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ORIGINAL RESEARCH

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Combined pudendal nerve electroacupuncture and transcranial acupuncture stimulation for premature ejaculation: a randomized clinical study

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Abstract

Background: Premature ejaculation (PE) is a common and distressing condition with a multifactorial etiology and limited tolerable long-term treatment options. Current literature suggests that neuromodulatory approaches that simultaneously target peripheral reflex pathways and central regulatory mechanisms may provide additive therapeutic benefits. **Methods**: In this single-center, block-randomized clinical study, 120 men with PE were assigned to an observation group (n = 60) or a control group (n = 60). The observation group received pudendal nerve electroacupuncture (PNEA) combined with repetitive transcranial acupuncture stimulation (rTAS) twice weekly for 8 weeks, whereas the control group received PNEA alone on the same schedule. Fifty-three participants in the observation group and 55 in the control group completed follow-up. Outcomes, including intravaginal ejaculation latency time (IELT), Premature Ejaculation Diagnostic Tool (PEDT), Self-rating Anxiety Scale (SAS), and Self-rating Depression Scale (SDS) scores, were assessed at baseline and at week 8. **Results**: At week 8, the observation group exhibited a longer IELT and greater reductions in PEDT, SAS, and SDS scores than the control group (all $p < 0.05$). Overall response rates were 94.34% in the observation group and 83.64% in the control group ($p = 0.12$). No serious adverse events were observed, and reported adverse events were mild and transient. **Conclusions**: Compared with PNEA alone, combined PNEA + rTAS provided greater improvements in ejaculatory latency and overall symptom burden over 8 weeks while maintaining good tolerability. These findings support integrated peripheral–central neuromodulation as a promising therapeutic option for PE and indicate that further confirmation in randomized, sham-controlled trials with longer follow-up is warranted. **Clinical Trial Registration**: The study was retrospectively registered with the International Traditional Medicine Clinical Trial Registry (ITMCTR) as: ITMCTR2025002555.

Keywords

Premature ejaculation; Pudendal nerve electroacupuncture; Repetitive transcranial acupuncture stimulation

Electroacupuntura del nervio pudendo combinada con estimulación acupuntural transcraneal para la eyaculación precoz: estudio clínico aleatorizado

Resumen

Antecedentes: La eyaculación precoz (EP) es una afección frecuente y angustiante, de etiología multifactorial y con opciones limitadas de tratamiento a largo plazo que sean tolerables. La literatura actual indica que los enfoques neuromoduladores que actúan simultáneamente sobre las vías reflejas periféricas y los mecanismos reguladores centrales pueden aportar beneficios terapéuticos aditivos. **Métodos**: En este estudio clínico unicéntrico, aleatorizado por bloques, 120 varones con EP fueron asignados a un grupo de observación (n = 60) o a un grupo control (n = 60). El grupo de observación recibió electroacupuntura del nervio pudendo (PNEA) combinada con estimulación acupuntural transcraneal repetitiva (rTAS) dos veces por semana durante 8 semanas, mientras que el grupo control recibió únicamente PNEA con la misma pauta. Completaron el seguimiento 53 participantes del grupo de observación y 55 del grupo control. Los desenlaces, incluidos el tiempo de latencia eyaculatoria intravaginal (IELT), la herramienta diagnóstica de eyaculación precoz (PEDT) y las puntuaciones de la escala de autoevaluación de ansiedad (SAS) y la escala de autoevaluación de depresión (SDS), se evaluaron al inicio y en la semana 8. **Resultados**: En la semana 8, el grupo de observación presentó un IELT más prolongado y mayores reducciones en las puntuaciones de PEDT, SAS y SDS que el grupo control (todos $p < 0.05$). Las tasas de respuesta global fueron del 94.34% en el grupo de observación y del 83.64% en el grupo control ($p = 0.12$). No se observaron acontecimientos adversos graves, y los acontecimientos adversos notificados fueron leves y transitorios. **Conclusiones**: En comparación con PNEA sola, la combinación PNEA + rTAS proporcionó mayores mejoras en la latencia eyaculatoria y en la carga global de síntomas durante 8 semanas, manteniendo una buena tolerabilidad. Estos hallazgos respaldan la neuromodulación periférico-central integrada como una opción terapéutica prometedora para la EP e indican que se requiere confirmación adicional en ensayos aleatorizados, controlados con simulación (sham) y con un seguimiento más prolongado. **Registro del Ensayo Clínico**: El estudio se registró retrospectivamente en el International Traditional Medicine Clinical Trial Registry (ITMCTR) con el número: ITMCTR2025002555.

Palabras Clave

Eyaculación precoz; Electroacupuntura del nervio pudendo; Estimulación acupuntural transcraneal repetitive

1. Introduction

Premature ejaculation (PE) is one of the most common forms of male sexual dysfunction, typically characterized by ejaculation that always or almost always occurs before vaginal penetration or within approximately one minute after penetration, accompanied by a persistent inability to delay ejaculation [1, 2]. Epidemiological surveys conducted in China have reported PE prevalence rates of up to 25.8% [3]. Beyond impairment of sexual function, PE negatively affects mental health, quality of life, and intimate relationships, and is therefore frequently accompanied by anxiety, depression, and reduced self-esteem [4].

