Randomized controlled study of Tuina in the treatment of insomnia: A Meta-analysis

Shao-Wei Yi, Xiang-Wen Meng, Si-Jia Liu, An-Chen Qiu, Jun-Fei Zhu, and Yi-Ding Fan

Abstract—Objective: To find out the clinical randomized controlled trials of Tuina in the treatment of insomnia, and to incorporate it into the research results of this subject for meta-analysis. While comparing the clinical effects, we can compare the literature and research related to Tuina treatment of insomnia and other treatments of insomnia, and summarize its characteristics and advantages. Methods: Relevant searches were performed on CNKI, VIP, CBMDisc, WanFang, Embase, Cochrance, PubMed, etc. Find out the effects of related massage therapy on the treatment of insomnia. Clinical Randomized Controlled Medical Research Clinical Trials (RCT). According to the inclusion criteria and exclusion criteria, the literature was screened, and then the included literature was extracted as data after screening. RevMan5.3 software was used to integrate and analyze the data. Results: 19 randomized controlled trials that met the criteria were classified as studies, with a total of 1625 patients. The results of Meta-analysis showed that the total effective rate of massage for insomnia (OR = 4.20, 95% CI: 3.00-5.88, \( P < 0.00001 \)), suggesting that the clinical efficacy of Tuina for insomnia is better than traditional Chinese medicine, western medicine, ear point treatment and acupuncture treatment. The difference in experimental effects was statistically significant, and no adverse reactions were found. Conclusion: The use of Tuina methods combined with different types of massage treatments to treat insomnia has a good therapeutic effect and no serious adverse events occurred. However, due to the limitations of this study, more large-sample, multi-center, in-depth clinical studies are needed to provide more reliable evidence-based evidence for the clinic, in order to better serve the development of guidelines.

Key words—Tuina, Insomnia, Randomized controlled trials, Meta-analysis

INTRODUCTION

Primary insomnia (primary insomnia, PI), also known as Disorders of initiating & maintaining sleep (DIMS), is a common disease in daily life. Patients often show that it is very difficult to enter sleep, easy to wake up during sleep, sleep is not lasting, and sleep quality is poor [1]. The disease occurs alone, but also often accompanied by symptoms such as headache, forgetfulness, and dizziness. At present, the rejuvenation of insomnia symptoms has become a hot topic. Insufficient sleep and decreased alertness after waking caused by poor sleep quality can cause major public safety issues. According to statistics from the World Health Organization (WHO), the direct and indirect economic losses caused by sleep-wake disorders in the United States are approximately $100 billion per year [2].

In terms of treatment, Chinese medicine and Western medicine have their own opinions and corresponding unique treatment systems and methods. The use of benzodiazepines, barbiturates and non-benzodiazepines is the current targeted treatment plan for insomnia. However, long-term use of these drugs will produce unavoidable adverse reactions. Patients will have cravings and dependence on these drugs that cannot be stopped, and the addictive hazards of this drug are greater [3]. Compared with Western medicine treatment programs, many Chinese medicine treatment methods, including Tuina, are more conservative and have fewer side effects [4]. In addition, its advantages include: the clinical effect of massage therapy is obvious, the operation method is simple, safe and reliable, and the treatment place is convenient. In recent years, the treatment of insomnia by traditional Chinese medicine has been accepted by the wider masses. This study adopts an evidence-based research model, evaluates the efficacy of Tuina in the treatment of insomnia, and clarifies the effectiveness and safety of combining different massage techniques. Prove the actual clinical effect of Tuina therapy from the perspective of visual data.

MATERIALS AND METHODS

Inclusion criteria

Types of research Clinical randomized controlled trials (RCTs) that are collected and published in authoritative databases and have a high correlation with Tuina in the treatment of insomnia.

Research objects To extract patients with insomnia diagnosed by the typical restriction requirements of domestic and internationally recognized diagnosis, and no non-essential restrictions on the baseline data such as the age and gender of the patients. (“Tuina” OR “Chinese massage”) AND (“insomnia” OR “sleep disease” OR “sleep disorders” OR “agypnia”) AND “effect” AND (“Randomized controlled trial” OR “RCT”) as the English search term. The Chinese search terms were (“tuina” OR “anmo”) AND (“insomnia” OR “sleep disease” OR “difficult to sleep” OR “sleep disorders”) AND “effect” AND “randomized controlled trial”.

