

MEP-Guided Scalp Acupuncture Combined with Repetitive Transcranial Magnetic Stimulation for Post-Stroke Upper Extremity Motor Impairment: A Randomized Controlled Study Protocol

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Background: Post-stroke upper extremity motor impairment poses a significant challenge to rehabilitation. While repetitive transcranial magnetic stimulation (rTMS) and scalp acupuncture are effective individually, the precise mechanisms and synergistic efficacy of their combination remain to be fully elucidated.

Purpose: This study aims to evaluate the therapeutic efficacy of MEP-guided scalp acupuncture combined with rTMS versus rTMS alone. Additionally, it intends to investigate the underlying neuromodulation mechanisms using functional near-infrared spectroscopy (fNIRS).

Methods: This prospective, single-blind, randomized controlled trial includes patients with stroke-induced upper limb motor deficits. Participants are randomly assigned to either an experimental group (combined therapy) or a control group (rTMS alone) for a 4-week intervention. Both groups receive concurrent conventional rehabilitation. Follow-up assessments will be conducted 4 weeks after the completion of the treatment to evaluate the sustained effects.

Results: Primary clinical outcome measures include the Fugl-Meyer Assessment-Upper Extremities (FMA-UE) and maximum amplitude of Motor Evoked Potentials (MEP). Secondary clinical outcome measures include Action Research Arm Test (ARAT), Modified Barthel Index (MBI) and fNIRS data acquisition.

Conclusion: This study is expected to provide evidence for an optimized, multi-target rehabilitation regimen. By integrating clinical scales with fNIRS neuroimaging, it seeks to reveal the neural mechanisms of brain network reorganization driven by this combined therapy.

Clinical Trial Registration: ClinicalTrials.gov, identifier NCT07210944.

Keywords: scalp acupuncture, repetitive transcranial magnetic stimulation, upper extremity motor impairment, protocol

Introduction

The Global Burden of Disease (GBD)¹ research reported that in 2021, the global incidence of stroke was 11.9 million cases, with a prevalence of 93 million cases and 7.3 million fatalities attributable to stroke, establishing it as the second greatest cause of mortality from noncommunicable diseases globally. Hemiplegia is a prominent clinical manifestation in post-stroke individuals. Statistics reveal that more than fifty percent of stroke patients suffer from varied levels of upper extremity motor impairment,² considerably diminishing their quality of daily living. The rehabilitation procedure for

hand function predominantly entails fine motor abilities, necessitating intricate and exact control from the cerebral cortex. The restoration of upper extremity motor function frequently lags behind that of the lower extremities. Traditional rehabilitation training aimed at enhancing extremity function (occupational treatment, active and passive exercises, physical agent therapy, etc.) exhibits limited efficacy and does not fully satisfy therapeutic requirements.³ Consequently, promoting the restoration of upper extremity motor function after stroke has emerged as a significant and hard priority in stroke therapy.

The motor center, located in Brodmann areas 4 and 6 of the cerebral cortex, specifically comprises the primary motor cortex (M1), premotor cortex (PMC), and supplementary motor area (SMA), representing the pinnacle of somatic movement coordination. These cortices are essential for the execution and planning of movement, serving as a core component of motor-related neural networks. Following a stroke, the damaged cerebral cortex not only diminishes connections within the motor cortex on the affected side but also leads to localized degradation of brain tissue, impacting functional connectivity in motor-related neural networks in distant regions. This ultimately disrupts the connections between the two hemispheres, resulting in motor impairment.⁴ Motor function restoration post-stroke depends on the reorganization of brain networks.^{5–7} Post-stroke, impaired neuronal networks undergo reconfiguration through various processes. Research indicates that stroke patients experience significant structural and functional changes in their motor networks, particularly an increase in connectivity within the affected hemisphere and between the affected and unaffected hemispheres.⁸ The foundation for promoting functional recovery stems from the brain's plasticity.⁹ This phase of heightened plasticity promotes novel axonal sprouting and new synaptogenesis. It also drives the remapping of sensorimotor functions. These changes are closely correlated with motor recovery. Stroke causes cellular damage and mortality, leading to significant neurological impairments. During the remodeling process, the affected area forms new functional neural connections with adjacent regions.^{10,11} However, not all new connections facilitate motor recovery; some may be ineffective or detrimental to functional restoration.^{12,13}

Non-invasive rTMS creates currents in the cerebral cortex using magnetic fields, influencing neuronal activity and brain function and behavior. It is widely used to treat post-stroke motor disorders due to its tolerance and safety.¹⁴ Interhemispheric inhibition supports rTMS. The corpus callosum transmits excitatory signals from one hemisphere to the other, stimulating inhibitory neurons. Activating these inhibitory neurons inhibits relevant brain areas or neural networks, inhibiting the contralateral hemisphere.¹⁵ Stroke disrupts interhemispheric connection by decreasing the inhibitory effect of the impacted hemisphere, which is crucial for post-stroke rehabilitation. By adjusting its frequency, repetitive transcranial magnetic stimulation (rTMS) can excite or inhibit cortical neurons in particular brain regions.¹⁶ Two methods are used to improve motor function post-stroke: low-frequency ($\leq 1\text{Hz}$) rTMS for the unaffected hemisphere to reduce its inhibitory effect on the affected hemisphere, and high-frequency ($\geq 5\text{Hz}$) rTMS for the affected hemisphere to restore competitive inhibitory equilibrium.¹⁷ Complete studies show that stroke can cause abnormal neurotransmitter release, including glutamate, GABA, and glycine. Abnormal neurotransmitters affect healing. By changing neurotransmitter concentrations, repetitive transcranial magnetic stimulation (rTMS) can affect neuronal activity and synaptic plasticity.¹⁸ Astrocytes, the main glial cells, maintain the blood-brain barrier (BBB) and central nervous system homeostasis. Astrocytes are categorized into two main types: A1 and A2. The classically activated A1 astrocytes release pro-inflammatory neurotoxins. These substances are known to harm neurons and oligodendrocytes. Alternatively activated astrocytes (A2) generate anti-inflammatory molecules to help neurons survive and repair tissue.¹⁹ rTMS changes astrocyte activity to protect neurons and regenerate tissue.²⁰

