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Efficacy of electrical pudendal nerve stimulation versus pelvic floor muscle training in treating postradical prostatectomy urinary incontinence: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Urinary incontinence (UI) is one of the main complications of radical prostatectomy. Electrical pudendal nerve stimulation (EPNS) has been used to treat stress UI based on its mechanism of passive pelvic floor muscle contraction reported in the previous research. However, there are no studies comparing the effects of EPNS and active pelvic floor muscle training (PFMT) in the treatment of postradical prostatectomy UI (PPUI). Here, we describe the protocol for a randomised controlled trial to evaluate the efficacy of EPNS in treating PPUI compared with PFMT.

Methods and analysis This study is designed as an open-label randomised controlled trial with blinded assessment and analysis. A total of 90 eligible men will be randomly allocated to two groups. The treatment group (n=45) will receive EPNS while the control group will perform PFMT by doing the Kegel exercise. Forty EPNS treatment sessions will occur over a period of 8 weeks. The primary outcome measure will be improvement rate, and the secondary outcome measures, the number of pads used, 24-hour pad test, and International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form will be compared between baseline and the study endpoint. The International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life and care compared as the quality of life and satisfaction outcomes between groups.

Ethics and dissemination This protocol has been approved by the Ethics Committee of the First Affiliated Hospital of Zhejiang Chinese Medical University (approval no. 2021 KL-040-02). Written informed consent will be obtained from each participant. The results of the study will be published in peer-reviewed journals.

Trial registration number ChiCTR2200055461.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The design of this trial compares the clinical efficacies of electrical pudendal nerve stimulation and pelvic floor muscle training (PFMT) in the treatment of postradical prostatectomy urinary incontinence (PPUI).
⇒ The severity of urine leakage after PPUI is assessed by a 24-hour pad test scoring system in our protocol.
⇒ A supervised PFMT is performed by a physiotherapist through a mobile app,WeChat, to improve the participants' adherence to PFMT.
⇒ Owing to the nature of acupuncture, acupuncturists and participants are not blinded.
⇒ The objective workup, such as urodynamic study and cystoscopy to segregate stress urinary incontinence patients from those with predominant urgency incontinence and overflow urinary incontinence, is lacking.

INTRODUCTION

Urinary incontinence (UI) is one of the main complications of radical prostatectomy (RP). The incidence of postradical prostatectomy UI (PPUI) ranges from 5% to 70%,[1] with the incidence of UI at 12 months postoperatively exceeding 20%.[2 3] Besides posing a heavy economic burden, UI also has a considerable negative impact on the social life and interpersonal relationships of patients.[3 4] Stress UI (SUI) is the main type of PPUI[5]; however, there are currently no recommended pharmacological agents for the non-surgical treatment of PPUI.[6] At present, pelvic floor muscle training (PFMT) is the most widely used approach for treating PPUI.[6 7] Although PFMT enables the strengthening ofpelvic floor muscles,[8] many patients find it difficult to perform the training correctly. In addition, the relatively long treatment duration makes it difficult for patients to persist with PFMT in the long term, ultimately resulting in poor treatment adherence.[9] Transanal electrical stimulation is a non-invasive, passive method

of PFMT that enhances patient adherence.[10] However, its effects are indirect in nature owing to the use of surface electrodes. A study comparing the effects of PFMT alone and in combination with transanal electrical stimulation for the treatment of PPUI reported that although both regimens improved UI, the difference in their effects was not statistically significant.[10 11]

Electrical pudendal nerve stimulation (EPNS) is a novel technique for the treatment of SUI. In the previous studies, we used CT in the transverse plane with simultaneous pelvic floor measurements to demonstrate that EPNS enabled pelvic floor muscle contraction and was effective in treating female SUI and urge incontinence.[12–14] In a recent study, we used simultaneous measurements of movement and surface electromyography of the pelvic floor muscles in male subjects to show that EPNS promoted the contraction and strengthening of pelvic floor muscles and the simulation of PFMT, thus leading to the effective treatment of PPUI.[15] Compared with active PFMT, EPNS can provide highly effective passive training for the pelvic floor muscles. This can help address the difficulties faced by patients in correctly locating the pelvic floor muscles and persisting with PFMT, thus improving overall patient adherence. However, across studies, there are significant differences in the indicators and assessment techniques for determining the degree of UI, and the long-term efficacy of EPNS for treating PPUI has not been reported. In addition, although it is known that EPNS can simulate PFMT, there are no studies comparing the effects of EPNS and PFMT in the treatment of PPUI.

