

ORIGINAL RESEARCH

Efficacy of acupuncture in the treatment of psychogenic erectile dysfunction: study protocol for a randomized control trial

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Abstract

Acupuncture is widely used in China for various conditions. Recently, due to the limitations of conventional treatment, many patients with psychogenic erectile dysfunction (ED) tend to choose acupuncture therapy, which is more commonly applied in countries such as China. The present clinical trial protocol aimed to initially verify the efficacy and safety of acupuncture in the treatment of psychogenic ED. Our study is a prospective, randomized control trial (RCT). The protocol for this RCT is based on the standard protocol items: recommendations for interventional trials (SPIRIT) 2013 statement. After the participants who met the inclusion and exclusion criteria sign an informed consent form, the investigator will schedule them for the trial. Patients will be randomly divided into two groups (acupuncture and sham acupuncture). Both groups will receive 18 sessions of interventions for 6 continuous weeks and will be followed up for 10 weeks. At five time points (0, 2, 4, 6 and 10 weeks), We will measure the primary and secondary outcomes. Emerging evidence support acupuncture therapy for improving male sexual function and its application in andrology. However, its efficacy on patients diagnosed with psychogenic ED has not been extensively studied. With our study, we anticipate to fill the knowledge gap in acupuncture as treatment for psychogenic ED.

Keywords

Psychogenic; Erectile dysfunction; Acupuncture therapy; Sexual satisfaction; Acupoint

1. Introduction

Erectile dysfunction (ED) is a condition in which a man's erection is not hard enough to last long enough or achieve a satisfactory sex life [1]. This disorder is more prevalent in the age group of more than 40 years old [2]. The global prevalence of ED in men aged 40–70 years is 52% [3]. Recently, there has been an increasing incidence in young men, possibly related to the enormous pressures in life and work [4]. ED is not life-threatening, but it has a detrimental effect on the quality of life of patients and their partners, resulting in a reduced sense of experience and fulfillment.

ED is commonly classified into organic, psychogenic, and mixed ED. Psychogenic ED, one of the common types of ED, is mainly caused by psychogenic factors (depression, anxiety, marital discord, and so on) without somatic lesions. It may occur as a result of inhibition of the centers regulating erection, for which there is a lack of specific biomarkers [5]. Phosphodiesterase inhibitor-5 (PDE5i), the first-line treatment recommended by the guidelines for both psychogenic and organic ED [1], is not always effective in improving erectile function in some mild-to-moderate ED cases [6] and in relieving patients' systemic manifestations such as anxiety and fatigue [7]. The other treatment options include testosterone

supplementation, vacuum erection devices, and intracavernous injection. However, there may also be adverse effects, such as erythrocytosis, pain or numbness in the penis, and cavernous fibrosis [8].

Recently, the use of acupuncture in andrology diseases has become more widespread in China [9]. Acupuncture is a vital part of traditional Chinese medicine (TCM) therapy. Acupuncture stimulates the body's inherent ability to resist disease and repair itself by adjusting its physiological function without medicine. Our team has analyzed through a literature review that acupuncture has certain TCM characteristics and corresponding mechanisms for ED treatment, and the duration of acupuncture for psychogenic ED varies from 1 to 6 weeks, with a total of 8 to 20 treatments [10]. The duration and number of treatments seem to depend on the presence or absence of organic damage [11]. A guideline from China for the treatment of ED with TCM therapy suggests that the application of acupuncture alone is appropriate for psychogenic ED and it recommends that the number of acupuncture treatments should be combined with the patient's own situation [12]. Aydin *et al.* [13] reported that the duration of acupuncture is mostly 6 weeks, and the frequency is maintained at 2–3 times/week. Additionally, acupuncture is known to have immediate, cumulative, and follow-up effects [14], and many studies have set

the follow-up period for ED treatment to 4 weeks to observe the follow-up effects [15, 16]. Based on this evidence, we will conduct a random, controlled trial to study the efficacy and safety of acupuncture in treating psychogenic ED patients, by comparing the findings with those of a sham acupuncture group. We hope this study will provide reliable evidence for the efficacy of acupuncture in psychogenic ED.

2. Materials and method

2.1 Study design and settings

Our study is a 1:1 randomized controlled trial with two parallel groups and will be reported in accordance with the SPIRIT 2013 Statement [17]. Sixty-six participants will be recruited for this study, with 33 participants assigned to each group. All participants will receive a course of acupuncture treatment after being informed about the study, risks, and benefits, and after signing an informed consent form. The trial flow chart and time point of the assessment are shown in Fig. 1 and Table 1.

2.2 Study participants

2.2.1 Recruitment strategy

We will be screening and recruiting participants from July 2022 to January 2023 at the Department of Andrology, Xiyuan Hospital, Chinese Academy of Traditional Chinese Medicine (Beijing, China). Our researchers will be systematically trained and fully informed of the trial procedures. Informed consent will be obtained from participants prior to enrollment. Participation will be entirely voluntary, and participants will have the right to withdraw from the trial at any time without penalty.