Acupuncture has been practiced for about 3000 years. In 2002, the World Health Organization (WHO) recommended its use for stroke treatment. Clinical studies have shown that acupuncture improves motor function, sensory impairments, language skills, and neurological repair.^{21,22} Particularly remarkable is scalp acupuncture. Its advantage over conventional acupuncture is modern anatomical principles. By activating head projection zones, it can locate cortical areas. The typical “Jiao’s Scalp Acupuncture” zoning methodology shows that the upper extremity functional zone is mostly in the central 2/5 of the anterior temporal oblique line on the parietal lobe. This is the precentral motor cortex’s hand and upper extremity representation zone.²³ Multiple clinical investigations have shown that acupuncture at this area improves post-stroke upper extremity motor deficits.^{24–26} Activating scalp acupuncture points may increase cortical activity and cerebral blood flow,^{27,28} modulating cerebral hemodynamics to promote collateral circulation and regulate motor function neurotransmitters. Acetylcholine (ACh), serotonin (5-HT), and norepinephrine (NE) levels rise while GABA levels fall. This process changes

the excitatory-inhibitory balance by reconfiguring brain excitatory and inhibitory neural pathways.²⁹ An MRI study found that scalp acupuncture strengthens functional connectivity between the lesion-side motor cortex (M1) and the frontal lobe,³⁰ which positively correlates with upper extremity Fugl-Meyer scores. Later investigations show that scalp acupuncture can stimulate functionally significant brain areas, slow gray matter degeneration, and reorganize white matter fiber pathways.³¹

The technique fNIRS measures cerebral metabolic activity. The dynamic monitoring of cortical oxyhemoglobin (HbO₂) and deoxyhemoglobin (HHb) levels can assess stroke severity. The evaluation is simple, safe, and noninvasive. Numerous studies show a strong correlation between fNIRS and fMRI.³² Researchers examined resting-state brain connections with fNIRS-derived resting-state data to prove its practicality and accuracy.³³ Compared to fMRI, fNIRS is safe, non-invasive, mobile, has better temporal resolution, and allows longer monitoring.³⁴ It allows dynamic real-time measurement of brain activity during movement.³⁵ Recent studies^{36,37} have used fNIRS to study stroke patient rehabilitation mechanisms. Initial studies show stroke patients have abnormal neural functional connections between motor brain regions and both hemispheres. Nils³⁸ showed that fNIRS continuous monitoring of cerebral hemodynamic parameters allows real-time tracking of sickness progression by seeing blood flow remodeling and redistribution in specific brain areas. This method illustrates how the brain reallocates blood flow after a stroke to reduce functional deficits in damaged regions, aiding stroke severity assessment. Prefrontal activation in dual-task conditions, comparison of effective brain networks during unilateral and bilateral motor training, and resting-state prefrontal network alteration can be detected by fNIRS. Long-term fNIRS observation of stroke patients' cortical activity patterns reveals neuronal plasticity during rehabilitation.³⁹

In conclusion, scalp acupuncture improves post-stroke upper extremity motor function, according to clinical data. RTMS is proven safe and effective. However, rTMS alone does not meet therapeutic needs and is not sustained. Numerous scalp acupuncture schools differ in point selection and localization methods, which vary between people. Previous studies have demonstrated the synergistic effects of rTMS combined with scalp acupuncture in improving post-stroke outcomes,^{40,41} such as cognitive impairment and motor function, these protocols predominantly rely on standardized anatomical landmarks for targeting. For instance, the motor cortex is usually placed in the precentral gyrus, but its location may vary. Individual motor cortex size and architecture may also differ.⁴² Given the significant inter-individual variability in motor cortex topography following stroke-induced cortical reorganization, anatomical positioning alone may not be able to accurately cover the key functional active areas. Despite advances in acupuncture-neurology research, scalp acupuncture stimulation zone identification is still difficult. To address this, our study introduces an MEP-guided approach to identify individual functional “hotspots”. This method offers superior targeting compared to anatomical landmarks alone by accommodating individual variations in cortical mapping, thereby ensuring that the combined stimulation is delivered to the most responsive neural substrates to maximize therapeutic efficacy. Few studies have used MEP-guided scalp acupuncture and rTMS to treat post-stroke upper extremity motor impairment. This study was designed to evaluate the therapeutic efficacy of integrating MEP-guided scalp acupuncture with rTMS, highlight its benefits, and provide an optimized clinical solution for post-stroke upper extremity motor impairment. We will also research neural mechanisms and provide objective proof by using fNIRS to study brain functional networks.

Methods

Study Design

We conducted an RCT in which eligible participants are grouped using a random number table method. Forty-four participants who qualify with post-stroke upper extremity motor impairment will be allocated in a 1:1 ratio to either the combined therapy group (rTMS + scalp acupuncture) or the rTMS-only group. The reporting for our protocol adheres to SPIRIT guidelines. The SPIRIT schedule and study flowchart are provided in [Figures 1](#) and [2](#), respectively.

