Comparison of blended care outpatient neurorehabilitation with traditional outpatient neurorehabilitation, a crossover pilot study

Study Type:	Other Clinical Trial according to ClinO, Chapter 4
Risk Categorisation:	A
Study Registration:	1. Intended registry: clinicaltrials.gov 2. Registration number from the FOPH portal HumRes (follows Approval)
Sponsor:	Dr. med. Noortje Maaijwee, Luzerner Kantonsspital, Spitalstrasse, 6003 Luzern
Principal Investigator	Dr. med. Noortje Maaijwee, Luzerner Kantonsspital, Spitalstrasse, 6003 Luzern
Investigated Intervention:	Traditional outpatient neurorehabilitation (Physiotherapy, occupational therapy, speech therapy and neuropsychology at the clinic), blended with telerehabilitation (Home setting)
Protocol ID	Comparison of blended care out
Version and Date	Version 2.1 (24.12.2025)

CONFIDENTIALITY STATEMENT

PROTOCOL SIGNATURE FORM

Study Title	Comparison of blended care outpatient neurorehabilitation with traditional outpatient neurorehabilitation, a crossover pilot study
Study ID	Comparison of blended care out

The Sponsor- Investigator has approved the protocol version 2.1 (dated 24.12.2025) and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki[1], the HRA[2] and ICH-GCP guidelines as well as the local legally applicable requirements.

Sponsor:

Name: Dr. med. Noortje Maaijwee

Date: 24.12.2025

Signature:

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GLOSSARY OF ABBREVATIONS

AE	*Adverse Event*
ANQ	*Nationaler Verein für Qualitätsentwicklung in Spitälern und Kliniken*
AST	*Apraxia Screening Test*
ASR	*Annual Safety Repot*
BASEC	*Business Administration System for Ethical Committees*
ClinO	*Ordinance on Clinical Trials in Human Research (in German: KlinV, in French: OClin, in Italian: OSRUm)*
CRF	*Case Report Form*
CTCAE	*Common Terminology Criteria for Adverse Events*
EQ-5D-5L	*5-Level EuroQol 5D questionnaire*
FADP	*Federal Act on Data Protection (in German: DSG, in French: LPD, in Italian: LPD)*
FIM	*Functional Independence Measurement*
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)*
ICF	*International Classification of Functioning, Disability, and Health*
ICH	*International Conference on Harmonisation*
LAST	*Language and Aphasia Screening Test*
LIMOS	*Lucerne International Classification of Functioning, Disability, and Health (ICF)-Based Multidisciplinary Observation Scale*
MiniBESTest	*Mini Balance Evaluation Systems Test*
MoCA	*Montreal Cognitive Assessment*
NHPT	*Nine Hole Peg Test*
PREM	*Patient Reported Experience Measure*
PROM	*Patient Reported Outcome Measure*
Short-LIMOS	*Short version of the Lucerne ICF-Based Multidisciplinary Observation Scale*
SAE	*Serious Adverse Event*

