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study protocol and Statistical Analysis Plan

Official Study Title:
Proprioceptive error correction technique development to promote post-stroke upper limbs motor rehabilitation.

NCT number:
not yes assigned

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Study Protocol

<table>
<tr><td>Study Title</td><td>English</td><td colspan="6">Proprioceptive error correction technique development to promote post-stroke upper limbs motor rehabilitation</td></tr>
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<tr><td colspan="2">Planned study duration</td><td colspan="6">June 2025 - May 2026 (1 year 0 months)</td></tr>
<tr><td colspan="2">Study identifier</td><td colspan="6">RS-2023-00209864</td></tr>
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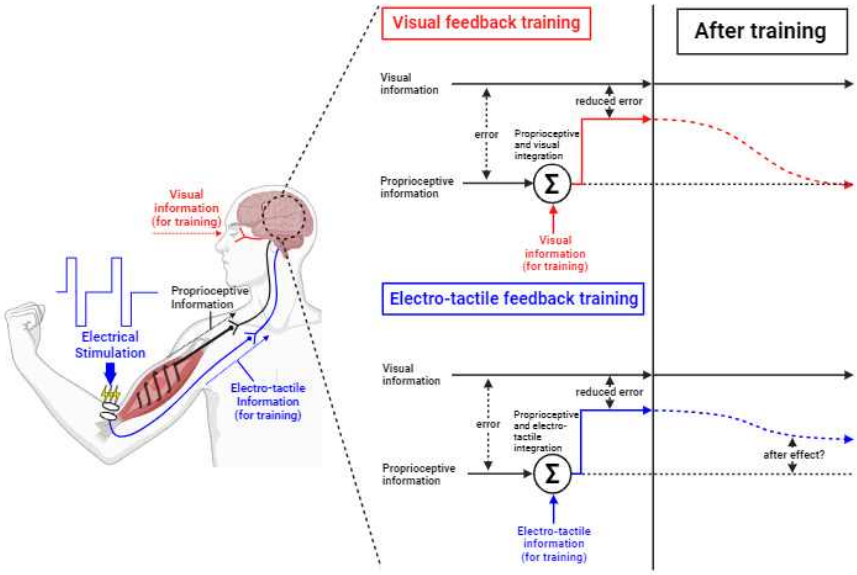
□Study Purpose and Background

- Purpose of the Study: The purpose of this study is to develop sensory transformation and augmentation techniques that minimize the effects of proprioceptive errors, with the goal of significantly improving motor learning and rehabilitation of the upper limbs. This study will evaluate the efficacy of the proprioceptive error correction techniques in individuals who have experienced a stroke.

- Rationale for the Study: Upper limb motor control is critical for stroke survivors to maintain independence in daily activities. The upper limbs are responsible for essential functions such as eating, dressing and undressing, body protection, hygiene management, and interaction with external objects. Therefore, it is important to investigate whether proprioceptive correction techniques can contribute to improved upper limb rehabilitation outcomes in this population.

- Scientific Background and Justification: The human nervous system often processes conflicting information from visual and proprioceptive inputs during upper limb control, which limits the effectiveness of motor learning. Real-time sensory feedback, a crucial component for motor learning, is often unreliable due to this sensory conflict. This study aims to address this issue

by delivering supplementary information via electrical stimulation to resolve sensory conflicts and thereby enhance motor rehabilitation outcomes (refer to Figure 1).



<Figure 1. Schematic diagram of proprioceptive error correction technology>

☐ **Expected Study Duration**

- From the approval date until May 2026, approximately 12 months (1 year) is anticipated for study completion.

☐ **Research Methods**

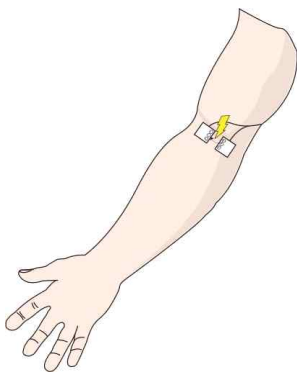
- **Overview of Research Methods**

1) **Development of Visual-Tactile Transformation Method:**

The study aims to develop a method for delivering intuitive angular information of the elbow using non-invasive electrical stimulation and to determine the optimal stimulation parameters (including electrode placement, frequency, and intensity).

1-1) **Determination of Electrode Placement:**

Electrodes will be placed on the cubital fossa, the most sensitive hollow area on the inside of the elbow [1]. Starting from this reference electrode position (see Figure 2), slight adjustments will be made based on participant feedback to identify the optimal electrode placement that produces a clear electrical tactile sensation at the target site (elbow).