Recruitment

Participants will be recruited from the Rehabilitation and Neurology Departments at the Zhejiang Chinese Medical University's third affiliated hospital. All individuals must have upper extremity impairment following a stroke. Before providing informed consent, each person or their family will be thoroughly briefed on the study procedures. Participants were explicitly informed of their unrestricted right to withdraw from the study at any point.

	TRIAL PERIOD								
	Enrollment		Treatment period					End of treatment	Follow-up Assessment
TIMEPOINT	$-T_1$	T_0	T_1	T_2	T_{2-3}	T_3	T_4	T_5	T_6
ENROLLMENT:									
Eligibility screen	X								
Informed consent	X								
Demographic information	X								
Allocation		X							
INTERVENTIONS:									
Scalp acupuncture and rTMS group									
rTMS group									
ASSESSMENTS:									
FMA-UE		X						X	X
Maximum amplitude of MEP		X						X	X
MBI		X						X	X
fNIRS scanning		X			X			X	X
ARAT		X						X	X

$-T_1$, the day before allocation. T_0 , the day before first treatment. T_1 - T_4 , the treatment for 4 weeks. T_{2-3} , the day after 2 weeks of treatment. T_5 , week 4 assessment (end of intervention). T_6 , week 8 assessment (4-week follow-up).

Figure 1 SPIRIT schedule of enrollment, interventions, and assessments at baseline (T_0), 4 weeks (T_1), and 8 weeks (T_2).

Participants

Diagnostic Criteria

Diagnosis of Cerebral Hemorrhage based on the Chinese Guidelines for Diagnosis and Treatment of Cerebral Hemorrhage (2019):

- (1) The onset of symptoms is typically acute.
- (2) Clinical presentation includes focal neurological deficits. These may be accompanied by headache, vomiting, elevated blood pressure, and varying levels of consciousness impairment.
- (3) A cranial CT or MRI scan must confirm the presence of a hemorrhagic lesion.
- (4) Non-vascular causes for the cerebral condition have been excluded.

Diagnosis of ischemic stroke is based on the Chinese Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke (2018):

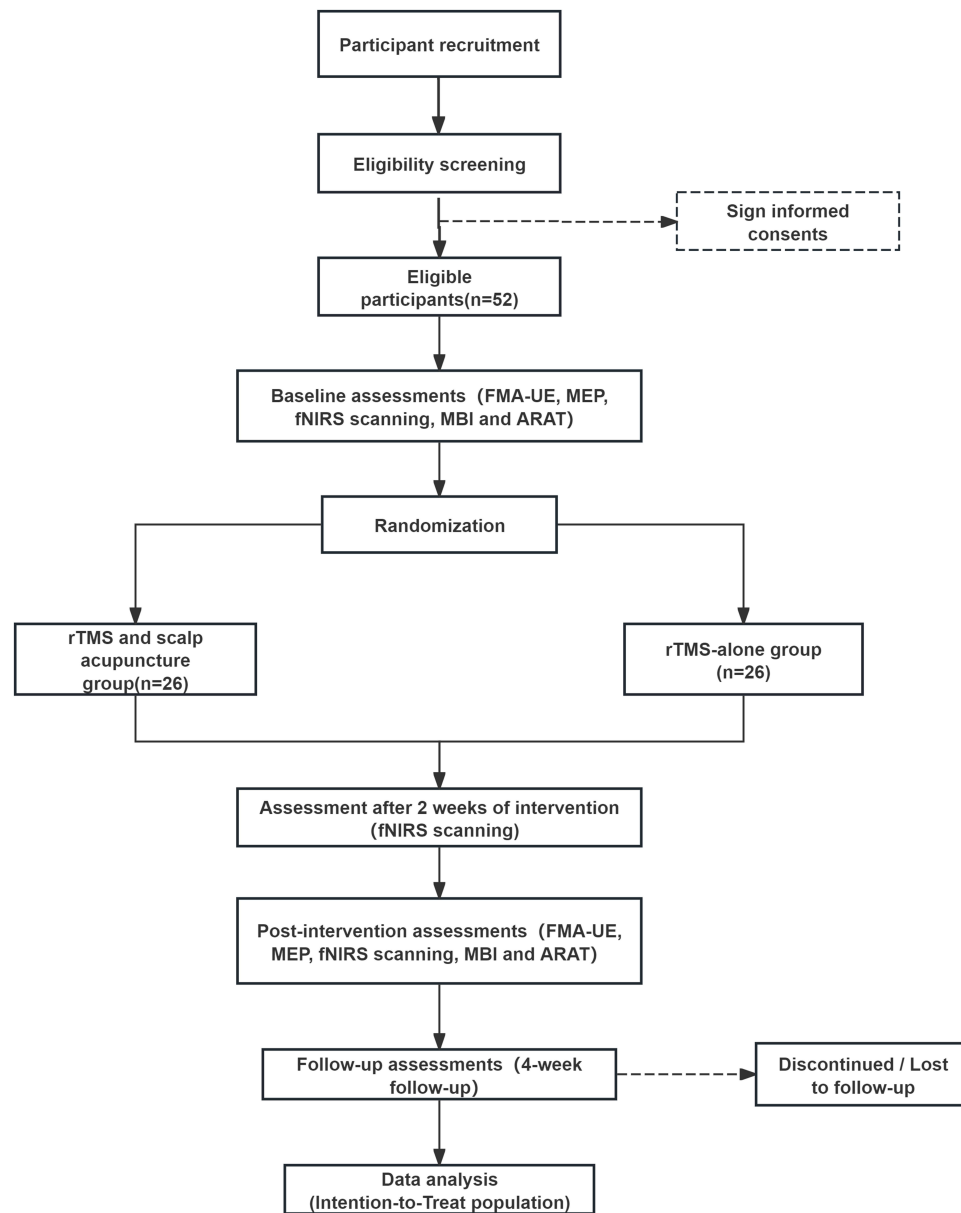


Figure 2 Study flow diagram. The chart illustrates participant enrollment, randomization into experimental or control groups ($n=26$ per group), and analysis based on the intention-to-treat (ITT) principle.