1 STUDY SYNOPSIS

Sponsor / Sponsor-Investigator	Luzerner Kantonsspital Luzern, Spitalstrasse, 6000 Luzern 16
Study Title	Comparison of blended care outpatient neurorehabilitation with traditional outpatient neurorehabilitation, a crossover pilot study
Short Title / Study ID	Comparison of blended care out
Protocol Version and Date	Version 24.1 (24.12.2025)
Study Registration	Clinicaltrials.gov, Swiss National Clinical trial Portal (HumRes via BASEC)
Study Category and Rationale	Risk category A
Background and Rationale	Outpatient neurorehabilitation is crucial for managing chronic neurological conditions, but digital tools have yet to be fully integrated due to challenges like billing and limited evidence. With rising patient numbers and resource constraints, innovative solutions are needed. Telerehabilitation shows promise but lacks sufficient evidence. Our study aims to assess a blended care model combining traditional therapy with digital tools to provide a more efficient solution. We will adjust our statistical analysis for sex, to exclude any possible differences between men and women on their recovery rate and outcomes.
Risk / Benefit Assessment	The patients undergo a comprehensive medical evaluation and are checked for their suitability for the study to minimize risks (mainly falls). A direct beneficial effect might be present, when patients experience high convenience by the new set-up in the home environment.
Objective	To explore the trend to non-inferiority of a blended care model in comparison with traditional outpatient neurorehabilitation.
Endpoint	Primary: The change in total sum score between start and end of the interventions A and B (See chapter 3.4) on the Lucerne ICF-based Multidisciplinary Observation Scale (*LIMOS*) Secondary endpoints (at start and end of intervention A and B: - 5-Level EuroQol 5D questionnaire *(EQ-5D-5L)* : - Short version of the Lucerne ICF-based Multidisciplinary Observation Scale (*Short-LIMOS*). - ANQ-Kurzfragebogen Rehabilitation V2.0. The aforementioned parameters at 3 months follow-up
Study Design	Cross-over-design, pilot
Inclusion- / Exclusion Criteria	Inclusion criteria: • Diagnosis of ischemic or haemorragic stroke or brain trauma. • People for whom at least 6 weeks of outpatient rehabilitation is foreseen to be indicated. • Ability for safe independent mobilisation (screening with MiniBesTest, Chedoke) • Access to and ability to operate MS Teams and Apps on computer and other digital devices (Smartphone, Tablet) (Screening with AST, LAST and NHPT) • Able to provide informed consent in German. • Age: 18 - 80 years Exclusion criteria: • Severe cardiopulmonary disease • Other neurological disease than mentioned in the inclusion criteria • Inability to provide informed consent in German
Number of Participants with Rationale	30 Patients
Study Intervention	Blended care: Participants will interchangeably receive on-site therapy and telerehabilitation in their home environment. Telerehabilitation will be provided by therapists via video call and apps.

Control Intervention	Participants will receive outpatient neurorehabilitation in the neurology outpatient clinic of the Luzerner Kantonsspital, according to current standard practice.
Study procedures	An overall study duration of ca. 5.5 to 6 months is needed, including the recruitment period (during last 2 weeks of inpatient rehabilitation), 1-2 weeks waiting time between discharge and start of outpatient rehabilitation due to organisational reasons, a 6 week intervention and a follow-up examination at 3 months.
Study Duration and Schedule	Planned 04/2026 of First-Participant-In Planned 04/2029 of Last-Participant-Out
Investigator	Dr. med. Noortje Maaijwee, Luzerner Kantonsspital, Spitalstrasse, 6003 Luzern E-Mail: noortje.maaijwee@luks.ch, Tel. 041 205 19 52
Study Center	Luzerner Kantonsspital Luzern, Spitalstrasse, 6000 Luzern 16
Statistical Considerations:	For the study, attention is paid to a balanced representation of the genders and the data is presented gender-specifically, if relevant differences are suspected. The data is recorded at the beginning as a baseline, after completion of the first intervention and after completion of the second intervention and 3 months after the end of the intervention and statistically evaluated.
Data privacy	Data protection is guaranteed by internal encryption, the separation of personal data and test data as well as the input in RedCap
Ethical consideration	Since the intervention has already been tested abroad, it does not pose any major risk to the test subjects. If the study is successful, patients will be able to choose in the future whether they would prefer to carry out their rehabilitation using the old or new system.
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.

2 BACKGROUND AND RATIONALE

Over the years, the outpatient neurorehabilitation model has become a crucial component in the care for individuals with neurological diseases. This model, which involves an interdisciplinary team of physical therapists, occupational therapists, speech therapists, and neuropsychologists, plays a vital role in the continuum of care—from acute medical treatment to long-term ambulatory management of patients, many of whom experience chronic neurological deficits.

However, as digitalization continues to transform healthcare, there are still significant barriers to fully integrating technology into neurorehabilitation programs. In Switzerland, for instance, challenges such as the inability to bill for digital services, insufficient adaptation of digital tools to the specific needs of neurorehabilitation, and a lack of established evidence on their efficacy, have hindered the widespread adoption of these innovations. At the same time, the healthcare sector is facing increasing challenges: more patients are surviving with neurological deficits, healthcare costs are rising, and there is a growing scarcity of both human and financial resources. This necessitates the development of innovative solutions that can ensure high-quality care while maintaining efficiency.

