Chinese herbal medicine combined with cognitive–behavioural therapy for avoidant paruresis: a controlled trial

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ABSTRACT

Background Avoidant paruresis is a common clinical condition in urology and psychosomatic medicine. However, it has limited treatment options that are safe and effective with few side effects.

Aims Our study aimed to investigate the effectiveness and safety of the Chinese herbal Yangxin Tongquan decoction combined with cognitive–behavioural therapy (CBT) for avoidant paruresis.

Methods Sixty-eight patients with avoidant paruresis were divided into a treatment group (33 patients) and a control group (35 patients). The control group was assigned 10 weeks of CBT and systematic desensitisation. In addition to CBT and systematic desensitisation, the treatment group was given the Chinese herbal Yangxin Tongquan decoction during the 10-week study. The Shy Bladder Syndrome Scale (SBS) and the Self-Rating Anxiety Scale (SAS) were administered before and after treatment to measure any change.

Results The overall efficacy in the treatment group (n=30) was 80.0% vs 62.5% in the control group (n=33). Comparing pretreatment and post-treatment measures, both groups showed improvement in SBS scores and SAS scores (t(SBS)=8.397, p(SBS)<0.001; t(SAS)=8.216, p(SAS)<0.001; control group: t(SBS)=6.802, p(SAS)<0.001; t(SAS)=5.171, p(SAS)<0.001). Moreover, both groups’ SBS and SAS scores changed significantly over time (SBS scores: Ftime=118.299, p<0.001; SAS scores: Ftime=92.114, p<0.001). However, the treatment group performed better than the control group (SBS scores: Ftime×group=5.709, p=0.020; SAS scores: Ftime×group=7.235, p=0.009).

Conclusions The Chinese herbal Yangxin Tongquan decoction combined with cognitive–behavioural psychotherapy positively affects the treatment of avoidant paruresis without significant adverse effects.

INTRODUCTION

Avoidant paruresis (AP), also known as shy bladder syndrome,1 is a common clinical condition in urology and psychosomatic medicine. The symptoms disappear entirely when others are not present during urination. The condition can occur at any age, in any race and for either gender but is predominantly found in young adult men.

The disorder involves physical and psychological aspects and is medically classified as a social phobia/anxiety disorder.1 Australian research revealed that AP, or shy bladder syndrome, affects between 2.8% and 16.4% of the population, occurring more frequently in men (75.0%–92.0%) than in women (8.1%–44.6%).2 Treatments such as antianxiety medication, behavioural therapy and even self-catheterisation using portable catheters are recommended in Europe and the USA when needed. Despite their effectiveness, these treatments still present unresolved issues, including adverse effects and potential drug dependence.3

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ An Australian study found that 2.8%–16.4% of the population suffer from avoidant paruresis (AP), with greater prevalence in men (75.0%–92.0%) than women (8.1%–44.6%). In Europe and the USA, antianxiety medication, cognitive–behavioural therapy and even self-catheterisation with portable catheters are recommended for treatment when necessary. Although they are effective, the problems of adverse effects and drug dependence remain to be solved.

WHAT THIS STUDY ADDS

⇒ The Chinese herbal Yangxin Tongquan decoction enhanced the effectiveness of AP treatment when combined with cognitive–behavioural psychotherapy by decreasing symptoms and relieving anxiety related to voiding in public without significant adverse effects.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study considers a new approach to treating AP.
neurological responses and trauma-induced. Situational voiding disorders such as these are a relatively common type of psychosomatic disorder in urology, but little research is available in China. However, based on statistical projections from the USA, we estimate that the disorder affects nearly 90 million individuals in China, ranging from mild to severe symptoms. The projected estimate of the male-to-female ratio in China is approximately 9:1, with the highest prevalence among young and middle-aged men.

While the pathogenesis of AP remains unclear, its root cause is generally believed to be primarily non-organic. An individual's negative evaluations of shameful and embarrassing situations and interpersonal relationships in social settings, accompanied by excessive and pronounced apprehension and fear, are characteristics of psychological disorders. The condition could also be related to childhood psychological trauma, producing profound and lasting effects on the individual.