- (1) The onset is typically acute.
- (2) Clinical presentation involves focal neurological deficits. These may manifest as unilateral facial or limb weakness, numbness, or speech difficulties. In some cases, global neurological impairment may be present.
- (3) Neuroimaging reveals a relevant ischemic lesion. Alternatively, clinical symptoms may persist for more than 24 hours.
- (4) Non-vascular causes must be ruled out.

Inclusion Criteria

- (1) A confirmed diagnosis of stroke is required. This diagnosis should be based on clinical presentation, neurological signs, and relevant imaging evidence. Additionally, The diagnosis requires independent confirmation by two associate chief physicians.
- (2) Age 18–70 years, first-time onset, disease duration 1–6 months;

- (3) Upper extremity impairment diagnosed according to Brunnstrom staging: Patients at Brunnstrom stages II–IV. Stage II: Joint reflexes present, joint movement possible, minimal voluntary movement; Stage III: Voluntary joint movement possible (eg, hand grasping but unable to extend); Stage IV: Isolated movement possible (eg, hand pinching, limited extension);
- (4) No severe visual or hearing impairment, able to cooperate with relevant assessments and examinations;
- (5) Mini-Mental State Examination (MMSE) score ≥ 20 ;
- (6) Stable vital signs, no progressive neurological symptoms;
- (7) Written informed consent was acquired from all participants or their legal guardians.

Exclusion Criteria

- (1) Severe visual impairment, hemispatial neglect, or body image disorder;
- (2) Ineligibility for rTMS treatment due to metallic implants, pacemakers, or cranial defects;
- (3) History of brain tumors, traumatic brain injury, epilepsy, or risk of epileptic seizures;
- (4) Any other factors affecting assessment or treatment;
- (5) Extremity motor impairment caused by other reasons (eg, trauma).

Withdrawal and Termination Criteria

- (1) Patients who develop complications such as pulmonary infection, urinary tract infection, deep vein thrombosis, or seizures during treatment;
- (2) Patients whose cerebrovascular disease recurs or worsens during treatment;
- (3) Patients whose compliance with medical instructions is inadequate or whose data are incomplete, thereby affecting the assessment of treatment efficacy or safety, or patients who experience adverse reactions during the clinical study that make continued participation inappropriate;
- (4) Patients or their families who refuse to continue observation or treatment.

Withdrawn cases will be handled as follows:

- (1) After a participant withdraws, the research team will contact them or their family by phone or letter. The purpose is to inquire about the reason for withdrawal. The team will then record the last treatment date and complete all necessary assessments.
- (2) The principal investigator will manage all cases that are discontinued due to adverse reactions or treatment failure. Any measures taken will be based on the subject's specific condition.
- (3) The "Treatment Completion Summary" and "Clinical Trial Completion" sections in the CRF will be completed.
- (4) The intention-to-treat analysis will incorporate all cases, including those who were excluded or discontinued.

Randomization and Blinding

A simple randomization approach was utilized. The predetermined sample size was entered into SPSS 26.0, which subsequently produced the random allocation sequence. The resulting sequence was used to determine group assignments, which were then written on randomization cards. The cards were placed in sealed, opaque envelopes. Participant assignment then followed the numerical sequence on the envelopes. Envelopes were opened sequentially, and subjects were assigned to groups according to the randomization cards to ensure allocation concealment.

We used a blinded approach for this study. A third party, unaware of group assignments, conducted the efficacy evaluations. For data analysis, we will perform blinded statistics. This process adheres to the principle of separating the roles of investigators, operators, and statisticians.

Sample Size

The study is a two-arm RCT: the rTMS combined with scalp acupuncture group and the rTMS-only group. Sample size estimation was performed using the maximum MEP amplitude change as the primary outcome measure. Based on

literature data,⁴³ the mean MEP increase post-treatment was projected to be 0.9mV and 0.3mV for the two groups, respectively. A two-tailed test with $\alpha = 0.05$ and 90% power is required. Using the formula:

$$n = \frac{2\sigma^2(Z_{\alpha/2} + Z_{\beta})^2}{(\mu_1 - \mu_2)^2}$$

The calculated 1 sample size of one group is approximately 21 cases. Considering a 20% attrition rate due to loss to follow-up or refusal to participate, the final minimum sample size required is 52 cases, with at least 26 participants per group. Statistical analysis will be conducted on variables including age, gender, disease duration, stroke location, stroke type (hemorrhagic/ischemic stroke), and MMSE scores.

Interventions

All practitioners are licensed professionals in both rehabilitation medicine and acupuncture. Each has at least five years of clinical experience. They will all receive training to master the study protocol.

Experimental Group

rTMS Treatment: The transcranial magnetic stimulator manufactured by Wuhan Yiruide Medical Treatment Equipment New Technology Company was used. The stimulation coil was positioned in a figure-eight configuration. The intensity was set at 80–100% of the motor threshold determined by MEP from the contralateral extremity. The stimulation site was the M1 area. We positioned the coil tangentially to the patient's scalp. The center of the coil was located at the designated site. The handle was oriented vertically toward the patient's occipital region. For the first 2 weeks, place the coil over the M1 area on the contralateral (unaffected) side. Apply stimulation at a frequency of 1 Hz, with a stimulation duration of 10 seconds per sequence and an interval of 5 seconds, for a total treatment time of 20 minutes (80 sequences). Weeks 2–4: Place the coil horizontally over the ipsilateral (affected) M1 area with a stimulation frequency of 10 Hz, stimulation duration of 3 seconds per sequence, and an inter-sequence interval of 12 seconds, totaling 20 minutes per session. The treatment regimen was administered five times per week over a four-week period. Monitor patient responses throughout treatment and inquire about any discomfort at the conclusion of each session, documenting findings.