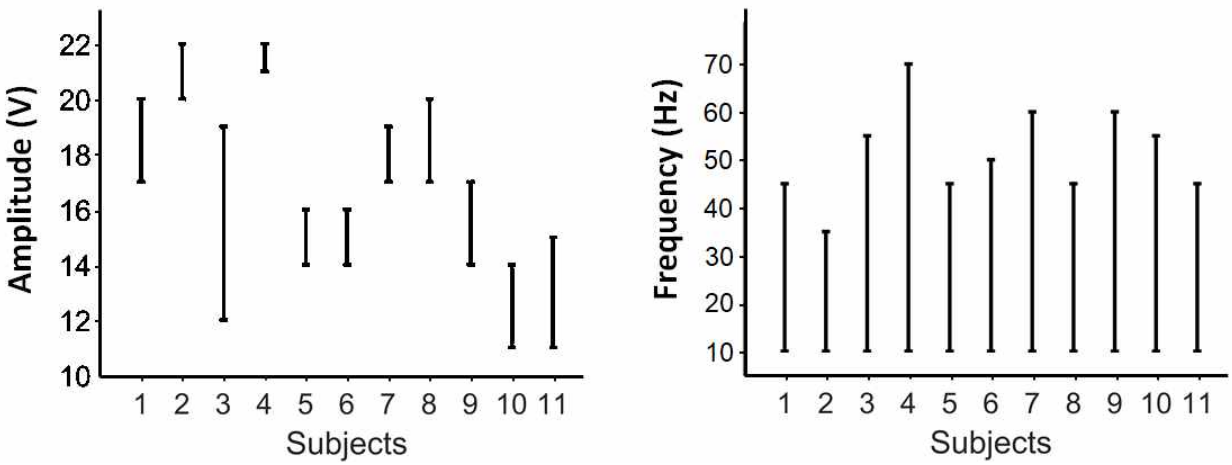
<Figure 2. Schematic illustration of electrode placement on the upper limb (elbow)>

1-2) **Setting of Stimulation Frequency and Voltage Intensity**

The range of stimulation frequencies and voltage intensities that evoke pulsing (flutter) and buzzing (electrical buzzing) sensations was determined. As reported in previous studies, the range for pulsing sensations in terms of stimulation frequency and voltage intensity has been established (see Figure 3). Specifically, the voltage intensity range was set between the minimum voltage at which each participant began to perceive the stimulation (V_min) and the maximum voltage at which discomfort was first reported (V_max). The frequency range was set from 10 Hz to 70 Hz, the typical upper limit at which participants can distinguish the stimulation.

Based on these criteria, the stimulation frequency and intensity ranges for each sensation were determined. In prior studies conducted by our research group, the maximum tolerable voltage (V_max) at which discomfort was reported ranged from approximately 10 to 22 V for both male and female participants [3, 4, 5, 6] (see Figure 3). Generally, females exhibit slightly lower V_max values than males (by approximately 0 to 5 V), which is attributed to thinner skin and muscle tissue in females [7].

It is noteworthy that the maximum voltage levels observed for both males and females correspond to approximately 30–70% of the safety voltage standards set by the Occupational Safety and Health Administration. During experiments, electrical stimulation is administered at voltage levels below the participant's discomfort threshold (V_max) to ensure safety and comfort.



<Figure 3. Example ranges of electrical stimulation intensity (left) and frequency (right) for individual participants.>

1-3) Measurement of Elbow Angle and Determination of Angle-to-Tactile Conversion Formula

The elbow angle is measured using a variable resistor (RV09H-20SQ, 50 kΩ). A goniometer marked in 1-degree increments from 0° to 150° is placed on the inner and outer surfaces of a box, aligned with the flexion and extension directions of the elbow joint. Velcro straps are used to secure the participant's upper limb to the inner goniometer, fixing the elbow joint and the distal radius and ulna in place. As the participant moves their arm, the inner goniometer moves accordingly, allowing the current elbow angle to be measured. A pointer is attached to the outer goniometer to enable the participant to indicate the angle. To ensure that the participant cannot

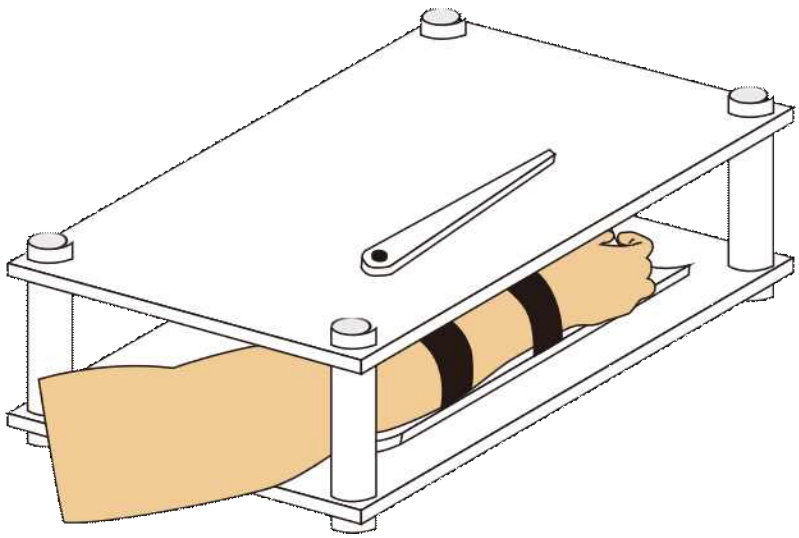
see their moving limb, the inner and outer goniometers are enclosed within a box of suitable size, as illustrated in <Figure 4>.