Objective

This trial aims to evaluate the long-term efficacy of EPNS in treating PPUI through the establishment of a PFMT control group and adoption of comprehensive assessment criteria and indicators.

METHODS AND ANALYSIS

Study design

This trial will compare the efficacy of EPNS with that of PFMT for the treatment of PPUI. It will be designed as a blind randomised study, and data will be analysed for two parallel groups over an 8-week treatment period. Ninety participants with PPUI will be randomly assigned to the treatment and control groups at a 1:1 ratio. The study will be conducted in the First Affiliated Hospital of Zhejiang Chinese Medical University (one of the tertiary hospitals in China) from 1 January 2022 and will end on 31 December 2023. All procedures and time frames are presented in figure 1 according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines.[16]

Recruitment

Eligible patients with UI after RP will be recruited from the inpatient and outpatient departments (mainly the Acupuncture and Moxibustion and Urology departments) of the First Affiliated Hospital of Zhejiang Chinese Medical University according to the inclusion and exclusion criteria. Advertisements will be displayed in health

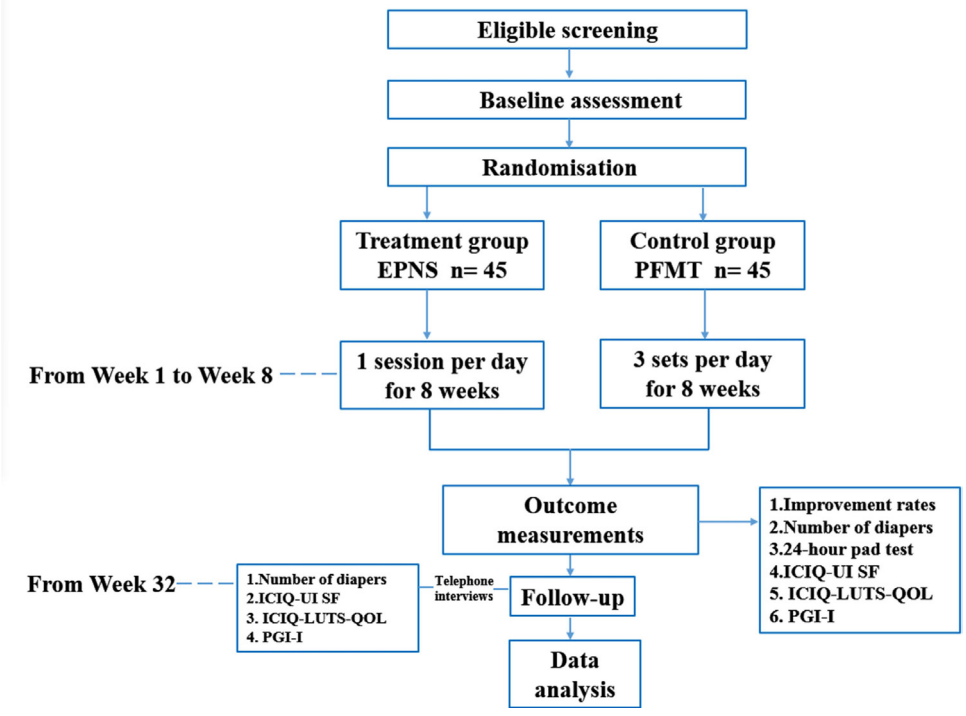

Figure 1 Flow diagram detailing the study procedure. EPNS, electrical pudendal nerve stimulation; ICIQ-LUTS-QOL, International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life; ICIQ-UI SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; PGI-I, Patient Global Impression of Improvement.