Patients with AP usually experience extreme fear of negative evaluation by others and being criticised or rejected in public. These may lead to physiological symptoms in specific situations, such as rapid heartbeat, blushing and difficult bowel movements. This condition may be exacerbated in China by the influence of the Chinese culture's focus on shame. Recent advances in research suggest that AP may be related to the brain's perception of threat that activates the sympathetic nervous system, thereby contracting the internal sphincter at the neck of the bladder and preventing the passage of urine. Even if the affected individuals manually press their lower abdomen to squeeze the bladder with an external force or consciously relaxes the external urethral sphincter, the bladder sphincter—not under conscious control—will not relax and remains contracted, so urination cannot occur. Therefore, the syndrome is formally classified as a social phobia/anxiety disorder. Standard treatments for the disorder include the following: cognitive–behavioural therapy (CBT); pharmacological use of drugs with anti-anxiety, obsessive-compulsive and depressive effects; cognitive–behavioural hypnotherapy; and systematic desensitisation behaviour therapy. Of these, cognitive–behavioural hypnotherapy and systematic desensitisation are the most clinically operable.

Traditional Chinese medicine (TCM) categorises this disease as ‘retention of urine’, as found in Huangdi Neijing: Suwen: Clarification of Five Qi. According to TCM formulations, this infirmity is defined as blocked urine. A renowned Shanghai TCM practitioner, Zhiheng Zhou, and his team have used a Chinese herbal medicine that ‘nourishes the heart and calms the mind, dredges the liver and relieves depression, and regulates qi and dissolves phlegm as the basic treatment for psychogenic urination abnormalities’. This ‘nourishing the heart and tranquillising the mind’ approach in treating refractory urinary disorders has been declared an innovative achievement by Shanghai's prominent, long-term TCM practitioners.

Searching for a safe and effective treatment with few side effects for situational voiding disorders has been a research focus in urology and psychosomatic medicine. In recent years, we have used Chinese medicine combined with CBT to treat paruresis with good efficacy; a summary of our work follows.

**METHODS**

**Diagnostic criteria**

The diagnostic criteria for AP include the following: (1) a nervous state and inability to urinate due to the presence of others or fear that someone will approach, but no impairment when urinating alone; (2) though organic causes are suspected, urinary examination reveals no organic change; (3) symptoms are autonomically induced; (4) self-awareness of the nervousness and fear is not required, but the individual cannot control or avoid the urinary problems; (5) the individual’s life, study, work and social activities are affected; (6) onset occurs in adolescence or young adulthood, but symptoms may fluctuate over time or be delayed; (7) numerous psychological or physical triggering factors may occur, but these vary among individuals; and (8) feelings of shame and pain are often accompanied by anxiety and depressive symptoms. The above clinical features are consistent with the F40.2 specific (isolated) phobia diagnostic points of the International Classification of Diseases 10th Revision: Mental and Behavioural Disorders.

**Participants**

Enrolment for the study included 68 patients with AP syndrome who met the above diagnostic criteria; they were admitted to the urology outpatient clinic of Longhua Hospital, Shanghai University of Traditional Chinese Medicine, from October 2016 to October 2021. They were divided into a treatment group (33 patients) and a control group (35 patients) according to each patient’s treatment preferences. The study flowchart is shown in figure 1. Inclusion criteria for study participation were as follows: (1) met the diagnostic criteria for AP; (2) a disease duration of 6 months or more; (3) male older than 18 years; and (4) signed informed consent to cooperate with the treatment. Exclusion criteria included the following: (1) recent administration of other therapeutic drugs that could interfere with the therapeutic efficacy observation; (2) obvious genital malformations (such as urine, prostate, foreskin and other types of urological-related abnormalities) and genitourinary system disorders; (3) a history of other psychiatric disorders; (4) comorbid severe primary diseases of the liver, kidney or the haematopoietic and cardiovascular systems, and hyperthyroidism or diabetes; (5) allergies or hypersensitivity to the drugs used in this study; (6) active infectious diseases; and (7) participants who were treated under non-standard provisions, or provided incomplete data, which might affect the efficacy or safety judgement.
Study design and procedure