The resistance value measured via the variable resistor is converted into the corresponding elbow angle. Based on the measured elbow angle, the electrical stimulation frequency is adjusted accordingly for the experiment. The conversion formula for mapping elbow angle to electrical stimulation frequency is as follows:

$$F_{stim} = \frac{(F_{\max} - F_{\min})}{(\theta_{\max} - \theta_{target})}(\theta_{current} - \theta_{target}) + F_{\min} \qquad \theta_{target} \le \theta_{current} \le \theta_{\max}$$

$$F_{stim} = \frac{(F_{\min} - F_{\max})}{(\theta_{target} - \theta_{\min})}(\theta_{current} - \theta_{target}) + F_{\min} \qquad \theta_{\min} \le \theta_{current} \le \theta_{target}$$

θ_{target}denotes the target angle to be learned, which is set differently depending on the experimental condition. $\theta_{\max}$and $\theta_{\min}$are defined as $\theta_{target} + 15°$, $\theta_{target} - 15°$, respectively. $F_{\max}$and $F_{\min}$are set to 70 Hz and 10 Hz, respectively. $\theta_{current}$represents the current elbow angle, and F_{stim}denotes the electrical stimulation frequency corresponding to the current elbow angle.



<Figure 4. Box-Type Elbow Angle Measurement Device>

2) Methods

2-1) Study Period

The total study duration spans a minimum of three weeks. For each of the three experimental conditions, assessments are conducted during Visit 1 and Visit 2, with a washout period of at least 7 days between conditions.

2-2) Randomization and Procedure

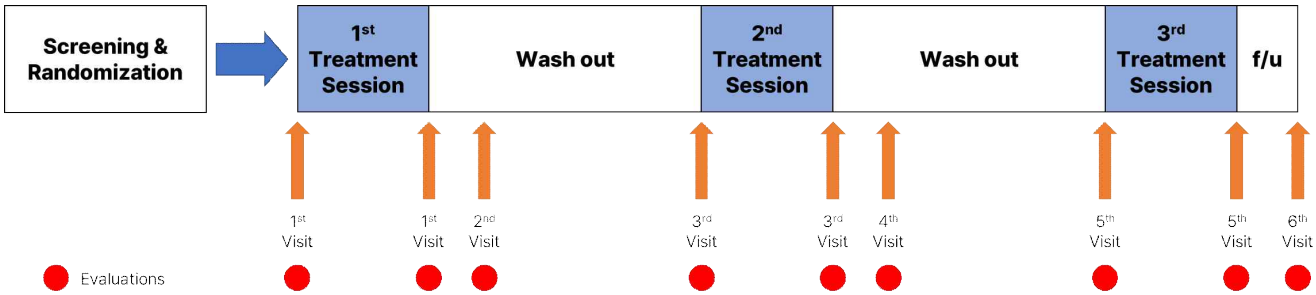
All participants enrolled in the study are assigned a random number generated using Python. Based on a pre-defined randomization protocol, each participant is randomly allocated to a specific sequence of the three experimental conditions: Electrical Stimulation Cue, Visual Cue, and No Cue.

2-3) Visit Schedule

All participants receive standard therapy in accordance with clinical guidelines for stroke rehabilitation. The study intervention is provided in addition to standard therapy. A total of six visits are planned. During the screening visit, participants (or their legal representatives) provide written informed consent. The participant's medical history and current clinical status are reviewed to confirm eligibility. Eligible participants are then assigned a randomization number and allocated to a randomized order of the three cueing conditions: Electrical Stimulation Cue, Visual Cue, and No Cue.

Baseline assessments are conducted at Visit 1, Visit 3, and Visit 5—prior to the start of each intervention. After the baseline assessment, one session of the corresponding intervention is administered. Following each intervention session, additional efficacy assessments are performed during all visits. A washout period of at least 7 days is maintained between each experimental condition.

The overall study flow is summarized in Figure 5.



<Figure 5. Study Protocol Flowchart>

2-4) Experimental Intervention Protocols

2-4-1) Electrical Stimulation Cue Protocol

The intervention is administered once for 30 minutes. An electrical stimulation device developed by the research team is attached to the participant's cubital fossa. Stimulation is provided with increasing frequency, reaching a maximum of 70 Hz as the elbow joint approaches a pre-defined target angle. This target angle is individually set within the participant's available range of motion based on baseline assessments. During the session, the participant attempts to match their elbow angle to the target angle while receiving verbal feedback from the examiner.

2-4-2) Visual Cue Protocol

The intervention is administered once for 30 minutes. A visual cue displays the difference between the current elbow joint angle and a predefined target angle on a screen. The target angle is individually set within each participant's range of motion based on baseline assessments. The participant is instructed to match their elbow angle to the target angle while receiving verbal feedback from the examiner.

2-4-3) No Cue Protocol

The intervention is administered once for 30 minutes. The participant attempts to match their elbow joint angle to a verbally instructed target angle, relying solely on verbal feedback from the examiner.

