CLINICAL STUDY PROTOCOL

An Assessment of the Usability of a Novel Upper Limb Rehabilitation Device in Patients with Stroke

VERSION NO. 1

DATES (2023/07/01)

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Section **Page**

1. Synopsis

Protocol Title：

Usability Analysis of a Novel Bilateral Upper Limb Rehabilitation Device in Post-Stroke Hemiplegia

Study Objectives：

Post-stroke patients commonly experience upper limb impairment, with approximately 85% affected during the acute phase and 40% continuing to experience dysfunction in the chronic phase. Functional upper limb use is essential for daily living and social participation. However, current rehabilitation often requires external assistance or costly robotic devices, which limits accessibility.

This study proposes a novel, non-powered mechanical bilateral upper limb rehabilitation system that is easy to don and operate, reduces assistance needs, and allows patients to independently perform rehabilitation exercises. The device aims to improve treatment accessibility and efficiency while promoting upper limb recovery. The study consists of three phases: Prototype adjustment; Device fitting and training assessment; Usability and satisfaction evaluation.

Investigational product(s)：

A non-powered, mechanically structured bilateral rehabilitation device designed to facilitate independent upper limb training and enhance rehabilitation accessibility.

Development Phase：☐ I ☐II ☐III ☐IV ☐other_____ ■Not applicable

Study Design：

1. ■ Experimental Group：Bilateral upper limb training with the novel device + conventional occupational therapy
   ■ Control Group ： ☐ Placebo
   ☐ Study Drug (Name、Dose、Usage) _____
   ■ Other：Upper limb functional training + conventional occupational therapy
2. Blinding：■ Open ☐ Evaluator-blind ☐ Single-blind(patient) ☐ Double-blind(patient+PI) ☐ Double Dummy ☐ Other _____
3. Randomization: ■ Yes ☐ No
4. ■ Parallel design ☐ Crossover design ☐ Other _____ ☐ Not applicable
5. Treatment Period：1 month ☐ Not applicable
6. Study Period: 1 years (2023/08/01-2024/07/31)
6. Dose adjustment：☐ Mandatory ☐ Selectively ☐ No ■ Not applicable
7. Study location：■ Single ☐ Multi-center ☐ Global

Endpoints (Outcome measure)：

Primary endpoint:

- Fugl-Meyer Assessment for Upper Extremities (FMA-UE)

Secondary endpoint:

- Brunnstrom stage

- Spasticity: Modified Ashworth Scale (MAS)
- Usability: System Usability Scale (SUS)
- Test-retest reliability of repeated training sessions
- User satisfaction: Satisfaction questionnaire

Inclusion/Exclusion Criteria：

Inclusion Criteria

- Stroke onset ≤12 months
- Age 18–70 years
- Stable physiological and neurological status for ≥72 hours
- Able to follow at least two-step commands
- Written informed consent obtained
- Unilateral upper limb hemiplegia
- Brunnstrom stage > I (proximal UE)
- MAS < 3 (affected UE)

Exclusion Criteria

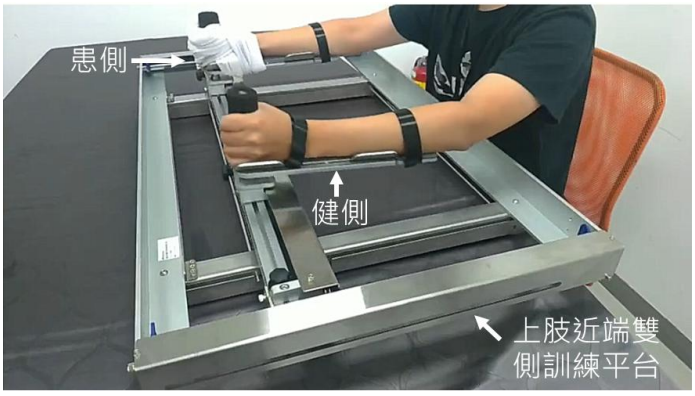
- Musculoskeletal impairments preventing device use
- Active, non-healed dermatological lesions
-

Study Procedures：

The study employs a novel non-powered bi-manual rehabilitation device based on mechanical transmission principles, specifically designed for upper limb training in post-stroke patients. The device operates through a linear guide rail system that enables the unaffected limb to drive the movement of the affected limb along a mirrored trajectory. This bilateral training approach allows simultaneous motion of both upper limbs, enabling the unaffected side to assist in generating active movement in the hemiplegic arm.