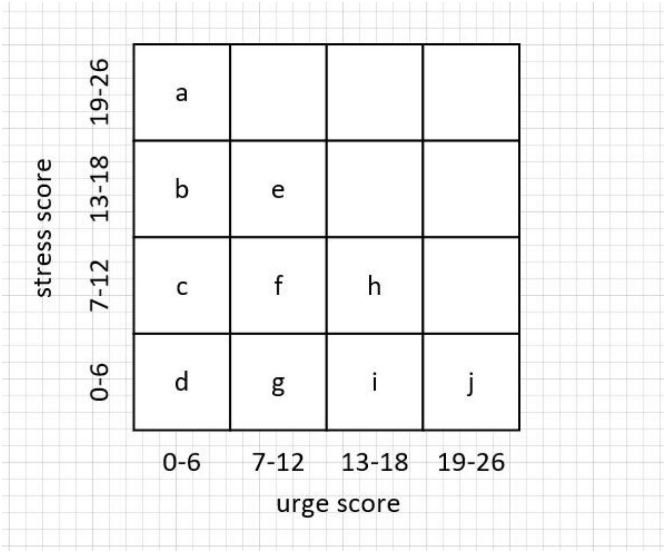

Figure 2 Diagnostic criteria of the scored urinary incontinence questionnaire. The y-axis plots scores for the stress urinary incontinence (SUI; 0–26 points) and the x-axis plots scores for urge urinary incontinence (UUI; 0–26 points). Zone 'a' indicates an SUI score of 19–26 points and a UUI score of 0–6 points. Zones 'a–c' indicate SUI; 'G', 'I' and 'J' indicate UUI; and 'E', 'F' and 'H' indicate mixed urinary incontinence (MUI). Patients with SUI within zones 'A-C', and patients with stress-predominant MUI (zone 'E') will be included in the present protocol. Patients in zone 'H' has urgency-dominant symptoms and patients in zone 'F' has symptoms from both types of urinary incontinence without significant differences in predominance; they will not be included in the present protocol.

education brochures and posters on the website of the First Affiliated Hospital of Zhejiang Chinese Medical University. At the beginning of recruitment, detailed information about the study, including the research objective, study procedure and potential benefits and risks, are provided to all eligible patients. Recruitment information will also be released through media, such as websites and mobile phone applications. A written informed consent form (online supplemental file 1) will be given to patients who agree to participate. Once the consent form is signed, the patient will be included for baseline evaluation and randomisation.

Participants

Inclusion criteria

1. Incontinence at 1 month or more after RP.
2. Symptoms of UI after RP with a positive 24-hour pad test (ie, >4 g increase in pad weight within 24 hours).[17]
3. Fulfilment of the diagnostic criteria for SUI or stress-predominant mixed UI (MUI),[18] with the additional use of a scored UI questionnaire comprising 15 questions (online supplemental table 1)[19 20] (figure 2).
4. No residual cancer after RP on pathological examination.
5. Age between 45 and 80 years.

Exclusion criteria

1. Urge-predominant MUI.
2. Overflow UI.
3. UI prior to surgery or UI caused by comorbidities, such as Parkinson's disease, multiple sclerosis, spinal cord injury, Alzheimer's disease and diabetes mellitus.
4. Undergoing or had prior radiation therapies.
5. Difficulty in voiding.
6. Urethral stricture, urinary tract obstruction, bladder neck obstruction, refractory urinary tract infection, hydronephrosis, urinary calculi or tumours.
7. Use of medications that affect bladder function (eg, antimuscarinics or beta-3 agonists).
8. Severe insufficiency in vital organs, such as the heart, lungs, liver and kidneys.

Participants with PPUI excluded from our study will be referred to a specialist to address their primary lesions first and will have a choice to receive EPNS or PFMT decided without taking part in our trial analysis.

Sample size

Referring to a previous study[15] with 96 patients (efficacy rate 68.7%:34.4%), the required sample size was calculated using the Power Analysis and Sample Size V.15 software (NCSS Statistical Software). A sample size of 40 patients was determined to have a power (1-beta) of 0.90, an alpha (significance level) of 0.05, and a ratio of 1:1. Taking potential drop-outs (10% of the participants) into account, the total sample size was increased to 90 in total (45 in each group).