2-5) Outcome Measures and Assessment Procedures

2-5-1) Threshold Detection

An angle-detecting sensor developed by the research team (see Section 1-3) is attached to the participant's affected elbow joint. The examiner holds the medial and lateral epicondyles of the participant's affected upper limb with one hand and the distal radius and ulna with the other. The test is conducted four times in total: two trials in the flexion direction and two in the extension direction, in random order. Each trial starts from 60° of elbow flexion. The examiner moves the joint at approximately 6° per second, and the participant is instructed to verbally report when they perceive joint movement. If the participant does not respond before the joint reaches 30° of motion, a score of 0 is recorded.

-2 points: Participant perceives movement of the elbow joint.

-0 points: Participant does not perceive movement of the elbow joint.

2-5-2) Joint Position Reproduction

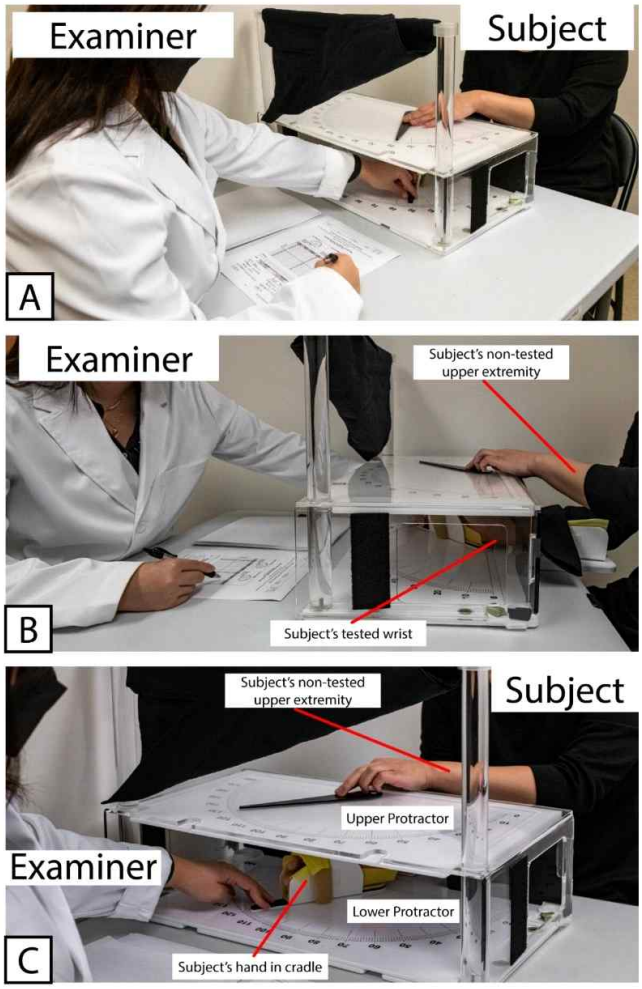
An angle-detecting sensor developed by the research team is attached to both of the participant's elbow joints. The examiner holds the medial and lateral epicondyles of the participant's affected upper limb with one hand and the distal radius and ulna with the other. The examiner passively moves the affected arm to one of 12 pre-defined flexion or extension angles in the following order: 60°, 90°, 30°, 120°, 60°, 30°, 90°, 120°, 30°, 60°, 120°, and 90°. After each presentation, the participant is asked to reproduce the same angle using the unaffected limb. The average difference between the target angles and the reproduced angles across the 12 trials is calculated and used for analysis.

2-5-3) position Sense Test

Apparatus

Goniometers marked in 1-degree increments from 0° to 120° are installed on the inner and outer surfaces of a box aligned with the elbow joint's flexion and extension axis. Velcro straps are used to secure the participant's upper limb and distal radius and ulna in place. A pointer is attached to the outer goniometer to allow the participant to indicate the perceived angle. A box of appropriate size is placed between the inner and outer surfaces to block the participant's view of their own arm during the test.

※ The apparatus was newly designed with reference to the Wrist Position Sense Test Apparatus (see Figures 4 and 6).



<그림 6. Wrist position sense test apparatus>

Procedure

The examiner passively moves the participant's upper limb to one of 12 predefined elbow flexion or extension angles in the following order: 60°, 90°, 30°, 120°, 60°, 30°, 90°, 120°, 30°, 60°, 120°, and 90°. The examiner attempts to maintain a consistent speed during both flexion and extension movements. After the target angle is reached, the participant uses their contralateral (unaffected) hand to indicate the perceived angle by adjusting a pointer on the outer goniometer of the device. The absolute differences between the presented and indicated angles are recorded for each of the 12 trials, and the average error is calculated for analysis.

2-5-4) Motor & Position Sense Test

Apparatus

Goniometers marked in 1-degree increments from 0° to 120° are installed on both the inner and outer surfaces of a box aligned with the flexion and extension axis of the elbow joint. Velcro straps are used to secure the participant's upper limb, including the elbow joint and distal radius and ulna. A pointer is attached to the outer goniometer to allow participants to indicate perceived joint angles. A box of appropriate size is placed between the inner and outer goniometers to ensure that the participant's tested arm remains out of view during the assessment.

