Systematic Review

Tuina for primary insomnia: a meta-analysis

推拿治疗原发性失眠的Meta分析

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Abstract

Objective: To systematically evaluate the therapeutic efficacy of tuina therapy for primary insomnia.

Methods: Nine Chinese and English databases were searched from the inception to May 2017 to identify randomized controlled trials (RCTs) studying tuina therapy for insomnia. The enrolled articles were all RCTs with tuina as the monotherapy or major therapy in the experiment group, with clear diagnostic criteria for primary insomnia well recognized worldwide or in China, and Pittsburgh sleep quality index (PSQI) as one of the outcome measures. Two researchers evaluated the risk of bias and quality of the enrolled studies by following Cochrane Handbook version 5.1.0. The meta-analysis was performed by using RevMan version 5.3.

Results: Eleven studies were included with a total of 1 076 participants. The Western medication adopted in the control groups were benzodiazepine receptor agonists. The studies were all assessed as high risk of bias for blinding since blinding method was unable to be performed due to the specificity of tuina therapy; no study reported the support of fund or potential interest conflict, so they were all rated unclear for selective reporting. The meta-analysis showed that compared with other traditional Chinese medicine therapies, tuina worked more effectively in reducing the PSQI score (MD=-4.11<0, 95% confidence interval (CI) -6.01 to -2.22, P<0.0001); compared with oral administration of Western medication, tuina showed more significant efficacy in reducing the PSQI score (MD=-3.42<0, 95%CI -5.19 to -1.66, P<0.0001). Subgroup analysis showed that head tuina alone showed no significant difference compared with oral administration of Western medication regarding the change of PSQI score (MD=-4.19<0, 95%CI -8.87 to 0.50, P>0.05); a combination of head and back tuina could more effectively reduce the PSQI score compared with oral administration of Western medication (MD=-2.08<0, 95%CI -3.09 to -1.06, P<0.0001).

Conclusion: This research shows that tuina can produce more significant efficacy in treating primary insomnia compared with other traditional Chinese medicine therapies and oral administration of Western medication, especially the combination of head and back tuina.

Keywords: Tuina; Massage; Insomnia; Acupoint, Head; Pittsburgh Sleep Quality Index; Randomized Controlled Trial; Systematic Review; Meta-analysis

【摘要】目的: 系统评价推拿疗法治疗原发性失眠的疗效。方法: 共检索9个中英文数据库中用推拿疗法治疗失眠的随机对照试验,检索时间为从数据库建立起至2017年5月。纳入文献均为随机对照试验、试验组单独使用推拿或以推拿为主、有明确的国际或国内公认的原发性失眠诊断标准、结局指标中有匹兹堡睡眠质量指数(PSQI)。由两名研究者按照Cochrane Handbook 5.1.0对每个纳入研究进行偏倚风险和质量评估,并使用RevMan 5.3软件进行Meta分析。结果: 共纳入11项研究,1076例患者。对照组中采用的西药均为苯二氮革受体激动剂。偏倚性分析显示,因推拿疗法的特殊性,盲法无法实现,所以盲法风险均为高风险,选择性报告的偏倚性分析因未提供足够的信息而不清楚,所有文献均未报告获得了资金支持或有潜在的利益冲突。对纳入文献进行meta分析显示,推拿疗法与其他中医疗法比较,合并MD=-4.11<0,95%CI [-6.01,-2.22],P<0.0001,提示推拿疗法能更有效地降低患者PSQI评分。按推拿部位不同进行亚组分析显示,单纯头部推拿与口服西药比较,PSQI评分差异f无统计学意义,合并MD=-4.19<0,95%CI[-8.87,0.50],P>0.05,头部结合背部推拿与口服西药比较,合并MD=-2.08