MEP-Guided Scalp Acupuncture Treatment: Utilizing the RD-CCY TMS stimulator with the MEP localization function monitored by the Viking Quest 4-channel surface EMG recorder from Thermo Nicolet Corporation, the MEP points in the corresponding cortical regions of both upper extremities are selected as insertion points based on the target localization cap. A total of two points are selected bilaterally. First, test for evoked MEPs in the corresponding cortical area of the contralateral target muscle (abductor pollicis brevis for the upper extremity), marking the location where MEPs are elicited as the hotspot. Next, test for MEPs in the corresponding cortical area of the ipsilateral side. If the ipsilateral MEP is negative, determine the hotspot by locating the mirror image position of the contralateral hotspot. Select the corresponding cortical hotspots on both upper extremities. Mark the affected side as Point A and the unaffected side as Point B. Choose a filiform needle with a diameter of 0.30mm and a length of 50mm (Huatuo brand, Suzhou Medical Supplies Factory Co., Ltd.) The line connecting A and B defines the needle insertion direction. Insert the first needle from Point A to Point B. For the second needle, continue along the insertion direction from Point B. After penetrating the scalp, rapidly rotate the needle for 2–3 minutes, until the patient feels a distinct sensation of soreness, numbness and swelling at the insertion area. Adjust the needle every 10 minutes. Leave needles in place for 30 minutes. Perform once daily for 5 days per week over 4 weeks.

Conventional Treatment: Conventional drug therapy includes secondary prevention of stroke, neurotrophic support, and improvement of cerebral circulation. Routine rehabilitation comprises exercise therapy (such as active and passive joint mobilization, neuromuscular facilitation techniques, sitting-to-standing training, balance training, etc.), physical agent therapy, and occupational therapy, totaling 90 minutes daily.

Control Group

rTMS Treatment: Same as the experimental group.

Conventional Treatment: Same as the experimental group.

Synchronized Intervention and Care

Participants may continue their standard medications for chronic conditions, such as hypertension or diabetes, during the study. The research team will record all such comorbidities, medications, and treatments in the case reports.

Outcomes Measurement

Primary Outcome

FMA-UE Score: The FMA employs a systematic scoring system to subdivide upper limb motor function into multiple dimensions, including reflex activity, synergistic movements, isolated movements, and wrist-hand function. A total of 19 items are included. Each item is scored on a 3-point scale (0–2 points), with a total score of 66 (upper limb part). Higher scores indicate better recovery of upper limb motor function.

Maximum Amplitude Of MEP: For detection, we used an RD-CCY TMS stimulator combined with the Viking Quest 4-channel surface electromyography of Thermo Nicolet Corporation recording system. The amplitude of motor evoked potentials is quantified by their peak-to-trough voltage difference, it serves as an indicator of corticospinal excitability. Higher scores indicate better recovery of upper limb motor function.

Secondary Outcome

ARAT Score: Includes four sections: grasping, pinching, and gross motor skills, comprising 19 items. The assessment employs a four-point scoring system for each item, with scores ranging from 0 to 3 points, totaling 57 points. Higher scores indicate better recovery of upper limb motor function.

MBI Score: This scale assesses independence in 10 essential daily activities: eating, personal hygiene, bathing, dressing, toileting, continence, transfers, mobility, and stair navigation. The total score ranges from 0 to 100 points, with scores above 60 signifying functional independence for community living.

fNIRS Data Acquisition and Processing: The measurements will be acquired using the 47-channel fNIRS imaging device Nir Smart (Huichuang, China) to collect data from subjects in resting state, task state and scalp acupuncture states (Figures 3 and 4). This device incorporates 23 light-emitting probes and 15 detection probes, forming 47 effective channels in the experimental design (Figure 5). Using continuous-wave near-infrared light at wavelengths of 760–850 nm with a sampling frequency of 11 Hz, this approach allows for dynamic tracking of HbO₂ and HHb concentration changes in the unaffected cerebral hemisphere. Based on the Montreal Neurological Institute (MNI) coordinates and Brodmann Area (BA) mapping, the 47 channels were assigned to seven regions of interest (ROIs): the prefrontal cortex (PFC), left and right motor areas (covering M1, PMC, and SMA), left and right parietal lobes (covering the primary somatosensory cortex and sensory association areas), and left and right temporal lobes (Figure 6). For the acquisition of fNIRS task-state data, a classical block design was employed to optimize the detection of hemodynamic responses. The experimental procedure initiated with a 60-second resting-state baseline acquisition to calibrate the initial signals. The subsequent task session comprised six cyclic blocks, with each block consisting of a 20-second task period and a 40-second rest period. During the 20-second task period, patients were instructed to perform repetitive finger grasping movements of the affected upper limb at a frequency of 1 Hz, paced by a metronome. For patients unable to execute active grasping, motor imagery of the same movement at the corresponding frequency was prescribed. The 40-second rest period was implemented to minimize physiological noise (such as Mayer waves) and ensure the hemodynamic response fully returned to baseline levels. The entire acquisition process lasted approximately 6 to 7 minutes, thereby ensuring a sufficient signal-to-noise ratio for subsequent functional brain activation analysis.