Key features of the device include: (1) bilateral limb synchronization, whereby movement of the unaffected upper limb facilitates motion of the affected limb; (2) a purely mechanical, power-free transmission system utilizing linear rail sliders; and (3) training guided along specific two-dimensional movement trajectories. The device is expected to maintain or improve joint range of motion (ROM), reduce spasticity as measured by the Modified Ashworth Scale (MAS), and promote neuroplasticity in the affected neural pathways.

The structural design centers around a central transmission module that links the motion of the two limbs via linear rails to minimize mechanical resistance. The forearm is secured using an end-effector mechanism, and the device allows for directional movement through longitudinal and lateral rail systems. Different training trajectories can be achieved by varying the patient's seated position, supporting functional training across a range of upper limb motion patterns.



Prior to training, the rehabilitation physician evaluates the affected shoulder and elbow joints using the Brunnstrom Recovery Stage, Fugl-Meyer Assessment for Upper Extremities (FMA-UE), and MAS. Based on MAS scores, patients are stratified into two groups: those with MAS <1 and those with MAS ≥1. Participants are then randomly assigned to either the experimental group—receiving bilateral upper limb training with the device combined with conventional occupational therapy—or the control group—receiving only conventional upper limb occupational therapy.

For the experimental group, patients are instructed on how to use the device, and a therapist provides assistance during operation. After the initial session, patients repeat the same training one week later to assess test-retest reliability. Training includes two components: (1) single-joint exercises targeting either the shoulder or elbow, with 20 repetitions per joint for 5 sets, each set separated by a 30-second rest; and (2) dual-joint exercises involving functional movement along rectangular and triangular paths, also conducted in 5 sets of 20 repetitions with similar rest intervals.

Control group training involves conventional functional tasks targeting the affected limb, such as box-pushing (standing or seated), alternating push-pull activities, and use of a hand-cycle. Both groups train for 30 minutes per day, five days a week, for a total of 15 sessions over three weeks. All participants continue their routine rehabilitation treatments throughout the study.At the conclusion of the three-week intervention, the rehabilitation physician reassesses Brunnstrom stage, FMA-UE, and MAS to evaluate functional changes in the affected upper limb.

To assess usability and user satisfaction, both patients and therapists complete the System Usability Scale (SUS) and a satisfaction questionnaire following the training period. The SUS consists of 10 items rated on a five-point Likert scale ranging from "strongly disagree" to "strongly agree." Odd-numbered items are positively worded, while even-numbered items are negatively worded. Scoring involves subtracting 1 from positive item scores and subtracting the original score from 5 for negative items; the total is then multiplied by 2.5 to yield a final SUS score out of 100.

The satisfaction questionnaire assesses five domains—overall satisfaction, comfort, ease of donning the device, perceived improvement in ROM, and rehabilitative assistance—using a five-point Likert-type scale ranging from 1 (very poor) to 5 (very good).

1. **Concomitant Treatments：** ■Not applicable

1. Concomitant Therapy：

2. Prohibited Therapy：

Statistical Methods：

1. Main study Hypothesis：☐ Equality ■ Superiority ☐ Non-inferiority ☐ Equivalence ☐ Other _____

2. Estimated Sample Size：

The planned enrollment for this trial includes 60 stroke patients, with an overall evaluable sample size of 70 individuals. This estimation is based on the recommendation by Lewis and Sauro (2009), who suggest that a minimum of 12 participants is appropriate for usability assessments. In the present study, participants will be categorized into four subgroups based on MAS scores (either <1 or ≥1) and intervention type (experimental or control). To ensure that each subgroup has at least 12 participants, a minimum of 48 participants is required (12 per subgroup). An additional 25% (12 participants) will be recruited to account for potential dropout, bringing the total number of stroke patients to be enrolled to 60. Our center has the capacity to recruit and evaluate all 70 participants.