【关键词】推拿;按摩;失眠症;穴位,头部;匹兹堡睡眠质量指数;随机对照试验;系统评价;Meta分析

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Insomnia is a very common disease mainly characterized by difficulty initiating or maintaining sleep or frequent waking up^[1-3]. It not only affects the daily function and quality of life^[4], but also closely relates to chronic mental disorders^[5-7]. There are many treatments available to treat insomnia, different methods for different groups of people, while benzodiazepine receptor agonists are most commonly used. However, there is a high risk of relapse after termination of this type of drug, not to mention that it may cause many side effects^[8-9]. Besides oral medications, non-drug therapies are also used to treat insomnia and generally considered safer and suitable for more people^[10] despite its slow action and indefinite efficacy. Different insomnia patients may have completely different requirements for treatment, and doctors should try different ways to treat it. Tuina is a traditional Chinese medicine (TCM) therapy. It is estimated that one of every four insomnia patients has used this therapy^[11-12]. Tuina has a very long history not only in China but also in countries like India where similar therapies have existed for a long time^[13]. Tuina has many advantages in treating insomnia, including high safety, sufficient number of tuina practitioners and high accessibility^[14-15]. Modern medical studies have verified the effect of tuina therapy in improving cardiovascular function, endocrine system, blood circulation, tension and pain [16-19]. The main action mechanism of tuina therapy is to produce neural stimulation and send it to autonomic nervous system and central nervous system to promote the release of neurotransmitters through touching, pressing and thermal effect^[20]. Recent studies have proved that tuina can mitigate insomnia in peri-menopausal women and the elderly [21-22]. Despite many literatures that provide evidence for the efficacy of tuina for insomnia, the overall efficacy has not been systematically evaluated. Therefore, we conducted this research to systematically review the therapeutic efficacy of tuina for insomnia.

1 Materials and Methods

1.1 Retrieve of study

Nine Chinese and English databases were searched from the inception to May 2017.

The English databases included: PubMed, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Central Register of Controlled Trials (CENTRAL) and the Allied and Complementary Medicine (AMED).

The Chinese databases included: Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), Chongqing VIP Database (CQVIP) and Wanfang Academic Journal Full-text Database (Wanfang).

Only randomized controlled trials (RCTs) were identified.

#1 Key words of disease name: including 'Shi Mian', 'Bu Mei', 'Shao Mian' and 'Shui Mian Zhang Ai' for Chinese databases; 'insomnia', 'sleeplessness' and 'sleep disorders' for English databases.

#2 Key words of interventions: including 'Tui Na', 'An Mo' and 'Shou Fa' for Chinese databases; 'tuina', 'manipulation' and 'massage' for English databases.

Search strategy: #1 AND #2. To avoid missed retrieval, 'randomized controlled trial' was not used as the research term but confirmed later by review of abstract and full text.

1.2 Inclusion criteria

1.2.1 Diagnostic criteria

Insomnia was the major complaint of the participants and the case conformed to the following diagnostic criteria: *Diagnostic and Statistical Manual of Mental Disorders* (DSM)^[4,23], *International Classification of Sleep Disorders* (ICSD)^[24], *International Classification of Diseases* (ICD)^[25], *Chinese Classification and Diagnosis of Mental Diseases* (CCMD, including CCMD-3 and CCMD-4)^[26-27], insomnia accompanied by other diseases and secondary insomnia were excluded.

1.2.2 Interventions and controls

acupuncture-moxibustion Tuina. and oral administration of Chinese medication are several major TCM interventions with totally different action mechanisms. Moreover, there are already systematic reviews of acupuncture-moxibustion and oral Chinese medication for primary insomnia. Hence, trials studying tuina plus acupuncture-moxibustion and tuina plus oral Chinese medication were excluded. Trials studying tuina as the major treatment plus other assistant TCM methods such as foot bath and auricular point sticking were included. The controls could be conventional modern medicine therapies, e.g. benzodiazepine receptor agonists, or other TCM methods for insomnia including acupuncture-moxibustion and medication, but controls containing tuina therapy were excluded.

1.2.3 Study design

Only RCTs were enrolled while the detailed method was not limited; regardless of blinding or concealing; written in Chinese or English.

1.2.4 Outcome measure

Pittsburgh sleep quality index (PSQI) was used as the main outcome measure since it is one of the most popular and well-recognized insomnia measures [28-29].