Randomisation and allocation concealment

The randomisation will be performed by the Clinical Evaluation and Analysis Centre of the First Affiliated Hospital of Zhejiang Chinese Medical University. A random 1:1 allocation sequence will be generated through SPSS software (V.26.0). Professionals involved in the allocation will not be recruited in the study. The random allocation will be strictly kept in an opaque, sequentially numbered envelope that is inaccessible to other research staff. After baseline assessment, the envelope will be opened by an independent staff member in the presence of the participants, who will be assigned into either the treatment or control group. The acupuncturists will be informed about the participant's allocation at the same time. Randomisation will be requested by the staff member responsible for recruitment and clinical interviewers from the First Affiliated Hospital of Zhejiang Chinese Medical University, who are not allowed to receive information about the group allocation.

Blinding

In this study, participants and acupuncturists will not be blinded due to the nature of acupuncture. Data analysts will be blinded to the participant's allocation throughout the trial. Telephone interviewers who collect follow-up information will also be blinded. Acupuncturists will not be permitted to communicate with any data analysts or telephone interviewers. If an unblinding event occurs

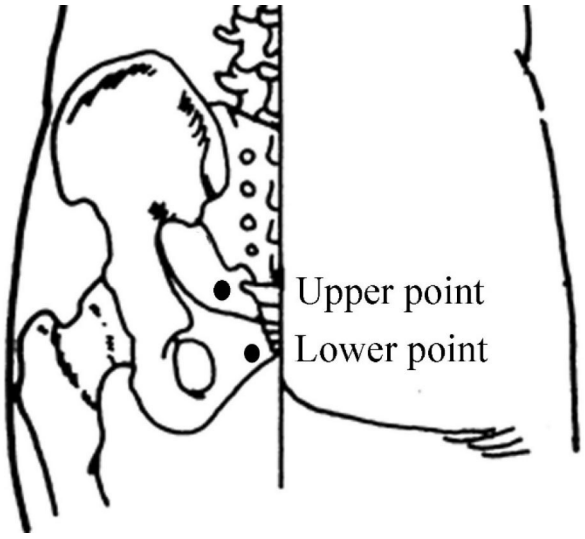

Figure 3 Location of the 'four sacrococcygeal points' for electrical pudendal nerve stimulation.

among data analysts or telephone interviewers, the relevant work will be transferred to other appropriately blinded research staff. The revealing of allocation will only be permitted when it is needed for final comparison between the treatment and control groups.

Intervention

Treatment group

Acupoint selection: We select four specific acupoints in the sacrococcygeal region(ie, the 'four sacrococcygeal points'). Upper acupuncture needles will be inserted at points located 1 cm from the sacrococcygeal joint (bilaterally symmetrical), and lower acupuncture needles will be inserted at points located 1 cm from the apex of the coccyx (bilaterally symmetrical) (figure 3).

Key points of the EPNS process: EPNS will be performed using long acupuncture needles (0.4 mm × 100 mm, Suzhou Shenlong Medical Apparatus Factory, Suzhou, China) on patients lying in the prone position. The upper needles will be inserted vertically to a depth of 75–90 mm for the transmission of needle sensations to the urinary tract or anus, and the lower needles will be inserted diagonally towards the lateral side (in the direction of the ischiorectal fossa) to a depth of 90–95 mm for the transmission of needle sensations to the perineum (penile root). When the needle sensations have reached the aforementioned body parts, the handles of the needles on each side will be connected to a pair of electrodes on a G6805 electro-acupuncture apparatus ((Shantou Medical Equipment Factory, Shantou, China), with the cathode connected to the upper needle and anode connected to the lower needle. Electrical stimulation will be performed using continuous waves at a frequency of 2.5 Hz (150 times/min) and the highest possible intensity (45–55 mA) that the patient can tolerate without experiencing discomfort. Each stimulation session will last for 1 hour, and a rhythmic sensation of strong contractions in the upward (cranial) direction centred around the penile root must be maintained in the pelvic floor muscle throughout the electroacupuncture session. Treatment will be administered once per day from Monday to Friday for 8 weeks.

