

Effects of Functional Magnetic Stimulation Combined with Pelvic Floor Muscle Training on Cerebral Hemodynamics and Brain Functional Connectivity in Women with Postpartum Pelvic Floor Dysfunction: A Randomized Controlled Trial

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Background: The central and peripheral effects of pelvic floor muscle training (PFMT) combined with functional magnetic stimulation (FMS) on postpartum pelvic floor dysfunction (PFD) remain unknown. This study aimed to compare the efficacy of PFMT + FMS versus PFMT + sham FMS on postpartum PFD and to explore the underlying central nervous mechanisms.

Methods: Sixty women with postpartum PFD were randomly assigned to receive 8 weeks of PFMT + FMS or PFMT + sham FMS. Women in both groups were assessed using pelvic floor surface electromyography, transperineal four-dimensional ultrasound, and functional near-infrared spectroscopy at baseline and after 8 weeks of treatment. The primary outcome was to compare the improvements in muscle strength between the two groups. T-tests and Pearson correlation analyses were employed for statistical analysis.

Results: After 8 weeks, compared with the sham stimulation group, the active stimulation group exhibited greater improvements in anterior ($p = 0.048$) and posterior ($p = 0.047$) resting muscle tone, fast-twitch [mean difference = $7.52 \mu\text{V}$ (95% CI, 4.36 to 10.68)] and slow-twitch muscle strength [$8.56 \mu\text{V}$ (4.77 to 12.34)], and slow-twitch muscle endurance [$7.13 \mu\text{V}$ (3.51 to 10.76)] ($p < 0.001$), with more pronounced improvements across all ultrasound metrics. Concurrently, oxyhemoglobin concentrations in sensorimotor cortex (SMC), supplementary motor area, and premotor cortex (PMC) were elevated in the active stimulation group during Kegel exercises. Functional connectivity increased between the ipsilateral PMC and SMC and between the bilateral SMC, with a rising trend in brain network connectivity efficiency [0.0639 (0.0136 to 0.1142), $p = 0.015$]. These reflected enhanced recruitment of the central nervous system and more efficient coordination of motor control strategies. Moreover, correlation analysis revealed a positive correlation between improvements in pelvic floor muscle function and changes in brain network efficiency.

Conclusion: Compared to PFMT alone, combined treatment demonstrates superior efficacy in improving pelvic floor muscle function and anatomical structure in women with postpartum PFD, centrally characterized by increased motor cortex activation and brain network connectivity efficiency.

Trial Registration: Chinese Clinical Trial Registry, ChiCTR2400084678. Registered 22 May 2024, <https://www.chictr.org.cn/>.

Keywords: pelvic floor disorders, magnetic field therapy, spectroscopy, near-infrared, motor cortex, brain mapping, connectome

Introduction

Postpartum pelvic floor dysfunction (PFD) refers to a range of pelvic floor symptoms resulting from injury or decreased function of pelvic floor supportive tissues as a result of pregnancy and childbirth,¹ including urinary incontinence, pelvic organ prolapse, sexual dysfunction, and overactive bladder.² Epidemiological studies indicate that approximately 45%–50% of postpartum women experience PFD of varying symptoms and severity, imposing a significant burden on the quality of life of women worldwide and on healthcare systems.^{3,4} Accordingly, the National Institute for Health and Care Excellence (NICE) global guidelines recommend pelvic floor muscle training (PFMT) as the first-line conservative treatment for postpartum women diagnosed with or exhibiting symptoms of PFD.⁵ PFMT employs a structured Kegel exercise program designed to enhance pelvic floor muscle strength, endurance, power, and coordinated relaxation.⁶ Extensive research confirms that PFMT effectively improves pelvic floor morphology, muscle strength, and clinical symptoms in women with PFD.^{7,8} However, according to guideline recommendations⁵ and meta-analyses,⁹ achieving optimal efficacy requires at least 3–4 months of professionally supervised training with close follow-up. Concurrently, for women with impaired proprioception or insufficient muscle strength, the guidelines recommend adjunctive therapies to establish their ability to contract and relax pelvic floor muscles, thereby supplementing and enhancing PFMT. However, current evidence on the efficacy of adjunctive therapies such as biofeedback, electrical stimulation, and vaginal cones remains inconsistent.¹⁰ Therefore, it remains necessary to explore whether there is an adjunctive therapy that can provide greater benefits than PFMT alone.

Functional magnetic stimulation (FMS) is a highly penetrative and easy-to-operate physical therapy method. Its unique painless and non-invasive characteristics allow postpartum women to complete treatment without removing clothing, making it widely concerned and favored. FMS generates induced currents through a pulsed magnetic field, transmits nerve impulses, and achieves sacral and pubic neuromodulation,¹¹ thus enhancing pelvic floor muscle contraction, promoting blood circulation, and improving muscle coordination.^{12–16} Evidences indicate that FMS helps improve pelvic floor muscle function, urinary incontinence symptoms, quality of life, and sexual function in women with stress urinary incontinence (SUI), while reducing pelvic floor discomfort.^{11,13,14,17–19} However, in the current research, the efficacy of FMS for postpartum PFD remains under discussion, and the therapeutic effect of combined PFMT for women with postpartum PFD is still unclear.

Previously, Gunnarsson et al demonstrated a correlation between the clinical efficacy of PFMT and cortical control of pelvic floor muscles using cortical transcranial magnetic stimulation.²⁰ Di Gangi Herms et al also found that PFMT under electromyography-biofeedback induced changes in the neuroplasticity of women with SUI, which manifested as alterations in the activation of the cerebral motor cortex during Kegel exercises.²¹ Accordingly, we believe that the comprehensive rehabilitation of the pelvic floor function after childbirth includes not only the external recovery of pelvic floor muscle strength and pelvic floor anatomy, but also is reflected in the internal improvement of a woman's ability to perceive the pelvic floor muscles and motor control. However, the central mechanism by which FMS improves pelvic floor function has not been reported. In particular, the role of remodeling between the supplementary motor area (SMA), sensorimotor cortex (SMC), and premotor cortex (PMC) related to pelvic floor muscle movement^{21,22} is unknown.

Assessments of brain function relevant to physical therapy and rehabilitation have been extensively explored through various computerized paradigms integrating neuroscience theories.^{23,24} These evaluation methods prove crucial for enhancing motor learning and control capabilities,²⁵ validating research approaches that quantify brain-behaviour relationships via technological interfaces and investigate the neural correlates of rehabilitation efficacy.

This study aimed to investigate the effects of FMS combined with PFMT on cerebral hemodynamics and functional brain connectivity in postpartum women with PFD by task-state functional near-infrared spectroscopy (fNIRS), based on routine pelvic floor surface electromyography (sEMG)²⁶ and transperineal four-dimensional ultrasound²⁷ assessment. We hypothesized that the combined treatment would lead to greater efficacy than PFMT alone in improving the pelvic floor muscle function and pelvic floor anatomical structure, enhance activation of the brain motor cortex during Kegel

exercises, optimize brain functional connectivity patterns, and increase network connectivity efficiency in postpartum women with PFD. In addition, we hypothesized that the improvement in peripheral pelvic floor muscle strength after treatment could be fed back to the centre and manifested as an increase in brain network connectivity efficiency.