In addition to prospective participants, retrospective data from 60 stroke patients will be included for analysis. Furthermore, a total of 10 individuals—including trained therapists and healthy subjects (such as caregivers or family members who have received prior instruction)—will be included to assess usability and support the study's broader evaluation framework.

3. Efficacy assessment group：☐ Intent-to-treat (ITT) ■ Per-Protocol (**PP)** ☐ Other _____

4. Interim analysis：■ Yes ☐ No

5. Statistical methods：

Continuous variables will be presented as means with standard deviations, while categorical variables will be expressed as proportions. Independent t-tests will be used to compare continuous variables between groups, and Pearson's chi-square test will be applied for categorical data. One-way analysis of variance (ANOVA) will be employed to assess differences across multiple groups. All statistical analyses will be conducted using the Statistical Package for the Social Sciences (SPSS). A p-value of less than 0.05 will be considered statistically significant.

6. Handling of Missing Data：

Only cases with complete datasets will be included in the analysis. Incomplete records will be excluded from statistical evaluation to maintain data integrity.

2. Introduction and Rationale

2.1 Investigational product(s)

A non-powered, mechanically structured bilateral rehabilitation device designed to facilitate independent upper limb training and enhance rehabilitation accessibility.

2.2 Animal and preclinical study data

Not Applicable

2.3 Clinical data

Not Applicable

2.4 Risks / benefits Assessment

During the operation of the equipment, there may be friction and shear effects on the skin, leading to potential skin lesion. Therefore, before conducting rehabilitation programs with the Synslai device, the skin that will touch the device will be covered with a bandage to avoid possible skin damage. Furthermore, risks are held to a minimum due to anonymous coding and keeping all data confidential with no identification to specific participants. No undue stress or uneven medical managements is anticipated as a result of patient's participation. Benefits for the participants is to be able to receive more types and longer time period of post-stroke rehabilitation programs for upper limbs paralysis. It facilitates the functional recovery of post-stroke hemiplegia.

2.5 Regulatory

This study will be conducted in compliance with the protocol approved by the Institutional Review Board, and according to Good Clinical Practice standards. No deviation from the protocol will be implemented without the prior review and approval of the IRB except where it may be necessary to eliminate an immediate hazard to a research subject. In such case, the deviation will be reported to the IRB as soon as possible.

3. Objectives and Endpoints

3.1 Study Objectives:

Current rehabilitation strategies for post-stroke upper limb hemiparesis primarily rely on conventional functional training. However, stroke patients often encounter significant barriers to performing such exercises due to muscle weakness, increased muscle tone, and impaired neuromuscular coordination, which frequently necessitate additional physical assistance. While certain rehabilitation devices can help reduce this burden, their high cost limits accessibility and widespread clinical use. To address these challenges, this study proposes a novel bilateral upper limb rehabilitation training program incorporating a non-powered mechanical device. The device is designed with a passive mechanical structure to significantly reduce production and operational costs, while simultaneously minimizing the need for external assistance during training. By combining affordability with functional utility, this approach aims to enhance rehabilitation accessibility and promote upper limb functional recovery in patients with post-stroke hemiplegia.

3.2 Study endpoints:

3.2.1 Primary endpoint:

Fugl-Meyer Assessment for Upper Extremities (FMA-UE)

3.2.2 Secondary endpoints:

Brunnstrom stage

Spasticity: Modified Ashworth Scale (MAS)

Usability: System Usability Scale (SUS)

Test-retest reliability of repeated training sessions

User satisfaction: Satisfaction questionnaire

4. Study Design

4.1 Overall Design

The study employs a novel non-powered bi-manual rehabilitation device based on mechanical transmission principles, specifically designed for upper limb training in post-stroke

patients. The device operates through a linear guide rail system that enables the unaffected limb to drive the movement of the affected limb along a mirrored trajectory. This bilateral training approach allows simultaneous motion of both upper limbs, enabling the unaffected side to assist in generating active movement in the hemiplegic arm.

Key features of the device include: (1) bilateral limb synchronization, whereby movement of the unaffected upper limb facilitates motion of the affected limb; (2) a purely mechanical, power-free transmission system utilizing linear rail sliders; and (3) training guided along specific two-dimensional movement trajectories. The device is expected to maintain or improve joint range of motion (ROM), reduce spasticity as measured by the Modified Ashworth Scale (MAS), and promote neuroplasticity in the affected neural pathways.