Current therapeutic options for PE include pharmacotherapy, topical anesthetics, behavioral interventions, and surgery [5]. Selective serotonin reuptake inhibitors (SSRIs), which are considered first-line pharmacologic agents, have been shown to prolong intravaginal ejaculatory latency time (IELT) by increasing synaptic 5-hydroxytryptamine (5-HT); however, they are often associated with adverse effects such as fatigue, nausea, and other dose-limiting symptoms [6]. Topical anesthetics (*e.g.*, lidocaine cream) can decrease penile sensitivity and provide a relatively rapid onset of action, yet may also induce penile numbness and diminish the sexual sensation of the partner. Additionally, behavioral techniques, such as the stop-start method, have demonstrated efficacy in principle but are challenging to implement consistently over the long term. In this regard, surgical procedures, including selective dorsal penile nerve neurectomy, may increase IELT, but carry the risks of persistent penile numbness and erectile dysfunction [7].

In recent years, neuromodulation has drawn increasing clinical interest as a non-pharmacologic, repeatable, and mechanistically rational approach. The pudendal nerve is a key peripheral component of the ejaculatory reflex, with its functional state closely linked to ejaculatory control. Peripheral nerve stimulation directed at the pudendal nerve has been applied in various pelvic floor disorders and is now being investigated for the treatment of PE. Concurrently, acupuncture, one of the most representative modalities of traditional Chinese medicine, has an important role in the integrative management of PE [8, 9]. Repetitive transcranial acupuncture stimulation (rTAS), proposed by Professor Shentian Sun, is a novel transcranial technique derived from traditional acupuncture. By stimulating scalp regions associated with affective regulation, rTAS is designed to modulate brain function and improve mood states. Given that emotional disturbances such as anxiety and tension are common in patients with PE and are closely related to the onset and fluctuation of symptoms, the application of rTAS in this population is of particular interest.

Given the complex and multifactorial etiology of PE, single treatment modality often yields suboptimal and unstable clinical outcomes. Since 2025, our hospital has implemented a combined neuromodulatory strategy using pudendal nerve electroacupuncture (PNEA) together with rTAS for the management of PE. Preliminary clinical observations have sug-

gested that this integrated approach may provide more pronounced symptom relief than conventional single-modality interventions. In this present study, we investigate the combined PNEA + rTAS treatment protocol and evaluate its therapeutic effects in a randomized clinical trial.

2. Methods

2.1 Design overview

This was a single-center, block-randomized clinical study approved by the Ethics Committee of the Second Affiliated Hospital of Zhejiang Chinese Medical University (approval no.: Ethics Review 2025 research No. 020-IH01). Written informed consent was obtained from all participants prior to enrollment. Participants were randomly assigned to the observation group or control group in a 1:1 ratio using a computer-generated randomization sequence. The randomization list was prepared by an investigator not involved in participant recruitment, treatment, or outcome assessment. Group assignments were placed in sequentially numbered, opaque, sealed envelopes, that were kept by an independent research assistant. After baseline assessments, the next envelope in numerical order was opened to determine each participant's allocation. Because the two acupuncture protocols differed visibly in needle locations and stimulation procedures, blinding of participants and treating acupuncturists was not feasible, and the trial was conducted in an open-label manner.

2.2 Participants

PE was diagnosed according to the 2014 International Society for Sexual Medicine criteria [2]. The inclusion criteria were as follows: (1) fulfilled the diagnostic criteria for PE; (2) had a Premature Ejaculation Diagnostic Tool (PEDT) score $\geq$11; (3) aged between 18 and 50 years; and (4) had a stable sexual partner for at least 6 months. Exclusion criteria were: (1) erectile dysfunction, defined as an International Index of Erectile Function-5 (IIEF-5) score $<$21; (2) neurological disease; (3) clinically significant urological inflammation (*e.g.*, severe prostatitis, lower urinary tract symptoms, or urinary tract infection); (4) severe psychiatric disorders (*e.g.*, schizophrenia); (5) psychotropic substance abuse; (6) underwent any PE-related treatment within the preceding 3 months; and (7) excessive foreskin requiring imminent surgical intervention. The participants were withdrawn or excluded if they enrolled in other clinical trials, failed to complete the prescribed treatment protocol, or experienced adverse reactions that necessitating discontinuation of the intervention.

2.3 Treatment protocols

The control group underwent PNEA only, whereas the observation group was given PNEA combined with rTAS. Both interventions were administered twice weekly for 8 consecutive weeks.

For rTAS, the target area was located over the anterior frontal region. Using the intersection of the anterior frontal line and the anterior–posterior midline as the central point of the frontal area, 1-cm line segments were drawn upward and downward along the anterior–posterior midline, and parallel line segments were then extended bilaterally at the same level, passing through the medial canthi. The region encompassed by these three parallel line segments was defined as the "cognitive-affective area" and served as the needling site (Fig. 1). The needle was accurately advanced into the subgaleal plane (beneath the galea aponeurotica). During manipulation, small-amplitude lift-thrust movements were used to elicit the arrival of qi, while high-frequency twirling at $\geq$200 rpm was applied. Each stimulation cycle lasted 3–5 minutes, with the intensity titrated to produce a distinct sensation of soreness and distension without pain, and the needles were retained after stimulation.