Materials and Methods

Study Design and Ethical Approval

This was a prospective, double-blind, randomized controlled trial, in which participants were randomly assigned to a sham stimulation group and an active stimulation group to receive 8 weeks of PFMT + sham FMS and PFMT + FMS, respectively. Pelvic floor sEMG, transperineal four-dimensional ultrasound, and fNIRS were assessed in both groups of women before and after 8 weeks of treatment. The trial report followed the CONSORT guidelines. The study was reviewed and approved by the Ethics Committee of the Fourth Affiliated Hospital of Soochow University (approval on 9/05/2024; No. 240012) and registered at [https://www.chictr.org.cn/\(ChiCTR2400084678\)](https://www.chictr.org.cn/(ChiCTR2400084678)) on 22/05/2024. The trial followed the Declaration of Helsinki (2013), and all participants were fully informed about the study procedures and signed an informed consent form.

Participants

Participants were recruited from women who underwent a 42-day postpartum follow-up at the Department of Obstetrics and Gynecology, the Fourth Affiliated Hospital of Soochow University (Suzhou Dushu Lake Hospital) between June 2024 and April 2025, and were diagnosed with postpartum PFD. Postpartum PFD was diagnosed by a senior-level chief obstetrician and gynaecologist according to the International Continence Society (ICS)/International Urogynecological Association (IUGA) criteria.²⁸ Subsequently, eligible women were invited to participate in the trial and referred to the pelvic floor rehabilitation center in the Department of Rehabilitation Medicine for further enrollment and baseline assessment. Inclusion criteria: 1) meeting the diagnostic criteria for urinary incontinence, pelvic organ prolapse, and/or sexual dysfunction. At least one of the following criteria must be met: presence of typical stress and/or urge urinary incontinence symptoms, defined as involuntary urine leakage associated with exertion or physical activity and/or urgency, confirmed by physical examination; pelvic organ prolapse assessed as Stage I (mild) or higher using the POP-Q staging system, with symptoms corresponding to the findings; complained of sexual dysfunction, such as dyspareunia, decreased libido, or loss of sexual pleasure; 2) aged 20–40 years (due to ethical and confounding controls); 3) in the early postpartum period (42 days to 3 months postpartum) at baseline assessment;²⁹ 4) no discharge; 5) singleton full-term gestation; and 6) being conscious and able to cooperate with the study, and voluntarily signing the informed consent form. Exclusion criteria: 1) Grade III/IV perineal laceration; 2) urinary retention, constipation; 3) persistent postpartum hemorrhage, discharge, and genitourinary infections; 4) malignant tumors, diabetes mellitus, and other serious illnesses; 5) previous pelvic surgeries; 6) pregnancy; 7) severe psychiatric disorders or cognitive disorders; and 8) contraindications to magnetic stimulation (eg, installing a pacemaker or having a metal foreign body in the body, etc).

Randomization and Blinding

A random number sequence was generated using SPSS 27.0, and participants were randomly assigned in a 1:1 ratio to sham and active stimulation groups, with an initial inclusion of 30 cases in each group. Grouping information was placed in opaque envelopes and assigned to participants in sequential order. Researchers responsible for recruitment, intervention allocation, intervention implementation, supervision, and the organization and archiving of study materials were aware of the group allocations. Participants, evaluators, and statistical analysts were unaware of the group allocations. Treatment was administered by postpartum physical therapists who were not involved in the core processes of this trial. They provided therapy solely based on the pre-assigned treatment protocol codes for each participant.

Interventions

Participants in both groups underwent 8 weeks of PFMT, which was instructed and supervised by the professional postpartum physical therapists. Women were instructed to lie on their backs with their legs flexed slightly apart, clench their buttocks and thighs while inhaling, imagine breaking the urine stream while urinating to find the contraction sensation, tighten the pelvic floor muscles, and then slowly relax them while exhaling. The therapist placed the index and middle fingers into the woman's vagina while wearing sterile gloves to ensure that the woman could properly contract and relax the pelvic floor muscles. A progressive resistance strengthening strength training program was developed according to the recommendations of the American College of Sports Medicine.^{30,31} Strength Training involved rapid contractions of the pelvic floor muscles with maximum force, completed 5 rapid contractions in 10 seconds, rested for 10 seconds, then repeated 4 times. Endurance training consisted of moderate strength vaginal-anal tightening manoeuvres held for 10 seconds each, with 10 seconds of rest, followed by 9 repetitions. Strength and endurance training were alternated. Participants initially performed 3 sets of repetitions per day, with 1 additional set added every 2 weeks for a total of 8 weeks. During training, the position could be gradually adjusted to lying, sitting, or standing. After each FMS (or sham FMS) treatment, guided PFMT was provided according to the above protocol 2–3 times a week, and the rest of the time, the women trained at home by themselves. To enhance training adherence, researchers sent daily reminders via WeChat group and required participants to report their training progress once a week. During hospital training sessions, the therapist provided guidance and exercise corrections based on participants' feedback. No other supplementary interventions were employed.

FMS was performed using the Weiss Magnetic Stimulator Magneuro 100 F. (Figure 1A) The woman sat in the treatment chair after urination with her legs slightly apart and placed her perineum in the centre of the magnetic coil located at the bottom of the chair. All participants received standardized stimulation parameters without individualized adjustments. The specific protocol was as follows: The active stimulation group received a treatment intensity of 40% at a frequency of 30 Hz for 5 seconds of stimulation at 5-second intervals for a total of 18,000 pulses for 20 minutes. The sham stimulation group underwent the same treatment protocol, but the pseudo-coil was connected to the treatment so that the instrument made the same sound without substantial magnetic stimulation. Treatments were administered 2–3 times a week for 8 weeks for a total of 20 treatments. If a woman was menstruating, treatment was suspended until the menstrual period was completely over to prevent adverse effects. Women were not told which treatments they were receiving until the study was completed. To ensure a standardized intervention protocol, all physical therapists administering treatment underwent uniform training. This included mastering the treatment regimens, adhering to standardized operating procedures for the magnetic stimulator and sham coil, and learning key considerations for communicating with participants.

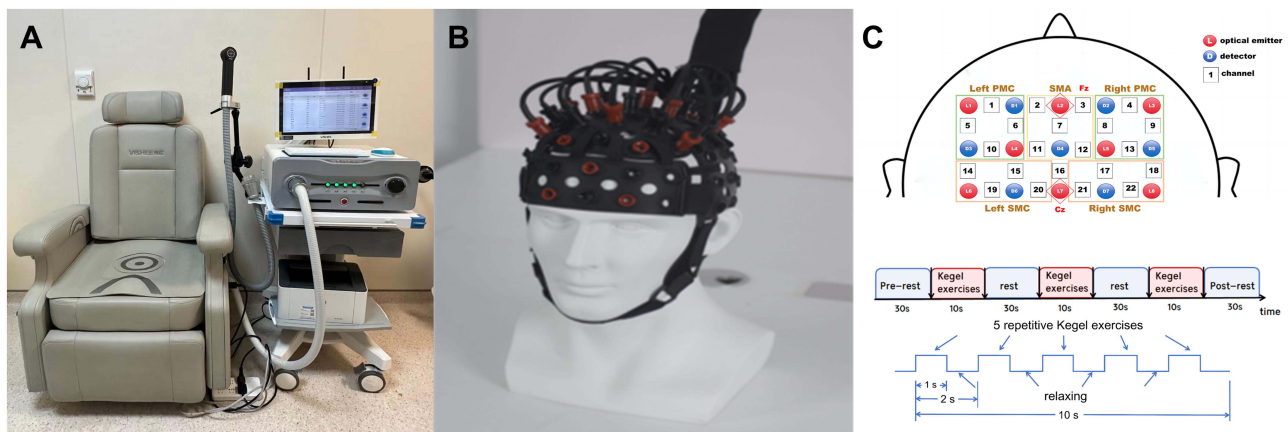


Figure 1 (A) Functional magnetic stimulation equipment; (B) fNIRS device optical fiber cap; (C) Distribution map of the probe and brain region of interest (ROI) and fNIRS testing procedure paradigm. The red "L" denotes the light source, the blue "D" denotes the detector, and different numerical indicators denote channels. The Fz point and Cz point circled by the red box represent the midline and central point respectively of the international 10–20 system electrode placement method.