The structural design centers around a central transmission module that links the motion of the two limbs via linear rails to minimize mechanical resistance. The forearm is secured using an end-effector mechanism, and the device allows for directional movement through longitudinal and lateral rail systems. Different training trajectories can be achieved by varying the patient's seated position, supporting functional training across a range of upper limb motion patterns.

Prior to training, the rehabilitation physician evaluates the affected shoulder and elbow joints using the Brunnstrom Recovery Stage, Fugl-Meyer Assessment for Upper Extremities (FMA-UE), and MAS. Based on MAS scores, patients are stratified into two groups: those with MAS <1 and those with MAS ≥ 1. Participants are then randomly assigned to either the experimental group—receiving bilateral upper limb training with the device combined with conventional occupational therapy—or the control group—receiving only conventional upper limb occupational therapy.

For the experimental group, patients are instructed on how to use the device, and a therapist provides assistance during operation. After the initial session, patients repeat the same training one week later to assess test-retest reliability. Training includes two components: (1) single-joint exercises targeting either the shoulder or elbow, with 20 repetitions per joint for 5 sets, each set separated by a 30-second rest; and (2) dual-joint exercises involving functional movement along rectangular and triangular paths, also conducted in 5 sets of 20 repetitions with similar rest intervals.

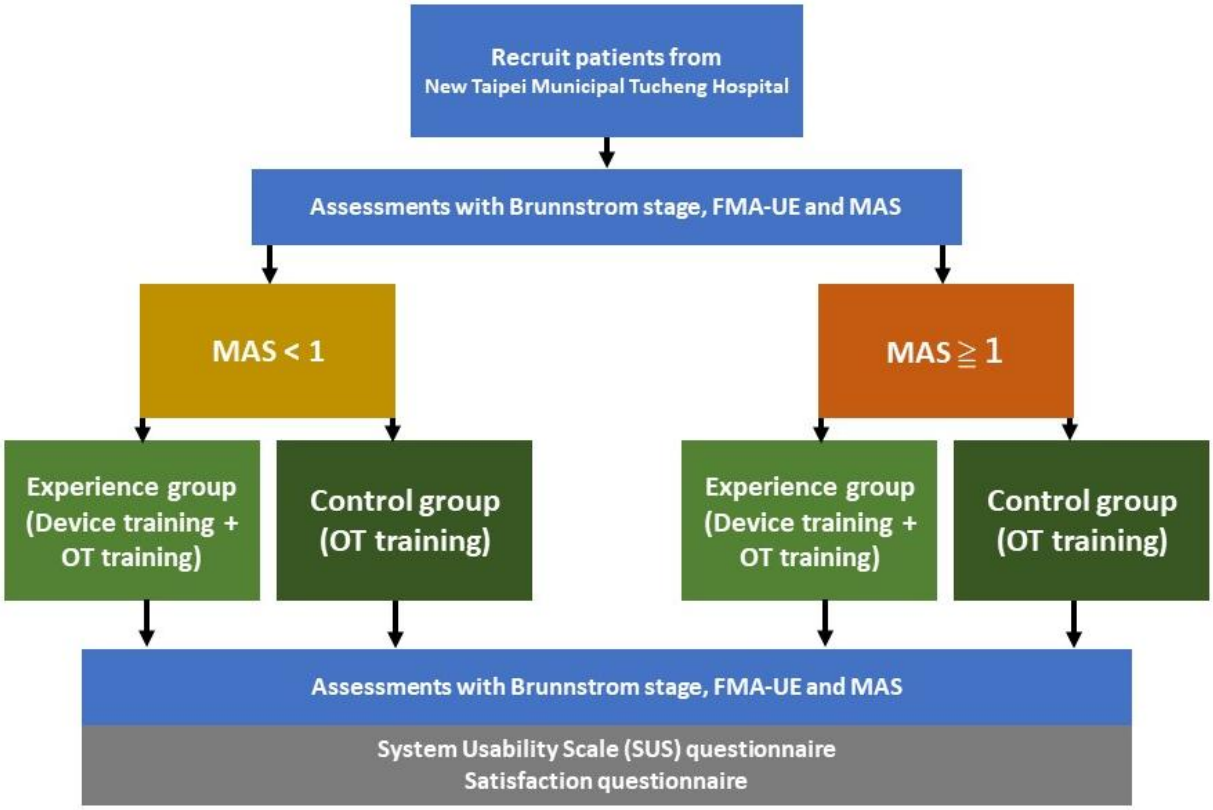
Control group training involves conventional functional tasks targeting the affected limb, such as box-pushing (standing or seated), alternating push-pull activities, and use of a hand-cycle. Both groups train for 30 minutes per day, five days a week, for a total of 15 sessions over three weeks. All participants continue their routine rehabilitation treatments throughout the study.At the conclusion of the three-week intervention, the rehabilitation physician reassesses Brunnstrom stage, FMA-UE, and MAS to evaluate functional changes in the affected upper limb.