2.2.2 Diagnostic criteria

The following diagnostic criteria are based on the 2021 guideline in psychogenic ED-related diagnostic standards [1]: (a) insufficient sexual stimulation to consistently obtain or maintain an erection sufficient to complete satisfactory sexual intercourse; (b) duration of the disease lasting ≥ 3 months; (c) exclusion of organic pathology; and (d) international index of erectile function-5 (IIEF-5) score ≤ 21 .

2.2.3 Inclusion criteria

The study inclusion criteria are as follows: (a) those who meet the psychogenic ED diagnostic criteria; (b) $8 \leq \text{IIEF-5} \leq 21$; (c) $20 \leq \text{age} \leq 50$ -year-old male; (d) have a regular sexual partner and a stable sex life, with a frequency of ≥ 1 time/week during treatment; and (e) accepted and signed the informed consent form.

2.2.4 Exclusion criteria

This study exclusion criteria are as follows: (a) patients with drug-related ED or organic ED; (b) patients with abnormalities in the genitourinary system; (c) patients with genitourinary infections; (d) patients with psychiatric or neurological disorders or serious organic diseases; (e) self-rating anxiety scale (SAS) > 69 or self-rating depression scale (SDS) > 72 or unable to guarantee discontinuation of anti-anxiety or depression medication during the trial; (f) patients with coagulation disorders;

(g) patients with hypogonadism; (h) patients with hypothyroidism; (i) patients with other serious systemic diseases; (j) spouse with serious systemic illness or pregnancy who is unable to cooperate (k) patients have taken any medication for ED within 1 month prior to study entry; and (l) patients are using other drugs related to the disease under study.

2.2.5 Termination criteria

The termination criteria are as follows: (a) if a serious adverse event occurs during the study course of the study, the treatment must be discontinued immediately; an analysis of the efficacy of the treatment will be required if the trial has been conducted for 1/2 of the total treatment time; (b) at any stage of the study, the participant has the right to request discontinuation of the study at his own initiative, and a statistical analysis of efficacy is required for those who have completed 1/2 of the total course of treatment or more; and (c) for any participant who withdraws from the trial for any reason, the reasons must be recorded and the necessary follow-up treatment must be given, taking into account the patient's condition and wishes; the investigator must record in detail the evaluation of the treatment at the time of discontinuation.

2.2.6 Sample size consideration

Based on a previous study, acupuncture had an effective rate of 69% for psychogenic ED [18]. We combined our clinical experience and averaged the results of previous clinical studies to estimate the response rate, which was at 30% [13, 19]. On this basis, we adopted a statistical validity test using the software power analysis and sample size (PASS) 2021 (NCSS LLC., Kaysville, UT, USA). In the present study, the $\alpha = 0.05$, $\beta = 0.1$, and power = 0.9, and a sample size of 30 was required for each of the acupuncture and sham acupuncture groups. We considered that the presence of shedding rate will be 10%. Finally, a total of 66 cases should be included in our study.

2.2.7 Randomization and allocation

We used the software program statistical product and service solutions (SPSS) (version 25.0, Chicago, IL, USA) to generate a table of random numbers according to the number of cases assigned and random proportion. The applications for random numbers will be made *via* short messaging service (SMS). The applicant will send the participants' information to the randomization center through short message service. After the central randomization system receives the application information, the patient's randomization number and group will be returned, and the randomization assignment email will be received. Grouping information will be numbered sequentially and hidden by opaque, and sealed envelopes.

2.2.8 Blinding

Participants, outcome assessors, and statisticians were blinded to treatment assignment, but acupuncturists will be not. Both the two groups will be pierced in the skin, but the location and depth of the needling will vary. We will take the acupoints with the participants in a supine position, and the participants will not be able to know the location and depth of his or her own needling. Moreover, to prevent patients from seeing each other's needling procedures, curtains on beds will be