Intervention measures Experimental group: the intervention measures are simple tuina or tuina combined with conventional treatment (Western medicine treatment, traditional Chinese medicine (TCM) treatment or supportive treatment, Acupuncture or supportive treatment), acupuncture is not limited, such as single acupuncture, auricular therapy, scalp acupuncture and so on. The standardized acupuncture point locations had been selected by massage in previous research suggesting a therapeutic effect such as Baihui (GV20), Shenmen (HT7), Fengchi...
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(GB20), Shenshu (BL23), Yongquan (KI11), Zusanli (ST36), Taichong (LR3), Fenglong (ST40), and Anmian points, etc. Among them, the Tuina was conducted 5-7 times a week or once every other day last 1-2 months. Do not limit the single stimulation amount caused by the length of the massage operation.

Control group: the control group received routine care and health education or conventional medicine or acupuncture if necessary.

Outcome indicators The total effective rate and the Pittsburgh Sleep Quality Index (PSQI) measured total score.

Exclusion criteria
Excluding non-random/semi-random/random methods, Tuina therapy as a control or auxiliary, non-Tuina therapy (acupuncture, needle knife, pointer type) related research. As well as retrospective research, dissertations, conference reports, repeated research, missing reports, retracted articles, research in special locations and time periods.

Data extraction
The extracted information is obtained from the included literature, mainly including: statistics, numbers, titles, authors, group information, research institutions, publication management institutions subject information, outcome indicators, adverse reactions, intervention measures information, random allocation methods, the concealment method used in the distribution, the blinding method, the integrity of the result data, etc.

Data analysis
The method is to use the software RevMan5.3 to process and analyze the extracted data. When calculating the effect size, two categorical variables are used, and the standardized mean difference (SMD) is selected as the continuous variable data to express the size of the effect size. And use the 95% confidence interval (95% CI) as the size of the effect to express.

First, perform a heterogeneity test on all the included literature. According to the results of the heterogeneity check, the $P$ value and $I^2$ statistics are used to reflect the heterogeneity, and it is determined whether a fixed effect model or a random effect model is needed. If $P > 0.1$ and $I^2 \leq 50\%$, we can judge that multiple independent studies are not statistically heterogeneous, so a fixed-effects model can be applied. If $P \leq 0.1$ and $I^2 > 50\%$, we can judge that there is a statistical heterogeneity in multiple independent research processes. Therefore, we need to analyze the reasons for this heterogeneity, and then analyze the sensitivity. The final results of the meta-analysis are displayed in a forest plot, and a funnel plot is used to analyze whether there is a publication bias.

RESULTS

Literature screening
The retrieval of this article is mainly based on the established retrieval strategy mentioned above, and a total of 70 documents were retrieved and used. According to the established retrieval methods and strategies, a total of 70 documents closely related to this research have been retrieved from various authoritative databases (0 supplementary document from other sources). After that, all 3 re-published documents were removed from the authoritative databases, and 38 articles were removed from the database after carefully reading the titles and abstracts. After restrictive screening based on the inclusion criteria and exclusion criteria, the study finally successfully included 19 RCTs [7-25], as shown in Figure 1.
Table 1 General information of the literatures