Control group: Patients in the control group will perform PFMT by doing the Kegel exercise.[8 10] A physiotherapist will provide guidance for training, explain pelvic floor muscle contraction, and give the instructions like 'stop the flow of urine and shorten the penis while continuing to breathe'.[21] A digital anal examination using the Oxford score (graded 0–5) will be applied by the therapist when giving instructions and will be communicated with the patients by verbal feedback.[22] Once the patients' abilities are known, they will be required to contract the pelvic floor muscles as much as possible for 3–10 s, depending on their ability and subsequently relax the muscles for an equal period of time. The contraction–relaxation cycle is to be repeated 15 times to form a set, and patients will be required to complete three sets daily in three positions after RP at home. In addition, a written training diary (table 1) will be given to the patients for ongoing training for 8 weeks.

Tips: If you have any questions, please do not hesitate to call us:

Office Tel: 0571–86919352 (08:00–17:00),

or you can scan our WeChat (a social media mobile app) QR-code for detailed information.

WeChat Official Account Department of Acupuncture and Moxibustion, the First Affiliated Hospital of Zhejiang Chinese Medical University.

The physiotherapist will pay a one-time office visit when the participants are recruited at baseline assessment interview on the PFMT technique and will continue with 24 times of online visits through WeChat (a social media mobile app) or phone calls (a few older people do not know how to use smartphones) three times a week for better execution of PFMT at home.

Fluid intake of patients in both groups will also be advised by clinicians during the 8-week trial time, recommending six glasses (approximately 1200–1500 mL) of fluid to take during the day and informing them to avoid having coffee, tea or alcohol, which may induce an increased risk of leakage.

Drop-out criteria

1. Poor participant compliance (lack of adherence to treatment for personal reasons).
2. Serious adverse events (AEs), complications or special physiological changes necessitating discontinuation of the intervention.
3. Voluntary drop-out.

Table 1 PFMT diary

PFMT therapy			
Name date of first visit			
Everyday exercises at home: Three sets of exercises with 15 repetitions of 3–10 s contraction followed by an equal period of relaxation			
In supine	15 repetitions	squeeze for 3–10 s	relax for equal time
Sitting	15 repetitions	squeeze for 3–10 s	relax for equal time
Standing	15 repetitions	squeeze for 3–10 s	relax for equal time
when you finish the day's home exercises, please write down the date at the following squares numbered from weeks 1 to 8			
Week date	eg: 3 September 2022		
1			
2			
3			
4			
5			
6			
7			
8			

PFMT, pelvic floor muscle training.

Outcome measures

Baseline assessment

A baseline assessment of the patients will be performed prior to the start of treatment. Basic data will be collected, including age, body mass index, Gleason score for grading prostate cancer, prostate size, surgical method preservation or non-preservation of neurovascular bundles and duration of postoperative urinary catheterisation, as well as a B ultrasound of urinary system, including residual urine. Patients will be asked to record the number of urinary pads required, complete the 24-hour pad test and assess urinary continence using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF)[23] (online supplemental table 2) and The International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTS-QOL)[24](online supplemental table 3). The pad test procedure is provided in online supplemental table 4.[25]

Primary outcome

Improvement rate has been set as the primary indicator. Scores for the number of urinary pads required, the 24-hour pad test and responses to the ICIQ-UI SF will be summed to form the total score for each patient, and the improvement rate will be calculated using the following formula:

Improvement rate (%)=[(total score before treatment– total score after treatment)÷total score before treatment]×100

Treatment will be deemed effective when the improvement rate exceeds 25%.

Secondary outcomes

1. Number of urinary pads used: scores will be awarded based on the number of urinary pads required:[26]

Not required: 0 points.
1–3 pads/week: 1 point.
4–6 pads/week: 2 points.
1–4 pads/day: 3 points.
>4 pads/day: 4 points.

2. 24-hour pad test: The weight change of urinary pads after 24 hours will be measured by a digital scale and recorded. Grades of UI severity and scores will be awarded based on the weight of the urinary pad:[17 27]

<4 g increase in pad weight within 24 hours: negative pad test result, 0 points.

5–20 g increase in pad weight within 24 hours: mild incontinence, 2 points.

21–74 g increase in pad weight within 24 hours: moderate incontinence, 4 points.

> 75 g increase in pad weight within 24 hours: severe incontinence, 6 points.

3. ICIQ-UI SF score.

Quality of life and satisfaction outcomes

1. ICIQ-LUTS-QOL score.
2. Patient Global Impression of Improvement (PGI-I) score. The PGI-I is given a numerical score from 1 (very much better) to 7 (very much worse)[28] (online supplemental table 5).