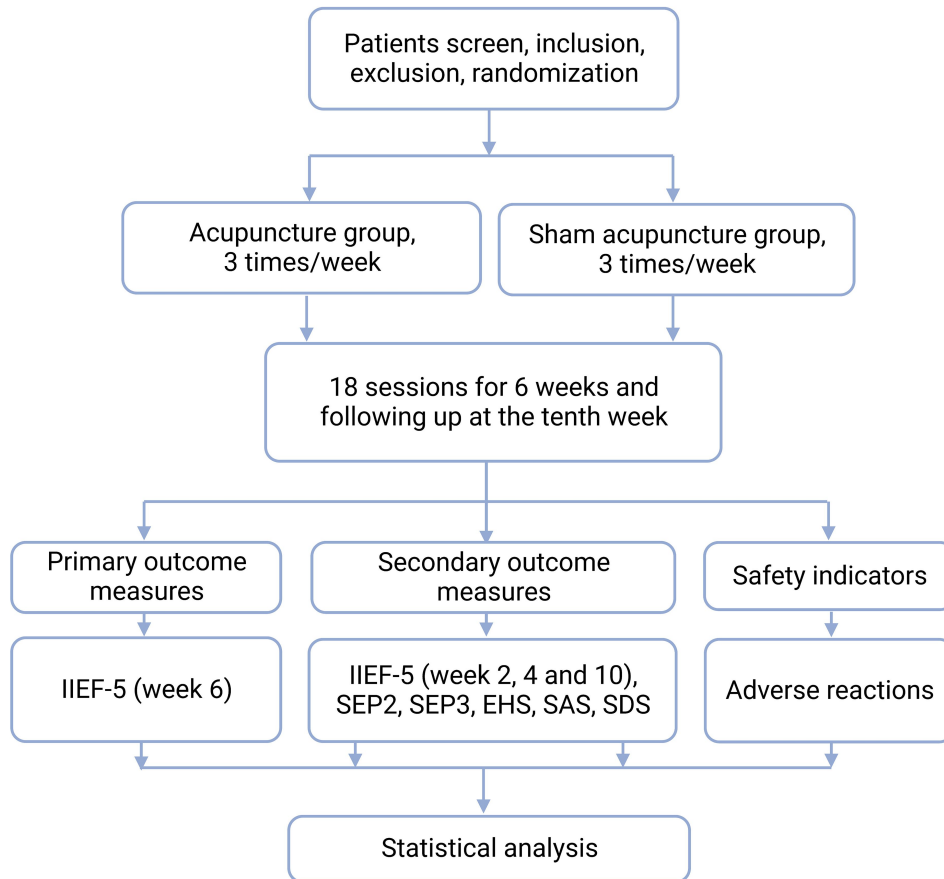


FIGURE 1. Study Flowchart. IIEF-5, international index of erectile function-5; SAS, self-rating anxiety scale; SDS, self-rating depression scale; EHS, erection hardness score; SEP-2, sexual encounter profile-2; SEP-3, sexual encounter profile.

TABLE 1. A process chart of the trial.

Timepoint	Baseline		Treatment phase			Follow-up phase
	Week 0	Week 1	Week 2	Week 4	Week 6	Week 10
Enrollment						
Inclusion/exclusion criteria	×					
Informed consent	×					
Physical examination	×					
Randomization and allocation	×					
Demographic characteristics	×					
Intervention						
Acupuncture		×	×	×	×	
Sham acupuncture		×	×	×	×	
Assessment						
IIEF-5	×		×	×	×	×
SAS	×		×	×	×	×
SDS	×		×	×	×	×
EHS	×		×	×	×	×
SEP2	×		×	×	×	×
SEP3	×		×	×	×	×
Adverse events			×	×	×	×

IIEF, international index of erectile function; *SAS*, self-rating anxiety scale; *SDS*, self-rating depression scale; *EHS*, erection hardness score; *SEP*, sexual encounter profile.

used to shield the participants before they undergo a needling treatment. Additionally, we treat participants by appointment in order to avoid conversation.

Before group allocation, the participants will be informed that they will be randomly allocated to either the acupuncture or sham acupuncture group. After either session in the last week of treatment, all participants will be performed and they will answer the question “Which treatment do you think you have received?”. One of the available answers should be answered “acupuncture treatment”, “sham acupuncture treatment” and “unclear”.

2.3 Intervention

Participants will be divided into the acupuncture and sham acupuncture groups by using the random number table method, and each group will have 33 participants. The physicians participating in the trial are acupuncturists from Xiyuan Hospital. The acupuncturists are all highly qualified with doctoral degrees in Chinese medicine, trained in a uniform standardized operating plan, and responsible for the acupuncture treatments. Acupuncture treatments will be performed in the supine position and the treatment room temperature will be maintained at 26 °C. Patients will have separate beds with bed curtains for blocking between each other. All patients will receive 18 sessions of acupuncture or sham acupuncture interventions (30 min each session, three sessions per week for 6 weeks).

2.3.1 Acupuncture group

Based on the TCM theory and combined with the findings of our previous review and clinical experience [10], we will select GV20 (Baihui), bilateral PC6 (Neiguan), CV4 (Guanyuan), CV3 (Zhongji), bilateral KI12 (Dahe), bilateral KI3 (Taixi), and bilateral LR3 (Taichong). All acupoints' locations are in Table 2 and Fig. 2. They are localized according to the World Health Organization Standard Acupuncture Point Location [20]. Patients will be placed in a supine position with the local skin routinely disinfected. The 0.3 mm × 40 mm stainless steel milli-needle will be selected for acupuncture. To avoid pores and blood vessels, the application should be performed gently and slowly until the needle tip will reach at the expected depth. The needle entry will be performed every 10 minutes for 30 seconds each time to obtain the sense of deqi.