To assess usability and user satisfaction, both patients and therapists complete the System Usability Scale (SUS) and a satisfaction questionnaire following the training period. The SUS consists of 10 items rated on a five-point Likert scale ranging from "strongly disagree" to "strongly agree." Odd-numbered items are positively worded, while even-numbered items are negatively worded. Scoring involves subtracting 1 from positive item scores and subtracting the original score from 5 for negative items; the total is then multiplied by 2.5 to yield a final SUS score out of 100.

The satisfaction questionnaire assesses five domains—overall satisfaction, comfort, ease of donning the device, perceived improvement in ROM, and rehabilitative assistance—using a

five-point Likert-type scale ranging from 1 (very poor) to 5 (very good).

Flow Chart：



4.2 Number of Patients

The planned enrollment for this trial includes 60 stroke patients, with an overall evaluable sample size of 70 individuals. This estimation is based on the recommendation by Lewis and Sauro (2009), who suggest that a minimum of 12 participants is appropriate for usability assessments. In the present study, participants will be categorized into four subgroups based on MAS scores (either <1 or ≥1) and intervention type (experimental or control). To ensure that each subgroup has at least 12 participants, a minimum of 48 participants is required (12 per subgroup). An additional 25% (12 participants) will be recruited to account for potential dropout, bringing the total number of stroke patients to be enrolled to 60. Our center has the capacity to recruit and evaluate all 70 participants.

In addition to prospective participants, retrospective data from 60 stroke patients will be included for analysis. Furthermore, a total of 10 individuals—including trained therapists and healthy subjects (such as caregivers or family members who have received prior instruction)—will be included to assess usability and support the study's broader evaluation framework.

4.3 Schedule of Activities

Time-Event scheme:

Phase	Recruitment	Pre-treatment Assessment	Allocation	Rehabilitation programs	Post-treatment Assessment
Evaluation					
Rehabilitation ward / Outpatient department	V				
Screening /Administration					
Inclusion / Exclusion criteria	V	V			
Patient profile	V	V			
Assessment					
Brunnstrom stage		V			V
Fugl-Meyer Assessment-Upper Extremities (FMA-UE)		V			V
Modified Ashworth scale (MAS)		V			V
Questionnaire					
System Usability Scale (SUS) questionnaire					V
Satisfaction questionnaire					V

5. Study Population

5.1 Inclusion Criteria

- Stroke onset ≤12 months
- Age 18–70 years
- Stable physiological and neurological status for ≥72 hours
- Able to follow at least two-step commands
- Written informed consent obtained
- Unilateral upper limb hemiplegia
- Brunnstrom stage > I (proximal UE)
- MAS < 3 (affected UE)

5.2 Exclusion Criteria

- Musculoskeletal impairments preventing device use
- Active, non-healed dermatological lesions

5.3 Withdrawal criteria

Participants will be withdrawn from the study if they (1) become lost to follow-up, (2) develop new central nervous system lesions, or (3) experience decompensated systemic diseases that may compromise safety or study participation.

6. Treatments

6.1. Treatment Administration

This study utilizes a non-powered bi-manual mechanical device for upper limb rehabilitation in post-stroke patients. The device operates via a linear rail transmission system that allows movements initiated by the unaffected upper limb to be mechanically transmitted to the affected limb, thereby facilitating bilateral synchronous motion along a defined trajectory within a single plane. This design enables joint mobilization without reliance on electric power, enhancing accessibility and reducing cost.

