

Meta-Analysis of the Efficacy and Safety of Umbilical Therapy in Patients with Insomnia

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Abstract. To systematically evaluate the efficacy and safety of umbilical therapy in improving symptoms of insomnia patients. Randomized controlled trials (RCTs) on the application of umbilical therapy in insomnia patients were retrieved from PubMed, MEDLINE, Cochrane Library, Web of Science, FMRIS, CNKI, VIP, Wanfang Database, and CBM from inception to March 20, 2025. Meta-analysis was performed using RevMan 5.3 software. A total of 703 articles were retrieved, and after deduplication, abstract screening, and full-text review, 28 studies were included, involving 894 patients in the observation group and 892 in the control group. The results showed that umbilical therapy was safe and effective in insomnia patients, significantly reducing Pittsburgh Sleep Quality Index (PSQI) scores ($P < 0.05$), decreasing TCM symptom scores ($P < 0.05$), and improving treatment efficacy ($P < 0.05$). Umbilical therapy can effectively improve symptoms in insomnia patients, enhance treatment outcomes, and is associated with no severe adverse reactions.

Keywords: Umbilical therapy, Umbilical moxibustion, Insomnia, Efficacy, Safety.

1. Introduction

The global average prevalence of insomnia is 30%, with rates of 35%–38.6% in the UK and 40.2% in Canada [1]. A 2016 report indicated that the prevalence of insomnia in mainland China was 9.2%, while it was 39.2% in Hong Kong and 25% in Taiwan [2]. Studies on sleep conditions suggest that up to 57% of adults in mainland China suffer from insomnia [3]. Recent research highlights that the prevalence of insomnia is 48.2% in men and 63.2% in women [4]. The National Sleep Foundation [5] notes that total sleep time decreases with age, but overall sleep quality remains poor for most people, with insomnia affecting global health. Many insomnia patients are resistant to Western sleep aids. The umbilicus, known as the "Shenque" acupoint, is the most precisely located acupoint in the human body, situated at the golden ratio point of 0.618. Umbilical therapy, a traditional Chinese external treatment, involves applying medications (e.g., pills, ointments, pastes, or powders) to the umbilicus or stimulating it with physical methods (e.g., acupuncture, moxibustion, hot compress, or cupping) to treat diseases. By stimulating the Shenque acupoint, this therapy regulates meridians, harmonizes qi and blood, and balances yin-yang and organ functions, thereby preventing and treating diseases [6]. The umbilicus is considered the "hub of meridians and the sea of qi." Umbilical moxibustion combines the effects of moxibustion, heat conduction, drug penetration, and acupoint stimulation, achieving therapeutic goals by regulating the acupoint-meridian-organ system, offering unique advantages [7].

However, most studies on umbilical therapy for insomnia are small-scale, lack standardized protocols, and have limited persuasiveness. This meta-analysis aims to provide evidence-based support for clinical practice and inspire further research on the standardization of umbilical therapy.

2. Objective

To systematically evaluate the efficacy and safety of umbilical therapy in improving outcomes for insomnia patients and identify gaps in current clinical research.

3. Methods

A literature review was conducted, retrieving studies on umbilical therapy for insomnia from inception to March 20, 2025, across multiple databases, including PubMed, MEDLINE, Cochrane Library, Web of Science, FMRS, CNKI, VIP, Wanfang Database, and CBM.

4. Literature Search Strategy

Subject terms are obtained from PubMed MeSH thesauri and Chinese Medical thesauri (CMeSH), and search strategies are formulated by combining with free words. Through professional search methods, nsomnia OR sleep disorders OR insomnia OR bumei / wen jiu OR moxibustion OR moxa roll moxibustion OR moxa cone acupuncture moxibustion OR health care OR rush moxibustion OR line strong effect OR indirect moxibustion OR isolate garlic ginger moxibustion OR moxibustion OR separated salt effect OR sparrow pecking moxibustion OR direct moxibustion OR scarring moxibustion OR festering moxibustion OR warm acupuncture OR mild moxibustion OR too b acupuncture OR electricity jiu OR thermal moxibustion / umbilical moxibustion OR umbilical OR moxibustion therapy OR Umbilical application OR Shenque OR Shenque OR CV8.

5. Inclusion and Exclusion Criteria

5.1. Inclusion Criteria

- a. Types of participants: Insomnia patients.
- b. Types of interventions: Umbilical moxibustion alone or combined with other treatments.
- c. Types of comparisons: The control group included blank control, reciprocal control, conditional control, placebo control, and standard control.
- d. Types of outcome measures: PSQI, treatment efficacy, or TCM symptom scores.
- e. Types of studies: Randomized controlled trial.
- f. Language: Chinese and English documents are included.

5.2. Exclusion Criteria

- a. Animal studies.
- b. Age<18 or pregnant women.
- c. Reviews, abstracts, case reports.
- d. Studies without umbilical therapy.
- e. Umbilical therapy was used as control group, while non-umbilical therapy was used in observation group;
- f. Joint point selection, but not including Shenque points;

5.3. Literature Screening and Data Extraction

The literature was screened independently by two researchers according to the exclusion criteria, and the data were extracted after reading the full text. Self-designed data summary table was used to extract data, including the author and year of the included study, intervention object, sample size, intervention method, dose, intervention period, outcome indicators, etc.