One such solution is telerehabilitation—the provision of therapeutic support remotely, allowing patients to receive treatment in their personal environments. Preliminary evidence suggests that telerehabilitation can be at least as effective as traditional, in-person neurorehabilitation.[3] While the available studies indicate positive outcomes, the overall quality of evidence remains low to moderate, and large-scale implementation of telerehabilitation in Switzerland has yet to occur. Additionally, we currently lack clear data on its effectiveness within the Swiss healthcare system.

Therefore, our study aims to explore the efficacy of a blended care neurorehabilitation model. This model combines traditional, in-person neurorehabilitation with innovative digital tools such as synchronous video therapy, asynchronous systems using sensors to monitor patient progress, and standalone app-based therapies tailored to individual needs.[4] By integrating these new technological solutions, we eventually seek to enhance the benefits of traditional therapies, and in some cases, replace them, offering a more contemporary, efficient, and cost-effective approach to neurorehabilitation. This approach could ultimately benefit all stakeholders—patients and their families, healthcare professionals, hospitals, insurance companies, and society at large—by improving care quality while addressing the challenges posed by the current healthcare landscape.

We classified our Study as Category A (low risk), since the concept has been studied in other countries before without any reports of safety concerns. Our main safety concern would be the fact, that patients might perform certain exercises in a wrong way, bringing not the desired profit. However, we expect no persisting negative consequences, since our therapy model consists of blended care, where patients will be guided on-site as well within a short timeframe, where any false exercise implementations will be timely discovered and corrected. The risk of falling, without a therapist directly supporting the patient, is being minimized by careful screening of participants.

We will adjust our statistical analysis for sex, to exclude any possible differences between men and women on their recovery rate and outcomes.[5]

3 STUDY OBJECTIVES AND DESIGN

3.1 Hypothesis and primary objective

The primary objective of this study is to investigate the effectiveness of the blended care neurorehabilitation model in our outpatient neurorehabilitation clinic, compared with the traditional interdisciplinary outpatient neurorehabilitation (on-site only). We hypothesize, that the blended care model will show a trend towards non-inferiority in comparison with the traditional neurorehabilitation.

3.2 Primary and secondary endpoints

The change in total sum score between start and end of the interventions A and B (See chapter 3.4) on the Lucerne ICF-based Multidisciplinary Observation Scale (*LIMOS*)[6] will serve as primary endpoint.

The LIMOS consists of 45 items in 7 different domains, namely 'interpersonal interactions and relationships', 'mobility', 'self-care', 'communication', 'learning and applying knowledge', 'general tasks and demands' and 'domestic life'. On every item, the therapist scores the performance of the participant on a Likert-scale of 1 (fully dependent) to 5 (fully independent/normal performance). This score has been well validated and is already in use in daily clinical practice, in which it is standardly filled out every two weeks as a standard assessment.

For assessment of the efficacy of the intervention, as experienced by the patient (PROM), and also general patient satisfaction (PREM), the total scores on the following self-assessment questionnaires will be used as secondary endpoints at the start and end of interventions A and B:

- **5-Level EuroQol 5D questionnaire *(EQ-5D-5L)* :** First, this questionnaire assesses 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. Then, a visual analogue scale is presented, on which the patient has to rate his/her current health status, ranging from '100, The best health you can imagine' to '0, The worst health you can imagine'.
- **Short version of the Lucerne ICF-based Multidisciplinary Observation Scale (*Short-LIMOS*).** This questionnaire consists of 18 separate items. Some items are combined into a mean score, so that - in the end - 10 subscores will be generated. On every item, the participant must choose an answer concerning how well he/she subjectively rates his/her performance in the activity described by the given item, on a Likert scale of 1 (fully dependent) to 5 (fully independent/normal performance). The 10 subscores will be summed to one total score, ranging between 10 (worst performance on all subscores) and 50 (normal performance on all subscores).
- **ANQ-Kurzfragebogen Rehabilitation V2.0.** This questionnaire consists of 6 questions measuring the participants' satisfaction with the treatment.

Also, the sustainability of the above mentioned primary and secondary endpoints will be measured by repeating the above assessments/questionnaires at 3 months follow-up.