Procedure

After assessing the participant's upper limb range of motion (ROM), the examiner manually moves the goniometer pointer to present 12 different target angles within the participant's available ROM. The participant is instructed to actively move their elbow joint to match the presented angle by flexing or extending the joint. During each trial, the participant is encouraged to move at a consistent speed. After the examiner presents the target angle using the pointer, the participant moves their limb to the angle they perceive as matching the target. The difference between the presented and perceived angles is recorded for each of the 12 trials, and the average error is calculated for analysis.

2-5-5) Fugl-Meyer Assessment (FMA): Upper Limb Position Sense Test

The examiner evaluates proprioception in the affected upper limb in the following order: shoulder joint, elbow joint, wrist joint, and thumb. Each joint is tested at least four times within the participant's available ROM. All assessments are conducted with the participant's eyes closed.

For the shoulder and elbow joints, the examiner holds the participant's medial and lateral epicondyles with one hand and the distal radius and ulna with the other. The examiner randomly moves the joint up or down in flexion/extension directions at least four times to evaluate position sense.

For the wrist joint, the examiner holds the distal radius and ulna with one hand and the heads of the second and fifth metacarpals with the other hand, then passively moves the wrist joint up or down in random order.

For the thumb, the examiner holds the interphalangeal joint with one hand and the lateral aspects of the distal phalanx with the other, passively moving the thumb up or down at least four times in random order.

Light touch testing is conducted using the tip of a cotton swab on each joint of the affected limb.

-2 points: Accurately perceives joint position.

-1 point: Inconsistent perception, but correctly identifies at least 3 out of 4 trials.

-0 points: Unable to perceive joint position.

2-5-6) Sensory Testing (Including Monofilament Sensory Test)

The examiner performs sensory testing on the shoulder, elbow, wrist, and thumb joints of the affected upper limb. All tests are conducted with the participant's eyes closed.

Sharp/Blunt Discrimination: A paperclip is used to deliver sharp and blunt stimuli, applied five times per joint. The number of correct responses out of five is recorded.

Temperature Sensation: Glass tubes filled with cold and warm water are used to assess thermal sensation. Each joint is tested five times, and the number of correct responses is recorded.

Monofilament Sensory Test: A 10g (5.07 Semmes-Weinstein) monofilament is applied perpendicularly to each joint until the monofilament bends. The participant is asked to report whether they feel the sensation of contact. This test is performed on each joint individually.

2-5-7) Box and Block Test: BBT

The Box and Block Test (BBT) is used to assess gross manual dexterity and agility of the upper limb, evaluating both the dominant and non-dominant hands. Participants are seated upright at a table approximately 65 cm in height, with the testing apparatus centered in front of them. A total of 150 wooden cubes measuring approximately 2.5 cm^3 are initially placed on the side corresponding to the dominant hand. The participant is instructed to pick up one block at a time and transfer it over a 15.2 cm-high partition into the opposite compartment. The number of blocks successfully transferred within 60 seconds is recorded. The same procedure is repeated for the non-dominant hand. Assessments are conducted under two conditions: with eyes open and eyes closed.

2-5-8) Action Research Arm Test: ARAT

The Action Research Arm Test (ARAT) evaluates upper limb function across 19 items divided into 4 domains, with a total possible score ranging from 0 to 57 points. Items within each domain must be administered in order. If the participant successfully completes the first item in a domain, the domain is scored as full points, and the test proceeds to the next domain. If the first and second items in a domain are not performed successfully, the domain is scored as zero and the test advances to the next domain. The domains and their corresponding items are detailed below.

Grasp

① Pick up a 10cm, block, wood cube
② Pick up a 2.5cm, block, wood cube
③ Pick up a 5cm, block, wood cube
④ Pick up a 7.5cm, block, wood cube
⑤ Pick up a 7.5cm diameter, cricket ball
⑥ Pick up a 10 x 2.5 x 1cm stone

Grip

① Pour water from glass to glass
② Insert 2.25cm tube
③ Insert 1 x 16cm tube
④ Washer (3.5cm diameter) over bolt

Pinch

① Pick up a 6mm ball bearing with 3rdfingerandthumb
② Pick up a 1.5cm marble with index finger and thumb
③ Pick up a 6mm ball bearing with 2ndfingerandthumb
④ Pick up a 6mm ball bearing with index finger and thumb
⑤ Pick up a 1.5cm marble with 3rdfingerandthumb
⑥ Pick up a 1.5cm marble with 2ndfingerandthumb

Gross movement

① Place hand behind head

② Place hand on top of head

③ Place hand to mouth

-3 points: Movement is performed normally within 5 seconds.

-2 points: Movement is completed but abnormally slow, taking between 5 and 60 seconds.

-1 point: Movement is partially performed within 60 seconds.

-0 points: No movement or unable to perform within 60 seconds.

3) Participant Selection and Exclusion Criteria

3-1) Inclusion Criteria: Participants meeting all of the following criteria will be included

① Patients diagnosed with ischemic or hemorrhagic stroke.

② Stroke confirmed by CT or MRI imaging.

③ Presence of proprioceptive sensory impairment associated with stroke.

④ Chronic phase stroke patients, at least 3 months post-stroke onset.