For PNEA, four points superior to the midpoint of the pubic symphysis were selected as pudendal nerve stimulation sites, with points on the same side aligned along the same neural conduction pathway. Using 0.40 mm $\times$ 100 mm needles, the pudendal nerve was approached percutaneously with slow, controlled advancement (Fig. 2). When the needle contacted the nerve, the patient experienced an electric shock-like sensation in the perineal region, and penile erection (mild engorgement) could occasionally be induced, at which point needle advancement was stopped. Each needle was then connected to a G6805-2 electroacupuncture device using a dense-disperse wave pattern. The stimulation intensity was adjusted to a level that the patient found comfortable, and needles were retained for 40 minutes.

2.4 Outcome assessments

All questionnaires were administered in a paper-based format and completed once at baseline and once after completion of the treatment period, and facsimiles of the original instruments are provided in the **Supplementary material**. IELT was partner-timed during vaginal intercourse and was defined as the interval from vaginal penetration to ejaculation. One value was recorded at treatment initiation, and a second value at the end of the 8-week intervention. For statistical analysis, IELT values were rounded to the nearest 5-second increment. PEDT comprises five items scored from 0 to 4 (total score 0–20) and evaluates key domains including ejaculatory control, sexual satisfaction, and ejaculatory-related anxiety; scores $\geq$11 indicate PE, scores of 9–10 suggest possible PE, and scores $\leq$8 are regarded as inconsistent with PE. The Self-Rating Anxiety Scale (SAS) and Self-Rating Depression Scale (SDS) each contain 20 items scored from 1 to 4, were used to assess anxiety and depressive symptoms, respectively, before and after treatment.

2.5 Criteria for response

Efficacy was determined using post-treatment IELT as follows: cured ($>$300 s), markedly effective (180–300 s), effective (60–180 s), and ineffective ($\leq$60 s). The overall response rate was calculated as (cured + markedly effective + effective)/total.

2.6 Statistical analysis

All statistical analyses were conducted using SPSS version 25.0 (International Business Machines Corporation, Armonk,

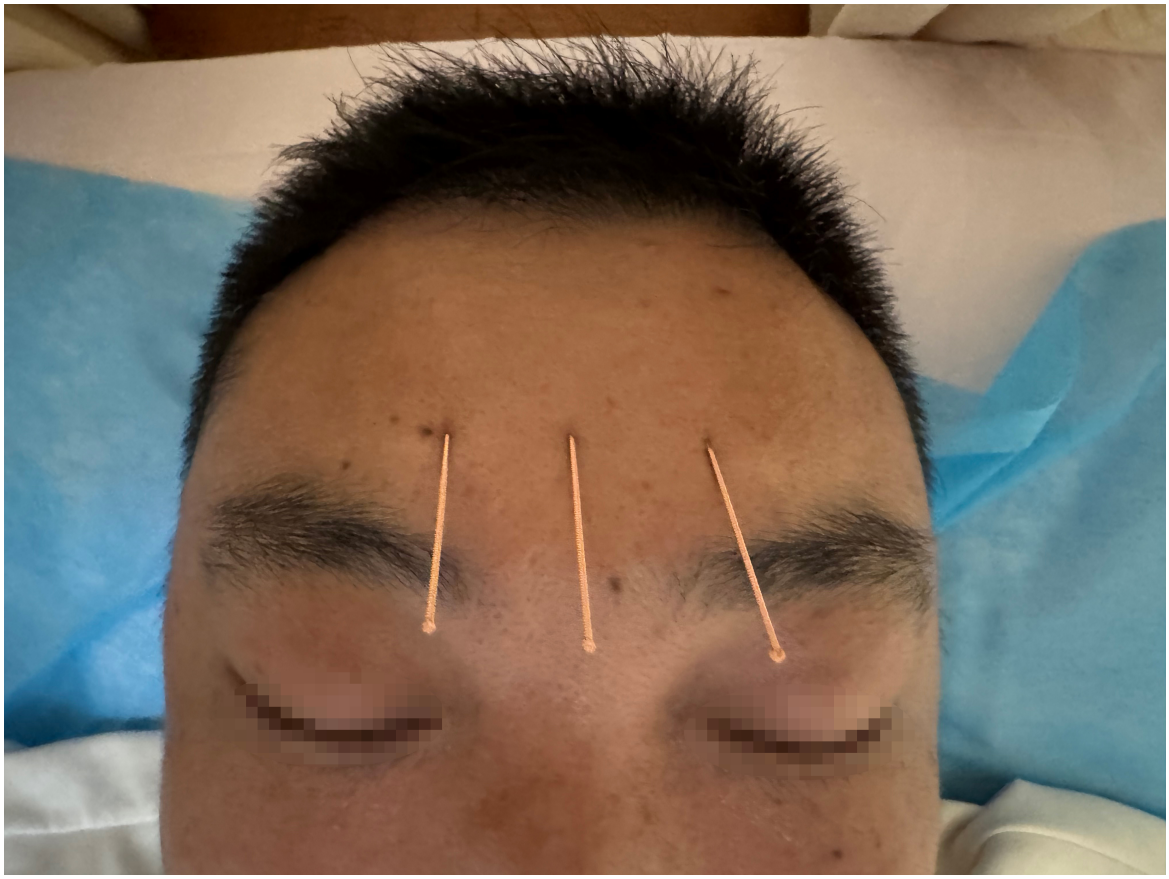

FIGURE 1. rTAS protocol: scalp mapping and needling sites.