The control group was given CBT by one of three qualified psychotherapists. The 50-minute psychotherapy sessions were held twice weekly for 10 weeks. The initial sessions explored participants’ first occurrence of urinary shyness, provided knowledge about the physiology of normal urination, gave an overview of healthy micturition habits and then discussed healthy individuals’ opinions about urinating in public toilets. In later sessions, the groups were assisted in identifying negative automatic thoughts and guided to eliminate misconceptions, especially negative self-evaluations. A second component was to teach self-relaxation techniques, especially those involving the pelvic area. A third component used systematic desensitisation. The participants began by drinking water, and then, when feeling the urge to urinate, a therapist progressively led participants through the following steps: (1) urinate alone in an enclosed space with no one outside; (2) urinate alone in an enclosed space with someone standing outside; (3) urinate in an open space with someone standing outside of this space; and (4) urinate in the same space shared by another person urinating, initially farther away and then closer to the participant. After approximately 8–10 times of this behavioural intervention practice, participants were encouraged to go to a public toilet where several people urinated while accompanied by the therapist who provided support and guidance.

The treatment group combined the psychotherapy treatment given to the control group with the oral Chinese herbal medicine Yangxin Tongquan decoction. The herbs were prescribed by hospital physicians and included Poria, Fushen, Polygalae Radix, Semen Ziziphi Spinosae, Fossilizid, Ostreae Concha, Magnetitum, Cortex Albiziae, Salviae Miltiorrhizae Radix et Rhizoma, Bupleuri Radix, Paeoniae Radix Alba, Acori Tatarinowii Rhizoma, Chen Dengxin, Glycyrrhizae Radix et Rhizoma, and so on. The TCM medicine was decocted twice. For the first decoction, the Chinese herbs were added to a pot filled with water and boiled for 30 min. The liquid was poured off, and more water was added to the pot with the herbal ingredients and boiled for another 20 min. Then the fluids from the two decoctions were mixed, totalling about 300 mL, and were ready for use. One dose was 150 mL and was given twice daily, morning and evening. The duration of treatment was 10 weeks. (The above steps were all completed by the Traditional Chinese Medicine Pharmacy at Longhua Hospital.)

Scales and efficacy rating

The Shy Bladder Syndrome Scale (SBS) is mainly used to measure paruresis and evaluate the occurrence of situational voiding disorder symptoms (see online supplemental appendix 1). The scale has been shown to have construct validity. SBS scores were observed before and after treatment, referring to the Self-Help Guide to Urinary Shyness recommended by the International Association for Situational Voiding Disorders.4 The Self-rating Anxiety Scale (SAS) is primarily used to assess an individual’s symptoms and severity of anxiety (see online supplemental appendix 2). The scale has been shown to have construct validity. SAS scores were observed before and after treatment.

We referred to the relevant literature standards to evaluate clinical efficacy at the end of this treatment course. They are as follows: (1) clinically controlled: ≥95% reduction in symptom scores compared with that before treatment, complete disappearance or basic disappearance of symptoms; (2) significantly effective: significant symptom relief, high patient satisfaction, ≥60% and <95% reduction in symptom score scale points compared with pretreatment; (3) effective: moderate symptom
improvement and patient satisfaction, ≥30% and <60% reduction in symptom rating scale score compared with that before treatment; and (4) ineffective: symptom rating scale score did not reach the above criteria. This is the efficacy formula: (total points before treatment–total points after treatment)/total points before treatment×100%; total effective rate= (number of clinical control cases+number of apparent effective cases+number of effective cases)/total cases×100%.

Safety-related treatment
During the treatment, close attention was paid to participants’ urination. If there had been a significant worsening of symptoms accompanied by other urinary system symptoms, our hospital’s doctors would have promptly conducted urinary system examinations, such as ultrasound (kidney, ureter, bladder, residual urine), renal function tests, and urine analysis, and provided appropriate treatment, based on the findings.

Statistical analysis
SPSS V.25 software was used for data entry and statistical analysis. The measurement data were tested for normality, and those that met the normality test were expressed as the mean (standard deviation, SD). The student’s t-test was used for comparison between groups. Those not meeting the normality test were expressed as median (first quartile (Q1), third quartile (Q3)). Mann-Whitney tests were used for comparison between groups, intragroup and rank data. Repeated measures data were analysed by repeated measures analysis of variance (ANOVA). The statistically significant difference value was set as p<0.05.