Abbreviations: PMC, premotor cortex; SMA, supplementary motor area; SMC, sensorimotor cortex.

Outcome Measures

The primary outcome measure of this trial was pelvic floor muscle strength assessed by pelvic floor sEMG. Secondary outcomes included resting muscle tone before and after exercise as assessed by pelvic floor sEMG, as well as transperineal four-dimensional ultrasound and fNIRS assessment. These measures were assessed one day before treatment initiation and one day after completion of the 8-week intervention.

Pelvic Floor sEMG Assessment

Following the international Glazer protocol,³² a biofeedback electrical stimulator model S480 (Nanjing Weisi) was used to measure EMG values in the pre-baseline, flick contraction, tonic contraction, endurance contraction, and post-baseline phases to quantify the woman's pre- and post-exercise pelvic floor muscle tone, fast-twitch muscle strength, slow-twitch muscle strength, and endurance. The impedance of the electrode and the sensitivity of the signal amplifier were checked before measurement. The woman was instructed to assume a supine position of approximately 120°, and a vaginal electrode was placed in the vagina, while reference electrodes were placed on the abdomen as the calibration for monitoring unwanted muscle activation. Before the test, the therapist explained the procedure and instructed the woman on how to perform the pelvic floor muscle contractions correctly without involving the anterior abdominal, inner thighs, and gluteal muscles. Measurements were repeated three times and averaged to obtain reliable sEMG data. All sEMG tests were performed by the same associate senior-level therapist with over ten years of postpartum rehabilitation experience. This therapist received specialized training before the trial on the Glazer protocol, equipment operation, and electrode placement specifications for this study to ensure data standardization and consistency. Two reliability tests by Grape et al³³ and Brækken et al³⁴ both confirmed excellent retest reliability at all stages of the sEMG test [intraclass correlation coefficients (ICC) were 0.83–0.96 and 0.86–0.99, respectively].

Transperineal Four-Dimensional Ultrasound Assessment and Diagnostic Criteria

Routine scanning was performed using a Resona 8 colour Doppler diagnostic ultrasound machine (Shenzhen Mindray) and an abdominal convex array probe in the 4–8 MHz frequency range. Check the horizontal and vertical linearity of the ultrasound instrument, as well as the sensitivity and signal-to-noise ratio of the probe before examination. Women were instructed to empty their bowels and bladder 10 minutes before the examination and to be in the lithotomy position. Subsequently, the women were given instructional training in the correct Valsalva manoeuvre. A valid Valsalva manoeuvre was considered to be a movement of the pelvic organs to the dorsal-caudal side or an enlargement of the anal raphe fissure with a duration of ≥ 6 seconds.³⁵ The bladder neck position (ie, the vertical distance between the bladder neck and the horizontal line of the posterior inferior border of the pubic symphysis) and the posterior bladder angle were observed and recorded in women at rest. As well as the bladder neck mobility, the urethral rotation angle, and the area of the levator hiatus during the Valsalva manoeuvre. Normally, the bladder neck position at rest is ≥ 25 mm and the posterior bladder angle is 90–120°.^{27,36} During the Valsalva manoeuvre, the bladder neck mobility is < 25 mm, the urethral rotation angle is $< 45^\circ$ and the area of the levator hiatus is < 20 cm². All measurements were repeated three times and averaged to ensure the accuracy of the measured parameters. Each examination and data extraction was performed by the same senior-level pelvic floor ultrasound specialist. The physician has completed standardized pelvic floor ultrasound training and was proficient in the uniform measurement protocols and diagnostic criteria adopted in this research. The studies by Tan et al³⁷ and Lone et al³⁸ demonstrated good to excellent reliability of transperineal ultrasound for measuring pelvic floor anatomy (ICC 0.73–0.93 and 0.75–0.98, respectively).

fNIRS Measurement

Functional brain imaging system software (Bairexin Intelligent Technology Co., Ltd., model: H01B, sampling frequency 10 Hz) was used to record the activity of the cerebral cortex in the form of continuous waves of 785 nm and 830 nm to obtain the changes in oxyhemoglobin (HbO₂), deoxyhemoglobin, and total hemoglobin concentrations. This experiment was based on the internationally used EEG tracing method 10–20 system for the localization of brain regions. The optical fiber cap consists of 8 optical emitters and 7 detectors, forming a total of 22 channels (numbered 1–22). (Figure 1B) The spacing was 3 cm, and the sampling period was 0.1 s. The regions of interest (ROI) included the bilateral PMC (left

PMC: channels 1, 5, 6, and 10; right PMC: channels 4, 8, 9, and 13), SMA (channels 2, 3, 7, 11, and 12), and bilateral SMC (left SMC: channels 14, 15, 19, and 20; right SMC: channels 17, 18, 21, and 22) (Figure 1C).

The test procedure was based on a block design: a rest period of 30 seconds and a task period of 10 seconds. The rest period was kept stationary, and the task period was completed with 5 best effort Kegel exercises (contraction for 1 second, rest for 1 second) within 10 seconds. The rest and task periods were repeated 3 times, ending with a final rest period of 30 seconds for a total of 150 seconds (Figure 1C).

The fNIRS data collection was completed by two intermediate-level physical therapists who underwent standardized training. The training covered the 10–20 system positioning method, optical fiber cap wearing procedure, signal quality calibration, and subject task guidance. Both operators passed practical assessments to ensure consistency and high quality throughout the data acquisition process. The fNIRS test was administered in a quiet and specialised room. Before starting, the physical therapist explained the testing procedure to the woman to ensure she was proficient. The woman was explicitly asked to concentrate on pelvic floor contractions without moving other body parts. The test was performed in the supine position at approximately 120°. After the woman was fitted with an optical fiber cap with the light sources and detectors attached, channel-by-channel commissioning and calibration were performed to ensure high signal quality. There were voice prompts during the test and the woman was not allowed to count or think.

fNIRS data processing and indexes: Data were preprocessed and analysed using functional brain imaging system software (Bairexin Intelligent Technology Co., Ltd). The preprocessing steps were as follows: 1) Identify and remove motion artifacts. 2) Process the acquired signals based on 0.01–0.50 Hz bandpass filtering of the Kalman filter to eliminate the interference of high-frequency noise and slow drift. 3) Solve the optical signal into the variation range of HbO₂ and HbR concentration. Analysis indicators: 1) HbO₂ concentration: Given the high sensitivity of the HbO₂ data, this item was chosen as the hemodynamic response index in this experiment to assess the degree of motor cortex activation during Kegel exercises.^{39,40} The entropy-weighted average method was employed to calculate the mean HbO₂ concentration changes in the ROIs during the three tasks. This method emphasized the contribution of high-information channels through objective weighting to mitigate signal interference caused by noisy channels, motion artifacts, and fiberoptic decoupling, thereby yielding more robust and representative ROI signals.⁴¹ 2) Brain functional connectivity: Pearson correlation coefficient was used to calculate the correlation of HbO₂ concentration among ROIs during the Kegel task, which was used to explore the dynamic interactions between ROIs during the activation of the brain motor cortex, thus exploring the cortical reorganization mechanism of pelvic floor rehabilitation.⁴² An undirected network was constructed based on the correlation coefficient *r* value, and the network connectivity efficiency was calculated based on the adjacency matrix to quantitatively assess the changes in functional connectivity of ROIs before and after treatment. Network connectivity efficiency, ie, global efficiency, is the reciprocal of the shortest average path in the network, which reflects the overall ability of the network to transmit information. Higher network connectivity efficiency indicates a faster rate of transferring information between network nodes and a stronger integration ability.⁴³ Niu et al showed that HbO₂ (ICC = 0.70), HbO₂-based functional connectivity (ICC = 0.70), and HbO₂-based global efficiency (ICC = 0.76) had good to excellent retest reliabilities.⁴⁴