2.3.2 Sham acupuncture group

The Sham acupuncture intervention was performed based on the method described in a previous study [9]. Patients will be placed in a supine position, and after routine local disinfection, a 0.3 mm × 25 mm stainless steel milli-needle will be used to pierce the acupoint without deqi. The retention time and treatment duration are the same as in the acupuncture group. Specific manipulations were performed, which were as follows: 5 mm lateral to the GV20 (Baihui), 1–2 mm flat stab; 5 mm lateral to the PC6 (Neiguan), 2–3 mm straight stab; 5-mm lateral to the LR3 (Taichong), 2–3 mm straight stab; 10 mm posterior to the KI3 (Taixi), 2–3 mm straight stab; 5 mm lateral to the KI12 (Dahe), 2–3 mm straight stab; 15 mm lateral to the CV3 (Zhongji), 2–3 mm straight stab; and 15 mm lateral to the CV4 (Guanyuan), 2–3 mm straight stab. No needle

manipulation will be performed.

2.4 Outcome measures

2.4.1 Primary outcome measures

IIEF-5 is a simplified scale of five erection-related questions in the IIEF and is commonly used clinically to assess erectile function and understand the severity of ED [21]. We will evaluate the efficacy of treatment at week 6 as the primary outcome.

2.4.2 Secondary outcome measures

The IIEF-5 scores obtained at weeks 2, 4, and 10 are used as the secondary outcome. The degree of anxiety and depression will be measured by using the self-rating anxiety scale (SAS) and self-rating depression scale (SDS); both are self-report questionnaires with 20 items rated on a four-point scale [22, 23]. The erection hardness score (EHS) is a questionnaire currently used specifically to evaluate penile erectile hardness and correlates with the success of sexual intercourse [24]. The EHS assesses penile erectile hardness through four scales, is easy to understand and use, and does not involve excessive subjectivity and has no time limit. Moreover, we will evaluate the efficacy from the changes in these indicators at weeks 2, 4, 6, and 10 of acupuncture treatment, as compared to the efficacy at baseline. Additionally, the sexual encounter profile (SEP) questions will be used (SEP-2: Were you able to insert your penis into your partner's vagina? SEP-3: Did your erection last long enough for you to have a sexual intercourse?). These two questions evaluate the success rate of the penile penetration and the completed intercourse [25]. The percentage change in SEP2 and SEP3 “yes” responses at weeks 2, 4, 6 and 10 compared to that baseline are also considered as secondary outcome measures.

2.4.3 Safety evaluation and adverse events

Adverse acupuncture reactions include pain, nausea, vomiting, palpitation, dizziness, headache, anorexia, local hematoma, and infection. Additionally, during acupuncture treatment needle breaking, needle leaving, and needle fainting may occur. All adverse reactions and events will be documented by the evaluators.

2.5 Data management and analysis

2.5.1 Data management

Quality controllers are responsible for establishing the treatment control and quality assurance system of the clinical study. The contents of the case report form (CRF) will be recorded carefully according to the requirements for completing the CRF to ensure that its contents are true and reliable and then enter them into the electronic database. If the study is completed, the paper CRFs will be stored in a locked cabinet. The electronic database should also be locked and the data cannot be modified by the investigator. All results should be verified to ensure data reliability. And the conclusion in our study will be derived from the original data. We have management measures in both clinical trials and data processing stages.