Participants will be randomly assigned to either the control group, which will receive conventional occupational therapy alone, or the experimental group, which will receive a combination of device-assisted bilateral upper limb training and standard occupational therapy. For the experimental group, the rehabilitation protocol consists of: (1) isolated joint training for the shoulder and elbow, and (2) combined joint training involving functional tasks using rectangular and triangular trajectories. For both types of training, each task will be performed in 5 sets of 20 repetitions, with a 30-second rest between sets. Training will be administered once daily for 30 minutes, five days per week, over a three-week period, totaling 15 sessions. All participants will continue to receive their usual standard care throughout the trial.

6.2. Concomitant Therapy

Not Applicable

7. Efficacy Assessments

Primary endpoint:

- Fugl-Meyer Assessment for Upper Extremities (FMA-UE)

Secondary endpoints:

- Brunnstrom stage
- Spasticity: Modified Ashworth Scale (MAS)
- Usability: System Usability Scale (SUS)
- Test-retest reliability of repeated training sessions
- User satisfaction: Satisfaction questionnaire

8. Safety Assessments

Not Applicable

9. Adverse event reporting

Liu, Kuo-Cheng will report SAEs to the IRB of Chang Gung Medical Foundation according to the Serious Adverse Event Reporting Procedures and Guidelines as posted in the Clinical Trials Resource on the website of Chang Gung Medical Foundation IRB. SAE reports to the IRB should include the following information when calling the Medical Monitor:

- Date and time of the SAE
- Date and time of the SAE report
- Name of reporter
- Call back phone number
- Affiliation/Institution conducting the study
- Protocol number
- Title of protocol
- Description of the SAE, including attribution to drug and expectedness

9.1 Definitions and reports of Adverse Events

All adverse events that occur after the informed consent is signed (including run-in) must be recorded on the adverse event CRF (paper and/or electronic) whether or not related to study agent. AE Data Elements including:

- AE reported date
- AE Verbatim Term
- CTCAE Term (v 5.0)
- Event onset date and event ended date
- Severity grade
- Attribution to study agent (relatedness)
- Whether or not the event was reported as a Serious Adverse Event (SAE)
- Action taken with the study agent
- Outcome of the event
- Comments

Identify the adverse event using the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. The CTCAE provides descriptive terminology and a grading scale for each adverse event listed.

AEs will be assessed according to the CTCAE grade associated with the AE term. AEs that do not have a corresponding CTCAE term will be assessed according to their impact on the participant's ability to perform daily activities as follows:

Grade	Severity	Description
1	Mild	• Barely noticeable, does not influence functioning • Causing no limitations of usual activities
2	Moderate	• Makes participant uncomfortable, influences functioning • Causing some limitations of usual activities

3	Severe	• Severe discomfort, treatment needed • Severe and undesirable, causing inability to carry out usual activities
4	Life threatening	• Immediate risk of death • Life threatening or disabling
5	Fatal	• Causes death of the participant

The possibility that the adverse event is related to study drug will be classified as one of the following: not related, unlikely, possible, probable, definite.

DEFINITION of Serious Adverse Events: ICH Guideline E2A and GCP of Taiwan define serious adverse events as those events, occurring at any dose, which meet any of the following criteria:

- Results in death
- Is life threatening (Note: the term life-threatening refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe).
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital abnormality/birth defect
- Events that may not meet these criteria, but which the investigator finds very unusual and/or potentially serious, will also be reported in the same manner.

9.2 Adverse event follow-up

All AEs, including lab abnormalities that in the opinion of the investigator are clinically significant, will be followed according to good medical practices and documented as such. Site staff should send follow-up reports as requested when additional information is available. Additional information should be entered on the IRB of Chang Gung Medical Foundation of SAE form in the appropriate format. Follow-up information should be sent to Chang Gung Medical Foundation IRB as soon as possible according to IRB's Serious Adverse Event Reporting Procedures and Guidelines.