Data Collection and Management

After consent is obtained, the principal investigator will record data on paper case report forms (CRFs). To protect privacy, we will replace personal names with unique coded identifiers. After the trial, the data manager will independently transfer all data from the paper CRFs into Excel spreadsheets. The statistical analyst will carefully review and confirm the data before performing the analysis. Once the database is verified and error-free, the principal investigator, data manager, and statistical analyst will jointly lock it. After locking, only authorized researchers can access the data. We will not disclose any participant data without their consent.



Figure 3 Frontal view of the fNIRS optode cap placement on the participant.



Figure 4 Lateral view of the fNIRS optode cap placement showing the arrangement of channels.

Safety Assessment

Safety assessments will monitor the frequency of adverse events. Participants will be instructed to report all harmful incidents. These may include known acupuncture reactions, such as soreness, bleeding, bruising, abscesses, blisters, or infections. For safety assessment, investigators will meticulously document and evaluate all adverse events at each visit.

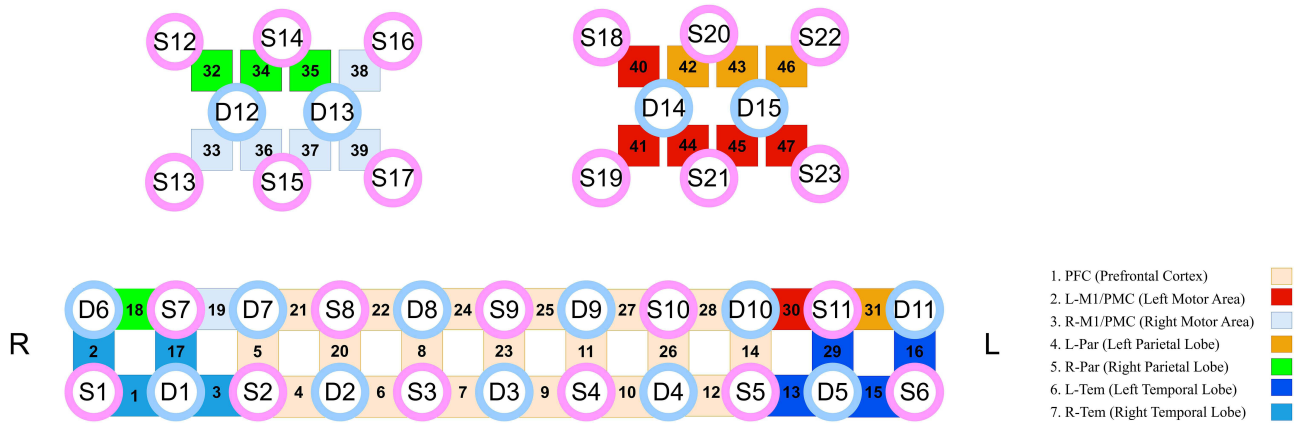


Figure 5 Visualization of fNIRS channel mapping and ROI segmentation. Channels are color-coded into seven regions corresponding to the figure key: Prefrontal Cortex (Light Pink), Left Motor Area (Red), Right Motor Area (Light Blue), Left Parietal Lobe (Orange), Right Parietal Lobe (Green), Left Temporal Lobe (Dark Blue), and Right Temporal Lobe (Medium Blue).

