

Acupuncture Research

Acupoint Catgut Embedding Alleviates Insomnia in Different Chinese Medicine Syndrome Types: A Randomized Controlled Trial*

XU Fu¹, XUAN Li-hua¹, ZHOU Hai-jiang¹, CHEN Fei-yu², ZHENG Zhao-jian³, BI Ying¹, and WU Xiang¹

ABSTRACT **Objective:** To investigate the effects and safety of catgut embedding on alleviating insomnia. **Methods:** Totally 510 patients with insomnia were divided into 5 Chinese medicine (CM) syndrome types: Xin (Heart) and Pi (Spleen) deficiency, yin deficiency with excess fire, Xin and gut qi deficiency, Wei (Stomach) disorder, and qi and blood deficiency, respectively. These 5 types of patients were randomly assigned to a catgut embedding group, an acupuncture group or a medication group (30 cases in Xin and Pi deficiency type, Wei disorder type, Xin and gut qi deficiency type, respectively; 40 cases in yin deficiency with excess fire type and qi and blood deficiency type, respectively). In the catgut embedding group, patients were treated by implanting catgut into acupoints once every 10 days for a total of 30 days. In the acupuncture group, patients were treated with acupuncture once per day over 30 days (excluding weekends); and patients in the medication group took 1 mg Eurodin Tablet orally every night for 30 days. Pittsburgh Sleep Quality Index (PSQI) was evaluated before treatment, on 30 and 60 days after the first treatment, respectively. The International Unified Sleep Efficiency Value (IUSEV) was measured at 30 and 60 days. The safety was evaluated after treatment and adverse events were analyzed. **Results:** The objective PSQI scores including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, daytime dysfunction, and total scores at 30 days were significantly improved compared with pre-treatment in the catgut embedding and acupuncture groups ($P < 0.01$ or $P < 0.05$). At 30 days, the PSQI scores in catgut embedding group were superior to the medication group in the patients with each type of insomnia, with the exception of sleep duration ($P < 0.01$ or $P < 0.05$). At 60 days, significant differences were found between the catgut embedding group and the medication group ($P < 0.01$ for all indices). The IUSEV scores in the catgut embedding group were significantly higher than the acupuncture group at 60 days, and the scores in acupuncture group were higher than the medication group at 30 days ($P < 0.05$ for all types). No severe adverse events were found in this study. **Conclusions:** Acupoint catgut embedding and acupuncture were more effective than medication in alleviating insomnia syndrome in different Chinese medicine syndrome type. However, the sustained effects of acupoint catgut embedding were superior to acupuncture.

KEYWORDS insomnia, acupoint catgut embedding, acupuncture therapy, medication, randomized controlled trial

Insomnia, a common refractory disease observed in the clinic, is quite harmful to individual physical and mental health. With the accelerating paces of work and life in modern society, the prevalence of insomnia has tended to increase.⁽¹⁾ Overuse of sedative-hypnotic drugs may cause dependency and side effects, which leads to new health concerns. The efficacy of acupuncture in the treatment of insomnia has been demonstrated,⁽²⁾ however, there are some shortcomings associated with acupuncture such as high frequency of doctors' office visiting. This study aims to test the effectiveness and safety of acupoint catgut embedding in alleviating insomnia of different Chinese medicine (CM) syndrome types by a randomized controlled trial (RCT).

METHODS

Diagnostic Criteria

The diagnostic criteria of insomnia was in

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accordance with Classification and Diagnostic Criteria of Mental Disorders in China-Third-Edition (CCMD-3).⁽³⁾ The diagnosis of 5 CM syndrome types of insomnia were established according to diagnostic standards of insomnia in Diagnosis Basis of Clinical Diseases and Standards of Cure and Improvement.⁽⁴⁾

Inclusion, Exclusion and Reject Criteria

The inclusion criteria were as follows: (1) diagnostic criteria combined with total scores of Pittsburgh Sleep Quality Index (PSQI)>7; (2) patients aged 18–70 years old; (3) without taking any other medication for insomnia treatment in last 4 weeks; (4) all patients provided written informed consents. The exclusion criteria were as follows: (1) systemic disease, such as pain, fever, or cough; (2) craniocerebral trauma or outside influence; pregnancy or nursing; (3) severe primary disease of cardiovascular, respiratory, digestive, urinary tract, or hematopoietic system; (4) severe organic brain disease; mental disease and (5) an allergic reaction to catgut. Reject criteria were as follows: (1) noncompliance with prescriptive therapy; (2) lack of information needed to evaluate the efficacy and safety of treatment.