⑤ Ability to voluntarily flex and extend the elbow joint.

⑥ Age 19 years or older.

⑦ Written informed consent provided voluntarily by the participant or their legal representative.

3-2) Exclusion Criteria: Participants meeting any of the following criteria will be excluded

① K-MMSE score < 10 or severe aphasia making communication difficult.

② Severe pain during elbow joint movement.

③ Presence of elbow joint contracture, spasticity, ataxia, musculoskeletal disorders, fractures unhealed ulcers, or open wounds.

④ Progressive or unstable stroke condition.

⑤ Presence of unilateral neglect.

⑥ Coexisting significant neurogenic disorders.

⑦ Presence of major psychiatric disorders such as major depressive disorder, schizophrenia bipolar disorder, or dementia.

⑧ Presence of a pacemaker.

4) Recruitment and Management of Study Participants

Ten chronic stroke patients with proprioceptive sensory impairment will be recruited. Recruitment will be conducted among inpatients at Yonsei Severance Hospital. Participants and their legal representatives will be provided with an explanation by a physician or research staff regarding the study details outlined below under 'Experimental Procedures' and will make an informed decision regarding participation.

4-1) Explanation of the Experimental Procedure

This experiment is conducted with the purpose of enabling participants to perceive the position of the arm by delivering information about the elbow joint angle through electrical stimulation.

Electrical stimulation refers to the application of current through electrodes attached to the skin, using a voltage supply device with current limitations. The applied voltage and current levels comply with safety standards set by the Korea Occupational Safety and Health Agency and the Ministry of Food and Drug Safety, specifically “voltages not exceeding 30 V and currents not exceeding 50 mA,” which are considered safe for human exposure.
The intensity of the electrical stimulation used in this study is comparable to or lower than that of low-frequency massage commonly employed in orthopedic physical therapy (refer to Section 7-3-3 of this document). Previous studies by our research team, which targeted sensitive regions of the hand, reported that the voltage level at which participants began to feel discomfort (V_max) ranged from approximately 10 to 22 V in both males and females. Generally, females exhibit slightly lower V_max values than males, attributed to thinner skin and muscle mass. These maximum voltage levels correspond to approximately 30–70% of the safety voltage standard of 30 V established by the Korea Occupational Safety and Health Agency for both sexes. During the experiment, electrical stimulation will be applied at intensities below the participant’s discomfort threshold (V_max). Furthermore, the maximum current will be restricted to 20% (10 mA) of the safety current standard.
All participants will receive treatment according to standard clinical guidelines for stroke, with the experimental intervention provided in addition to standard care. The voltage of electrical stimulation will be gradually increased from 0 V in increments of 0.1 V. If a participant reports any discomfort, the stimulation will be immediately discontinued. Electrical stimulation will be preceded by a cue to inform the participant that stimulation is about to be applied. Stimulation will be delivered to the affected side’s cubital fossa. For participant safety, the investigator will continuously monitor for any abnormal arm movement or reported discomfort throughout the experiment. Participants may terminate the experiment at any time according to their own will.

4-2) Pre-experiment Procedures

Prior to participation, subjects will complete a pre-experiment questionnaire to confirm informed consent and eligibility for participation. Responses, including personal information and consent forms, will be securely stored.

4-3) Procedures on the Day of the Experiment

Immediately before the experiment, participants will complete a brief questionnaire assessing their sleep duration from the previous night and current physical condition to evaluate readiness for the session. Potential risks will be verbally explained. Participants will be informed that they may withdraw from the study at any point during the procedure for any reason. If severe discomfort arises from the electrical stimulation, the experiment will be terminated immediately.

4-4) Post-experiment Monitoring

Participants will be monitored through questionnaires administered 3 and 7 days after the experiment to assess any adverse effects such as skin allergic reactions or arm discomfort. Safety will be further verified by comparing these responses to those collected prior to the

experiment (Section 4-2).

4-5) Justification for Target Sample Size

This study is a preliminary investigation involving stroke patients, designed to evaluate the feasibility of the study protocol and to estimate effect sizes of key outcome variables. Accordingly, an initial sample size of 10 participants will be recruited. Given the exploratory nature of this pilot study, a limited sample is appropriate for assessing the suitability of the study design, reliability of measurement instruments, and feasibility of procedures. The chosen sample size is consistent with the scale of similar preliminary studies and takes into consideration both the exploratory aims and practical feasibility of the research. The data obtained will provide foundational information necessary for designing future studies and calculating appropriate sample sizes.

5) Study Procedures

5-1) Recruitment and Screening of Clinical Research Participants

Stroke patients admitted to or receiving outpatient treatment at the Department of Rehabilitation Medicine, Severance Hospital, located in Seodaemun-gu, Seoul, will be recruited. After providing an explanation of the study in a private setting, sufficient time will be allowed for participants and their legal guardians to review the information. Written informed consent will be obtained only from those who agree to participate.

Screening will be conducted exclusively for participants who have provided written consent. The screening process will include a review of medical records, interviews, manual physical examination, and the administration of the Korean Mini-Mental State Examination (K-MMSE) by the investigator to determine eligibility. Participants deemed eligible will be formally enrolled in the study; those who do not meet inclusion criteria will not be enrolled.