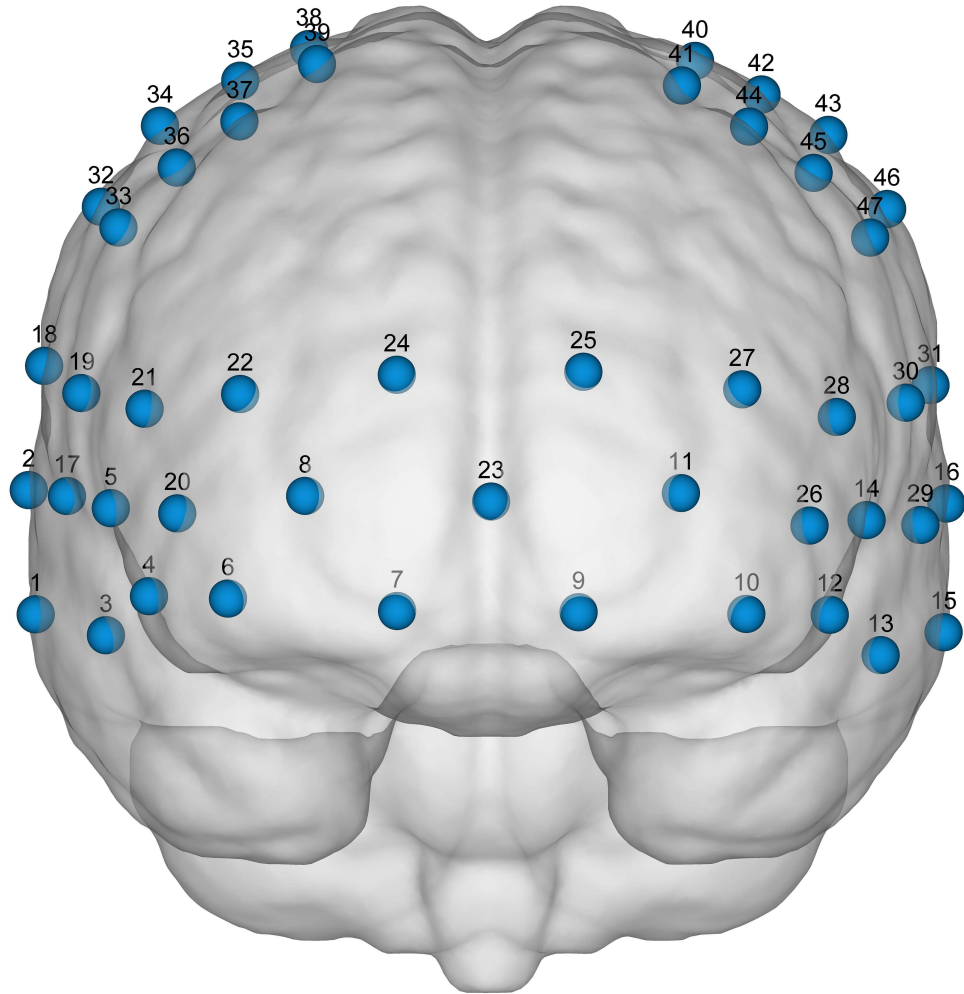


Figure 6 Configuration of fNIRS optodes.

This documentation will include the event's time of onset, symptom duration, severity, management strategy, resolution time, and causality classification. Any serious adverse event requires completion of a dedicated form within 24 hours. Management approaches may include modifying, suspending, or stopping the treatment, adding new medications, or hospitalizing the patient. We will record all management measures on the adverse event pages of the CRF.

Quality Control

Prior to the commencement of the study, all researchers will undergo training to ensure adherence to the research protocol, thereby guaranteeing study quality. Furthermore, Our team will continuously monitor all research activities. This vigilance ensures data accuracy and reliability from collection through analysis. Quarterly meetings will be held to discuss and resolve any issues arising during the study.

Statistical Analysis

All statistical analyses were performed with SPSS 26.0. Continuous data with normal distribution are expressed as mean $\pm$ SD ($\bar{x} \pm s$). One-way analysis of variance was applied for multiple group comparisons. If either group failed to meet normal distribution, the rank-sum test was employed. Qualitative data were presented as relative proportions, and intergroup comparisons were performed using the chi-square (χ^2) test. The two-tailed test level was set at $\alpha = 0.05$, with $P < 0.05$ indicating statistically significant differences.

After completing fNIRS data collection, the raw light intensity data was preprocessed using the NIRSKIT software based on MATLAB 2020b. First, a polynomial regression model is employed to estimate and remove linear or nonlinear trends in the signal, thereby achieving drift correction. Subsequently, Time Derivative Distribution Repair (TDDR) is applied to eliminate potential head motion artifacts. A bandpass filter (0.01–0.2 Hz) was applied to eliminate common physiological noise from cardiac, respiratory, and Mayer wave sources. These filtered optical density signals were then converted into concentration changes for both HbO₂ and HHb. This conversion uses a modified Beer-Lambert law. We then use single-sample and paired *t*-tests to assess brain activation in each channel. These tests generate *t*-value heatmaps for visualization.

Discussion

To date, how scalp acupuncture and rTMS improve upper extremity function after a stroke is not fully clear. The precise mechanisms behind this combined therapy require further investigation. Most researchers currently agree that rTMS achieves therapeutic effects by modulating cortical excitability balance. The 2019 updated rTMS application guidelines from the International Federation of Clinical Neurophysiology (IFCN) recommend: Low-frequency stimulation of the contralateral M1 area during the acute and subacute phases is recommended with a Grade A (high certainty) for improving hand motor impairment. High-frequency stimulation of the ipsilateral M1 area during the acute and subacute phases is recommended with a Grade B. Low-frequency stimulation of the contralateral M1 area during the chronic phase is recommended with a Grade C.⁴⁴ However, the efficacy of rTMS alone is not sustained and fails to meet clinical demands. Building upon this, researchers⁴⁵ have proposed combining rTMS with scalp acupuncture to more effectively improve upper limb motor impairment following stroke. Similar to TMS, scalp acupuncture modulates cortical excitability balance through multiple pathways: Firstly, needle stimulation activates sensory afferent fibers, transmitting high-frequency signals to M1 and SMA (supplementary motor area). This reverses post-stroke hyperinhibition by GABA, thereby enhancing cortical excitability.⁴⁶ On the other hand, bioelectric signals generated by scalp acupuncture stimulate glutamatergic excitatory transmission through the thalamocortical projection network, thereby improving synaptic efficacy.⁴⁷ Research has found that combining scalp acupuncture with rTMS can also regulate neurotransmitters by activating the protein kinase A (PKA)/cAMP response element-binding protein (CREB) signaling pathway, thereby improving neurological function after stroke. (PKA is an essential factor for synaptic plasticity, while CREB, a nuclear transcription factor, mediates neurotransmitter regulation). This combination therapy yields superior outcomes compared to either scalp acupuncture or rTMS alone.⁴⁸ Compared to traditional scalp acupuncture, the MEP localization feature of transcranial magnetic stimulation devices offers a more precise and personalized therapeutic approach. It identifies the location of the motor cortex by stimulating specific regions of the cerebral cortex and recording the motor-evoked

potentials in the contralateral target muscles. Based on individual neurophysiological assessments, MEP localization uses TMS to map specific “functional hotspots” within the individual’s cerebral cortex (M1 area) that control upper limb muscles. Acupuncture stimulation is then precisely targeted to these intact cortical areas, enabling “personalized treatment” and “area-specific treatment.” This avoids the potential under-stimulation or misalignment associated with the relatively broad selection methods of traditional scalp acupuncture.⁴⁹ A study similarly based on MEP-guided scalp acupuncture found that, compared to conventional scalp acupuncture (using bilateral parietal-temporal oblique lines), MEP-guided scalp acupuncture combined with rTMS treatment significantly improved the Fugl-Meyer motor function score and MBI of the affected limb. It also more effectively reduced Modified Ashworth Scale (MAS) scores and alleviated upper limb spasticity.⁵⁰ Additional studies indicate that MEP-guided interventions promote cortical reorganization and neural functional remodeling. Post-treatment, patients exhibited shorter MEP latencies and improved central motor conduction time, suggesting enhanced efficiency in motor command transmission from brain to muscle and strengthened corticospinal tract conduction function.^{51,52} Theoretically, increased MEP amplitude indicates functional recovery. However, in clinical practice, patients with severe hemiplegia often exhibit impaired integrity of the corticospinal tract, making MEP elicitation difficult or even impossible. Nevertheless, a recent study revealed that the absence of MEPs does not predict poor recovery in patients with severe stroke,⁵³ suggesting that relying solely on MEP status may fail to fully capture the multifaceted nature of motor recovery following stroke.