Sample Size Calculation

According to our previous study,⁽³⁾

$P_{Max} = 0.85$, $P_{Min} = 0.40$, $\lambda = 12.56$, $n = \frac{1641.6 \lambda}{(\text{Sin}^{-1} \sqrt{P_{MAX}} - \text{Sin}^{-1} \sqrt{P_{MIN}})^2} = 27$, the drop-out rate was 10%, the sample size of each syndrome type receiving one of the three therapies should be more than 30.

Patients Grouping

Patients from 2 centers in China participated in the study, including Zhejiang Hospital of Traditional Chinese Medicine and Zhejiang Wenling First People's Hospital. A total of 510 insomnia patients were recruited from the acupuncture out-patient clinic between July 2011 and June 2013. All patients were divided into 5 CM syndrome types: Xin (Heart) and Pi (Spleen) deficiency (90 cases), yin deficiency with excess fire (120 cases), Xin and gut qi deficiency (90 cases), Wei (Stomach) disorder (90 cases) and qi and blood deficiency (120 cases). Then participants in each type were randomly assigned to 3 groups: catgut embedding group, acupuncture group, or medication group. Randomization was performed by a statistician using a computerized list with an assignment ratio of 1:1:1 and a block size of 3 (Figure 1).

Ethics Statement

This study was sanctioned by the Medical Ethics

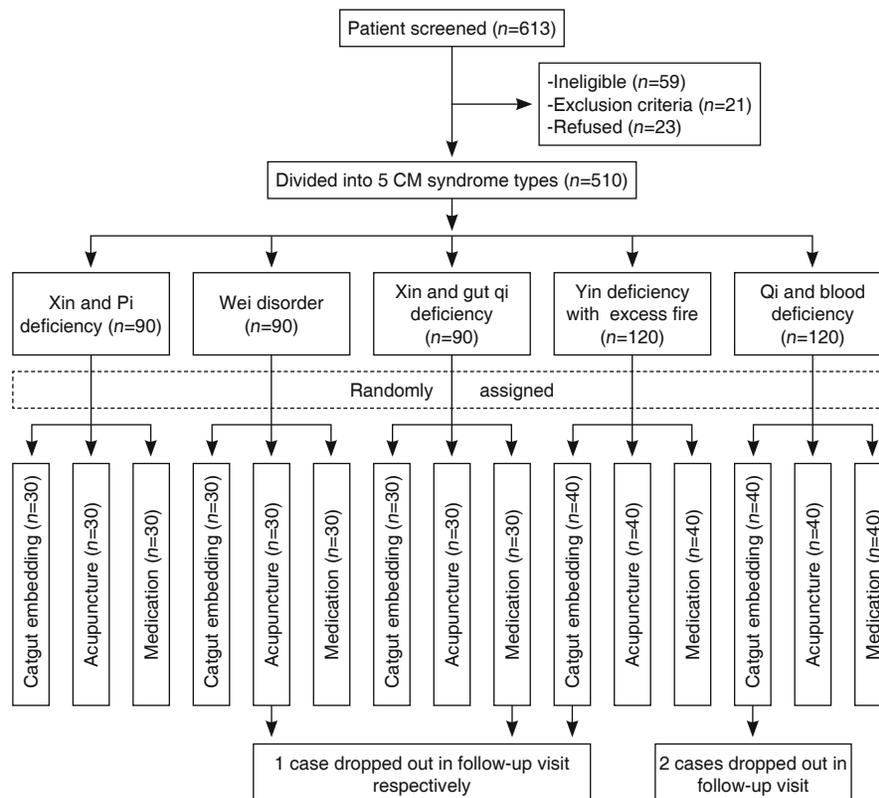


Figure 1. Flowchart of Patients Recruitment

Committee of Zhejiang Hospital of Traditional Chinese Medicine (No. 2011-K-030-01). The patients were fully informed about the therapies, and possible adverse events.

Interventions

All catgut embedding and acupuncture treatments were conducted by oriental medical doctors with more than 3 years with clinical acupuncture experience.