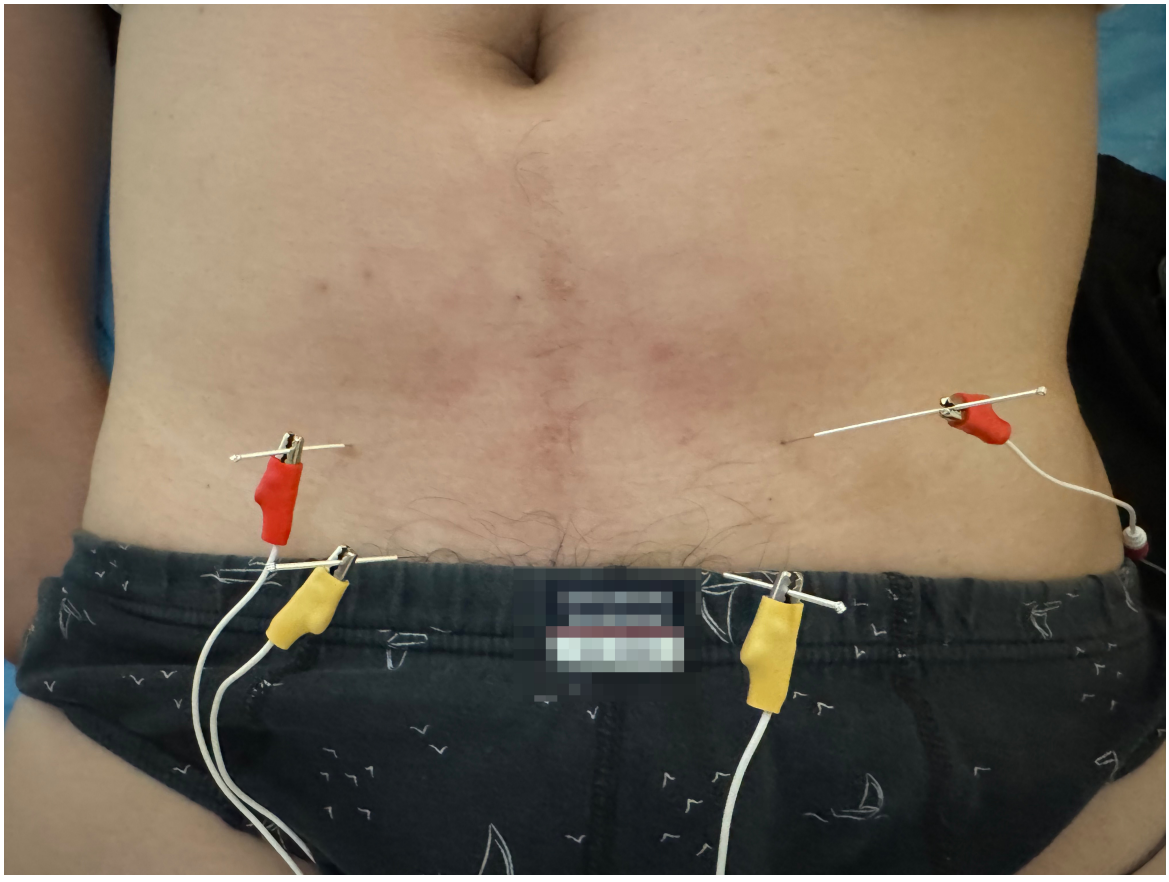

FIGURE 2. PNEA protocol: anatomical landmarks and needle path.

NY, USA). Continuous variables that met the assumption of normality are presented as mean ± standard deviation (SD), with between-group differences examined using independent-samples *t*-tests and within-group changes from baseline were evaluated using paired *t*-tests. Skewed continuous data are summarized as median (interquartile range, IQR) and analyzed using non-parametric tests. Categorical variables are expressed as frequencies and percentages and were compared between groups using the χ^2 test. All statistical tests were two-sided, and $p < 0.05$ was considered statistically significant.