<table>
<thead>
<tr>
<th>Literature</th>
<th>Number of treatment/control groups</th>
<th>Diagnostic criteria</th>
<th>Intervention of treatment/control groups</th>
<th>Outcome indicator</th>
<th>Main treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Li 2016 [7]</td>
<td>35/35</td>
<td>CCMD-3</td>
<td>Conical stone needle/Acupuncture</td>
<td>PSQI</td>
<td>Rolling, Kneading, Clapping</td>
</tr>
<tr>
<td>Tang 2015 [8]</td>
<td>38/38</td>
<td>CCMD-3</td>
<td>Pivotal massage/Estazolam</td>
<td>Total effective rate, PSQI</td>
<td>Sweeping, Pressing, Kneading</td>
</tr>
<tr>
<td>Zhang 2020 [10]</td>
<td>30/30</td>
<td>CCMD-3</td>
<td>Acupoint massage/Estazolam</td>
<td>Clinical efficacy, PSQI</td>
<td>One-finger zen pushing, Kneading, Grasping</td>
</tr>
<tr>
<td>Xu 2019 [11]</td>
<td>30/30</td>
<td>-</td>
<td>Acupoint massage/Acupuncture points</td>
<td>Clinical efficacy, Total effective rate</td>
<td>Pressing, Clicking</td>
</tr>
<tr>
<td>Sun 2020 [12]</td>
<td>49/49</td>
<td>CCMD-3</td>
<td>Moxibustion, Acupoint massage/Conventional treatment</td>
<td>Clinical efficacy,</td>
<td>Pressing, Kneading</td>
</tr>
<tr>
<td>Li 2019 [13]</td>
<td>74/74</td>
<td>CCMD-3</td>
<td>Massage/Estazolam</td>
<td>Clinical efficacy, Total effective rate</td>
<td>One-finger zen pushing, Sweeping, Pressing, Kneading</td>
</tr>
<tr>
<td>Li 2019 [14]</td>
<td>68/68</td>
<td>ICSD-3</td>
<td>Foot bath acupoint massage/Estazolam</td>
<td>Clinical efficacy, Total effective rate</td>
<td>One-finger zen pushing</td>
</tr>
<tr>
<td>Gao 2018 [15]</td>
<td>18/18</td>
<td>CCMD-3</td>
<td>Traditional massage with midnight-noon and ebb-flow doctrine/Traditional massage</td>
<td>Clinical efficacy, Total effective rate, PSQI</td>
<td>One-finger zen pushing, Sweeping</td>
</tr>
<tr>
<td>Dian 2020 [16]</td>
<td>50/50</td>
<td>CCMD-3, TCIM</td>
<td>Head gossip massage with TCM/Massage with traditional Chinese medicine</td>
<td>Clinical efficacy, Total effective rate, PSQI</td>
<td>One-finger zen pushing, Sweeping, Pressing, Kneading</td>
</tr>
<tr>
<td>Pan 2018 [17]</td>
<td>30/30</td>
<td>DSM-5, CCMD-3</td>
<td>Tuina of induction of Yang into Yin/Estazolam</td>
<td>Clinical efficacy, Total effective rate, PSQI</td>
<td>Pressing, Kneading, Rolling, Pushing</td>
</tr>
<tr>
<td>Ling 2017 [18]</td>
<td>30/30</td>
<td>CCMD-3</td>
<td>Massage with TCM/Conventional treatment</td>
<td>Clinical efficacy, Total effective rate, PSQI</td>
<td>Scrubbing, Pressing, Kneading</td>
</tr>
<tr>
<td>Luo 2020 [19]</td>
<td>66/66</td>
<td>CCMD-3</td>
<td>Foot bath with head facial massage/Conventional treatment</td>
<td>Clinical efficacy, Total effective rate</td>
<td>Pushing, Pressing, Kneading</td>
</tr>
<tr>
<td>Zhang 2019 [20]</td>
<td>30/30</td>
<td>CCMD-3</td>
<td>Vibriing abdominal ring kneading/Renshen Guipi Pills</td>
<td>Clinical efficacy, Total effective rate, PSQI</td>
<td>Vibriing abdominal ring kneading</td>
</tr>
<tr>
<td>Liang 2020 [21]</td>
<td>30/30</td>
<td>CCMD-3</td>
<td>Auricular point sticking of midnight-noon and ebb-flow doctrine/Auricular point sticking and Conventional treatment</td>
<td>Clinical efficacy, PSQI</td>
<td>Pressing</td>
</tr>
<tr>
<td>Hu 2017 [22]</td>
<td>32/32</td>
<td>-</td>
<td>Acupuncture with TCM and massage/Acupuncture</td>
<td>Clinical efficacy, PSQI</td>
<td>One-finger zen pushing</td>
</tr>
<tr>
<td>Xia 2017 [23]</td>
<td>41/41</td>
<td>-</td>
<td>Massage with moxibustion/Tuina</td>
<td>Clinical efficacy, Total effective rate</td>
<td>Rolling, Clicking, Pressing</td>
</tr>
<tr>
<td>Sun 2020 [25]</td>
<td>50/50</td>
<td>-</td>
<td>Head massage with abdominal Tuina/Head massage</td>
<td>Clinical efficacy, Total effective rate</td>
<td>One-finger zen pushing, Kneading, Clicking</td>
</tr>
</tbody>
</table>


Basic characteristics of the literatures

The basic performance characteristics of the literature as included in the research have been controlled and measured. The 19 RCTs are all simplified Chinese documents (Table 1).

Research objects A total of 1625 patients were enrolled, 812 in the treatment group and 813 in the control group. Western medicine mostly uses the Chinese Classification and Diagnostic Criteria of Mental Disorders (CCMD) as the reference standard, and the reference standards of traditional Chinese medicine are diverse.