Adverse events

An AE of acupuncture will be assessed according to its severity based on local reactions, such as subcutaneous haematoma, subcutaneous bruise, regional muscle spasm, regional pain, regional skin allergy and infection, or systemic reactions, such as fainting, abdominal distention, vertigo, fatigue, systemic allergy, systemic infection and organ injury. Systemic infection and organ injury will be considered severe AEs. The level of severity, time of occurrence and corresponding management will be recorded on the case report forms (CRFs). All the acupuncturists and research staff will be trained to deal with AEs, and severe AEs will be reported to the Ethics Committee within 24 hours. The Ethics Committee will also decide the necessity for withdrawal of the participant from the trial.

Patients having local adverse reactions will be given medical care to ease the bleeding, irritation and bruising. Those having severe reactions leading to organ injury, systematic infection and systematic allergy will be given compensation by our research team to cover their medical costs.

Data management, monitoring and auditing

The baseline data and assessment information of all participants will be collected by a trained assistant who

is blinded to treatment group allocation. The participants will be required to provide the number of pads used for UI, complete the24-hour pad test and respond to the ICIQ-UI SF and ICIQ-LUTS-QOL at baseline and after 8 weeks. PGI-I will be provided after 8-week intervention. An independent blinded researcher will conduct telephone interviews of all participants to collect the number of pads they used and, ICIQ-UI SF score, ICIQ-LUTS-QOL score and PGI-Iat 32 weeks after baseline. All data will be recorded on the CRFs. If a participant discontinues treatment early, their final evaluation data will be collected and used in the analysis.

On the completion of the CRFs, including intervention and follow-up, all the participants' data will be entered into an Excel spreadsheet by two independent researchers blinded to the group allocation. An independent supervisor will check the two datasets for accuracy. If inconsistencies are discovered, the supervisor will compare the datasets with the original CRFs and mark the modifications on the CRFs. All the original documents (papers or electronic files) will be accessible only to the principal investigator of the research team. The First Affiliated Hospital of Zhejiang Chinese Medical University will be responsible for the storage and management of all documents.

Members of the Clinical Evaluation and Analysis Centre of the First Affiliated Hospital of Zhejiang Chinese Medical University will organise an independent data monitoring committee who are blinded to the treatment allocations and will meet regularly to monitor the study data. When half of the patients have been randomised and have completed the primary outcome measurement, interim analysis will be performed by the data monitoring committee.The First Affiliated Hospital of Zhejiang Chinese Medical University will audit this study mainly for participant enrolment, consent and financial costs.

Statistical analysis

A statistician from the Clinical Evaluation and Analysis Centre of the First Affiliated Hospital of Zhejiang Chinese Medical University will perform all statistical analyses using SPSS Statistics (V.26.0). A normality test will be used to determine whether the data are normally distributed. If there is an imbalance in the baseline characteristics and outcome measures, analysis of covariance will be used. Continuous variables with a normal distribution will be reported as means±SD, and those with a non-normal distribution or ordinal variables will be expressed as medians (with lower and upper quartiles). Counts and proportions will be expressed for categorical variables. The last observation carried forward method will be used to process the missing data.

For the primary outcome measures, Student's t-tests will be used to analyse normally distributed data. A paired t-test will be used to compare pretreatment and post-treatment improvement rates. An independent sample t-test will be used to compare improvement rates between the two groups. For non-normally distributed data, a Mann-Whitney U test will be used for between-group comparison, and a Wilcoxon signed-rank test will be used to compare pretreatment and post-treatment improvement rates. Differences between the two groups will be compared by the intergroup rank sum test.

The secondary outcome measures—including scores for the number of pads used, the 24-hour pad test, and responses to the ICIQ-UI SF—will be analysed following the same methods as those used to analyse the primary outcome measures. All reported p values will be two tailed, and CIs will be at the 95% level. A $p<0.05$ will be considered statistically significant.

The quality of life and satisfaction outcomes, ICIQ-LUTS-QOL score and PGI-I score will be analysed following the same methods.