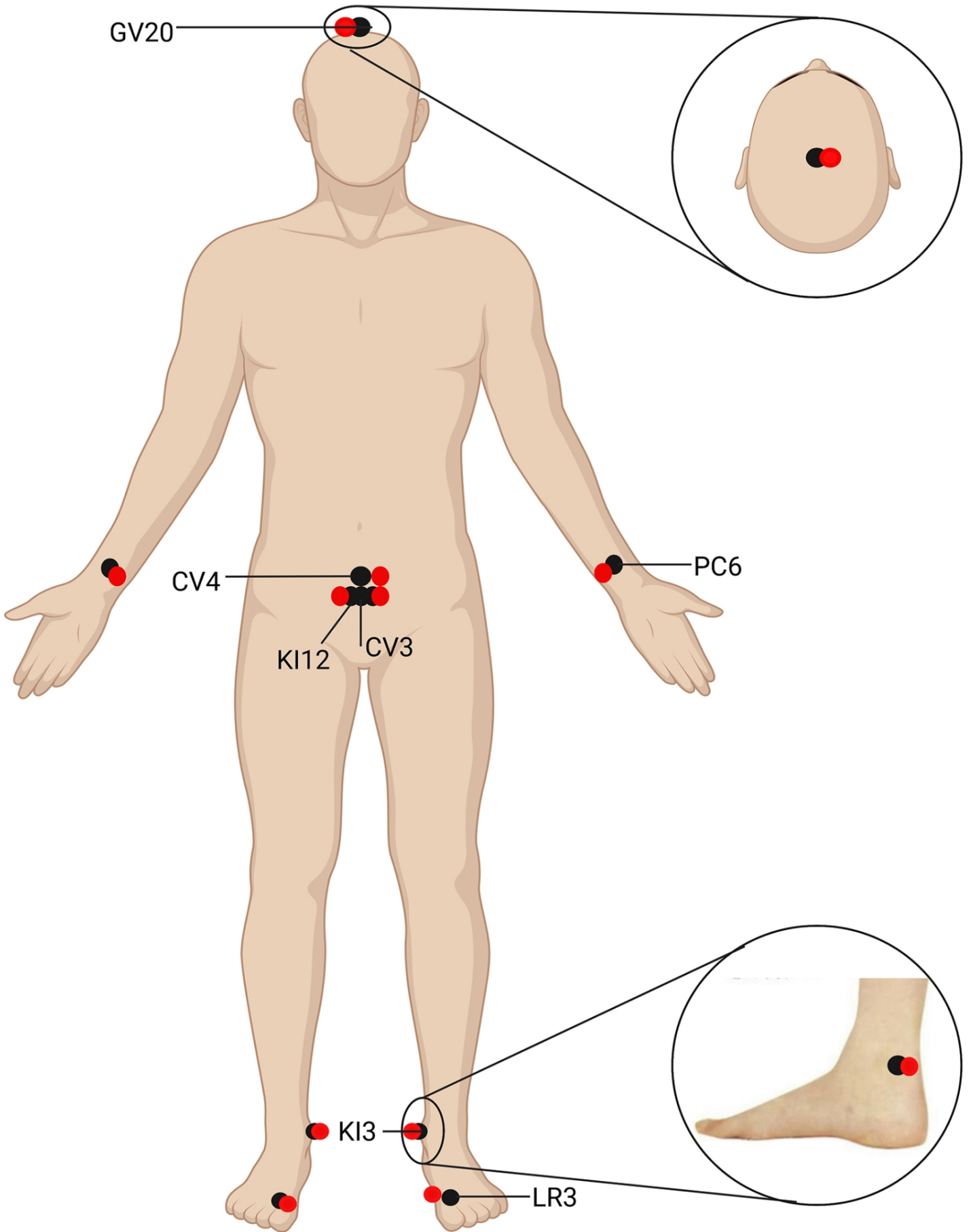


FIGURE 2. Acupoint selection in the acupuncture and sham acupuncture groups. The black circles represent the acpoints selected by the acupuncture group, the red circles represent the acpoints selected by the sham acupuncture group. (Created with [BioRender.com](https://www.biorender.com)).

TABLE 2. Intervention in the acupuncture group.

Acupoints	Location	Insert angle	Insert depth
GV20 (Baihui)	The intersection of the median line at the top of the head and the line connecting the tips of the ears	15°	15~20 mm
PC6 (Neiguan)	2 cun above the transverse wrist stripe, between the palmaris longus tendon and the radial wrist flexor tendon	90°	15~20 mm
CV4 (Guanyuan)	Front median line of the body, 3 cun below the middle of the navel	90°	25~30 mm
CV3 (Zhongji)	Front median line of the body, 4 cun below the middle of the navel	90°	25~30 mm
KI12 (Dahe)	Front median line of the body, 4 cun below the middle of the navel, 0.5 cun next to the anterior median line	90°	25~30 mm
KI3 (Taixi)	Medial side of the foot, depression between the posterior aspect of the medial ankle and the tendon of the heel bone	90°	15~20 mm
LR3 (Taichong)	On the dorsum of the foot, in the depression proximal to the first metatarsal space	90°	15~20 mm

2.5.2 Data analysis

We will invite a third-party professional statistician, and he or she does not know the protocol. The statistical analysis software SPSS 20.0 will be applied, with $p < 0.05$ indicating statistically significant differences. The t -test will be used if the data conformed to a normal distribution and the variances are homogeneous. If the variances will not be homogeneous, the corrected t -test will be applied; if not, the rank sum test will be used. Count data will be analyzed by χ^2 test, and within-group comparisons by repeated-measures analysis of variance.

(a) The number of enrolled and completed cases as well as the dislodged and excluded cases and their reasons will be listed.

(b) Case enrollment, demographic data, and baseline data analyses: in the descriptive statistics, including demographic data and other baseline characteristic values, continuous variables will be calculated for their number of cases, mean and standard deviation. For the frequency and composition ratios, count and rank data will be used in the calculation.

(c) Efficacy analysis: the main efficacy indicators will be analyzed and the IIEF-5 scores after treatment will be determined. The rank sum test will be used to compare the differences between groups. Secondary efficacy indexes will be analyzed, and the rank sum test and t -test will be used to compare post-treatment SAS, SDS, and so on between groups.

