocol adherence.

A study team from ETH Zurich will perform a quality control after at least 2 individuals have been recruited to validate all procedures and data entries.

For quality assurance the sponsor, the Ethics Committee or an independent trial monitor may visit the research sites. Direct access to the source data and all study related files is granted on such occasions. All involved parties keep the participant data strictly confidential.

8.2 Data recording and source data

Study data include participant eligibility information (inclusion/exclusion criteria), anthropometric information, wearable sensor recordings, therapist-controlled audio recordings, video recordings of therapy sessions, and digital effort questionnaires.

All data is stored on the secure ETH Zurich Leonhard Med server. The server provides:

- encrypted access
- user-controlled access rights
- restricted write permissions
- automated data backup
- logging of file operations to ensure traceability

Only researchers directly involved in the project have access to the stored data. Unauthorised access, alteration, deletion and copying are technically restricted and monitored. Video recordings, wearable movement data and physiological signals are captured electronically and transferred directly to the secure ETH infrastructure. No data is stored on unsecured local devices beyond temporary technical buffering required for transfer. Digital effort questionnaires and demographic data are entered electronically and stored directly under the coded study ID on the same secure server. Raw data folders are write-protected. A designated study team member is responsible for managing file structure and ensuring correct data allocation. Other authorised study staff have read-only access, preventing unintended modifications.

Source data consist of:

- Original wearable sensor recordings (Corsano wrist devices)
- Original therapist-controlled audio recordings

- Original video recordings of therapy sessions
- Digital effort questionnaires
- Digital demographic questionnaire

Wearable, audio and video files are considered source data in their original electronic form. Digital questionnaires are considered source data in their original electronic format. Routinely collected clinical data (e.g. therapist notes) remain part of the official clinical record at Nextherapy AG Zurich. If information is referenced in the CRF for contextual purposes, the clinical record remains the authoritative source. All study data are stored exclusively in coded form. The identification key linking personal information to study IDs is stored separately on the ETH Zurich secure server with restricted access and is accessible only to the principal investigator.

8.3 Confidentiality and coding

The investigator affirms and upholds the principle of the participant's right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals. The investigator has appropriate knowledge and skills in the areas of data security and data protection or is able to ensure compliance by calling in appropriate expertise (Art. 6, ClinO).
Individual subject medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited. All trial and participant data are handled with the utmost discretion and are accessible only to authorised personnel who require the data to fulfil their duties within the scope of the study. On the CRFs and all study-specific documents, participants are identified exclusively by a unique study identification number. The participant identification list linking coded study IDs to personal identifying information (name and date of birth) is stored separately from all research data and is maintained exclusively by the principal investigator. The identification list is stored on the secure, access-restricted Leonhard Med server of ETH Zurich. Access is protected by individual password authentication and role-based permissions and is limited to authorised study personnel only. All access and modification activities are logged to ensure traceability in accordance with applicable regulatory requirements. Routine encrypted backups are performed to prevent data loss. No directly identifying personal data are stored together with wearable, audio, or video recordings.

Coded estimation and generation of abstract skeletal or mesh-based motion data used for analysis. The skeletal or mesh data cannot be used to reconstruct the participant’s physical appearance.

Raw, unprocessed video files are stored in coded form and are accessible only to authorised study personnel. They are not transferred outside ETH Zurich infrastructure and are not made publicly available. No open-access release of raw video data is planned in this clinical feasibility clinical trial. If visual material is used for scientific dissemination, faces and identifying features will be irreversibly blurred otudy data, including wearable sensor files, therapist voice recordings, video recordings, questionnaires, and anthropometric database are stored exclusively on the secure Leonhard Med server at ETH Zurich. The server provides encrypted storage, access-restricted directories, logged file operations, institutional IT monitoring, and regular encrypted backups. No research data is stored on private devices, unsecured cloud services, or external storage media.