1.3 Data extraction and study quality assessment

Two authors independently extracted data (Cao Miao and Deng Fang-fang were in charge of English articles; Cao Miao and Yuan Qun were in charge of Chinese articles). The extracted data included: where the trial was conducted, diagnostic criteria, disease duration,

sample size, age, gender, interventions and controls, treatment duration, follow-up, outcome measures and adverse reactions. The methodological quality was assessed using Cochrane Collaboration's risk of bias tool (Cochrane Handbook 5.1.0) from nine aspects: random sequence generation; allocation concealment; blinding method; incomplete outcome data; selective reporting; other bias (baseline, fund support or potential conflict of interest).

1.4 Statistical analysis

The data were analyzed using RevMan version 5.3. We examined heterogeneity among the studies. A fixed effects model was used when P>0.01 and $I^2<50\%$ which indicated insignificant heterogeneity; when $P\le0.01$ and $I^2\ge50\%$ which indicated significant heterogeneity, and the heterogeneity was unexplainable by clinical or methodological heterogeneity, a random effects model would be used. Enumeration data were analyzed as dichotomous data and expressed as relative risk (RR)

and 95% confidence interval (CI); measurement data were examined as continuous data and expressed as mean difference (MD) and 95%CI. Subgroup analysis was conducted according to the different body parts that received tuina treatment. A funnel plot was carried out to analyze the publication bias.

2 Results

2.1 Literature search and screening result

According to the search strategy, 1 613 articles were identified at the initial search; 162 full-text articles were remained after general screening; 151 articles were removed after review of detailed information including participants, intervention methods, control methods and outcome measures. As a result, 11 articles were included for meta-analysis^[30-40]. The screening process is shown in Figure 1.

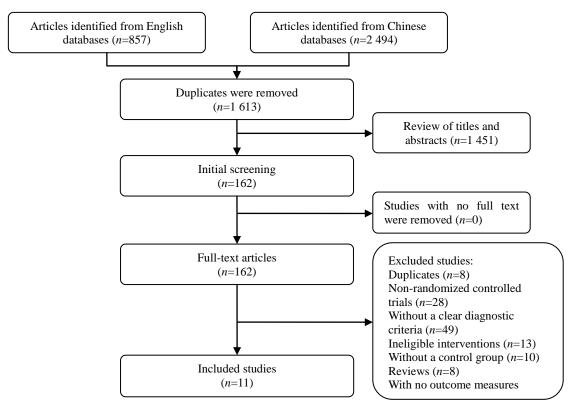


Figure 1. Literature screening process

Of the included studies, 7 adopted the diagnostic criteria of CCMD, 3 used the criteria of ICD and 1 conformed to the criteria of DSM. The 11 studies enrolled a total of 1 076 participants whose data of gender and age were unclear. Of the 11 studies, 4 studies used tuina plus other TCM therapies in the experiment group, including auricular point sticking [39], foot bath [34,38] and acupoint injection [36]; one study used a combination of tuina and Western medication as the

experiment intervention $^{[31]}$. The details are shown in Table 1.

2.2 Risk of bias analysis

Only five trials reported the method of random sequence generation, using a randomization table or computer-generated randomization number^[31,37-40], while the rest did not report the method of randomization. None of the studies reported the allocation concealment. Because it is difficult to

perform blinding in the study of tuina treatment, all studies were evaluated as 'high risk' in the performance of blinding. The studies were all rated 'unclear' in the selective reporting as the provided data were inadequate. All trials were evaluated as 'low risk' in the domain of other bias. No trial reported fund support or potential conflict of interest. Details of the risk of bias analysis are presented in Table 2.

The analysis did not reveal any significant publication bias in the 11 studies and the Egger's test showed t=1.40, 95%CI [-3.89, 16.56], P=0.195 (Figure 2).

2.3 Tuina therapy versus other TCM therapies

Of the 11 included studies, 3 compared tuina therapy with other TCM therapies by evaluating the PSQI score. The heterogeneity analysis of the three trials showed $P \le 0.1$ and $I^2 \ge 50\%$, indicating significant heterogeneity. Therefore, a random effects model was used for synthesis and the result showed that tuina therapy was more effective than other TCM therapies in reducing the PSQI score (MD=-4.11<0, 95%CI -6.01 to -2.22, P<0.0001), (Figure 3).