Safety Assessment

The safety of the treatment and any possible adverse effects in women were monitored throughout the study. Women were asked how they felt before and after each intervention and any discomfort was recorded in detail. Women's status was closely monitored during treatment and any abnormalities were dealt with immediately. Women were also asked to report any adverse reactions directly related to FMS and/or PFMT treatment, such as dizziness, vomiting, tinnitus, diarrhoea, constipation, vaginal/urethral bleeding, and pain. The data collected on adverse reactions were pooled and analysed to evaluate the side effects and safety of the treatment.

Statistical Analysis

This study used G*Power 3.1.9.4 software (University of Düsseldorf, Germany) to calculate sample size. The primary outcome measures were fast-twitch and slow-twitch muscle strength in women. Based on data reported by Wang et al:⁴⁵ For fast-twitch muscle strength, the post-treatment difference between the combined group and the control group

(38.9 μV vs 33.5 μV) was 5.4 μV , with an overall standard deviation of 5.7 μV , statistical power = 90%, $\alpha = 0.05$ (two-tailed t test), then a sample size of 25 was calculated for each group. For slow-twitch muscle strength, the post-treatment difference between the combined group and the control group (37.9 μV vs 32.7 μV) was 5.2 μV , with an overall standard deviation of 5.2 μV , statistical power = 90%, $\alpha = 0.05$ (two-tailed t test), then a sample size of 23 per group was calculated. Since the calculated sample size was highest for fast-twitch muscle strength, and taking into account a 20% dropout rate, a final sample size of 30 per group was determined.

Statistical analysis was conducted using SPSS Statistics 27.0 (IBM, United States). The normality of the data was assessed with the Shapiro–Wilk test. Independent samples t tests, Mann–Whitney U -tests, and chi-square tests were used for comparisons of baseline data. Efficacy analysis of experimental factors included within-group paired-samples t tests and between-group independent-samples t tests for normally distributed data. The differences were quantified by Cohen's d . Pearson correlation was used to explore the relationship between improvements in pelvic floor muscle function and changes in brain network efficiency. A significance level of $p < 0.05$ was used.

Results

General Parameters of Participants

Sixty-eight participants were assessed for eligibility and finally 60 eligible women with postpartum PFD who accepted the invitation were enrolled in the trial. All completed the intervention in the sham stimulation group and 2 women in the active stimulation group discontinued the intervention (due to the distance of the hospital from their home and the need to care for children). Ultimately, 30 women in the sham stimulation group and 28 women in the active stimulation group were included in the analysis of results. (Figure 2) The baseline demographic parameters and measures were comparable between the sham and active stimulation groups (Table 1).

sEMG and Ultrasound Assessments

Between-Group Comparisons

The data from the sEMG and ultrasound assessments are presented in Table 2. Following treatment, the active stimulation group demonstrated significantly greater improvements in fast-twitch muscle strength, slow-twitch muscle strength, and slow-twitch muscle endurance compared to the sham stimulation group ($p < 0.001$). It also exhibited superior reductions in anterior and posterior resting muscle tone ($p < 0.05$). Ultrasound assessments revealed that the active stimulation group demonstrated superior improvements in bladder neck position and posterior bladder angle, as well as in bladder neck mobility, urethral rotation angle, and levator ani hiatus area ($p < 0.05$).

Within-Group Comparisons

After 8 weeks of treatment, both groups of women demonstrated significant improvements in fast-twitch muscle strength, slow-twitch muscle strength, and slow-twitch muscle endurance compared to pre-treatment ($p < 0.001$). Both groups exhibited a significant decrease in anterior and posterior resting muscle tone ($p < 0.001$). Concurrently, the bladder neck position obviously increased while the posterior bladder angle, bladder neck mobility, urethral rotation angle, and levator ani hiatus area decreased in both groups ($p < 0.01$).

fNIRS Measurement

Between-Group Comparisons

Between-group analysis revealed that compared to the sham stimulation group, the active stimulation group exhibited significantly greater increases in HbO₂ concentration across all five ROIs ($p < 0.001$) (Table 3), indicating higher levels of brain region recruitment and activation during Kegel exercises in the active stimulation group. (Figure 3A) After treatment, greater improvements in brain network connectivity efficiency were observed in the active stimulation group, although intergroup comparison was non-significant (0.0639 vs 0.0144, $p = 0.131$). (Figure 3B) Furthermore, post-treatment functional connectivity networks revealed more pronounced connectivity enhancements in the active stimulation group between the ipsilateral PMC and SMC regions, as well as between bilateral SMC regions (Figure 3C).