Video recordings are obtained during therapy sessions to document therapy-related movement in synchronisation with wearable and voice data. From the raw video files, automated computer vision algorithms may be applied to extract motion-related representations such as two-dimensional joint coordinates, three-dimensional joint trajectories, kinematic parameters, or simplified digital skeletal or mesh-based representations. These derived representations contain biomechanical coordinate data only and do not include facial texture, skin detail, or directly identifying visual features. The processing pipeline therefore consists of raw video acquisition followed by automated pose esr pixelated prior to presentation, and only coded excerpts will be shown.



Figure 3: Example of 3D body shape mesh generated

If a participant withdraws consent and requests deletion of data, all pseudonymised wearable, audio, and video recordings linked to the respective study ID will be irreversibly deleted. After completion of the study and final data consolidation, the identification key linking personal data to study IDs will be destroyed to ensure irreversible pseudonymization of the retained dataset. The study collects only non-genetic physiological, motion, and questionnaire data. No biological samples, genetic analyses, or genomic information are obtained or processed.

8.4 Retention and destruction of study data and biological material

The investigator retains all documents necessary for the identification and follow-up of the trial participants and all other original data for at least ten years after completion or discontinuation of the clinical trial.

Archiving will be performed on secure, access-controlled servers at ETH Zurich. Access is restricted to authorised study personnel only. After the legally required retention period, all archived documents and electronic data will be permanently destroyed using ETH Zurich's certified deletion procedures.

If participants consent to future use of their data, the research dataset will first be irreversibly coded through deletion of the identification key linking study IDs to personal information. After pseudonymization, data may be used for further method development or validation work without additional approval, in line with the HFG.

No biological material is collected in this study; therefore, no storage or destruction procedures for biological samples are required. No biobank storage is planned.

9 Monitoring and Registration

Monitoring duties for this Category A minimal-risk clinical trial are fulfilled internally by the study sponsor at ETH Zurich. Given the observational design, limited number of participants and absence of investigational treatments, monitoring is performed through periodic internal reviews rather than formal on-site monitoring visits. The principal investigator or delegated qualified staff will verify adherence to the protocol, completeness of informed consent documentation, correct use of coded identifiers, accuracy of data transfer from Nextherapy AG Zurich to ETH Zurich, and proper storage of source data and CRFs. All wearable data files, voice recordings, paper questionnaires and the participant identification list are available for review during these checks, and study staff will answer any related questions.

A formal monitoring plan is not required due to the minimal risk and small scale of the study; however, monitoring activities will be documented, and any issues identified will be addressed promptly.

The study must be registered in the Swiss Human Research Portal (HumRes) via BASEC in the national language of Switzerland in which recruitment is intended.

The study will also be registered in a WHO-recognised primary registry, as required for clinical trials of this type. Registration will occur prior to enrolment of the first participant and will include the study design, objectives, sample size and data collection procedures.

10. Funding / Publication / declaration of Interest

The study is funded internally by ETH Zurich as part of an academic research project. Nextherapy AG provides access to the clinical environment and supports participant recruitment but does not influence the study design, data analysis or publication of results. There are no commercial sponsors, no industry involvement and no financial incentives for investigators or participants. No conflicts of interest- financial, proprietary or intellectual- are known. Authorship of scientific publications will follow internationally accepted authorship guidelines (e.g. ICMJE). Raw an data will be accessible only to the responsible study team at ETH Zurich. Sharing of coded datasets with external researchers may be considered for future scientific work only if participants have provided consent for future coded use; otherwise, no data will be shared outside ETH Zurich. All publications arising from the study will maintain participant confidentiality. If sex- or gender-related effects are observed in the data, these findings will be reported in the final study report and in scientific publications. If analyses show no such effects, this will also be stated explicitly. The sponsor enters and publishes a summary of the trial results in a public registry in accordance with ClinO Art. 65a within one year of completion or discontinuation of the trial. An interruption lasting more than two years is considered a discontinuation. In addition, the sponsor ensures that a lay summary of trial results is entered in BASEC within one year of study completion or discontinuation, in the national language(s) in which participants were recruited. The investigator will provide each participant directly with the lay summary at the end of the study. Participants are informed in the patient information document that a lay summary will be made available and where it will be published online.