In the catgut embedding group, acupoints were selected according to different CM syndrome types.⁽⁵⁾ The acupoints used for the patients with Xin and Pi deficiency included Xinshu (BL 15) and Pishu (BL 20); the patients with yin deficiency with excess fire included Ganshu (BL 18), Shenshu (BL 23), and Guanyuan (CV 4). BL 15, Danshu (BL 19), and Qihai (CV 6) were used for patients with Xin and gut qi deficiency, and Weishu (BL 21), Zhongwan (CV 12), Fenglong (ST 40) were applied for patients with Wei disorder; CV 6 was used for patients with qi and blood deficiency. CV 4 was used for patients with only qi deficiency, while BL 20 and CV 4 were used for patients with only blood deficiency. In addition, Neiguan (PC 6), Zusanli (ST 36), and Sanyinjiao (SP 6) were added bilaterally to each treatments.

The catgut embedding operation was performed as follows: a 0.7 × 30 TWLB disposable hypodermic needle (Jiangsu Kangbao Medical Equipment Co. Ltd., China) was inserted with a flat head acupuncture needle (0.40 mm × 50 mm, Wujiang Jiachen Acupuncture Devices Co. Ltd., China) using a plastic clamp. After the skin was sterilized, a 1.0-cm catgut sutures (4-0', Hangzhou Huawei Medical Supplies Co. Ltd., China) was threaded into the hypodermic needle and introduced into the acupoints via hypodermic needle. After the catgut was sufficiently embedded in the acupoint and the patient felt a developing needle sensation, the hypodermic needle was withdrawn from the skin. The depth of perpendicular insertion was 1 cun for all points to avoid stimulating the surrounding nerve, except for PC 6 (0.5 cun) and SP 6 (0.5 cun). If the patient had any tingling sensation, the direction of needle insertion was adjusted. Needle insertions to BL 15, BL 20, BL 18, BL 23, BL 19, and BL 21 were performed obliquely, while the patient was in a prone position. Catgut was implanted once every 10 days for a total of 30 days.

In the acupuncture group, the acupoints selected were as same as those chosen in the catgut embedding group. Disposable needles (0.25 mm × 40 mm, Wujiang Jiachen Acupuncture Devices Co. Ltd.) were used. Each needle was rotated until the participants and the practitioner felt de-qi sensations. The needle was retained in place for 30 min. The procedure was conducted once per day, excluding weekends, over 30 days of treatment.

In the medication group, the patients took 1 mg Eurodin Tablet (Zhejiang Medicine Co., Ltd. Xinchang Pharmaceye, lot No. H33020353) orally every night for 30 days.

Outcomes Evaluation

Before and after treatment for 30 days, the outcomes including the International Unified Sleep Efficiency Value (IUSEV)⁽⁶⁾ and PSQI⁽⁷⁾ were evaluated. And a telephone follow-up was conducted at 60 days. The therapeutic effects measured at 30 and 60 days were considered short-term or sustained effects, respectively. For IUSEV, the clinical effect is stratified as follows:⁽⁸⁾ cured: disappearance of symptoms and sleep efficiency of over 75%; markedly effective: relief of symptoms and sleep efficiency of over 65%–74%; effective: amelioration of symptoms and sleep efficiency of over 55%–64%; or ineffective: unvarying symptoms and sleep efficiency of less than 40%. Sleep efficiency was calculated via formulae as follows: sleep efficiency=actual bed time/the time between going to bed and waking up × 100%. The PSQI consists of 6 components, ie. subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, and daytime dysfunction. Each component is scored from 0 to 3, and the 6 component scores are summed for a total score of 0 to 21. The higher the score, the poorer the sleep quality.

Adverse Events

Throughout the experiment, abnormal changes in vital signs or experimental factors were observed and recorded in the patients in any group, such as fainting, stuck needle or hematoma.

Statistical Analysis

Significant differences in the total effective rate were identified by Chi-squared test. Clinical grades were compared by Ridit test. One-way analysis of variance (ANOVA) for continuous data was conducted

after Kolmogorov–Smirnov test for normality. The data gathered from the patients were processed with SPSS software (version 19.0) by independent statisticians. $P < 0.05$ was considered as the significant level.

RESULTS

Baseline Characteristics

At 60 days, 5 patients were lost to follow-up, including 1 patient in the catgut embedding group with yin deficiency and excess fire, 1 in the acupuncture group with Wei disorder, 2 in the catgut embedding group with qi and blood deficiency and 1 in the medication group with Xin and gut qi deficiency (Figure 1). There were no significant differences in baseline characteristics among 3 treatment groups for the patients with each type of insomnia.