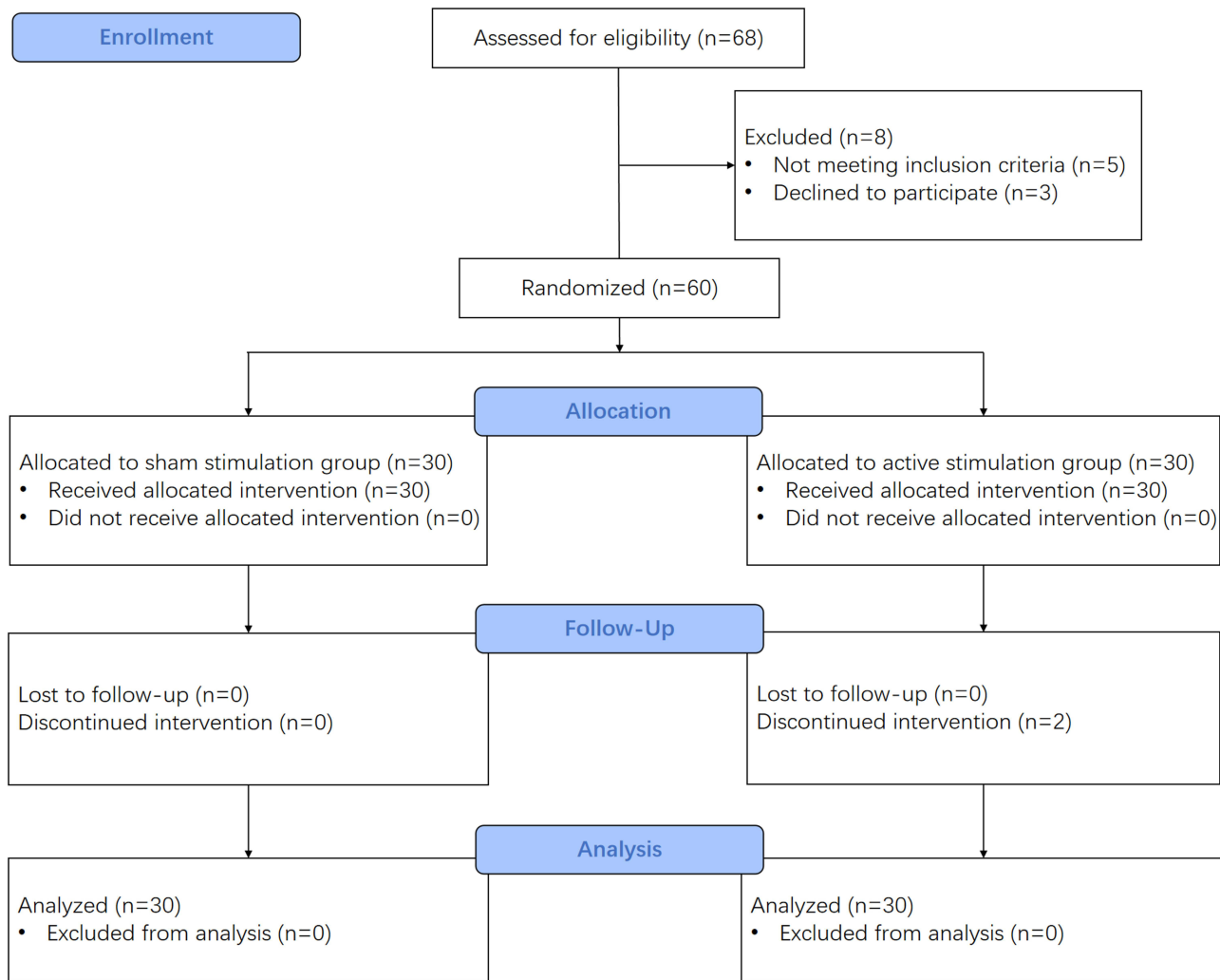


Figure 2 CONSORT flowchart.

Within-Group Comparisons

Within-group analysis revealed significantly elevated HbO₂ concentrations in all five ROIs after treatment in the active stimulation group ($p < 0.001$). The sham stimulation group demonstrated increased HbO₂ levels in four brain regions

Table 1 Baseline Demographics of Both Groups

	Sham (n=30)	Active (n=28)
Characteristics		
Age (years)	29.13 ± 2.73	28.82 ± 2.92
Parity (times)	1.20 ± 0.41	1.21 ± 0.42
Delivery mode (Eutocia/Cesarean), n	20 (10)	20 (8)
Lateral episiotomy/laceration (Yes/No), n	15 (15)	18 (10)
PFD symptoms (%)		
UI	63.3	71.4
POP	50.0	46.4
FSD	26.7	32.1
Postpartum (days)	55.87 ± 7.62	56.21 ± 7.76

(Continued)

Table 1 (Continued).

	Sham (n=30)	Active (n=28)
sEMG (μ V)		
Pre-baseline rest	7.05 \pm 2.22	7.43 \pm 3.17
Flick contraction	21.81 \pm 5.64	20.61 \pm 5.96
Tonic contraction	16.96 \pm 5.96	16.63 \pm 5.95
Endurance contraction	14.70 \pm 5.41	13.67 \pm 5.04
Post-baseline rest	6.17 \pm 1.90	6.77 \pm 3.16
Ultrasound		
Bladder neck position (mm)	25.10 \pm 2.77	25.07 \pm 2.54
Posterior bladder angle ($^{\circ}$)	128.83 \pm 9.53	128.75 \pm 9.45
Bladder neck mobility (mm)	30.23 \pm 4.49	31.21 \pm 5.25
Urethral rotation angle ($^{\circ}$)	77.40 \pm 17.40	78.54 \pm 17.92
Area of levator hiatus (cm^2)	24.47 \pm 5.08	23.53 \pm 4.11

Abbreviations: UI, urinary incontinence; POP, pelvic organ prolapse; FSD, female sexual dysfunction; sEMG, pelvic floor surface electromyography; Ultrasound, transperineal four-dimensional ultrasound.

Table 2 Comparison of Pelvic Floor Surface Electromyography and Transperineal Four-Dimensional Ultrasound Between Groups After Treatment

Variable	Group	Before (Mean \pm SD)	After (Mean \pm SD)	Between-Group Difference (95% CI)	Cohen's <i>d</i>	<i>p</i> ^c
sEMG (μ V)						
Pre-baseline rest	Sham	7.05 \pm 2.22	4.49 \pm 1.94 ^b	-1.57 (-0.01 to -3.14)	0.547	0.048
	Active	7.43 \pm 3.17	3.29 \pm 1.51 ^b			
Flick contractions	Sham	21.81 \pm 5.64	31.77 \pm 7.26 ^b	7.52 (4.36 to 10.68)	-1.253	< 0.001
	Active	20.61 \pm 5.96	38.09 \pm 7.55 ^b			
Tonic contractions	Sham	16.96 \pm 5.96	23.61 \pm 7.33 ^b	8.56 (4.77 to 12.34)	-1.191	< 0.001
	Active	16.63 \pm 5.95	31.84 \pm 7.92 ^b			
Endurance contraction	Sham	14.70 \pm 5.41	21.39 \pm 6.90 ^b	7.13 (3.51 to 10.76)	-1.035	< 0.001
	Active	13.67 \pm 5.04	27.49 \pm 7.49 ^b			
Post-baseline rest	Sham	6.17 \pm 1.90	4.08 \pm 1.60 ^b	-1.59 (-0.02 to -3.16)	0.550	0.047
	Active	6.77 \pm 3.16	3.09 \pm 1.43 ^b			
Ultrasound						
Bladder neck position (mm)	Sham	25.10 \pm 2.77	26.20 \pm 2.47 ^a	1.44 (0.21 to 2.67)	-0.615	0.023
	Active	25.07 \pm 2.54	27.61 \pm 2.36 ^b			
Posterior bladder angle ($^{\circ}$)	Sham	128.83 \pm 9.53	122.73 \pm 9.87 ^a	-7.33 (-12.93 to -1.73)	0.689	0.011
	Active	128.75 \pm 9.45	115.32 \pm 10.64 ^b			
Bladder neck mobility (mm)	Sham	30.23 \pm 4.49	24.77 \pm 3.10 ^b	-2.93 (-5.79 to -0.06)	0.551	0.046
	Active	31.21 \pm 5.25	22.82 \pm 5.51 ^b			
Urethral rotation angle ($^{\circ}$)	Sham	77.40 \pm 17.40	67.70 \pm 11.56 ^a	-8.34 (-15.52 to -1.15)	0.610	0.024
	Active	78.54 \pm 17.92	60.50 \pm 15.28 ^b			
Area of levator hiatus (cm^2)	Sham	24.47 \pm 5.08	22.21 \pm 4.38 ^b	-2.27 (-3.73 to -0.80)	0.812	0.003
	Active	23.53 \pm 4.11	19.01 \pm 4.32 ^b			

Notes: ^a $p < 0.01$, ^b $p < 0.001$ compared with pre-treatment by paired sample *t* test; ^c the *p*-values for the between-group comparison of changes before and after treatment.