6. Literature quality evaluation

Randomized controlled studies were included and evaluated independently by 2 researchers according to the Cochrane handbook (5.1.0) quality assessment list, with a total of 7 items: including the generation of random sequences; Allocation hiding; The subjects and interveners were blinded. Results The evaluators implemented the blind method; Outcome index integrity; Optional reporting possible; Other bias. The evaluation results of the two people were compared, the objecting articles

were discussed, and a consensus could not be reached, so a third party was invited to arbitrate, and the evaluation of low, medium and high quality of the literature was finally formed. That is, quality level A: completely satisfied, the possibility of bias is minimal; Quality grade B: partially satisfied, moderate possibility of bias; Quality Grade C: completely unsatisfactory, high likelihood of bias.

7. Statistical Analysis

Meta-analysis was performed using RevMan5.3 software. Sample mean $\pm$ standard deviation ($\bar{x} \pm s$) was used for continuity variables, and the adoption rate of bitaxonomic variables (%) was adopted. Calculate a 95% confidence interval. χ^2 test was used to determine whether there was heterogeneity among the studies. If $I^2 < 50\%$ and $P > 0.1$, fixed-effect model was used for analysis. If $I^2 \geq 50\%$, $P \leq 0.1$, indicating heterogeneity, the random effects model was selected for analysis. $P < 0.05$ was considered statistically significant.

8. Results

8.1. Literature Search

A total of 703 literatures were retrieved, 45 were deleted after review by NoteExpress, 534 were deleted after reading the abstract, 81 were excluded after reading the full text, and 18 were excluded after reading the inner umbilical ring needle and Wushenque point, and 3 additional literatures were obtained. Finally, 28 literatures were included for analysis. See Figure 1 for details.

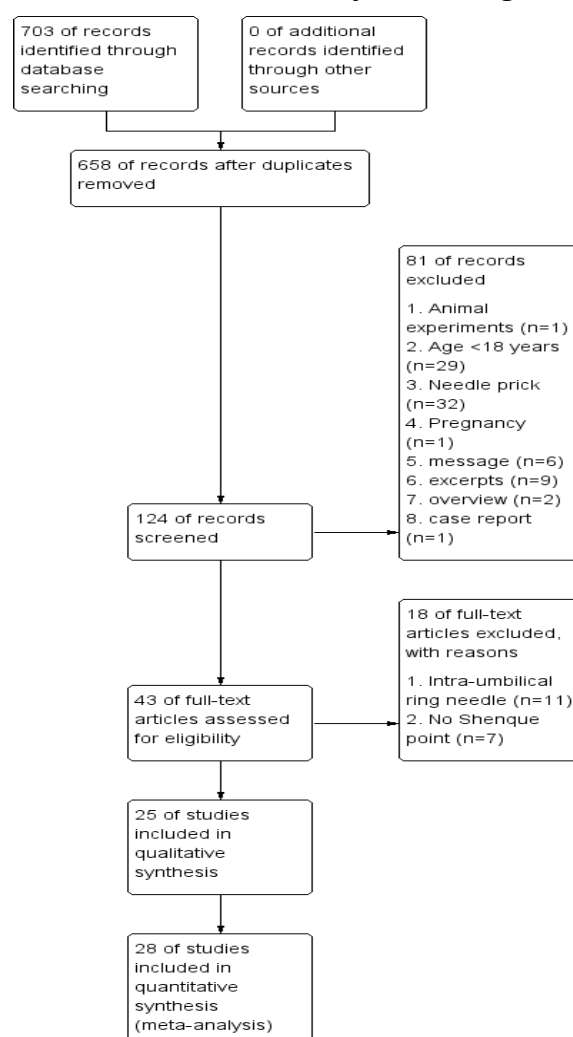


Figure 1. Literature search results

8.2. Results of literature inclusion

Finally, 28 relevant literatures were included. There were 894 cases in the observation group and 892 cases in the control group. Basic characteristics of the literature (see Table 1):