Evaluation of IUSEV Scores

The 3 treatments achieved satisfactory efficacy for each type of insomnia (Table 1). Evaluation of the IUSEV scores revealed differences between acupuncture and medication groups ($P < 0.05$ for all types), as well as the catgut embedding group and the medication group ($P < 0.01$ for all types). At 30 days, the effective rate in the catgut embedding and the acupuncture groups were significantly higher than the medication group ($P < 0.05$ or $P < 0.01$). There were no differences between the catgut embedding and the acupuncture groups in IUSEV scores ($P > 0.05$). Although some recurrence of insomnia occurred, especially in the medication groups, the sustained effective rate in the catgut embedding groups were still higher than the acupuncture groups on 60 days ($P < 0.05$ for all types). Additionally, the effects in the acupuncture and the catgut embedding groups were superior to the medication groups ($P < 0.05$ for all types).

Evaluation of PSQI Scores

Yin Deficiency with Excess Fire Type

As shown in Figure 2A, the total scores in PSQI of yin deficiency with excess fire type were significantly decreased after all 3 therapies ($P < 0.05$ or $P < 0.01$). The total scores of the catgut embedding and the acupuncture groups were both lower than the medication group (catgut embedding, 8.35 ± 2.60 ; acupuncture, 9.23 ± 2.68 ; and medication, 13.83 ± 2.31 ; $P < 0.01$ for both comparisons).

Significant between-treatment differences in efficacy were observed at 30 and 60 days ($P < 0.01$). Based on analysis of the total scores, the sustained effects in both catgut embedding and acupuncture were similar, and surpassed the medication (catgut embedding, 11.53 ± 4.14 ; acupuncture, 12.70 ± 3.89 ; and medication, 15.18 ± 2.12 ; $P < 0.01$ for both comparisons). No significant differences were found between catgut embedding and acupuncture groups in various components of PSQI scores ($P > 0.05$, Appendix 1).

Wei Disorder Type

The PSQI total score distribution for the patients with Wei disorder type of insomnia is shown in Figure 2B. The total scores of PSQI were significantly more lower after treatment among 3 groups ($P < 0.01$ for all comparisons). The outcomes were similar to patients with yin deficiency and excess fire type of insomnia. Based on analysis of the total scores, the short-term curative effects of catgut embedding and acupuncture were similar, and total scores of them were both more lower than the medication group (catgut embedding, 8.31 ± 2.65 ; acupuncture, 9.53 ± 2.76 ; and medication, 13.93 ± 2.45 ; $P < 0.01$ for both comparisons). Based on analysis of the scores in various components of PSQI, no significant differences were found between

Table 1. Effective Rate on IUSEV Scores of all Chinese Medicine Types Insomnia Patients at Each Visit [Case (%)]

Group	Time (Day)	Effective rate of IUSEV score				
		YDFE (40 cases)	WD (30 cases)	QBD (40 cases)	XGDQ (30 cases)	DXP (30 cases)
Catgut embedding	30	38 (95.0)**	29 (96.7)**	38 (95.0)**	29 (96.7)**	29 (96.7)**
	60	30 (80.0) [△] [▲]	24 (80.0) [△] [▲]	32 (80.0) [△] [▲]	25 (83.3) [△] [▲]	24 (80.0) [△] [▲]
Acupuncture	30	34 (85.0)*	25 (83.3)*	31 (82.5)*	25 (83.3)*	26 (86.7)*
	60	26 (65.0) [▲]	18 (60.0) [▲]	28 (70.0) [▲]	21 (70.0) [▲]	21 (70.0) [▲]
Medication	30	26 (65.0)	20 (66.7)	26 (65.0)	21 (70.0)	22 (73.3)
	60	15 (37.5)	9 (30.0)	16 (40.0)	8 (26.7)	12 (40.0)

Notes: YDFE: yin deficiency and fire excess; WD: Wei disorder; QBD: qi and blood deficiency; XGDQ: Xin and gut deficiency of qi; DXP: deficiency of Xin and Pi; * $P < 0.05$, ** $P < 0.01$, vs. medication group at 30 days; [△] $P < 0.05$, vs. acupuncture group at 60 days; [▲] $P < 0.05$, vs. medication group at 60 days