fNIRS is a multi-channel functional brain imaging technique capable of simultaneously monitoring activity across entire cortical networks. By calculating the correlation coefficients of fNIRS signal time series across different brain regions, it enables assessment of cortical activation patterns and functional connectivity strength.^{54,55} Researchers^{36,56} employed fNIRS to monitor HbO₂ and HbR levels in the M1, PMC and SMA. Results revealed a significant increase in HbO₂ levels in these regions of the affected hemisphere post-treatment compared to pre-treatment, with no significant change in HbR levels. This indicates marked activation in these regions of the affected hemisphere following treatment. Other non-motor cortical areas, such as the sensorimotor cortex, integrate sensory information and motor commands to enhance movement precision and coordination. Following stroke, repetitive motor training and sensory stimulation can promote recovery of the SMC’s integrative function, thereby improving control over limb movements.⁵⁷ The frontal lobe and prefrontal cortex may also contribute to post-stroke reorganization processes.⁵⁸ A previous fNIRS study showed that stroke patients have extra activation in non-motor areas like the prefrontal cortex during early recovery. This region⁵⁹ helps integrate different types of information needed for complex behavior. In fact, difficult motor tasks require more attention and sensorimotor processing, which involves combining sensory feedback with motor commands.⁶⁰ Psychophysical evidence⁶¹ suggests that prefrontal regions may contribute to motor skill learning. Prefrontal activity observed during stroke recovery indicates that motor recovery may represent a motor learning process. In promoting rehabilitation for patients with post-stroke motor disorders, attention should also be directed toward the functional roles of other brain regions. Furthermore, the inclusion of the parietal and temporal lobes in our ROI analysis allows for a more comprehensive understanding of the “sensorimotor integration” mechanism underlying acupuncture-induced recovery. The parietal cortex, particularly the primary somatosensory cortex (S1) and the posterior parietal cortex (PPC), acts as a critical hub for processing sensory feedback essential for motor control.⁵⁷ Previous studies have demonstrated that acupuncture stimulation can modulate functional connectivity between the parietal and frontal motor areas, thereby facilitating the “sensory-to-motor” information flow necessary for re-learning skilled movements.⁶² Similarly, the temporal lobe, while traditionally associated with auditory and language processing, has been shown to play a compensatory role in post-stroke motor recovery through the reorganization of the fronto-temporo-parietal network.⁶³ Enhanced functional connectivity between the prefrontal cortex and temporal regions has been observed following acupuncture, suggesting that the therapy may recruit broader multidomain neural networks to support functional restoration.⁶⁴ By monitoring these regions, we aim to elucidate whether the combined therapy accelerates recovery by strengthening these specific long-range cortico-cortical connections.

To my knowledge, only one study has employed a treatment regimen combining MEP-guided transcranial needle stimulation with rTMS. However, this study included only clinical behavioral scales such as the FMA, MAS, and MBI, lacking objective evaluation metrics. This study innovatively employs a multimodal assessment strategy integrating fNIRS with rTMS technology. Its advantage lies in utilizing fNIRS measurements of local cerebral hemodynamic activity and changes in network functional connectivity to provide a neural mechanism explanation for the altered cortical-spinal tract excitability detected by rTMS. This approach overcomes the limitation of rTMS in assessing excitability at localized points.

From the perspective of whole-brain network functional reorganization, it elucidates the central mechanisms underlying therapeutic efficacy. This comprehensive, multidimensional approach demonstrates the effectiveness and neural mechanisms of combined scalp acupuncture and rTMS therapy guided by MEP localization, offering improved clinical treatment options for patients with upper limb motor deficits following stroke.

While our study has innovative elements, certain limitations should be acknowledged. The study's design as a single-center trial with a limited sample size and strict enrollment criteria (including first-onset strokes and specific Brunnstrom stages) restricts its generalizability. These factors mean caution should be exercised when applying these findings to broader stroke populations. Furthermore, despite our efforts to implement blinding, therapists and patients could not be fully blinded, potentially introducing expectation bias. Additionally, inherent limitations in fNIRS technology regarding penetration depth and spatial resolution prevented investigation of activity changes in deeper brain regions. Finally, while this study primarily demonstrated correlations between treatment and neurofunctional changes, definitive causal relationships require confirmation in future research. Finally, the absence of long-term follow-up data precludes assessment of the treatment's long-term efficacy.

Generative AI Statement

The authors declare that no Gen AI was used in the creation of this manuscript.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author (Hangkai Xie) on reasonable request.

Ethics Statement

This research will be conducted in accordance with the Declaration of Helsinki. The Ethics Committee of The Third Affiliated Hospital of Zhejiang Chinese Medical University approved this study (ZSLL-KY-2025-046). The studies adhered to local legislation and institutional requirements. Written informed consent was obtained from every participant prior to enrollment.

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Disclosure

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