(L-PMC, SMA, R-PMC, R-SMC) ($p < 0.05$). (Figure 4A and B) The active stimulation group exhibited higher network connectivity efficiency than pre-treatment [$p = 0.015$, Cohen's $d = 0.493$ (95% CI, 0.096 to 0.882)], while no significant difference was observed in the sham stimulation group. (Figure 3B) After 8 weeks, both groups exhibited broadly

Table 3 Comparison of the HbO₂ Concentration (mmol*mm) and Network Efficiency in the Regions of Interest Before and After Treatment in the Two Groups

	Group	Before (Mean ± SD)	After (Mean ± SD)	Between-Group Difference (95% CI)	Cohen's d	p ^d
L-PMC	Sham	0.0434 ± 0.0147	0.0523 ± 0.0262 ^a	0.0672 (0.0464 to 0.0879)	-1.774	< 0.001
	Active	0.0404 ± 0.0201	0.1165 ± 0.0527 ^c			
SMA	Sham	0.0475 ± 0.0282	0.0627 ± 0.0303 ^b	0.0805 (0.0492 to 0.1119)	-1.406	< 0.001
	Active	0.0573 ± 0.0196	0.1530 ± 0.0747 ^c			
R-PMC	Sham	0.0593 ± 0.0324	0.1016 ± 0.0288 ^c	0.1890 (0.1482 to 0.2298)	-2.564	< 0.001
	Active	0.0638 ± 0.0188	0.2950 ± 0.1020 ^c			
L-SMC	Sham	0.0521 ± 0.0225	0.0551 ± 0.0265	0.0476 (0.0290 to 0.0663)	-1.366	< 0.001
	Active	0.0587 ± 0.0132	0.1095 ± 0.0346 ^c			
R-SMC	Sham	0.0602 ± 0.0168	0.0978 ± 0.0357 ^c	0.2241 (0.1822 to 0.2660)	-2.925	< 0.001
	Active	0.0613 ± 0.0225	0.3230 ± 0.1193 ^c			
Network efficiency	Sham	0.1439 ± 0.0877	0.1583 ± 0.0922	0.0495 (0.0152 to 0.1142)	-0.402	0.131
	Active	0.1348 ± 0.0740	0.1987 ± 0.1043 ^a			

Notes: ^a $p < 0.05$, ^b $p < 0.01$, ^c $p < 0.001$ compared with pre-treatment by paired sample t test; ^d the p-values for the between-group comparison of changes before and after treatment.

enhanced functional connectivity across brain networks, particularly between ipsilateral PMC and SMC regions and between bilateral SMC regions. Concurrently, relatively compact connectivity was maintained within the SMA and bilateral PMC regions (Figure 3C).

Correlation Analysis

Further correlation analysis revealed that enhancement in pelvic floor fast muscle strength was positively correlated with changes in brain network connectivity efficiency in both groups of women (sham: $r = 0.464$, $p = 0.010$; active: $r = 0.434$, $p = 0.021$). Similarly, there was a positive correlation between the improvement in

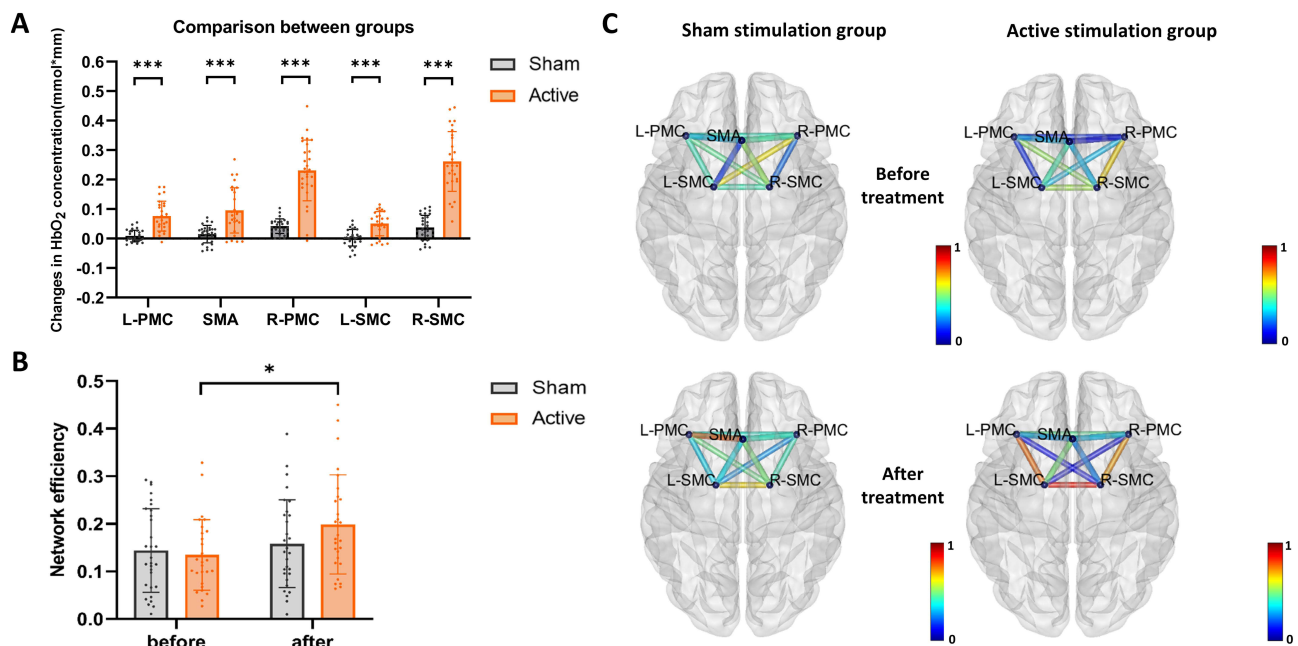


Figure 3 (A) Between-group comparisons of changes in the HbO₂ concentration in the ROI before and after treatment. (B) Comparison of brain network efficiency before and after treatment in the two groups. (C) Brain functional connectivity maps. The connection strength is indicated by the colours of the line. * $p < 0.05$, *** $p < 0.001$.