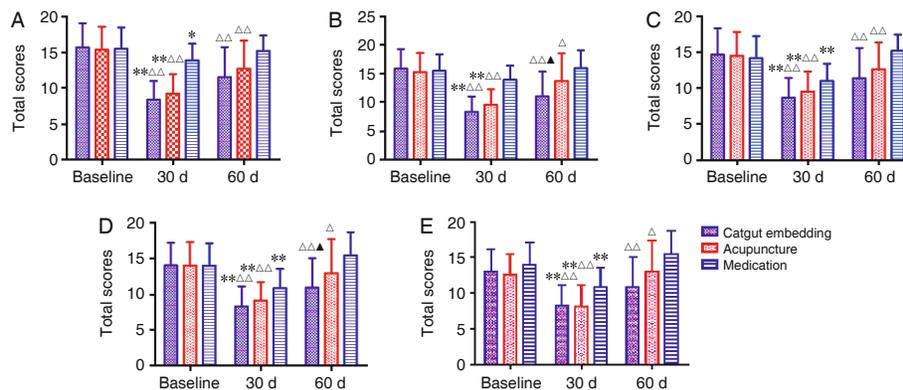


Figure 2. Comparison of PQSI Total Scores between Different Groups of Insomnia Patients in 5 Different Chinese Medicine Syndrome Types

Notes: A: yin deficiency and fire excess; B: Wei disorder; C: qi and blood deficiency; D: Xin and gut deficiency of qi; E: deficiency of xin and qi; * $P < 0.05$, ** $P < 0.01$, vs. baseline (pre-treatment); $\Delta P < 0.05$, $\Delta\Delta P < 0.01$, vs. medication group at the same time; $\blacktriangle P < 0.05$ vs. acupuncture group at the same time.

catgut embedding and acupuncture groups at 30 days ($P > 0.05$, Appendix 2).

Comparisons of outcomes at 60 days with those at 30 days indicated that recurrence occurred to some extent after 3 therapies. The patients in the catgut embedding group exhibited more stable therapeutic effects for sleep duration and daytime dysfunction than the other components. The total scores of catgut embedding group were superior to the acupuncture group ($P < 0.05$) and were also significantly better than the medication group ($P < 0.01$). Analysis of the total scores showed that less recurrence occurred in the catgut embedding group compared with the acupuncture and medication groups.

Qi and Blood Deficiency Type

The total scores and the scores for various components of PSQI in patients with qi and blood deficiency type of insomnia were assessed following treatments (Figure 2C, Appendix 3). The outcomes of patients with qi and blood deficiency type of insomnia were similar to yin deficiency and excess fire type of insomnia at both 30 and 60 days.

Xin and Gut Qi Deficiency Type

The PSQI score distribution for the patients with Xin and gut qi deficiency type of insomnia is shown in Figure 2D and Appendix 4. The outcomes of these patients were similar to patients with Wei disorder type of insomnia at both 30 and 60 days.

Xin and Pi Deficiency Type

The PSQI score distribution for the patients with Xin and Pi deficiency type of insomnia is shown in

Figure 2E and Appendix 5. The outcomes of these patients were similar to those of the patients with Wei disorder type of insomnia at both 30 and 60 days. However, the stability of the therapeutic effects in these patients was less than patients with Xin and gut qi deficiency and Wei disorder types of insomnia.

Adverse Events

Throughout the experiment, no abnormal changes in vital signs or experimental factors were observed in any group. There were 2 cases of fainting during acupuncture in the acupuncture group. These incidents were resolved after expectant treatment, and no adverse reactions, such as stuck needle or hematoma were reported. There were 2 instances of swelling at SP 6 in the catgut embedding group. The swelling disappeared after several days without any treatment. Twelve patients in the medication group experienced adverse reactions, such as thirst and weak, and the discomfort disappeared after cessation.

DISCUSSION

Currently, drugs used to treat insomnia include benzodiazepines, non-benzodiazepines, melatonin and antidepressants. These drugs commonly inhibit the central nervous system, leading to dependence, withdrawal symptoms, and a hangover phenomenon.⁽⁹⁻¹¹⁾ Numerous studies showed that acupuncture had an obvious effect on improved insomnia.^(12,13) However, classically, acupuncture will be carry out day by day or 2 to 3 times a week, which is inappropriate to the fast-paced lifestyle of modern people.