Table 1. Summary of the included studies

Study	n (experiment group/control group)	Interventions (experiment group)	Treated body parts	Interventions (control group)	Treatment duration/ observation duration (day)	Outcome measure
Zhang X 2011	36/30	Tuina	Back	Jie Yu An Shen granules	21/21	PSQI
Zhou YF 2006	84/82	Tuina	Abdomen	Gui Pi pills	15/15	PSQI
Luo YB 2015	35/33	Tuina plus auricular point sticking	Head	Auricular point sticking	40/40	PSQI
Zhou J 2007	30/30	Tuina plus alprazolam	Head and back	Alprazolam	20/40	PSQI
Wei M 2013	40/40	Tuina	Head and back	Estazolam	20/20	PSQI
Xu MM 2013	120/120	Tuina plus foot bath	Head	Estazolam	14/14	PSQI
Zhao D 2013	30/30	Tuina	Abdomen	Estazolam	20/20	PSQI
Bao ZW 2014	60/56	Tuina plus acupoint injection	Acupoints	Estazolam	20/40	PSQI
Wang H 2014	35/33	Tuina	Head	Estazolam	14/14	PSQI
Zhang ZP 2014	40/40	Tuina plus foot bath	Soles	Estazolam	20/20	PSQI
Tang HL 2015	40/40	Tuina	Head	Estazolam	30/30	PSQI

Table 2. Publication bias of the included studies

Study	Random sequence generation	Allocation concealment	Blinding participants	Blinding of personnel	Blinding of outcome assessment	Incomplete outcome assessment	Selective outcome reporting	Other
Zhang X 2011	U	U	Н	Н	Н	L	U	L
Zhou YF 2006	U	U	Н	Н	Н	L	U	L
Luo YB 2015	L	U	Н	Н	Н	L	U	L
Zhou J 2007	L	U	Н	Н	Н	L	U	L
Wei M 2013	U	U	Н	Н	Н	L	U	L
Xu MM 2013	U	U	Н	Н	Н	L	U	L
Zhao D 2013	U	U	Н	Н	Н	L	U	L
Bao ZQ 2014	U	U	Н	Н	Н	L	U	L
Wang H 2014	L	U	Н	Н	Н	L	U	L
Zhang ZP 2014	L	U	Н	Н	Н	L	U	L
Tang HL 2015	L	U	Н	Н	Н	L	U	L

Note: U=Unclear; H=High risk; L=Low risk

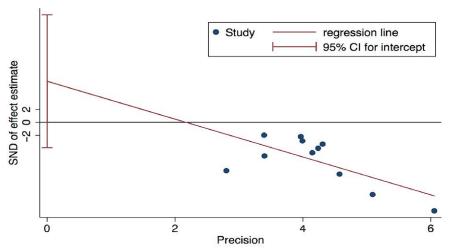


Figure 2. Funnel plot of the publication bias

	Experimental Co			Control			Mean Difference		Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	Year	IV, Random, 9	5% CI
Zhou YF 2006	5.29	2.64	84	11.23	2.81	82	35.4%	-5.94 [-6.77, -5.11]	2006	-	
Zhang X 2011	5.8	3.03	36	7.73	3.97	30	28.9%	-1.93 [-3.66, -0.20]	2011		
Luo YB 2015	5.26	1.23	30	9.33	1.79	30	35.7%	-4.07 [-4.85, -3.29]	2015	-	
Total (95% CI)			150			142	100.0%	-4.11 [-6.01, -2.22]		•	
Heterogeneity: Tau ²					P < 0	.0001);	$I^2 = 90\%$			-10 -5 0	5 10
Test for overall effect	Z = 4.6	26 (P	< 0.000	1)						Favours [experimental] Favo	ours [control]