11. REFERENCES

3. Common Terminology Criteria for Adverse Events (CTCAE): https://evs.nci.nih.gov/ftp1/CTCAE/
4. Declaration of Helsinki: https://www.wma.net
5. Federal Act on Data Protection (FADP): https://www.fedlex.admin.ch/eli/cc/2022/491/en
6. Human Research Act (HRA) https://www.fedlex.admin.ch/eli/cc/2013/617/en
7. International Conference on Harmonization (ICH) E6 Guideline for Good Clinical Practice (GCP): https://www.ich.org
8. International Conference on Harmonization (ICH) E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting: https://www.ich.org
9. Medical Device Ordinance (MeDO): https://www.fedlex.admin.ch/eli/cc/2020/552/en
10. Ordinance on Clinical Trials in Human Research (ClinO): https://www.fedlex.admin.ch/eli/cc/2013/643/en
11. Porciúncula, F., Roto, A. V., Kumar, D., Davis, I., Roy, A., Walsh, C. J., & Awad, L. N. (2018). *Wearable movement sensors for rehabilitation: A focused review of technological and clinical advances.* PM&R, 10(10 Suppl 2), S220–S231. https://doi.org/10.1016/j.pmrj.2018.06.013 (PMID: 30269807)
12. Wei, S., & Wu, Z. (2023). *The application of wearable sensors and machine-learning algorithms in rehabilitation training: A systematic review.* Sensors (Basel), 23(18), 7667. https://doi.org/10.3390/s23187667 (PMID: 37765724)
13. Marek, K., Górski, J., Karolczyk, P., Redlicka, J., Zubrycki, I., & Miller, E. (2025). *Feasibility of wearable devices for motivating post-stroke patients.* Sensors (Basel), 25(16), 5204. https://doi.org/10.3390/s25165204
14. Ermolina, A., & Tiberius, V. (2021). *Voice-controlled intelligent personal assistants in health care: International Delphi study.* Journal of Medical Internet Research, 23(4), e25312. https://doi.org/10.2196/25312 (PMID: 33835032)
15. Sevil, M., Rashid, M., Askari, M. R., Maloney, Z., Hajizadeh, I., & Cinar, A. (2020). *Detection and characterization of physical activity and psychological stress from wristband data.* Signals, 1(2), 188–208. https://doi.org/10.3390/signals1020011
16. Sevil M, Rashid M, Hajizadeh I, Maloney Z, Samadi S, Askari MR, Cinar A. (2020). *Determining physical activity characteristics from wristband data for use in automated insulin delivery systems.* IEEE Sensors Journal, 20(21), 12859-12870. DOI: 10.1109/JSEN.2020.3000772
17. Cardiowatch Bracelet 287-2 (Crosano, Hague, Netherlands): heart rate and respiratory rate intervals (PPG and ECG based), breaths per minute, activity, core body temperature, oxygen saturation, electrodermal activity and acceleration. https://corsano.com/products/bracelet-2/
18. AX6, Activity(Axivity, UK): angular velocity, acceleration. https://axivity.com/product/ax6
19. Headphones: DT 990 PRO, 250 OHM https://www.beyerdynamic.ch/p/dt-990-pro
20. Cao, Z., Simon, T., Wei, S.E. & Sheikh, Y. (2017). Realtime multi-person 2D pose estimation using Part Affinity Fields. *Proceedings of the IEEE Conference on Computer Vision and Pattern Recognition (CVPR)*, 7291–7299. https://doi.org/10.1109/CVPR.2017.486

Appendix 1: Schedule of assessments

Time (hour, day, week)	**>-1 day**	**0**	**+1**	**+3**
Visit	Information	Screening/ 1st visit	2nd visit	3rd visit
Oral and written patient information	+			
Written consent		+		
Inclusion-/ exclusion criteria		+		
Medical history		+		
Physical examination				
Participant characteristics		+		
Procedures				
Data Recording		+	+	+
Questionnaire		+	+	+
Sampling				
Safety		+	+	+