10. Criteria for the termination of the trial

(1) Enroll requested number of patients and complete the study
(2) Relevant research has been published and could confirmed the hypothesis of this study

11. Statistical Considerations

11.1 Sample size Determination

Based on the recommendations by Lewis and Sauro (2009), a minimum of 12 participants per group is considered appropriate for usability testing. In this study, participants will be categorized into four subgroups based on muscle tone classification (MAS < 1 or MAS ≥ 1) and treatment allocation (experimental or control group), resulting in a minimum required sample size of 48 (12 participants per subgroup). To account for an anticipated dropout rate of approximately 25%, an additional 12 participants will be recruited, leading to a total target enrollment of 60 stroke patients. In addition, 10 trained healthy participants—including caregivers or family members—will be included for usability assessments and device operation training. The total number of evaluable subjects for the study will therefore be 70.

11.2 Planned Statistical methods of analysis

Continuous variables will be presented as means and standard deviations, while categorical variables will be reported as frequencies and percentages. Independent sample t-tests will be used to compare continuous variables between groups, and Pearson's chi-square test will be used for comparisons of categorical variables. One-way analysis of variance (ANOVA) will be applied to assess differences among the multiple subgroups. All statistical analyses will be conducted using SPSS (Statistical Package for the Social Sciences). A p-value of less than 0.05 will be considered indicative of statistical significance.

11.2.1 Efficacy analysis

Primary endpoint:

- Fugl-Meyer Assessment for Upper Extremities (FMA-UE)

Secondary endpoints:

- Brunnstrom stage
- Spasticity: Modified Ashworth Scale (MAS)
- Usability: System Usability Scale (SUS)
- Test-retest reliability of repeated training sessions
- User satisfaction: Satisfaction questionnaire

11.2.2 Safety analysis

Not Applicable

11.2.3 Additional analysis

Not Applicable

11.2.4 The level of significance

A p-value less than 0.05 was considered significant and was denoted by alternative hypothesis and p-value more than 0.05 was denoted by null hypothesis.

11.3 Analysis Population

The analysis population of this study is the patient aged 18-70 years with the onset of stroke attack within 12 months, Brunnstrom stage of upper limb >1 and Modified Ashworth Scale of upper limb < 3. All the subjects should be able to understand and cooperate with the instructions from the therapists or caregivers.

11.4 Procedure for accounting for missing, unused and spurious data

The approach to the missing data is to simply omit those cases with the missing data and analyze the remaining data.

11.5 Procedures for reporting any deviation(s) from the original statistical plan

The collected data will not be used in the statistical analysis if the patients do not meet the inclusion criteria. For unused data, the trial investigators will analyze the possible factors which cause this specific condition and record them in the case report form. Any deviation from the original statistical design must have a reasonable explanation and be reported in the final report.

12. Direct access to source data/documents

Investigators permit IRB to access to the source data of experiment for trial-related monitoring,

audits and regulatory inspection.

13. Ethical considerations

This study will be conducted according to Taiwan and international standards of Good Clinical Practice for all studies. Applicable government regulations and Chang Gung Medical Foundation research policies and procedures will also be followed.

This protocol and any amendments will be submitted to the Chang Gung Medical Foundation Institutional Review Board (IRB) for formal approval to conduct the study. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator.

All subjects for this study will be provided an informed consent describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This informed consent will be submitted with the protocol for review and approval by the IRB. The formal consent of a subject, using the IRB-approved informed consent, will be obtained before that subject is submitted to any study procedure. The informed consent must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

14. Data handling and keeping

Clinical data will be collected in Chang Gung Medical Foundation till the end of the study. The sequencing data will be stored in computers of laboratory with an electronic encryption. The clinical and source data can only be assessed by clinical doctors and investigators of the study. Each participant will be renamed with a number to keep the privacy of personal information. The clinical records for all participants, including protocol-specific case report forms, all source documentation (containing evidence to study eligibility, history and physical findings, laboratory data, and images), as well as IRB records and other regulatory documentation will be maintained at a minimum for 3 years in the well-protected device owned by the protocol lead investigator.

15. Financing and Insurance

There will be no costs to subjects for any research related activities. All research-related costs will be paid by the Chang Gung Medical Foundation and the research team. The hospital and the trial lead investigator will be responsible for paying for injuries in case of accident.

16. References

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