Since age, sex, location of brain damage, cognitive performance (MoCA) and severeness of disability (FIM) are potential confounders, these parameters will be recorded at baseline.

3.3 Study design

This study will be a monocentric, cross-over study. After screening of eligibility and safety, participants will either start with the telerehabilitation blended care (intervention A) followed by crossover to traditional outpatient neurorehabilitation ('control' intervention B) or start with traditional outpatient neurorehabilitation ('control' intervention B) followed by crossover to telerehabilitation blended care (intervention A). The feasibility of telerehabilitation has already been documented in previous studies (e.g. Chen et al., Journal of NeuroEngineering and Rehabilitation, 2021; Cacciante et al., Digital Health, 2025), so this is not the focus of the present study. The current study aims to collect preliminary data on the non-inferiority of the treatment method. As funding for the study is unavailable without preliminary data, a large RCT cannot be implemented. As the patient group is highly heterogeneous in terms of clinical condition and demographic data, it is not realistic to recruit a separate control group matched for all confounders within a reasonable timeframe. We have therefore opted for the crossover model.[7, 8]

3.4. Study intervention

Intervention A, the intervention under current investigation:

Participants will interchangeably receive on-site therapy (1 day per week) and telerehabilitation in their home environment (2 days per week) with an average of 180 minutes per day. Telerehabilitation will be provided by therapists via video call (MS Teams, available at the Luzerner Kantonsspital), alternated with a practice program, implemented by the participant, guided by apps. The following apps will be used:

Physiotherapy and occupational therapy: Physitrack, www.physitrack.com

Occupational therapy and Neuropsychology: MS-Kognition, MS Kognition - Startseite

Occupational therapy and Neuropsychology: Brain Yoga, Brain Yoga Brain Training Game-App – App Store

If indicated: Speech therapy: Tactus Therapy, Tactus Therapy: Speech Therapy Apps for Adults with Aphasia after Stroke

'Comparison' intervention B

Participants will receive outpatient neurorehabilitation in the neurology outpatient clinic of the Luzerner Kantonsspital, according to current standard practice, 3 days per week with an average of 180 minutes per day. They will receive therapies from the following disciplines: physiotherapy, occupational therapy and, if indicated, speech therapy and neuropsychology.

4 STUDY POPULATION AND STUDY PROCEDURES

4.1 Inclusion and exclusion criteria, justification of study population

Since the implementation of blended care rehabilitation is still in a developmental phase worldwide, we consider this intervention in a pilot phase. Therefore, we aim for a study population of 30 participants, based on the median number of participants which are usually included in these kind of pilot studies.[9]

Inclusion criteria:

- Diagnosis of ischemic or haemorragic stroke or brain trauma.
- People for whom at least 6 weeks of outpatient rehabilitation is foreseen to be indicated.
- Ability for safe independent mobilisation (screening with MiniBesTest, Chedoke)

- Access to and ability to operate MS Teams and Apps on computer and other digital devices (Smartphone, Tablet) (Screening with AST, LAST and NHPT)
- Able to provide informed consent in German.
- Age: 18 - 80 years

Exclusion criteria:

- Severe cardiopulmonary disease
- Other neurological disease than mentioned in the inclusion criteria
- Inability to provide informed consent

4.2 Recruitment, screening and informed consent procedure

The recruitment will take place during in-hospital rehabilitation. When the treatment team decides for a patient to receive outpatient rehabilitation following discharge from in-patient rehabilitation, the study coordinator will screen this possible participant for eligibility and safety and start the informed consent procedure.

A screening is performed using the following tests with the aim of evaluating whether the risk of falling is low and whether the patient can follow a home programme:
Mini Balance Evaluation Systems Test (MiniBESTest): assessment of risk of falling (if score <20 points);
Chedoke: Assessment of trunk stability, arm and leg function;
Apraxia Screening Test (AST): ability to use a computer;
Nine Hole Peg Test (NHPT): ability to use a computer;
Language and Aphasia Screening Test (LAST): understanding of spoken language.

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 participant to make an informed decision about their participation in the study.

Participants will be given at least one day between information and consent. When needed, participants can take longer time before decision.

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.