RESULTS
Of the 33 enrollees in the treatment group, two were excluded for non-compliance with the medication requirements, and one was excluded for failure to meet the standardised psychotherapy requirements. In total, 30 subjects were included in the outcome analysis, with an exclusion rate of 9.1%. Of the 35 enrollees in the control group, three were excluded for failure to meet the standardised psychotherapy requirements. In total, 32 subjects were included in the outcome analysis, with an exclusion rate of 8.6%. All participants were young males. The age of those in the treatment group ranged from 19 to 36 years, with a mean of 25.80 (3.60) years; for the control group, it was 0.5–11 years, with a mean of 3.05 (2.13) years; for the control group, it was 0.5–10 years, with a mean of 2.98 (2.26) years. The differences in baseline data between the two groups were not statistically significant (p>0.05), and the groups were comparable. See table 1.

The total clinical efficacy rate was 80.0% and 62.5% in the treatment and control groups, respectively. The difference was statistically significant when comparing the clinical efficacy between groups (Z=−2.006, p=0.045). See table 2.

Comparison of treatment outcome
There were no significant differences in SBS and SAS scores between the two groups before treatment (Z(SBS)=−0.57, p(SBS)=0.555; Z(SAS)=−0.46, p(SAS)=0.645). In comparison with the efficacy of pretreatment and post-treatment within each group, the two groups showed improvements in SBS and SAS scores (treatment group: t(SBS)=8.397, p(SBS)<0.001, t(SAS)=8.216, p(SAS)<0.001; control group: t(SBS)=6.802, p(SBS)<0.001, t(SAS)=5.171, p(SAS)<0.001). The SBS and SAS scores of the treatment group were better than the control group after treatment (t(SBS)=−2.581, p(SBS)=0.012; t(SAS)=−2.508, p(SAS)=0.015). See table 3.

Multivariate tests of the correlation scale scores were measured by separately entering the SBS and SAS scoring data and then using treatment time as a within-subjects variable and the group as a between-subjects factor. Multivariate test results were obtained by applying the repeated measures ANOVA model. The integrated multivariate scores are shown in table 4, from which it can be concluded that the time point effect of subjects’ SBS scores was significant (F time=118.299, p<0.001), implying that their SBS score change with the interaction effect (time*group) was significant (F time*group=5.709, p=0.020), and that the SBS score change over time in the treatment group differed from that of the control group, that is, the SBS score change differed by group. In addition, the time point effect of the subject’s SAS score was significant (F time=92.114, p<0.001), implying that their SAS score change with the interaction effect (time*group) was significant (F time*group=7.235, p=0.009) and that the change in SAS score over time in the treatment group was different from that of the control group, that is, the SAS score change differed by group. See table 4.

The mean plots were estimated using repeated measures ANOVA; simple effects analysis and integrating the estimated means of the two scale scores resulted in figures 2 and 3. The results implied that both groups had a trend of decreasing SBS and SAS scores post-treatment, but the effect was better for both in the treatment group. See figures 2 and 3.
Finally, no safety concerns or other symptoms related to urological diseases or psychiatric disorders were observed in either group during or after treatment, and participants had no significant adverse reactions or complaints of other related discomfort.

**DISCUSSION**

**Main findings**

AP is a psychosomatic disorder commonly treated with psychological therapy. CBT and systematic desensitisation are recognised as being the most effective methods and were used in this study. In the initial stage of CBT for AP treatment, the focus was primarily on correcting and eliminating misperceptions because voiding disorder is caused by anxiety and fear related to negative automatic thoughts, most of which originate from one’s own negative core beliefs and underlying negative assumptions. The patients’ negative automatic thoughts mainly relate to their personalities and past experiences. When their brains process and interpret information, they often experience cognitive biases in social environments, including memory, interpretation and attention biases. It is these cognitive biases that lead to the emergence of social anxiety and related symptoms. Helping patients identify their negative automatic thoughts and eliminate misperceptions is a critical first step in treating this disorder. Another form of behavioural therapy, systematic desensitisation, followed this. Its founder, Joseph Wolpe, established this method in 1958 and based it on inhibiting anxiety states by confronting them with relaxed states. The therapy gradually achieves desensitisation and treatment by exposing the patient to different levels of conditioned reflexes. Some studies have shown that people undergoing systematic desensitisation therapy are more prone to relapse, and its therapeutic effects have poorer long-term efficacy than early CBT, which can break the vicious cycles between erroneous cognition and pathological behaviours. Therefore, combining the two therapies can achieve good short-term and long-term therapeutic effects.