3. Results

3.1 Baseline characteristics

Between March and July 2025, a total of 120 men with PE were allocated using block randomization to either the observation group or the control group, with 60 patients in each group (Fig. 3). By week 8, 12 participants did not complete the 8-week treatment or follow-up and were excluded from the outcome analysis, leaving 53 participants in the observation group and 55 in the control group who completed the protocol. Week 8 was pre-specified as the primary assessment time point,

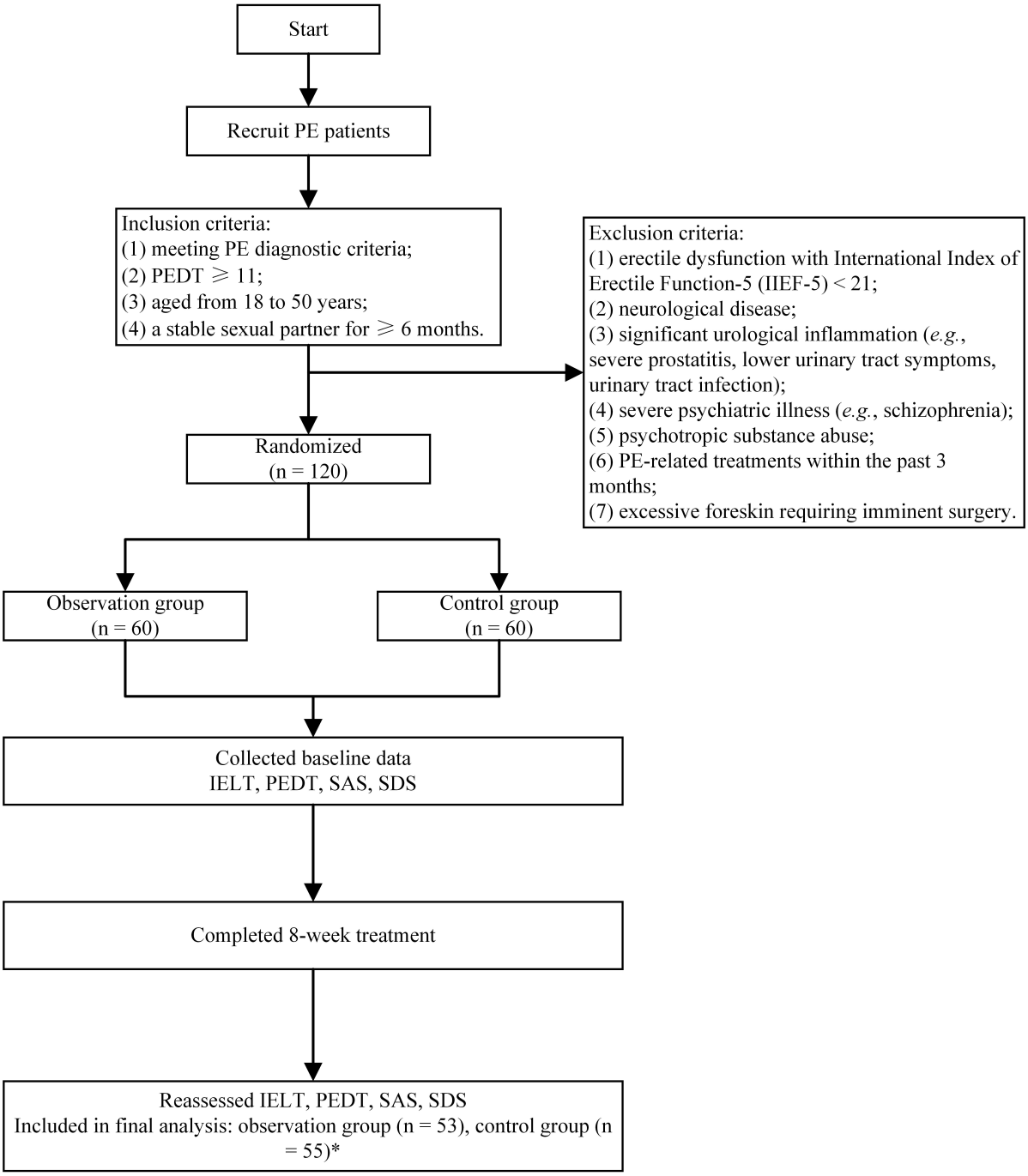

FIGURE 3. Study flow diagram. *, Seven patients in the observation group and five in the control group did not complete the 8-week treatment or follow-up and were excluded from the week-8 outcome analysis. PE: Premature ejaculation; PEDT: Premature Ejaculation Diagnostic Tool; IELT: intravaginal ejaculation latency time; SAS: Self-rating Anxiety Scale; SDS: Self-rating Depression Scale.

at which IELT, PEDT, SDS, and SAS were compared both within groups (pre- *vs.* post-treatment) and between groups. The overall mean age of the cohort was 32.65 years. Initial analysis showed that baseline characteristics, including age, body mass index (BMI), and IIEF-5 scores, were well balanced between the two groups, supporting their comparability for subsequent efficacy analyses (Table 1).

3.2 Pretreatment outcomes

At baseline, the observation and control groups were comparable across all primary and secondary outcome measures (including IELT, PEDT, SAS, or SDS scores) (all $p > 0.05$; Table 2), indicating a balanced distribution of clinical and psychological characteristics before treatment initiation.