2.6 Quality control

All relevant personnel will participate will attend specific training about the study objectives, protocol of intervention strategies, and quality control before the study so as to make them understand the protocol and be consistency in the interventions and evaluations during the study process. A quality control team will be established and responsible for conducting quality control reviews every 2 weeks, and they will report on the quality of the entire study process.

3. Discussion

ED seriously impairs the quality of sexual life among men, and although it is not life-threatening, it affects the physical

and mental health of men and places a burden on the patients' relationships [26]. Acupuncture may affect the IIEF-5 scores of ED patients and improve their erection quality to some extent [27]. However, these results seem to be somewhat unreliable. On the one hand, patients with organic ED were included in the inclusion criteria of these studies, and their results suggest that the outcome of patients with organic ED after acupuncture treatment may be less promising [28]. Studies focused on psychogenic ED tend to explore pathogenesis [29, 30]. Although few studies have tried to use other therapies, such as intracavernous self-injection treatment or PDE5i [31, 32]. recent studies supporting the application of acupuncture is lacking. On the other hand, the final results were also affected by the relatively old literature data, small sample size, imperfect nadir criteria, and too single evaluation index [13, 19]. Therefore, we hope that this single-center, randomized, sham-controlled trial will be able to preliminary verify the efficacy of acupuncture in psychogenic ED and provide conclusive evidence for acupuncture as therapy of psychogenic ED.

According to the TCM theory, the main causes of psychogenic ED are kidney deficiency, liver depression, and mostly due to unhealthy lifestyle, such as irregular work schedule and rest, excessive masturbation and room strain, and increased psychological stress [33, 34]. These potential and long-term psychological factors affect patients' erectile function [35]. SAS and SDS are commonly used to evaluate sexual dysfunction caused by psychological factors [36, 37]. Therefore, we used them as the evaluation outcomes. From the perspective of TCM, psychogenic ED is mostly seen in young adults and, in most cases, is not accompanied by some basic diseases; thus, we set the included population to include individuals aged between 20 and 50 years. In our study, we will perform intracavernous injection combined with color Doppler duplex ultrasonography in patients with abnormal audiovisual stimulation, and will exclude patients with ED due to psychiatric disorders, surgical trauma, pharmacological factors, and other related factors by careful history taking. We will also rule out hypogonadism, hyperprolactinemia, and hypothyroidism by testing the patients' sex hormones and thyroid function to ensure the accuracy of the condition in our

included patients.

In our acupuncture group, the acupoints with effects of tonifying the kidney and regulating the patient's mood under the principles of treatment based on TCM will be selected. We referred to the findings of a previous study on the treatment of ED by acupuncture [10], with emphasis on the acupoints of the Ren meridian, such as C4 and CV3, and along with the acupoints of the meridians of foot-jueyin and foot-shaoyin. Additionally, anxiety and depression may also be present in psychogenic ED patients [38]. Acupuncture of GV20 can effectively improve the anxiety and depression state of patients [39, 40]. For the selection of non-acupoints in the sham acupuncture group, we combined the findings of previous clinical studies on acupuncture and found that these methods are controversial [41]. In the present trial, we will adopt the common method of non-acupoint shallow acupuncture by using the selected acupoints as a reference and at a certain distance from the side [9]. Moreover, to avoid overlap of the other meridians after needling, we further referred to other studies to recognize related standards and consulted experts in the field. Then, we finalized the operation plan for the sham acupuncture group.

4. Conclusions

This randomized controlled trial may represent a step forward in the acupuncture treatment for ED. To the best of our knowledge, this will be the first protocol to examine the efficacy and safety of acupuncture therapy for psychogenic ED. Importantly, this approach will bring benefits to those patients who refuse oral drug therapy, avoiding side effects that occur after taking medications and local physical therapy, and reducing treatment costs.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

HW—Conceptualization; JWZ—funding acquisition and writing-review and editing; HW and JG—writing-original draft; MZ and BY—writing-review and editing.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study involving human participants was reviewed and approved by the Research Ethical Committee of Xiyuan Hospital, China Academy of Chinese Medical Sciences (2022XLA092-3). And the study has also been registered with the <http://www.chictr.org.cn> (ChiCTR number is ChiCTR2200064345). The patients/participants provided their written informed consent to participate in this study.

ACKNOWLEDGMENT

The authors would like to thank <https://www.biorender.com> to assist us in creating our figure.

FUNDING

This research was supported by the National Natural Science Foundation of China (No. 82205134) and Qihuang Scholars Support Project of National Traditional Chinese Medicine Inheritance and Innovation (No. 020450008).