Figure 3. Tuina therapy versus other TCM therapies for the PSQI score

2.4 Tuina therapy applied to different body parts versus oral Western medication

Of the 11 included studies, 2 adopted head and back tuina in the experiment group, 3 adopted head tuina, and 3 applied tuina to other body parts. They all took oral Western medication as the control and employed the PSQI score as the outcome measure. These 8 articles were also enrolled for a subgroup analysis based on the different treated regions. The heterogeneity analysis of the eight studies showed $P \le 0.1$ and $l^2 \ge 50\%$ which indicated significant heterogeneity. Therefore, a random effects model was used for synthesis and the

result showed a significant difference in favor of tuina therapy versus oral Western medication in reducing the PSQI score (MD=-3.42<0, 95%CI -5.19 to -1.66, P<0.0001). The subgroup analysis based on different tuina regions showed that there was no significant difference in the improvement of PSQI score between head tuina and oral Western medication (MD=-4.19<0, 95%CI -8.87 to 0.50, P>0.05); the results identified a significant difference in favor of head and back tuina versus oral Western medication in the improvement of PSQI score (MD=-2.08<0, 95%CI -3.09 to -1.06, P<0.0001), (Figure 4).

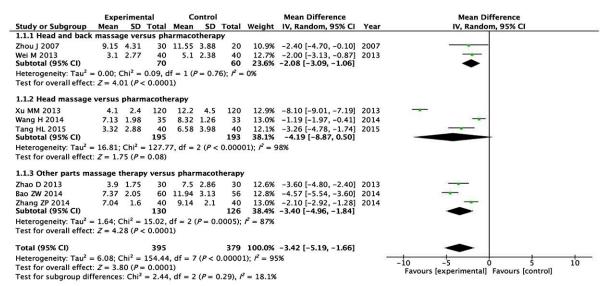


Figure 4. Tuina at different body parts versus oral Western medication for the PSQI score

2.5 Adverse reactions

None of the included studies reported adverse reactions.

3 Discussion

This research identified a significant difference in favor of tuina therapy versus oral administration of Western medication for the improvement of PSQI score and sleep quality. This conclusion conformed to recent study findings that tuina could ease the tension and anxiety in insomnia patients^[22-23]. Treatment of insomnia with tuina involves a very complex physiological mechanism. Modern science majorly uses reflexology to explain the action mechanism, which holds that stimulation to different parts of skins and muscles can produce corresponding changes in activities of central nervous system. There was also evidence showing that tuina could stimulate the body to produce sleep-promoting factors such as 5-hydroxytryptamine (5-HT)^[35]. A prospective study used polysomnography to observe women with insomnia and found that tuina shortened stage I of non-rapid eye movement (NREM) sleep and rapid eye movement (REM) sleep duration, and significantly extended state III and IV of NREM, which may be related to the function of tuina^[41]. TCM believes that yin-yang imbalance should be the major factor causing insomnia. In a normal state, yang qi runs superficially in the daytime while internally in the nighttime. When yin and yang are imbalanced, yang qi will be unable to go internally but remain in the surface at night, manifested by excitement, difficulty initiating sleep or even insomnia. Via stimulating meridians and acupoints, tuina can regulate yin-yang and restore their balance^[42-43]. Currently, tuina is mainly applied to head, back and soles, where most of the meridians associated with sleep distribute.

However, the following factors may influence the reliability of the conclusion in this research. Firstly, the included studies were different in the inclusion criteria, and were not quantified or unified in manipulations, treated body parts and treatment duration of tuina. Secondly, this study only searched Chinese and English databases, while there may be relevant studies written in other languages. Thirdly, the quality of the included trials was generally low and the risk of bias was high since double-blind method cannot be performed for tuina study. Fourthly, there were not enough studies comparing tuina with other forms of TCM therapies, making it unable to determine the advantage of tuina therapy.

4 Conclusion

To conclude, this meta-analysis identified a significant

difference in favor of tuina versus oral administration of benzodiazepine receptor agonists for the improvement of PSQI score and sleep quality. Tuina should be recommended as one of the options to treat insomnia, and it should be applied to both head and back instead of head alone. Nevertheless, with regards to the low quality of the included studies, the conclusion in favor of tuina for insomnia needs to be supported by more rigorous RCTs with a large sample size.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

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