3.3 Post-treatment outcomes

After 8 weeks of treatment, IELT increased significantly from baseline in both the observation and control groups (both $p < 0.05$), increasing from 34.62 s to 188.68 s in the observation group and from 37.46 s to 124.91 s in the control group. Between-group comparison at week 8 demonstrated a significantly longer IELT in the observation group than in the control group ($p < 0.05$). PEDT scores likewise decreased significantly in both groups (both $p < 0.05$), declining from 14.49 to 9.96 in the observation group and from 14.98 to 12.89 in the control group, with the magnitude of reduction being significantly greater in the observation group than in the control group ($p < 0.05$), indicating superior improvement in ejaculatory control and PE-related symptom burden in the combined-treatment group. For affective outcomes, SAS and SDS scores both decreased significantly from baseline in the observation group (both $p < 0.05$). In the control group, SAS scores showed a significant reduction ($p < 0.05$), whereas SDS scores did not change significantly over the treatment period ($p > 0.05$). At week 8, both SAS and SDS scores were significantly lower in the observation group than in the control group (both $p < 0.05$), indicating that the combined PNEA + rTAS protocol was associated with greater improvements in anxiety and depressive symptoms than PNEA alone (Table 3).

3.4 Clinical response rates

The overall clinical response rate was 94.34% in the observation group and 83.64% in the control group. Although the observation group showed a numerically higher proportion of responders, the between-group difference did not reach statistical significance on χ^2 testing (Table 4). Consistent with this finding, overall response rates were not significantly different between groups ($p = 0.12$).

3.5 Safety analysis

Adverse events were reported in both treatment groups, with 8 of 53 participants (15.09%) in the observation group and 4 of 55 participants (7.27%) in the control group. Minor bleeding at needle insertion sites was the most common event in both the groups. In the observation group, a small number of patients experienced transient dizziness following rTAS sessions, which resolved spontaneously after a brief period of rest and did not require additional medical intervention. Importantly, no serious adverse events, including abdominal pain, infection, or bowel perforation, were observed in either group during the study period (Table 5).

4. Discussion

In this randomized trial, the 8-week course of combined PNEA and rTAS significantly improved all measured outcomes in the observation group compared with baseline and were consistently greater than in the control group. The greater increase in IELT and larger reduction in PEDT scores in the observation group support rTAS for providing incremental efficacy in delaying ejaculation and alleviating PE-related symptom burden beyond that achieved by peripheral pudendal nerve stimulation alone. In parallel, the significant reductions in both SAS and SDS scores in the observation group suggest that central neuromodulation targeting cognitive-affective regions may contribute to mood stabilization, which may, in turn, facilitate further improvement in sexual function through reductions in performance anxiety and depressive symptoms. Although the control group did not receive a central neuromodulatory intervention, SAS scores also declined over the treatment period, a pattern that is plausibly attributable to partial improvement in ejaculatory symptoms and the resulting secondary reduction in anxiety.

When clinical response was evaluated using IELT-based categorical grading, overall response rates were high in both groups, and the numerically higher rate in the observation group did not reach statistical significance ($p = 0.12$). Given the limited sample size and the loss of information from categorizing a continuous endpoint, this analysis should be interpreted as exploratory. Overall, the concordant pattern observed across both continuous and categorical outcomes supports the interpretation that adding rTAS, directed to a scalp region involved in cognitive-affective regulation, to PNEA enhances both ejaculatory control and mood symptoms, while remaining a clinically feasible and well-tolerated neuromodulatory strategy for men with PE.

Anatomically, the pudendal nerve arises from S2–S4 and conveys sensory input from the external genitalia to the central nervous system, primarily via the dorsal penile nerve, thereby serving as a key peripheral substrate for ejaculatory control. Stimulation delivered through PNEA may induce neural activation along this pathway and, with repeated sessions, increase tolerance to sexual stimulation, thereby contributing to delayed ejaculation. In addition, electrical stimulation may enhance local perfusion and promote the release of vasoactive mediators [10]. Previous studies have reported favorable outcomes of pudendal nerve electrical stimulation in stress urinary incontinence, possibly through the induction of rhythmic pelvic floor contractions and strengthening of pelvic floor musculature [11, 12]. Given that many patients with PE exhibit pelvic floor muscle weakness, we extended this approach to men with PE [13], and the outcomes observed in the control group of the present study further support the therapeutic value of PNEA in this setting; however, PNEA alone did not sufficiently alleviate depressive symptoms, highlighting the need for adjunctive strategies that target central affective regulation.

TABLE 1. Baseline characteristics of the study population.

Characteristics	Observation group (n = 53)	Control group (n = 55)	*p*-value
Age (yr)	32.38 ± 6.57	32.91 ± 3.79	0.61
BMI (kg/m^2)	23.54 ± 2.87	23.70 ± 3.00	0.78
IIEF-5	24.0 (23.5, 25.0)	24.0 (23.0, 25.0)	0.89
Education			
Junior high or lower	12 (22.64%)	14 (25.50%)	
High school	15 (28.30%)	17 (30.91%)	0.85
University	26 (49.06%)	24 (43.64%)	
Smoking	28 (52.83%)	27 (49.10%)	0.85
Alcohol use	21 (39.62%)	26 (47.27%)	0.54
Married	33 (62.26%)	38 (69.10%)	0.59
Hypertension	4 (7.55%)	3 (5.45%)	0.96
Diabetes	4 (7.55%)	2 (3.64%)	0.64

Normally distributed continuous variables are expressed as mean ± standard deviation, non-normally distributed continuous variables as median (interquartile range), and categorical variables as number (percentage). BMI: Body Mass Index; IIEF-5: International Index of Erectile Function-5.