Patient and public involvement

The patients and general public are not directly involved in the design, recruitment or conduct of this pilot study. The design of the study is based on existing knowledge from our previous studies on female SUI as well as communications with colleagues from the Urology department. At the end of this trial, the results of this study will be disseminated in peer-reviewed journals and at academic conferences. A brief plain language summary of the results will be displayed for the patients on a website (https://sandychenshan.haodf.com/) and on BiliBili (a video sharing mobile phone application).

ETHICS AND DISSEMINATION

The Ethics Committee of the First Affiliated Hospital of Zhejiang Chinese Medical University has reviewed and approved this protocol (approval no. 2021KL-040-02). This study will adhere to the principles of the Declaration of Helsinki. The study will be conducted at the First Affiliated Hospital of Zhejiang Chinese Medical University.

Each participant will voluntarily sign a written informed consent form. Each study participant will be assigned an identification number throughout the trial to assure confidentiality. The results of this study will be published in open-access and peer-reviewed journals and presented at relevant conferences.

DISCUSSION

In men, urinary control is mainly realised through support from the urethral sphincter complex (including the internal and external urethral sphincters) and surrounding pelvic floor muscles (including the levator ani muscle).[29] The internal urethral sphincter consists of smooth muscles and is innervated by the sympathetic nervous system; the external urethral sphincter consists of striated muscles and, like the levator ani muscle, is mainly innervated by the pudendal nerve.[30] RP inevitably requires the resection of sphincter muscle tissue fibres surrounding the prostate, leading to damage to the function of the internal urethral sphincter. Therefore,

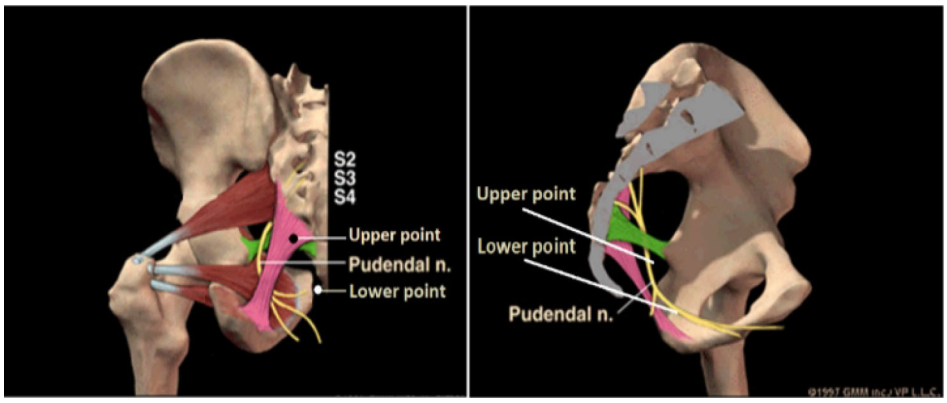

Figure 4 Anatomical positions of the 'four sacrococcygeal points' for electrical pudendal nerve stimulation.

following RP, urinary control depends primarily on the support of the external urethral sphincter and pelvic floor muscles.[31]

The 2019 guidelines on incontinence after prostate cancer treatment published by the American Urological Association state that PFMT is beneficial for the postoperative recovery of urinary control. However, surgical methods are recommended for patients with severe UI or UI that persists at 1 year postoperatively.[32] In our clinical work, we have found that in patients with UI lasting for >1 year, the severity of UI can decrease from severe to mild after EPNS treatment, which considerably enhances the quality of life of these patients. We have also received feedback from patients about their inability to perform PFMT correctly and the difficulties they face in persevering with PFMT in the long term (due to the long treatment duration).With EPNS treatment, patients were able to sense strong contractions in their pelvic floor muscles during the treatment process, and some patients observed a reduction in the amount of urine leaked within 1–2 weeks. These observations and the findings of our previous studies jointly indicate that EPNS is indeed capable of stimulating the pudendal nerve, which triggers rhythmic contractions of the pelvic floor muscles and enables the simulation of PFMT. Therefore, the proposed trial aims to compare the clinical efficacies of EPNS and PFMT in treating PPUI.