The patients in this study’s control group showed a degree of relief from clinical symptoms and anxious emotions by only following this psychological treatment process. Because of the associated side effects of psychotropic drugs sometimes prescribed to treat this disorder and their unstable efficacy, our team used TCM as the research treatment intervention in this study. An increasing number of studies have shown that TCM can achieve certain therapeutic effects in treating many mental and neuropsychiatric disorders. Obsessive-compulsive disorder, a neuropsychiatric condition characterised by obsessions and compulsions, is typically treated with CBT and medication. However, some nutritional and herbal supplements may also be effective. Moreover, in the past 2 years, an increasing number of Chinese traditional herbal medicines, including Liuweidihuang capsules, Taisi capsules, Bushenyijing granules, Yizhi decoction and Wujiayizhi granules, have been introduced to clinical trials for the treatment of Alzheimer’s disease. TCM categorises situational voiding disorder as ‘Longbi’ (urinary dysfunction). Our team found that true situational urinary dysfunction caused by kidney deficiency is uncommon in present-day society, where people have material abundance but face enormous mental pressure. On the other hand, urinary flow dynamic abnormalities caused by liver and kidney dysfunction due to the accumulation of various negative psychological emotions and high-intensity and pressured work and life rhythms are more common. Our hospital’s Male Urology Department has used Chinese herbal medicine to treat psychogenic

**Table 2** Comparison of clinical efficacy between two male groups with avoidant paruresis

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Clinically controlled</th>
<th>Significantly effective</th>
<th>Effective</th>
<th>Ineffective</th>
<th>Total effectiveness rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>30</td>
<td>3</td>
<td>7</td>
<td>14</td>
<td>6</td>
<td>80.00*</td>
</tr>
<tr>
<td>Control group</td>
<td>32</td>
<td>2</td>
<td>2</td>
<td>16</td>
<td>12</td>
<td>62.50*</td>
</tr>
</tbody>
</table>

*The difference was statistically significant when comparing the clinical efficacy between groups (Z=-2.006, P = 0.045)

**Table 3** Comparison of the changes in the scores of each relevant scale between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Time</th>
<th>SBS (points)*</th>
<th>SAS (points)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>Before treatment</td>
<td>24.73 (3.79)</td>
<td>58.27 (7.97)</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>12.03 (7.53)†‡</td>
<td>37.87 (15.89)†‡</td>
</tr>
<tr>
<td>Control group</td>
<td>Before treatment</td>
<td>24.84 (3.39)</td>
<td>58.84 (8.64)</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>16.72 (6.76)†</td>
<td>47.38 (13.95)†</td>
</tr>
</tbody>
</table>