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

- [1] Salonia A, Bettocchi C, Boeri L, Capogrosso P, Carvalho J, Cilesiz NC, *et al.* European association of urology guidelines on sexual and reproductive health-2021 update: male sexual dysfunction. *European Urology*. 2021; 80: 333–357.
- [2] Capogrosso P, Colicchia M, Ventimiglia E, Castagna G, Clementi MC, Suardi N, *et al.* One patient out of four with newly diagnosed erectile dysfunction is a young man—worrying picture from the everyday clinical practice. *The Journal of Sexual Medicine*. 2013; 10: 1833–1841.
- [3] Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and psychosocial correlates: results of the Massachusetts male aging study. *The Journal of Urology*. 1994; 151: 54–61.
- [4] Wilcox SL, Redmond S, Davis TL. Genital image, sexual anxiety, and erectile dysfunction among young male military personnel. *The Journal of Sexual Medicine*. 2015; 12: 1389–1397.
- [5] Chen L, Shi G, Huang D, Li Y, Ma C, Shi M, *et al.* Male sexual dysfunction: a review of literature on its pathological mechanisms, potential risk factors, and herbal drug intervention. *Biomedicine & Pharmacotherapy*. 2019; 112: 108585.
- [6] Hatzichristou DG, Apostolidis A, Tzortzis V, Ioannides E, Yannakoyorgos K, Kalinderis A. Sildenafil versus intracavernous injection therapy: efficacy and preference in patients on intracavernous injection for more than 1 year. *The Journal of Urology*. 2000; 164: 1197–1200.
- [7] Rosen RC. PSYCHOGENIC ERECTILE DYSFUNCTION: classification and management. *Urologic Clinics of North America*. 2001; 28: 269–278.
- [8] Mobley DF, Khera M, Baum N. Recent advances in the treatment of erectile dysfunction. *Postgraduate Medical Journal*. 2017; 93: 679–685.
- [9] Sun Y, Liu Y, Liu B, Zhou K, Yue Z, Zhang W, *et al.* Efficacy of acupuncture for chronic prostatitis/chronic pelvic pain syndrome: a randomized trial. *Annals of Internal Medicine*. 2021; 174: 1357–1366.
- [10] Wang H, Zhao M, Zhang J, Yan B, Liu S, Zhao F, *et al.* The efficacy of acupuncture on patients with erectile dysfunction: a review. *Evidence-Based Complementary and Alternative Medicine*. 2022; 2022: 1–10.
- [11] Kaptchuk TJ. Acupuncture: theory, efficacy, and practice. *Annals of Internal Medicine*. 2002; 136: 374–383.
- [12] The Andrology Branch of the Chinese Society of Traditional Chinese Medicine Information. Guidelines for the multidisciplinary treatment of erectile dysfunction with Chinese and Western medicine. *Chinese Journal of Andrology*. 2022; 36: 3–9.
- [13] Aydin S, Ercan M, Caşkurulu T, Taşçi AI, Karaman I, Odabaş O, *et al.* Acupuncture and hypnotic suggestions in the treatment of non-organic male sexual dysfunction. *Scandinavian Journal of Urology and Nephrology*. 1997; 31: 271–274.
- [14] Lehmann H. Acupuncture in ancient China: how important was it really? *Journal of Integrative Medicine*. 2013; 11: 45–53.
- [15] Yin X, Gou M, Xu J, Dong B, Yin P, Masquelin F, *et al.* Efficacy and safety