Intervention Treatment options selected by each treatment group: 11 studies chose pure Tuina therapy; 3 studies chose Tuina therapy + combined acupuncture therapy. The treatment plan selected by each group was compared: 9 plans used oral western medicine; 2 studies used oral Chinese patent medicine Guipi Pills; 1 study used ear acupoint stickers; 2 studies used acupuncture.

Outcome indicators 19 studies used total effective rate and total PSQI score as outcome indicators.

Result analysis Efficacy The 19 groups of studies all use the total effective rate as the main outcome evaluation index. Among them, there were 812 patients in the treatment group and 813 patients in the control group. There was no statistical heterogeneity between treatment studies in each group ($P = 0.31, I^2 = 12\%$), so a fixed-effect model should be used for Meta-analysis. The results can be seen that the
comparison between the two groups of patients after treatment has a certain statistical significance (OR = 4.20, 95% CI: 3.00-5.88, P < 0.00001, Figure 2).

From the results of the meta-analysis of the total effective rate studied in this article, it can also be fully demonstrated that the actual clinical application effect of Tuina therapy for insomnia is higher than that of other insomnia treatment methods, and the safety of Tuina therapy for insomnia is relatively high.

**Publication bias** Through the total effective rate data of massage treatment for insomnia in each included research, explore the differences and publication bias between the various studies. Take the OR value of each study as an abscissa, SE (Log (OR)) as an ordinate, and draw a funnel chart for analysis. The results show that the distribution of the scattered points of the graph shown in the funnel chart is basically symmetrical, indicating that the publication bias of this study is small when it is included in the literature (Figure 3).

**DISCUSSION**

Patients with insomnia often report symptoms such as dizziness, headache, palpitations, and forgetfulness. The classification can be roughly divided into the following types: 1. Heart-spleen deficiency 2. Asthenic Yin causing excessive pyrexia 3. Phlegm-heat internal disturbance 4. Liver stagnation transforming fire 5. Gastric disorders and some other syndrome types. And their basic pathogenesis is generally: Overabundance of Yang with deficiency of Yin causing incoordination between Yin and Yang. The essence of the disease is the imbalance of Yin and Yang. Tuina can be applied to the acupoints and key parts of the whole body to balance the Yin and Yang and cure the disease.

The cause of insomnia is also related to inner irritability and emotional restlessness. It can be seen from Table 1 that the one-finger Zen push method has the most use times among the swing techniques, and the squeeze techniques such as pressing, tapping, kneading, etc. are selected and used the most times. In general, the most frequent use is the light and soft type of technique.

A total of 19 randomized trials were included in this analysis, all of which are clinical randomized controlled trials of clinical manipulation for the treatment of insomnia. In these clinical trials, the main options for massage treatment of insomnia are massage operations such as kneading, tapping, pressing and other swing operations and squeezing massage operations. The method of selecting acupoints is mainly based on proximal acupoint selection and distal matching of acupoints, mainly from the governor channel, bladder meridian, kidney meridian, spleen meridian, gallbladder meridian and other meridians. Among them, Anmian is the unique point outside the meridian, and the selected acupoints generally include Baihui (GV20), Fengchi (GB20), Shenshu (BL16), Shenmen (HT7), Yongquan (K11), Sanyinjiao (SP6), Zhaohai (K16) and so on. According to different clinical manifestations, the acupoints will be selected after the syndromes are gradually identified. Insomnia patients diagnosed with heart- spleen deficiency can choose Neiguan (PC6), Xinshu (BL15), and Pishu (BL17). Taixi (K13) and Sanyinjiao (SP6) should be used for patients
with Asthenic Yin causing excessive pyrexia. The patient has phlegm (Phlegm-heat internal disturbance), combined with the treatment of Fenglong (ST40) and Neiting (ST44). Patients with liver stagnation transforming fire use Taichong (LR3), Sanyinjiao (SP6), and Xiaixi (GB43) points. Patients diagnosed with gastric disorders should choose Zhongwan (CV12), Zusanli (ST36), and Taichong (LR3) [7-25]. Pang Jun et al. [9] used the method of massage along the meridian of the gall bladder meridian of foot-Shaoyang, the meridian-qì communication between the Shaoyang meridian and the five internal organs can regulate the blood and regulate the benefits of yin and yang, and has a good effect on improving insomnia. Among the more distinctive techniques are midnight-noon and ebb-flow doctrine massage and head gossip techniques. Among them, the sweeping method and the kneading method are the most representative. The head gossip massage method selects acupuncture points based on the correspondence between ancient gossip and acupuncture points. According to the position distribution of the Bagua diagram, combined with the principle of the distribution of yin and yang, it is combined with the massage treatment of the head and face. Midnight-noon and ebb-flow doctrine massage is a treatment method that combines the special method of midnight-noon and ebb-flow doctrine. The main theory is to treat at different times of the day. The primary method of this therapy is the point method. According to the active level of menstrual Qì at different times, massage points are selected, and the effect of massage is better when the menstrual Qi is active. Gao Peiyou [15] et al. compared the traditional massage therapy for insomnia with midnight-noon and ebb-flow doctrine massage, and the results showed that the cure rate of midnight-noon and ebb-flow doctrine is significant and the advantages are obvious. Traditional Chinese medicine teaches that Yang enters Yin, and the secret of Yin and Yang helps people sleep well. There is even the traditional saying that “the stomach is upset and you sleep restless”, using methods such as point method and pinch method. Sun Peibao et al. used abdominal massage, which can invigorate the spleen and calm the nerves, dredge the Qi and Blood, regulate the vitality, make the Yin and Yang unite, and make the “stomach harmony”. It can also produce sedative and hypnotic effects, mainly using one-finger Zen push, point, and kneading methods. Therefore, dialectical acupoint selection for different types of insomnia combined with different but similar massage techniques can have a better curative effect. The massage technique is not only soft and irritating, but also economical and convenient. It is highly accepted by people and is worthy of further research, development and application.