*Mean (SD).
†p<0.001.
‡Comparison between pretreatment and post-treatment within each group. The SBS and SAS scores of the treatment group were better than the control group after treatment, and the difference was statistically significant (t\(_{\text{SBS}}\)=−2.581, p\(_{\text{SBS}}\)=0.012, t\(_{\text{SAS}}\)=−2.508, p\(_{\text{SAS}}\)=0.015).
\(\text{SBS, Self-rating Bladder Syndrome Scale; SAS, Shy Bladder Syndrome Scale; SD, standard deviation.}\)
urinary abnormalities for many years. The formula used in this study’s voiding disorders treatment group is the agreed-upon prescription ‘Yangxin Tongquan decoction’. Poria, Fushen, Polygala Radix and Semen Ziziphi Spinosae are the main drugs in this formula. Modern pharmacological studies have shown that Fu Shen, Polygala Radix, Semen Ziziphi Spinosae and Cortex Albiziae can exert anxiolytic and depressive effects by regulating astrocyte dysfunction. Further studies have shown that the mechanism of action is similar to that of selective serotonin reuptake inhibitors (SSRIs) and it alleviates anxiety by increasing the expression of γ-aminobutyric acid (GABA) type A receptor mRNA in brain tissue. Studies have shown that the main active component of the pharmacological action of Semen Ziziphi Spinosae is flavonoids that have anxiolytic and depressive effects. The total flavonoids of Semen Ziziphi Spinosae can enhance stress tolerance, reduce immobility time in desperate animals, and have significant experimental anti-depressive effects in mice under the stress condition of forced restraint, where animals exhibit a state of despair characterized by immobility after struggling. Cortex Albiziae also has anxiolytic and antidepressant effects. Xiong et al conducted anxiolytic studies on the aqueous extract, the alcohol extract and each extracted part of Cortex Albiziae using an elevated cross maze and light and dark box experiments. They found that the n-butanol extracted part exerted anxiolytic effects by increasing the GABA content and decreasing the Glu and 5-HT content in the mouse brain. In addition, Liao et al found that Cortex Albiziae extract shortened the cumulative immobility time in mice in the tail suspension test and forced swimming test and counteracted the decrease in body temperature and eyelid drooping in mice induced by reserpine, fully indicating the antidepressant effect of Cortex Albiziae extract. The sedative-hypnotic effects of heavy tranquilisers such as Fossilizid and Magnetitum can regulate the excitatory and inhibitory processes of the central nervous system by decreasing the content of certain monoamine transmitters in brain tissue. Bupleuri Radix and Paeoniae Radix Alba can regulate the norepinephrine-activated system by increasing monoamine oxidase (MAO) activity and decreasing 5-hydroxytryptamine (5-HT) levels. They may exert an anxiolytic-depressive effect by potentially inhibiting serotonin through the modulation of GABA receptors near serotonergic nerve terminals. Acori Tata- rinowii Rhizoma has a mechanism of action similar to diazepam that may be related to increasing central GABA levels and decreasing Glu and 5-HT levels. The active ingredient in Salviae Miltiorrhiza Radix et Rhizoma inhibits MAO-A activity in anxiety model mice. It is blocked by the D1 receptor antagonist of dopamine (DA) (SCH23390), suggesting that its anxiolytic mechanism may be related to DAergic nerver. The research team has selected the prescriptions based on the theory of Chinese medicine combined with modern pharmacological research results of Chinese medicine. It has repeatedly adjusted and refined this agreement prescription in clinical practice for many years. The final results in the treatment group were also verified, showing that the total effectiveness rate of the treatment group was 80%, significantly better than the control group (62.07%) (p<0.05). The results also showed that although the SBS and SAS
scores were significantly reduced in both groups after treatment (p<0.05), the treatment group with the addition of Chinese herbs had improved symptoms and significantly better anxiety relief than the control group when compared between groups (p<0.05). We hypothesised that many herbs in the pharmacology of Chinese medicine may act on monoamine neurotransmitters and that some herbs affect amino acid neurotransmitters. These herbs, effectively alleviate the anxiety state of patients during symptomatic episodes and improve the symptoms of situational voiding disorder by relieving voiding stress through multiple channels and targets. Compared to using psychotherapy alone, the combination of Chinese herbal medicine and psychotherapy yields better therapeutic results.

Limitations
There were several limitations to our study. First, patients self-selecting which group they joined created selection bias. In future research, randomised controlled trials can be employed to enhance the credibility of the studies. Second, we did not assess early life psychological or sexual trauma and the number of these events that likely played a role in the onset of the disorder. In future research, it would be beneficial to include additional variables to broaden the scope and depth of the study. Third, we only took measures immediately post-treatment. In future research, we can increase the frequency of follow-up measurements to determine the duration of treatment effectiveness.

Implications
The results of this study indicate that combining Chinese herbal medicine with CBT and systematic desensitisation therapy can improve treatment efficacy for AP. Additionally, specific treatment plans that conform to TCM theory can be chosen based on the different symptoms of each patient. Furthermore, the findings of this study can guide the clinical application of psychosomatic medicine in the field of urology.

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Competing interests None declared.

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

Ethics approval This study involves human participants and the research content of this article is a subtopic of the project, which has been approved by the Medical Ethics Committee of Longhua Hospital, Shanghai University of TCM (ethics approval ID: 2020LS0097). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data refer to the patient’s identity information such as name, age, address, SBS, SAS, etc. But at the beginning of the trial, most of the participants made it clear that they refused to disclose their private information such as name. The statistical data of patients can be obtained from the author of the communication through the mailbox. The data can be reused after getting the patient’s consent again.

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