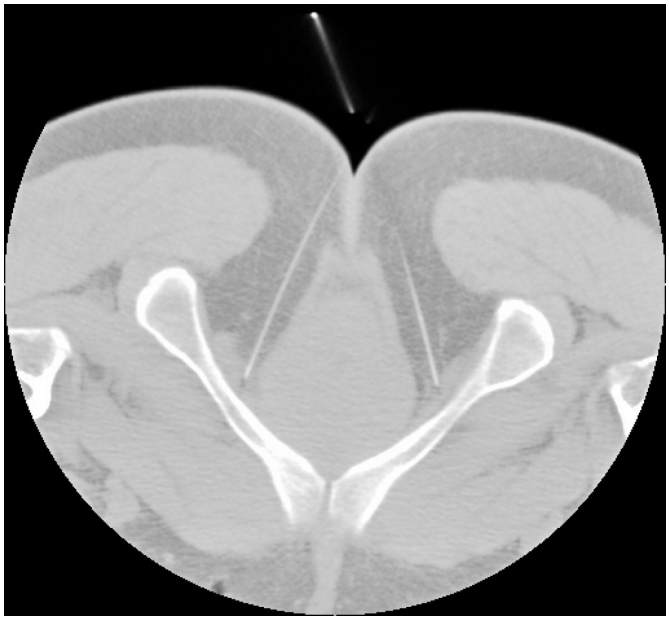

Figure 5 Transverse CT image of the coccygeal apex. The tip of the needle inserted at the lower sacral point is visible in the ischiorectal fossa (adjacent to the pudendal nerve in the Alcock's canal).

We selected points on the body surface located 1 cm from the sacrococcygeal joint (bilaterally symmetrical) for the vertical insertion of upper acupuncture needles because the main trunk of the pudendal nerve passes through this region.[33] During the needle insertion process, needle sensations can be transmitted to the urinary tract or anus because the pudendal nerve contains sensory fibres innervating the external genitalia and anus[30] In the ischiorectal fossa, the pudendal nerve divides into the perineal nerve (innervating the external urethral sphincter, levator ani muscle, superficial perineal muscles and scrotal skin) and the dorsal nerve of the penis/clitoris (innervating the skin of the penis/clitoris).[34] Therefore, we selected points on the body surface located 1 cm from the apex of the coccyx (bilaterally symmetrical) for the diagonal insertion of lower acupuncture needles in the direction of the ischiorectal fossa. When the needle tips reach the perineal nerve, needle sensations are solely transmitted to the urinary tract (figures 4 and 5). As a result, electrical stimulation using these needles produces rhythmic, strong contractions of the pelvic floor muscles centred around the penile root in the upward direction.

PFMT will be adopted as a treatment for the control group, yet the inability of patients to persevere with PFMT has been encountered in clinical practice and reported in the literature,[35] which may potentially affect the treatment efficacy in the control group. Mobile apps have been increasingly used to address this issue and facilitate patients' compliance with PFMT.[36 37] In our study, we adopted WeChat, a social media mobile app, to provide a supervised PFMT through dedicated physiotherapy in our clinical trial.

This study has the following strengths. (1) This protocol is the first to compare the clinical efficacies of EPNS and PFMTin the treatment of PPUI. (2) Based on our previous

work, we have optimised the outcome assessment and included the 24-hour pad test, which provides a good indication of actual urine leakage in patients.[17] Although the number of pads used may change significantly in patients with severe UI, this is not the case in patients with moderate or mild UI, as they generally use 1–2 pads per day.This makes it difficult to observe changes in the amount of urine leakage, and our protocol ensures that these data will be recorded accurately. (3) All patients will be followed up at 6 months after the completion of treatment for the observation of the long-term efficacy of EPNS.

The limitations of this trial are as follows. (1) Owing to the nature of acupuncture, acupuncturists and participants will not be blinded. (2) The objective workup, such as urodynamic study and cystoscopy to specifically segregate SUI patients from those with predominant urgency incontinence and overflow UI, is lacking. (3) Although it has been designed that both short-term and long-term effects will be followed, the overall study duration is relatively short for PPUI, some of which could last for years.

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Contributors SC conceived the study and developed the protocol; SW and YG contributed to the study design; SL contributed to the sample size calculation and planned the statistical analysis; and LX and SW prepared the flowchart, figures and tables. All authors have read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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