The flow of Qi and Blood is closely related to the smoothness of the meridians. If the meridians are connected, Qi and Blood can be circulated to the whole body in a timely manner, exerting their nourishment and warming effect. If the meridians are obstructed, the Qi and Blood are not smooth, and if many places are difficult to reach, the Qi and Blood will not work, and the internal organs will be damaged. Traditional Chinese medicine believes that the viscera is essentially a core functional organ that transforms vital energy and blood, adjusts the meridians, and maintains normal life activities. The core function of Tuina is to regulate the viscera. If the viscera function is out of balance, the pathological changes will be reflected through the meridians, showing different symptoms such as lack of energy and emotional disorders. Therefore, in general, massage therapy for insomnia, the general is to invigorate the spleen and soothe the nerves [25], mainly with gentle manipulation. Based on the basic theories of modern Chinese medicine to determine the deficiency and empirical evidence. Properly pushing or kneading can ventilate and dredge the collaterals, regulate Qi and Blood and internal organs, promote local blood circulation, improve local tissue oxygen and blood supply capabilities, relieve tension and fatigue, and inhibit excessive nerve excitement. It can also increase the immunity and produce a calming and hypnotic effect. People with frequent insomnia can choose Baihui (GV20), Taiyang (EX-HN5), Neiguan (PC6), Shenmen (HT7), Sanyinjiao (SP6), Yongquan (K11) and other degrees for treatment. Different acupuncture points have different functions. The individual action of specific acupoints has special effects on certain syndromes of diseases. For example, Anmian, as a peculiar point outside the meridian, has a good effect on insomnia and soothes the nerves, and the brisk and soft technique itself has the effect of relaxing and mentally stabilizing. This may be related to the release of neurotransmitter (5-hydroxytryptamine) [26]. With the formation of a consensus on the concept system of Evidence-based Medicine (EBM) [27], the evidence-based thinking model based on theory and evidence-based standards will be further closely integrated with the thinking of the selection of massage techniques to form a unique model, which will further improve the quality of clinical reports.

Since the 21st century, the clinical research of Tuina has further expanded to the fields of chronic diseases, visceral diseases, sub-health and health care. Due to software functions and export limitations, this study only conducts co-occurrence analysis based on the basic published information of each document, and lacks in-depth discussion of specific content and cross-citing mass spectrometry analysis of cited network documents. There is a small probability that the included literature is not found, the lack of supplements from other literature databases, and the lack of foreign literature mining and comparative studies, leading to the occurrence of missed negative results. Tuina, acupuncture and other methods of treatment, depending on the choice of different prescriptions, the frequency of treatment in each study is also different, the different order of the combination therapy will also have an impact on the results. Subjective situations may also appear in the literature screening. At the same time, due to the large age span, there may be defects such as differences in export formats, overlap of names with institutions, and irregular vocabulary expression. Therefore, this study still has certain limitations.

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