TABLE 2. Baseline comparisons of IELT, PEDT, SAS, and SDS.

Outcome	Observation group (n = 53)		Control group (n = 55)		*p*-value
	Mean ± SD	95% CI	Mean ± SD	95% CI	
IELT(s)	34.62 ± 9.90	31.90–37.35	37.46 ± 9.07	35.00–39.91	0.06
PEDT	14.49 ± 1.89	13.97–15.01	14.98 ± 2.26	14.37–15.59	0.22
SAS	45.11 ± 11.66	41.90–48.33	44.89 ± 3.60	43.92–45.87	0.89
SDS	51.66 ± 9.40	49.07–54.25	48.82 ± 8.07	46.64–51.00	0.09

Values are expressed as mean ± standard deviation, with 95% confidence intervals (CI). IELT: intravaginal ejaculation latency time; SAS: Self-rating Anxiety Scale; SDS: Self-rating Depression Scale; PEDT: Premature Ejaculation Diagnostic Tool; SD: standard deviation.

TABLE 3. Week-8 comparisons of IELT, PEDT, SAS, and SDS.

Outcome	Observation group (n = 53)			Control group (n = 55)			*p*-value**
	Mean ± SD	95% CI	*p*-value*	Mean ± SD	95% CI	*p*-value*	
IELT(s)	188.68 ± 69.07	169.64–207.72	<0.001	124.91 ± 58.65	113.42–145.13	<0.001	<0.001
PEDT	9.96 ± 2.44	9.28–10.64	<0.001	12.89 ± 2.47	12.22–13.56	<0.001	<0.001
SAS	38.02 ± 5.53	36.49–39.54	0.003	41.51 ± 6.69	39.70–43.32	<0.001	0.004
SDS	41.96 ± 8.46	39.63–44.29	<0.001	46.98 ± 5.50	45.50–48.47	0.236	<0.001

*Values are expressed as mean ± standard deviation, with 95% confidence intervals (CI). *p-value indicates within-group comparisons (baseline vs. week 8). **p-value indicates between-group comparisons at week 8 (observation vs. control). IELT: intravaginal ejaculation latency time; SAS: Self-rating Anxiety Scale; SDS: Self-rating Depression Scale; PEDT: Premature Ejaculation Diagnostic Tool; SD: standard deviation.*

TABLE 4. Clinical response.

Category	Cured	Markedly effective	Effective	Ineffective	Overall response
Observation (n = 53)	3 (5.66%)	26 (49.06%)	21 (39.62%)	3 (5.66%)	50 (94.34%)
Control (n = 55)	0 (0%)	15 (27.27%)	31 (56.36%)	9 (16.36%)	46 (83.64%)

Values are presented as number (percentage).

TABLE 5. Adverse events.

Adverse Event	Observation group (n = 53)	Control group (n = 55)
Any adverse events	8 (15.09%)	4 (7.27%)
Serious adverse events	0	0
Minor bleeding	6 (11.32%)	4 (7.27%)
Dizziness	2 (3.77%)	0
Abdominal pain	0	0
Infection	0	0
Bowel perforation	0	0

Values are presented as number (percentage).

Given the close links between PE, central nervous system function, and psychological status, we combined rTAS with PNEA in this study. rTAS stimulates scalp projections of cortical functional regions and uses high-frequency twirling to achieve sufficient stimulus intensity, enabling the signal to traverse the skull and act on corresponding cortical areas to modulate brain function. To our knowledge, this technique has not previously been applied in the field of andrology. We targeted the cognitive-affective area, which approximately corresponds to the prefrontal pole and plays a critical role in the regulation of mental state, cognition, and emotion; prefrontal involvement in ejaculatory control has also been reported [14]. In the present study, SAS and SDS scores declined significantly after treatment in the observation group, accompanied by greater improvement in PE symptoms than in the control group, thereby supporting the potential utility of rTAS as an adjunctive neuromodulatory approach for PE.

rTAS represents a form of brain neuromodulation. Among established non-invasive neuromodulatory techniques, repetitive transcranial magnetic stimulation (rTMS) modifies cortical excitability by delivering rapidly changing magnetic fields via scalp-mounted coils, with the induced electromagnetic fields penetrating the skull and acting directly on the cerebral cortex. rTMS has demonstrated promise in various neurological and psychiatric disorders, and has even been reported to improve anejaculation [15]. rTAS shares this transcranial regulatory principle but differs in that it utilizes acupuncture needles inserted into the scalp and driven by high-frequency twirling, a mode of stimulation that may enhance energy transmission across the skull and thereby augment modulation of cortical targets and clinical efficacy.

During rTAS sessions, most patients reported a localized scalp deqi sensation, an indicator in Traditional Chinese Medicine that adequate needling stimulation has been achieved. This sensation typically subsided shortly after the session and was frequently followed by a sense of relaxation or comfort, a pattern that aligns with the expected neuromodulatory effects of transcranial acupuncture stimulation.