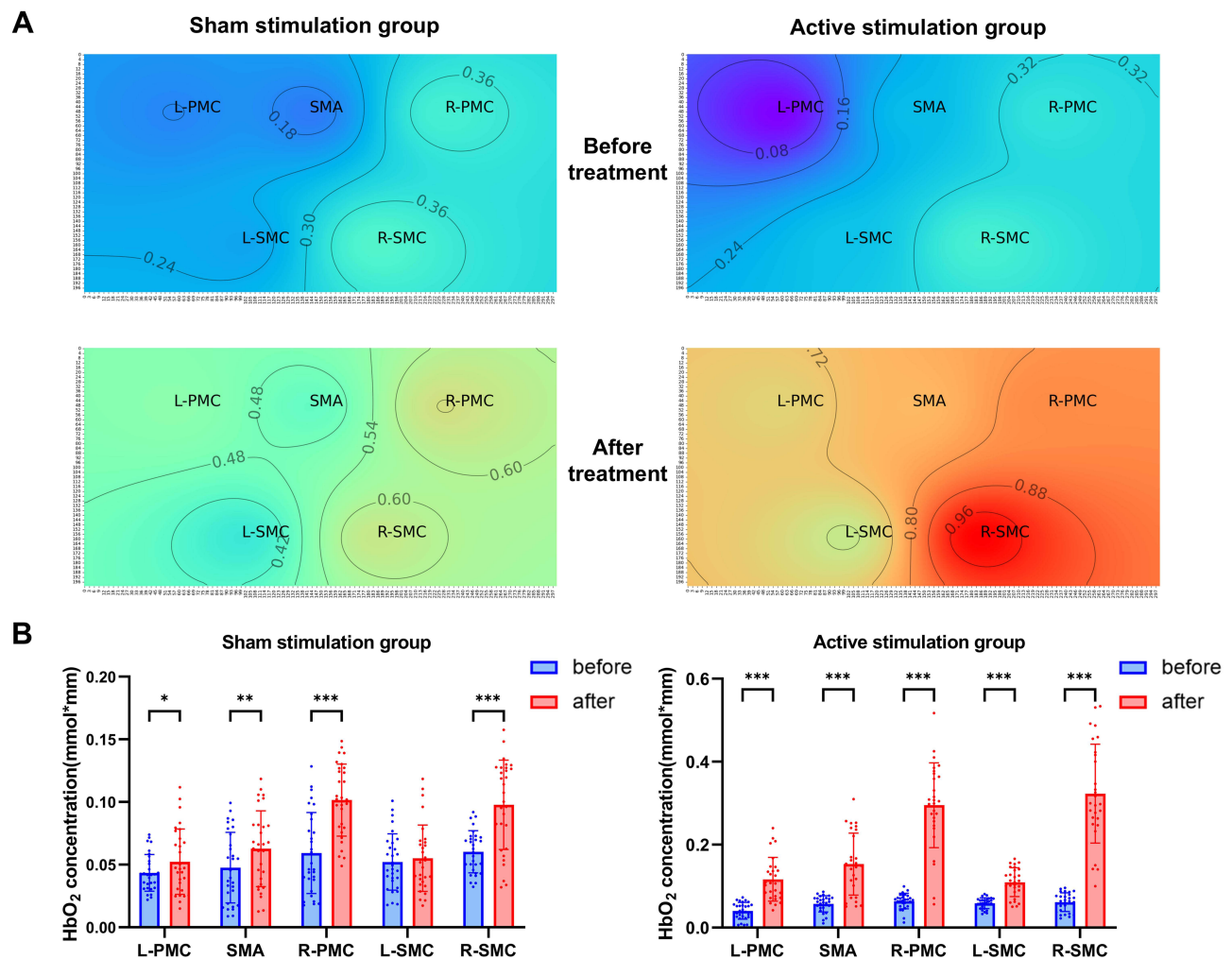


Figure 4 (A) Heatmap of the HbO₂ concentration in the ROI in the two groups. Raw HbO₂ concentration values were normalized and plotted, and the colours represent the degree of activation of the brain regions. **(B)** Comparison of the HbO₂ concentration in the ROI before and after treatment in the two groups. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

slow muscle strength (sham: $r = 0.398$, $p = 0.030$; active: $r = 0.378$, $p = 0.048$) and the improvement in slow muscle endurance (sham: $r = 0.369$, $p = 0.045$; active: $r = 0.396$, $p = 0.037$) (Figure 5).

Safety

During the treatment period, diarrhoea and temporary unpleasant sensations in the pelvic floor were reported by two (7.1%) women in the active stimulation group, and an increase in vaginal discharge was reported by one (3.3%) woman in the sham stimulation group. However, these symptoms were mild and temporary and did not affect daily life. Other than that, neither of the women in the two groups reported any serious adverse reactions or pain associated with the treatment.

Discussion

As hypothesized, this study confirms that FMS combined with PFMT demonstrates superior efficacy to PFMT alone in improving postpartum PFD, with no significant side effects observed and good safety. To our knowledge, this study is the first to report fNIRS-detected neuroplastic changes in cortical representations related to pelvic floor motor function following treatment. The findings indicate that pelvic floor function recovery in women with PFD is not only associated with enhanced peripheral muscle strength but also benefits from improved autonomic control of pelvic floor muscles.

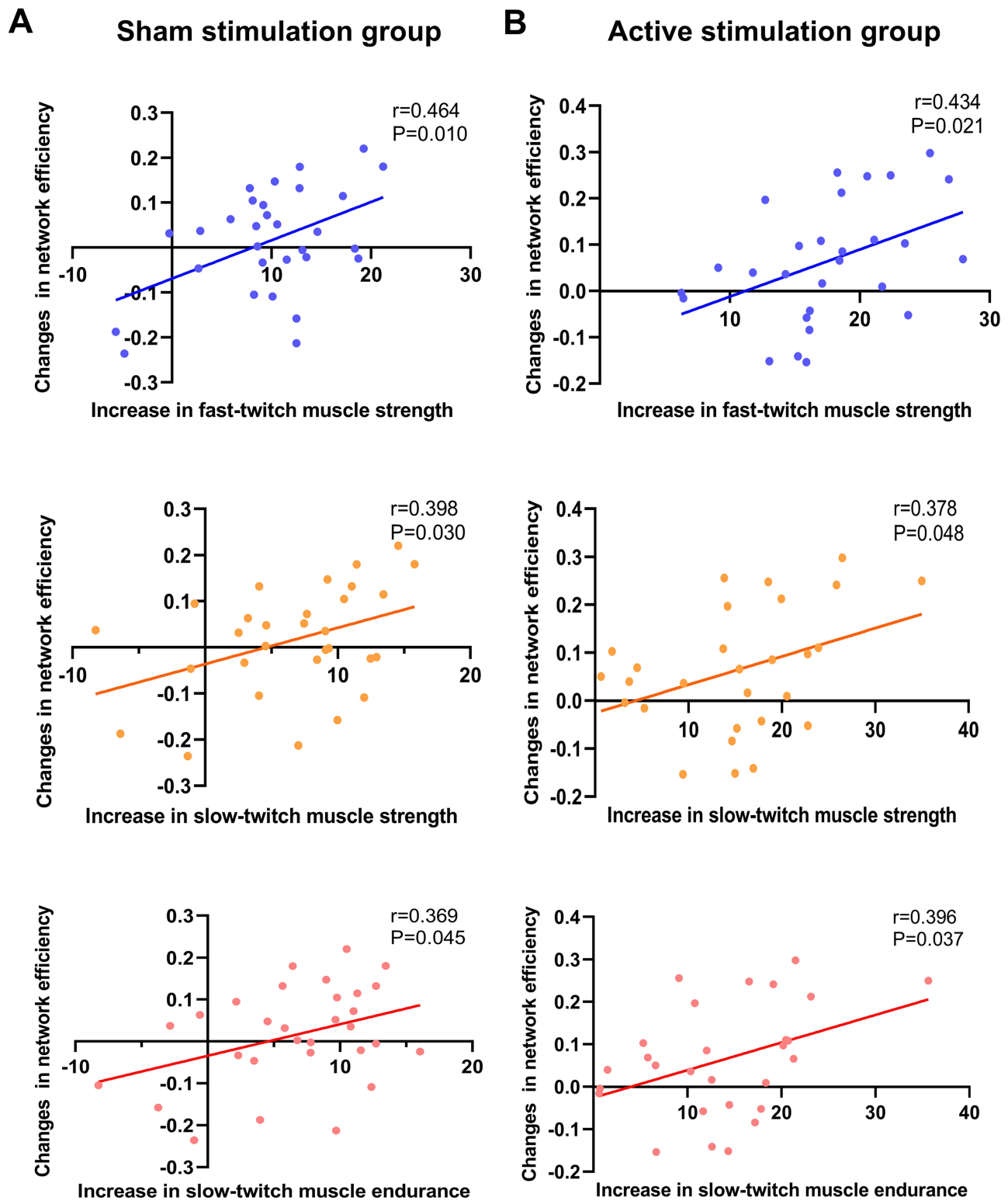


Figure 5 Correlation of improved pelvic floor muscle strength with changes in network efficiency. (A) The sham stimulation group. (B) The active stimulation group.

This is manifested by more focused and active motor cortex activity and enhanced connectivity efficiency within brain functional networks.