The investigator 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

An overall study duration of ca. 5.5 to 6 months is needed, including the recruitment period (during last 2 weeks of inpatient rehabilitation), 1-2 weeks waiting time between discharge and start of outpatient rehabilitation due to organisational reasons, a 6 week intervention and a follow-up examination after 3 months. Participants are allocated in a 1:1 ratio to either start with traditional outpatient neurorehabilitation or with blended care. Allocation is performed in REDCap®.

See the table below for an overview of the assessments

Time (hour, day, week)	>-15d	-14d	Baseline	3 Weeks	6 Weeks	Follow Up at 3 Months
Visit	Screening	Inclusion	1st visit	2nd visit	3rd visit	4th Visit
Safety and eligibility-Screening (MiniBesTest, Chedoke, AST, NHPT, LAST)	+					
Oral and written patient information	+					
Written consent		+				
Randomisation		+				
Baseline variables (MoCA, FIM)			+			+
Primary Outcome Variable (LIMOS)			+	+	+	+
Secondary outcome Variables (Eq-5D-5L, Short-LIMOS, ANQ Kurzfragebogen)			+	+	+	+

4.4 Withdrawal and discontinuation

Participants are withdrawn from the study upon withdrawal of informed consent by the participant or if safety concerns (mainly risk of falling) exist within the treatment team, despite positive screening for eligibility. The participant is handled as drop-out.

5 STATISTICS AND METHODOLOGY

5.1. Statistical analysis plan and sample size calculation

The change in total sum score on the LIMOS will be compared between Intervention A and Intervention B with a paired t-test or Wilcoxon signed ranks test in case of skewed data. A correction for Age, sex, location of brain damage and baseline FIM and MoCA will be made, as these are considered confounders of the primary endpoint. The significance level will be two-sided, with α set at 0.05

Our hypothesis is that there will be a trend towards non-inferiority between the two groups. The goal is to provide preliminary data, which can be used for a power analyse for sample size calculation on a future randomized controlled trial.

See chapter 4.1 for justification of the sample size.

Statistical analysis will be made in Jamovi, version 2.6.26.[10]

In case of deviation from the original statistical plan, arguments will be described in the final trial report.

5.2. Handling of missing data and drop-outs

Only cases with complete data on the primary outcome will be analyzed. We consider other methods, like multiple imputation or last observation carried forward to be too vulnerable for outliers within a relatively small sample size.

Drop-outs are replaced by recruitment of new participants.

Secondary outcomes will be analyzed descriptively.

6 REGULATORY ASPECTS AND SAFETY

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 subject 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-Investigator 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-Investigator 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)

SAEs that are possibly, probably or definitely related is classified as related to the trial intervention are documented and reported immediately (within a maximum of 24 hours) to the Sponsor-Investigator of the study.

If it cannot be excluded that the SAE occurring in Switzerland is attributable to the intervention under investigation, the Investigator reports it to the Ethics Committee via BASEC within 15 days.

Falls in the domestic environment during the telerehabilitation sessions are seen as possibly, probably or definitely related as (S)AEs, since these might be the result of a difference between therapy in the clinic environment and at home.

Exemptions from expedited reporting may be possible if the SAE is either a clear result of the underlying disease or well-known. Since participants have a neurological disease, the disease may not be stable, have an intrinsic risk of recurrence or is known for regularly occurrence of late consequences. Examples include a recurrent stroke in participants with stroke as primary diagnosis or post concussion syndrome in participants with traumatic brain injury.

Follow up of (Serious) Adverse Events

Patients with possibly, probably or definitely related (S)AEs will be handled as drop-out from our study. Since an intervention is planned for of 3 weeks, a reinclusion after stabilisation from the (S)AE is not aimed for. The necessary medical care will be organised by the study coordinator. Follow-up will be coordinated via study of the patient records or, if performed at an external institution, by request of the patient record after written consent of the participant.

Relevant (S)AEs will be reported in the publication.

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) safety reporting

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 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

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

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

The Investigator 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

Upon premature study termination or study interruption, the Ethics Committee is notified via BASEC within 15 days (ClinO, Art. 38).

All health-related data are encrypted upon end of data analysis.

6.6 Insurance

In the event of study-related damage or injuries, the liability of the institution Luzerner Kantonsspital provides compensation.