5-2) Experimental Site

The evaluation and intervention for this study will take place in the Brain Stimulation Treatment Room on the 6th floor of Severance Rehabilitation Hospital, where the electrical stimulation platform is installed.

5-3) Roles of Collaborative Research Institutions

The Integrated Neuroprosthetics Laboratory at Sungkyunkwan University is responsible for the development, maintenance, and servicing of the electrical stimulation platform used for the intervention.

The Severance Institute for Rehabilitation Medicine is responsible for participant recruitment, clinical intervention, and assessment. The institute consists of one Rehabilitation Medicine professor (principal investigator), one specialist (researcher), and one therapist (researcher). The principal investigator oversees appropriate participant selection and conducts weekly inspections of equipment such as electrical stimulators and electrode patches to prevent accidents. The investigator also has the authority to immediately terminate the experiment if any safety concerns arise during the procedure.

6) Interview Items, Analysis Methods, and Interview Tools

[Post-experiment Questionnaire Items]

1. Did you experience any discomfort in your arm or wrist due to the band, electrodes, or other setup during the experiment?

Not at all		Moderately		Extremely
1	2	3	4	5 or more

2. Did the electrical stimulation help you in perceiving or controlling the angle of your elbow during the experiment?

Not at all		Moderately		Extremely
1	2	3	4	5 or more

3. Did you find the electrical stimulation uncomfortable during the experiment?

Not at all		Moderately		Extremely
1	2	3	4	5 or more

4. Did you perceive the electrical stimulation clearly during the experiment?

Not at all		Moderately		Extremely
1	2	3	4	5 or more

5. Did you pay attention to the information delivered via the electrical stimulation during the experiment?

Not at all		Moderately		Extremely
1	2	3	4	5 or more

6. Please freely provide any suggestions or comments regarding the experimental procedure, equipment, or other related aspects.

7) Criteria and Methods for Participant Safety Evaluation

7-1) Continuous Monitoring of Skin Allergic Reactions

Gel-type electrodes attached to the skin may cause mild allergic reactions. These reactions will be objectively assessed through visual inspection by the experimenter and a questionnaire based on a Likert scale. If any noticeable allergic reactions are observed or the participant reports any such reactions, the experiment will be immediately terminated.

7-2) Continuous Monitoring of Participant Discomfort

Electrical stimulation applied to the skin may cause mild discomfort. Discomfort levels will be objectively assessed using a Likert scale-based questionnaire, and continuously monitored through verbal reports from participants.

7-3) Safety Verification of the Electrical Stimulator Used in the Experiment

7-3-1) Safety and Performance Evaluation Guidelines for Personal Electrical Stimulators

The safety of the stimulation intensity is ensured based on the Guidelines for Safety and Performance Evaluation of Personal Electrical Stimulators published by the Ministry of Food and Drug Safety (MFDS) [2], specifically referring to Table 7: Current Limits. According to the guideline, the maximum stimulation frequency is 400 Hz, and the current limit is 50 mA. The stimulation parameters used in the experiment will be set well within these safety thresholds.

7-3-2) Electrical Stimulator Settings Used in the Experiment

The electrical stimulator used in this study is configured to ensure that both voltage and current remain below predefined maximum safety limits. This stimulator has previously received

IRB approval more than 10 times each in the United States and Korea, and has been employed in over 20 peer-reviewed publications over the past 10 years [3, 4, 5, 6, 10, 11].
-Frequency Setting: The stimulation frequency is capped at 100 Hz, which corresponds to less than 25% of the maximum allowable frequency (400 Hz) specified by regulatory guidelines.
-Current Setting: Based on a maximum stimulation voltage of 30V and an average skin impedance of 10k, the theoretical maximum current is approximately 3mA. Empirical measurements using electrodes attached to human skin confirmed a stimulation current between 2-4mA, which is below 8% of the regulatory current limit of 50mA according to the safety and performance evaluation guidelines for personal electrical stimulators. Furthermore, an additional safety limit is imposed at 10mA, representing 20% of the allowable limit.
According to the Korea Occupational Safety and Health Agency's guidelines on electrical hazards and electrocution prevention [12], currents around ~1mA are referred to as the 'minimum perceptible current' and cause only mild sensation, while pain typically occurs at ~15mA. Thus, even at the maximum current level set in this study, no pain is expected.
-Voltage Setting: The maximum stimulation voltage is restricted to 30 V. According to safety guidelines from the Korea Occupational Safety and Health Agency [13], voltages of 30V or below are considered safe and non-hazardous even under worst-case scenarios, such as low skin impedance. This ensures that the participant's safety is preserved even in the event of unusual physiological conditions.