- of acupuncture treatment on primary insomnia: a randomized controlled trial. *Sleep Medicine*. 2017; 37: 193–200.
- [16] Qu S, Huang Y, Zhang Z, Chen J, Lin R, Wang C, *et al.* A 6-week randomized controlled trial with 4-week follow-up of acupuncture combined with paroxetine in patients with major depressive disorder. *Journal of Psychiatric Research*. 2013; 47: 726–732.
- [17] Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, *et al.* SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ*. 2013; 346: e7586.
- [18] Yaman LS, Kiliç S, Sarica K, Bayar M, Saygin B. The place of acupuncture in the management of psychogenic impotence. *European Urology*. 1994; 26: 52–55.
- [19] Engelhardt PF, Daha LK, Zils T, Simak R, König K, Pflüger H. Acupuncture in the treatment of psychogenic erectile dysfunction: first results of a prospective randomized placebo-controlled study. *International Journal of Impotence Research*. 2003; 15: 343–346.
- [20] Lim S. WHO standard acupuncture point locations. *Evidence-Based Complementary and Alternative Medicine*. 2010; 7: 167–168.
- [21] Kassouf W, Carrier S. A comparison of the international index of erectile function and erectile dysfunction studies. *BJU International*. 2003; 91: 667–669.
- [22] ZUNG WWK. A self-rating depression scale. *Archives of General Psychiatry*. 1965; 12: 63–70.
- [23] Zung WWK. A rating instrument for anxiety disorders. *Psychosomatics*. 1971; 12: 371–379.
- [24] Parisot J, Yiou R, Salomon L, de la Taille A, Lingombet O, Audureau E. Erection hardness score for the evaluation of erectile dysfunction: further psychometric assessment in patients treated by intracavernous prostaglandins injections after radical prostatectomy. *The Journal of Sexual Medicine*. 2014; 11: 2109–2118.
- [25] Wang H, Yuan J, Hu X, Tao K, Liu J, Hu D. The effectiveness and safety of avanafil for erectile dysfunction: a systematic review and meta-analysis. *Current Medical Research and Opinion*. 2014; 30: 1565–1571.
- [26] Burnett AL, Nehra A, Breau RH, Culkin DJ, Faraday MM, Hakim LS, *et al.* Erectile dysfunction: AUA guideline. *Journal of Urology*. 2018; 200: 633–641.
- [27] Lai BY, Cao HJ, Yang GY, Jia LY, Grant S, Fei YT, *et al.* Acupuncture for treatment of erectile dysfunction: a systematic review and meta-analysis. *The World Journal of Men's Health*. 2019; 37: 322–338.
- [28] Kho HG, Sweep CG, Chen X, Rabsztyrn PR, Meuleman EJ. The use of acupuncture in the treatment of erectile dysfunction. *International Journal of Impotence Research*. 1999; 11: 41–46.
- [29] Xu J, Chen Y, Gu L, Liu X, Yang J, Li M, *et al.* Hypothalamic-pituitary-adrenal axis activity and its relationship to the autonomic nervous system in patients with psychogenic erectile dysfunction. *Frontiers in Endocrinology*. 2023; 14: 1103621.
- [30] Zhang X, Guan M, Chen X, Zhang P, Wu J, Zhang X, *et al.* Identifying neuroimaging biomarkers for psychogenic erectile dysfunction by fusing multi-level brain information: a resting-state functional magnetic resonance imaging study. *Andrology*. 2022; 10: 1398–1410.
- [31] Lidawi G, Asali M, Majdoub M, Rub R. Short-term intracavernous self-injection treatment of psychogenic erectile dysfunction secondary to sexual performance anxiety in unconsummated marriages. *International Journal of Impotence Research*. 2022; 34: 407–410.
- [32] Li G, Lan H, Liang J, Zhang C, Huang C. Efficacy of tadalafil de-escalation in the treatment of psychogenic erectile dysfunction. *Urologia Internationalis*. 2017; 98: 205–209.
- [33] Flaherty KR, Demirjian CC, Nelson CJ. The psychological reasons for limiting implant surgery for men with erectile dysfunction. *The Journal of Sexual Medicine*. 2022; 19: 1499–1501.
- [34] Maestre-Lorén F, Castillo-Garayoa JA, López-i-Martín X, Sarquella-Geli J, Andrés A, Cifre I. Psychological distress in erectile dysfunction: the moderating role of attachment. *Sexual Medicine*. 2021; 9: 100436.
- [35] Ciaccio V, Di Giacomo D. Psychological factors related to impotence as a sexual dysfunction in young men: a literature scan for noteworthy research frameworks. *Clinics and Practice*. 2022; 12: 501–512.
- [36] Yu C, Hequn C, Longfei L, Minfeng C, Zhi C, Feng Z, *et al.* Sexual function after partial penectomy: a prospectively study from China. *Scientific Reports*. 2016; 6: 21862.
- [37] Zhang Y, Zhang X, Wang Q, Yuan Y, Yang J, Zhang X, *et al.* Psychological burden, sexual satisfaction and erectile function in men whose partners experience recurrent pregnancy loss in China: a cross-sectional study. *Reproductive Health*. 2016; 13: 73.
- [38] Bilal A, Abbasi NUH. Randomized placebo controlled trial of sildenafil citrate, cognitive behavior sex therapy and integrated treatment in men diagnosed with non organic erectile dysfunction. *Sexual Medicine*. 2022; 10: 100464.
- [39] Schiller J, Niederer D, Kellner T, Eckhardt I, Egen C, Zheng W, *et al.* Effects of acupuncture and medical training therapy on depression, anxiety, and quality of life in patients with frequent tension-type headache: a randomized controlled study. *Cephalalgia*. 2023; 43: 03331024221132800.
- [40] Liu C, Zhao Y, Qin S, Wang X, Jiang Y, Wu W. Randomized controlled trial of acupuncture for anxiety and depression in patients with chronic insomnia. *Annals of Translational Medicine*. 2021; 9: 1426.
- [41] Kim TH, Lee MS, Lee H. Sham acupuncture is not just a placebo. *Journal of Acupuncture and Meridian Studies*. 2022; 15: 333–335.

How to cite this article: Hao Wang, Bin Yan, Ming Zhao, Jun Guo, Jiwei Zhang. Efficacy of acupuncture in the treatment of psychogenic erectile dysfunction: study protocol for a randomized control trial. *Journal of Men's Health*. 2023; 19(7): 31-38. doi: 10.22514/jomh.2023.055.