7 FURTHER ASPECTS

7.1 Overall ethical considerations

The concept of our traditional outpatient neurological rehabilitation is well-established and is taken as an example by other clinics. Therefore, the effects of our telerehabilitation concept are expected to be generalizable to all outpatient clinics in Switzerland and even other countries with comparable health care offers (e.g. Western Europe).

Telerehabilitation is still in its infancy in Switzerland. Little research has been done into its limits and possibilities. Therefore, we considered a pilot project suitable for our study to provide findings on therapy effects.

Participants will be included only after careful consideration and evaluation if they can follow instructions and exercises independently to minimize risk. Since the therapy setting is in the patients' home environment, we expect the participants to experience more comfort in participating in their neurorehabilitation program. The efficacy remains to be established as part of the research project, but we expect this aspect to bring direct advantage to the study participants.

7.2 Risk-benefit assessment

We assume that the benefits are on a par with the traditional method and expect added value in terms of life balance as less time must be spent traveling to and from home. There should also be added value from the systematic use of media, which can facilitate rapid social and professional reintegration.

However, a negative aspect could be if it becomes apparent that patients at this stage of therapy still have too little compliance and/or skills to be able to make optimum use of the therapies. The consecutive risk would be unexpected falls. Since patients are assessed by the multidiscpiplinary team before participation, we expect this risk to be minimized.

The encryption methods that the Lucerne Cantonal Hospital has generally introduced for IT (additional key for MS teams), the encryption of data and the use of RedCap with access via hospital servers minimize the risks of unauthorized access to data.

Future patients will benefit from the data from this study as they can receive more specific therapy (on-site or telerehabilitation) based on the knowledge gained. We expect this concept to reduce healthcare costs eventually, although this remains to be established, which would offer a gain to society.

8 QUALITY CONTROL AND DATA PROTECTION

8.1 Quality measures

Quality assurance and quality control is guaranteed by data entry check by a second person (trial monitor), study personnel trained on all important study related aspects and weekly medical records discussion, already implemented in regular care.

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

REDcap® will be used for data entry from assessments and outcome measures.

Source data:

Demographical variables

- Age
- Sex

Clinical characteristics

- Primary diagnosis for inclusion
- Localisation of brain lesion
- FIM
- MoCA

Safety and eligibility Screening assessments

- MiniBesTest
- Chedoke
- AST
- NHPT
- LAST

Primary outcome variables

- LIMOS

Secondary outcome variables

- EQ-5D-5L
- Short-LIMOS
- ANQ Kurzfragebogen

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.
Trial and participant data will be handled with uttermost discretion and is only accessible to authorised personnel who require the data to fulfil their duties within the scope of the study. On the study specific documents, participants are only identified by a unique participant number.

All identifying data (names, addresses, date of birth and patient number at the hospital, etc.) will be stored separately from the actual study data and will be only available to the Principal Investigator and Study Coordinator. All digital documents are ~~password protected~~saved in a protected MS TEAMS Channel only accessible to persons with manually granted access by the PI.

8.4 Retention and destruction of study data and biological material

All study data are archived for 20 years after study termination or premature termination of the study.

9 MONITORING AND REGISTRATION

Source data and study documents are accessible upon request for monitoring. Monitoring will be conducted according to the separate monitoring plan.

The study will be registered in the clinicaltrials.gov registry and Swiss National Clinical trial Portal (HumRes via BASEC) (after receiving ethical approval).

10. FUNDING / PUBLICATION / DECLARATION OF INTEREST

There are no declarations of interest.

No separate funding is used and the project is integrated into standard care, since it is regarded a pilot study. Results might be used for applications for future fundings.

Publication: We confirm that if sex and gender effects are observed, these will be published in the final report of the study. If an analysis is conducted but no sex and gender effects are observed, we will also publish this in the final report of the study.

The sponsor enters and publishes a summary of the trial results in a public register 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 of the trial.
For the purpose of publication in the public register the sponsor also ensures that a lay summary of the trial results is entered in BASEC within one year of completion or discontinuation of the trial. The entry is made at least in the national languages of Switzerland in which the study participants were recruited.

11. REFERENCES

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