7-3-3) List of Studies Using Electrical Stimulators with the Same Specifications as the One Used in This Experiment

To account for the physical characteristics of the study participants, reference data obtained from East Asian populations have been incorporated into this research [18], [19], [20], [21], [22], [23], [24]. This inclusion reflects a consideration that East Asians may differ from Western populations in terms of skin thickness and sensitivity.
The following is a list of previous studies that utilized electrical stimulators with specifications equivalent to the device used in this experiment:
7-3-3-1) [3] (International): Used electrical stimulation to convey the point of contact of a ball on a VR table tennis paddle.
7-3-3-2) [14] (International): Delivered postural sway information via electrical stimulation while standing on a balance board.
7-3-3-3) [15] (International): Applied electrical stimulation to the tongue for haptic feedback purposes.
7-3-3-4) [16] (International): Employed electrical stimulation to modulate elbow joint angles.
7-3-3-5) [17] (International): Used electrical stimulation to control the angles of the index finger and thumb.
7-3-3-6) [18] (Korea): Investigated the effects of EMS frequency on performance in a visual stimulus-response task.
7-3-3-7) [19] (Korea): Designed and evaluated a dry e-tactile electrode EMS brace for elite badminton players with knee pain.
7-3-3-8) [20] (Korea): Developed injury-prevention socks integrating EMS and stretch sensors for

home training.
7-3-3-9) [21] (Japan): Studied the early application of EMS to prevent muscle atrophy and weakness after ACL reconstruction.
7-3-3-10) [22] (Japan): Developed a gravity-free training method combining voluntary muscle contractions with electrical stimulation.
7-3-3-11) [23] (China): Created an electric muscle simulator based on functional electrical stimulation (FES).
7-3-3-12) [24] (China): Applied electrical stimulation therapy to treat peripheral nerve injuries.
7-3-3-13) Studies [18], [19], and [20] were conducted on Korean participants.
7-3-3-14) Studies [21] and [22] were conducted on Japanese participants.
7-3-3-15) Studies [23] and [24] were conducted on Chinese participants.

7-3-4) Commercial Personal Electrical Stimulators
The electrical stimulator used in this study operates with lower current and frequency levels compared to specifications of commonly available commercial personal electrical stimulation devices:
-The EMS 1000 (Hyundai Bio Medical Co., Ltd., Seoul, Republic of Korea) specifies a maximum output current of 17 mA and a maximum frequency of 200 Hz.
-The EMGFES 1000 (Cypermedic Co., Ltd., Gwangju, Republic of Korea) specifies a maximum output current of 99 mA and a maximum frequency of 200 Hz.
-The KD-PRO-5000 Gold (Kukdong Electronics Co., Ltd., Incheon, Republic of Korea) specifies a maximum output current of 12.2 mA and a maximum frequency of 1,190 Hz.
-The SERA (GOS Co., Ltd., Gyeongsan, Republic of Korea), a personal rehabilitation walking assist device, specifies a maximum output current of 80 mA and a maximum frequency of 120 Hz.

8) Subject Withdrawal Criteria
8-1) Subjects who exhibit visually identifiable allergic skin reactions upon attachment of the gel-type electrodes, or who report discomfort greater than or equal to 3 on a Likert scale, will be excluded from the study.

8-2) Subjects who consistently report discomfort due to electrical stimulation will also be excluded.
First, stimulation intensity is set significantly lower than the discomfort-inducing threshold to prevent such issues.
Second, if a subject verbally reports discomfort during the experiment, the procedure will be immediately paused.
After a rest period of approximately 3-5 minutes, the experiment may be resumed.
If discomfort persists upon resumption, the subject will be withdrawn from the study.

9) Research Timeline
Subject recruitment and experimental procedures are scheduled to begin after July 1, 2025.

The study aims to complete experiments with 10 participants by August 31, 2027.

10) Participant Compensation

The electrical stimulation used in this study does not involve invasive therapy; therefore, no known or anticipated adverse effects are expected. However, participants may experience minor discomfort such as skin irritation or slight muscle contractions. In the event of any unexpected incidents during the experiment, the research staff will immediately notify the principal investigator, Professor Hankyu Park. If a clear causal relationship is established between the study and any injury, Professor Park will assume responsibility for compensation and treatment costs.

11) Informed Consent and Study Information Sheet

Please refer to the separately attached document titled “5. Informed Consent Form.”

12) Other Ethical Considerations for Research Conduct

All experimenters will thoroughly familiarize themselves with and strictly adhere to this protocol to ensure the ethical conduct of the research. The principal investigator, Professor Hankyu Park, will periodically assess whether the experimenters fully understand and comply with the protocol.

□ Expected Outcomes of the Study

Although sensory errors frequently occur after stroke, conventional motor rehabilitation relies mainly on repetitive training without addressing these sensory deficits, resulting in limited effectiveness. This study aims to improve the effectiveness of upper limb and finger motor rehabilitation by delivering proprioceptive information through tactile channels via electrical stimulation (proprioceptive error correction technology). By addressing sensory errors overlooked in traditional rehabilitation, this approach is expected to reduce patients’ frustration and fatigue during rehabilitation, thereby significantly enhancing their quality of life despite the time and effort required.

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The principal investigator hereby submits the recent curriculum vitae and documentation of completed IRB training

June 30, 2025

Principal Investigator: Hankyu Park (인)

To: Chairperson of the Institutional Review Board, Sungkyunkwan University