Mechanistically, the rationale for combining PNEA with rTAS lies in achieving a "dual-pathway synergy" that simultaneously engages peripheral and central regulatory mechanisms. Ejaculation is coordinated by a spinal "ejaculatory generator" in the lumbosacral cord, which integrates afferent input from the pudendal nerve with descending signals from cortical and subcortical structures [16]. As discussed above, PNEA primarily modulates pudendal afferent input and lumbosacral spinal reflex circuits, whereas rTAS predominantly targets central neural networks. Rather than acting in isolation, these two modalities intervene along the same ejaculatory control axis, concurrently activating bottom-up peripheral reflex pathways and top-down supraspinal regulatory circuits. Comparable "peripheral + central" neuromodulation paradigms have been investigated in other disease contexts, for example, post-stroke motor rehabilitation and sports medicine, where combining rTMS with repetitive peripheral magnetic stimulation or peripheral nerve electrical stimulation has been reported to enhance neuroplasticity and promote functional recovery by co-recruiting peripheral and central mechanisms [17]. Taken together, this integrated peripheral–central framework provides a plausible mechanistic explanation for the combined regimen in the present study, which produced greater improvements in IELT and mood symptoms than PNEA alone.

Safety was also assessed in this study. Both groups experienced adverse events, all of which were mild and self-limited. Minor bleeding at the needle site was the most frequently observed event and resolved within 1–3 minutes of sterile compression. In the observation group, two participants reported transient dizziness following scalp needling; symptoms subsided after a short period of rest and did not require further intervention. No serious adverse events occurred in either group, indicating that both PNEA alone and the combined PNEA + rTAS regimen were well tolerated and demonstrated a favorable safety profile [18].

In the setting of an integrative traditional Chinese and Western medicine hospital, many men with PE express a high level of confidence in acupuncture-based interventions. Some patients in our cohort had previously attempted pharmacological treatments but with limited benefit or recurrence of symptoms after discontinuation, further reinforcing their willingness to pursue non-pharmacologic neuromodulatory options. Although PNEA and rTAS are procedurally more invasive than oral pharmacotherapy, they are locally acting, minimally invasive, and reversible neuromodulatory interventions, which may account for the mild and transient adverse events. In addition to the well-recognized side-effect profile of SSRIs, a clinical study suggested that a three-month course of sertraline for PE may adversely affect semen quality [19], which is of particular concerning for younger men wishing to preserve fertility. For patients apprehensive about the potential long-term adverse effects of medication, non-pharmacologic neuromodulatory treatments such as PNEA and rTAS may represent an acceptable and attractive alternative. Compared with standard pharmacological therapy and behavioral interventions, whose effectiveness often depends on sustained motivation and close partner cooperation, the combined PNEA + rTAS regimen offers a non-pharmacologic approach that simultaneously targets peripheral ejaculatory reflex pathways and central affective regulation. This strategy is not intended to supplant guideline-recommended pharmacotherapy but rather to provide an additional treatment option for individuals who decline medication or are unsuitable candidates for long-term

drug therapy. However, future head-to-head comparative trials against standard treatments are warranted to further clarify its role in clinical practice.

In summary, this study demonstrates that PNEA combined with rTAS can effectively treat PE while also improving anxiety and depressive symptoms, thereby providing a novel non-pharmacologic treatment option. Nonetheless, several limitations should be acknowledged. First, this was a single-center study with a relatively small sample size, which may affect the precision, generalizability, and reliability of the findings. Second, IELT was measured by patients' partners using a stopwatch during intercourse; although this approach reflects real-world clinical practice, it is susceptible to measurement error and expectation bias. In addition, the trial was not blinded with respect to participants or treating acupuncturists, as the two acupuncture protocols differed visibly in needle locations and stimulation procedures, which may have introduced expectancy or performance bias, particularly for subjective outcomes. Third, the trial did not include a sham acupuncture control, and most outcomes relied on patient-reported scales; therefore, future studies should incorporate sham-controlled designs and more objective neurophysiological or imaging measures (*e.g.*, fMRI) [20]. Lastly, follow-up was limited to 8 weeks, so the durability of benefits remains unknown, and larger multicenter trials with longer follow-up are warranted.

5. Conclusions

Compared with PNEA alone, PNEA combined with rTAS demonstrated greater efficacy in prolonging intravaginal ejaculatory latency time and in alleviating PE-related symptoms and affective distress. Taken together, these findings indicate that this combined neuromodulatory regimen is a promising and clinically feasible option, which warrants confirmation in larger, adequately powered trials.

AVAILABILITY OF DATA AND MATERIALS

The data are contained within this article.

AUTHOR CONTRIBUTIONS

JG and HZ—designed the research study. TZ—performed the treatment. YL and HH—analyzed the data. YD—interpreted the results. JG—drafted the manuscript. All authors contributed to editorial revisions in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was conducted with approval from the Ethics Committee of the Second Affiliated Hospital of Zhejiang Chinese Medical University (approval no.: Ethics Review 2025 research No. 020-IH01). Written informed consent was obtained from all participants before their inclusion in the study. Additionally, written informed consent for publication of the clinical images in this journal was obtained from the patient.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://files.intandro.com/files/article/2038516832443219968/attachment/Supplementary%20material.docx.

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