Previous studies have shown that both FMS⁴⁶ and PFMT alone can improve vaginal resting pressure, pelvic floor muscle strength, and endurance in women with SUI, but no significant difference in efficacy was observed between the two approaches.¹¹ Wang et al found that PFMT combined with FMS significantly improved fast-twitch and slow-twitch muscle strength in women with moderate SUI, with a better efficacy than FMS alone.⁴⁵ Filippini et al⁴⁷ and Elena et al⁴⁸ found that FMS significantly reduced the area, anteroposterior diameter, and laterolateral diameter of the levator hiatus in women with PFD. Whereas Chang et al concluded that FMS was effective in treating SUI by enhancing pelvic floor muscle strength without significantly decreasing bladder neck mobility.⁴⁹ In the present study, we found that the combination treatment demonstrated superior efficacy in improving the anterior and posterior resting muscle tone as well as the fast-twitch and slow-twitch muscle strength and endurance compared with PFMT alone. At the same time, it was able to improve the pelvic floor structure more comprehensively and improve the supportive function of the pelvic floor tissues.

We used fNIRS to observe cortical hemodynamic changes before and after treatment in both groups of women. It was found that after 8 weeks of treatment, the degree of activation of brain regions and functional brain connectivity during the Kegel exercise task was generally increased in the combined treatment group. Meanwhile, the efficiency of brain network connectivity was also improved. Our study found an increased activation of the SMC in females after treatment, which is consistent with the findings of Di Gangi Herms et al.²¹ This may indicate improved motor function and proprioception of the female pelvic floor muscles. At the same time, activation of the SMA and PMC was also increased in women. Previous studies have shown that healthy individuals exhibit efficient and focused SMA activation during the spontaneous pelvic floor muscle contractions.⁵⁰ However, postpartum PFD women may experience impaired central motor control due to pelvic floor nerve and muscle damage caused by pregnancy and childbirth.⁵¹ This manifests as insufficient SMA activation and necessitates recruiting broader brain regions for abnormal compensation.²¹ This study found that after treatment, women demonstrated enhanced SMA activation levels during Kegel exercises, converging toward the healthy pattern, indicating a restoration of motor control toward normalcy.⁵² Additionally, enhanced PMC activation may be associated with the process of “motor skill relearning.” Unlike PFMT alone, which relies solely on proprioceptive feedback, combined FMS more efficiently activates the motor planning and coordination functions of the PMC through enhanced sensory input and repetitive training. This accelerates the transition of pelvic floor muscle voluntary control from conscious practice to an automated skill.⁵³

Functional connectivity analyses revealed enhanced functional connectivity between the ipsilateral PMC and SMC and between the bilateral SMC in both groups. This finding aligns with the theory of collaborative optimization of neural networks during motor skill learning. Researches in the field of neurorehabilitation science indicate that enhanced functional connectivity between the PMC and SMC is closely associated with the efficiency of motor planning preparation and execution.⁵⁴ At the same time, activation and connectivity of brain regions were more focused on the SMC compared to pre-treatment. Enhanced connectivity between bilateral SMC is considered a hallmark of improved bilateral motor coordination and control.⁵⁵ Accordingly, we speculate that more cost-effective activation of sensorimotor regions could focus attentional resources to improve sensorimotor integration functions, leading to successful pelvic floor muscle training. Further analysis of the brain network efficiency revealed that after treatment, the network efficiency of the active stimulation group significantly improved, which represented the optimization of the brain motor cortex in terms of information transmission and information processing.⁵⁶ Meanwhile, the sham stimulation group also improved, but the difference was not significant. This may imply that FMS is more effective for central modulation.

Notably, correlation analyses showed that improvements in pelvic floor muscle function were positively correlated with changes in brain network connectivity efficiency. This may suggest that peripheral improvements can feed back to the centre, manifesting as increased cortical control of the pelvic floor muscles. Di Gangi Herms²¹ suggested that changes in pelvic floor muscle EMG were associated with enhanced blood oxygen level-dependent responses at representative sites of the SMC in the lower genitourinary tract, and our study found that the fNIRS brain functional imaging technique can also be used to detect cortical representations and to some extent observe the clinical efficacy of pelvic floor rehabilitation.

PFMT increases muscle strength and mass through long-term active strength training.⁹ FMS, on the other hand, induces large and deep repetitive passive contractions of the pelvic floor muscles through time-varying magnetic fields inducing depolarisation of the nerve fibres, which promotes the repair of damaged nerves and supporting tissues and improves muscle strength.^{12,47} FMS, by transmitting a large amount of motor sensory information to the central nervous system, enables women to better perceive the pelvic floor muscles and improves proprioception and muscle motor coordination, therefore improving the success rate of PFMT. Combined treatment is based on the theory of neuroplasticity⁵⁷ and the biomechanical principles of pelvic floor muscle rehabilitation.⁷ While the combination of active and passive training directly improves the function of the pelvic floor muscles, the excitability and functional connectivity of the motor cortex of the brain are regulated through neurofeedback, and the brain functional network is reshaped to achieve an overall improvement in the effect of rehabilitation.

Of course, there are some limitations to this study. First, we only evaluated the immediate effects after 8 weeks of treatment without conducting medium-term or long-term follow-ups. The durability of treatment efficacy and the long-term impact on brain functional network characteristics remain unclear. Second, because of the diversity of comorbidities in postpartum PFD, this study did not categorize the diseases of women to consider the effect of disease type on treatment outcomes. Furthermore, despite monitoring home training through daily reminders and weekly follow-ups, the detailed data from training records were incomplete due to inadequate participant reporting, which prevented accurate compliance analysis and dose-response assessment. Finally, due to the limited probing depth of fNIRS, this study only observed the effect of treatment on the motor cortex and did not address deeper brain tissue. More studies are needed in the future to demonstrate the reliability of fNIRS for observing pelvic floor rehabilitation.

Conclusion

Compared with PFMT alone, FMS combined with PFMT demonstrated superior potential in improving pelvic floor muscle function and anatomical structure in women with postpartum PFD, as well as enhancing motor cortex control, while maintaining good safety. This study preliminarily confirms the feasibility of combined therapy as a safe and effective conservative treatment option for early postpartum PFD. Furthermore, the post-treatment neuroplasticity changes observed by fNIRS provide new insights into the central mechanisms underlying pelvic floor rehabilitation, offering implications for clinical practice. However, given the limited follow-up period in this study, its long-term efficacy requires further validation. Future studies with extended follow-up periods and larger sample sizes are needed to confirm the efficacy of combined therapy and further validate the reliability and clinical utility of fNIRS technology in pelvic floor rehabilitation assessment.

Abbreviations

PFD, pelvic floor dysfunction; PFMT, Pelvic floor muscle training; FMS, functional magnetic stimulation; sEMG, surface electromyography; SMA, supplementary motor area; SMC, sensorimotor cortex; PMC, premotor cortex; fNIRS, functional near-infrared spectroscopy; Sham, sham stimulation group; Active, active stimulation group; ROI, region of interest.

Data Sharing Statement

The datasets used and/or analysed during the current study are available from the two corresponding authors upon reasonable request. Relevant requests should be directed to the main corresponding author at sumin@suda.edu.cn.

Ethics Approval and Consent to Participate

The trial followed the Declaration of Helsinki (revised 2013) and was approved by the Ethics Committee of the Fourth Affiliated Hospital of Soochow University (Approval No. 240012). Informed consent was obtained from all participants.

Acknowledgments

The authors would like to thank all the patients and their families who participated, as well as the physiotherapists and other team members who were involved in this study.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This work was supported by the National Key Research and Development Program of China (Grant Nos.: 2022YFC2009700, 2022YFC2009706) and the Horizontal Project of Soochow University (Project No. H201173).

Disclosure

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as potential conflicts of interest.

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