Acupoint catgut embedding is one kind of

technique of acupuncture, which has been used for thousands of years in CM for treatment of obesity,⁽¹⁴⁾ perimenopausal syndrome,⁽¹⁵⁾ irritable bowel syndrome,⁽¹⁶⁾ hyperlipemia,⁽¹⁷⁾ sciatica,⁽¹⁸⁾ ulcerative colitis,⁽¹⁹⁾ facial paralysis,⁽²⁰⁾ trigeminal neuralgia⁽²¹⁾ and so on. Catgut is a type of cord that is made from the natural fibers of sheep or goat intestine. It is embedded in the specific acupoints and acupoints are gently and continuously stimulated for 7–14 days until the catgut is absorbed by the body. Different from the acupuncture, which will be carried out day by day or 2 to 3 times a week, acupoint catgut embedding can be implemented 2 times a week or once every 2 weeks. In recent years, the use of acupoint catgut embedding for insomnia theraon has been occasionally reported,⁽²²⁻²⁵⁾ and these initial reports have shown that this therapy was efficacious. However, clinical researches based on the differentiation of syndromes have not been previously reported. Based on the differentiation of syndrome types and utilized a large sample for clinical observation, we evaluated the results of acupoint catgut embedding therapy across all insomnia types using effective combinations of acupoints, and strict operational specifications.

The results showed that all 3 therapies reduced insomnia in the patients with all CM syndrome types of insomnia. Acupoint catgut embedding and acupuncture were more effective than medication in alleviating insomnia including improvement on PSQI and IUSEV scores. Meanwhile, acupoint catgut embedding and acupuncture were equally effective for the patients with Xin and Pi deficiency, yin deficiency and excess fire, as well as blood and qi deficiency types of insomnia. In the insomnia patients with Wei disorder and Xin and gut deficiency types, acupoint catgut embedding and acupuncture were also similarly effective over the short-term, but the sustained effects of catgut embedding were superior to acupuncture in the patients with Wei disorder and Xin and gut qi deficiency types.

The efficacy and timing of the therapeutic effects of catgut embedding vary across different types of insomnia. Generally, catgut embedding was found to be superior to acupuncture. Based on analysis of total scores and various components scores of PSQI, insomnia reoccurred to some extent in all treatment groups. Overall, the catgut embedding and acupuncture group exhibited almost the same results with respect to the extent of insomnia recurrence. The

symptom relapse rates of these 2 groups were less than the medication group, especially for patients who received catgut embedding. This result may have occurred because the catgut that was implanted at the acupoints consists of heterogeneous proteins softened, resolved, and liquefied in the body before absorbed, and this process results in complex effects.⁽²⁶⁾ The physiological and biochemical reactions promoted by catgut embedding prolong the effects of acupuncture, enhance the therapeutic effects of acupoints, facilitate the body's metabolic processes, increase immunity, promote circulation and regulate visceral functions, and all of these effects are the result of benign induction. This stimulus is also transferred to the cerebral cortex via spinal dorsal horn and enhances the interference, suppression, and replacement of excitation from the center to the afferent nerve due to the pathological stimulus. Further, insomnia symptoms have shown to be relieved by the stimulus.^(27,28) However, the underlying mechanisms need to be elucidated in further animal and biochemical studies.

The Back-shu acupoints used in this study, CV 6 and CV 4, which were needled along with PC 6, ST 36, and SP 6, regulate yin and yang and Zangfu to calm the nerves. Catgut embedding therapy had a sustained effect on the acupoints with implanted catgut. Although the therapeutic effects of acupuncture have been clearly demonstrated, the time required for needle retention and stimulation is limiting. Patients need a longer time to receive acupuncture treatment; therefore, acupoint catgut embedding may be more convenient and effective than acupuncture. Although the medication used took effect quickly, the patients relapsed after it was withdrawn. Long-term usage of medication produces side effects, induces drug resistance, and leads to dependency. Therefore, acupoint catgut embedding for the treatment of insomnia not only has a significant therapeutic effect and high safety, it is easy and simple to administer and requires much less time than traditional acupuncture. This study provides reliable clinical evidence for popularization of the application of acupoint catgut embedding therapy for the treatment of insomnia.

Conflict of Interest

All the authors have no any possible conflicts of interest.

Author Contributions

Xu F and Xuan LH designed the research; Zhou HJ and Zheng ZJ performed the research; Bi Y and Wu X contributed

the new reagents and analytic tools; Chen FY wrote the paper.

Electronic Supplementary Material: Supplementary materials (Appendixes) are available in the online version of this article at DOI: <https://doi.org/10.1007/s11655-018-2770-3>.

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