Table 1. Basic characterization of literature

Included Literature ^a	Subject	Sample Size	Methods	Dosages	Cyclicity	Exit Indicator
Author	Years published	Observation Group	Observation Group	control group		
WU ^[8]	2017	Stroke 30	Poling (TCM)	Acupuncture	30min/1time/day	28days
DUAN ^[9]	2018	Insomnia 60	Poling (TCM)	Medicine	120min/1time/day	28days
XIE ^[10]	2018	Diabetic Foot 40	Poling (TCM)	Medicine	30min/1time /day	28days
JI ^[11]	2018	Hypothyroidism 20	Poling (TCM)	Indirect Starch Moxibustion	90min/1time /week	3months
AN ^[12]	2018	Coronary Artery Disease 30	Poling (TCM)	Medicine	90min/1time/day	21days
SONG ^[13]	2018	Hypothyroidism 20	Poling (TCM)	Indirect Starch Moxibustion	90min/1time /week	2months
YE ^[14]	2018	Insomnia 20	Poling (TCM)	Medicine	1time /week	3months
HUANG ^[15]	2019	Insomnia 50	Poling (TCM)	Medicine	45min/1time/day	28days
SU ^[16]	2019	Insomnia 30	Poling (TCM)	Indirect Starch Moxibustion	90min/1time /week	2months
ZHOU ^[17]	2020	Menopause 30	Thermal Moxibustion	Medicine	120min/1time/day	30days
PAN ^[18]	2020	Insomnia 35	Moxibustion throughGinger + Chinese Herbal Tonics	Medicine	1time/day	30days
HE ^[19]	2020	Insomnia 48	Poling (TCM)	Moxa Roll	30min/1time/day	20days
LI ^[20]	2020	Insomnia 50	Poling (TCM)	Acupressure	50min/1time/other day	28days
ZHANG ^[21]	2021	Insomnia 45	Poling (TCM)	Medicine	13min/1time/day	Not mentioned
HAN ^[22]	2021	Insomnia 10	Poling (TCM)	Medicine	10min/2times/day	9days
ZHANG ^[23]	2021	Cirrhosis 42	Poling (TCM)	Medicine	15min/1time/day	2weeks
LI ^[24]	2021	Insomnia 36	Poling (TCM)	Medicine	30min/1time/day	14days
LI ^[25]	2022	Perimenopause 30	Poling (TCM)	Acupuncture	1time/day	8weeks
GUO ^[26]	2022	Insomnia 26	Lit.Fine moxibustion (TCM)	Medicine	2times/week	4weeks
ZHANG ^[27]	2022	Stroke 44	Poling (TCM)	Medicine	30min/1time/day	2weeks
HE ^[28]	2022	Insomnia 50	Gentle Moxibustion	Medicine	10min/1time/day	2weeks
SONG ^[29]	2023	Stroke 30	Gentle Moxibustion	Medicine	30min/5times /week	4weeks
ZOU ^[30]	2023	Perimenopause 35	Lit.Fine moxibustion (TCM)	lit.false spermatozoa (TCM)	2times/week	8weeks
HE ^[31]	2023	Insomnia 34	Poling (TCM)	Moxa Roll	1time/3 weeks/every other day	3weeks
YANG	2023	Insomnia 33	Poling (TCM)	Application of Medicine	1h/1time/day	4weeks
LIU ^[33]	2024	Chronic Hepatitis B 30	Poling (TCM)	Medicine	2min/other day/week	2weeks
PAN ^[34]	2024	Perimenopause 49	Poling (TCM)	Medicine	4h/1time/day	4weeks
SHI ^[35]	2024	Insomnia 35	Poling (TCM)	Medicine	90min/other day/week	4weeks
PENG ^[36]	2024	Insomnia 61	Poling (TCM)	Medicine	10min/1time/day	4weeks

Remarks: 1. PSQI evaluation 2. Efficacy evaluation 3. TCM symptom evaluation

8.3. Literature quality evaluation

28 literatures, including A grade 1; Grade B 22 articles; Grade C: 5 articles. Literature quality evaluation (see Table 2 and Figure 2):

Table 2. Literature quality assessment

Included Studies		Randomization	Allocation Concealment Subjects	Subject Interventionist	Assessor	Closing Completeness	Selective Reporting	Other Biases	Quality Level
AUTHOR	YEAR			Blinding	Blinding		Possibility		
WU	2017	A	C	B	C	A	A	A	B
DUAN	2018	A	C	C	C	A	A	A	B
XIE	2018	A	A	C	C	A	A	A	B
JI	2018	C	C	C	C	A	A	A	C
AN	2018	B	C	C	C	B	A	C	C
SONG	2018	A	A	C	C	A	B	A	B
SONG	2018	A	A	C	C	A	B	A	B
HUANG	2019	B	C	C	C	A	A	C	C
SU	2019	B	C	C	C	A	A	A	B
ZHOU	2020	A	A	C	C	A	B	A	B
PAN	2020	A	C	B	C	A	A	A	B
HE	2020	C	C	C	C	A	A	C	C
LI	2020	A	C	C	C	A	A	A	B
ZHANG	2021	B	C	C	C	A	A	B	C
HAN	2021	A	A	B	A	A	A	A	A
ZHANG	2021	A	C	C	C	A	B	A	B
LI	2021	A	B	C	C	A	A	A	B
LI	2022	A	B	C	C	A	A	A	B
GUO	2022	A	A	B	C	A	A	A	B
ZHANG	2022	A	B	C	C	A	B	A	B
HE	2022	A	C	B	C	A	A	A	B
SONG	2023	A	C	C	C	A	A	A	B
ZOU	2023	B	B	C	C	A	A	A	B
HE	2023	A	A	C	C	A	A	A	B
YANG	2023	A	B	C	C	A	A	A	B
LIU	2024	A	C	C	C	A	A	A	B
PAN	2024	A	A	C	C	A	A	A	B
SHI	2024	A	A	A	C	A	A	A	B

Remarks: A low risk B high risk C unclear

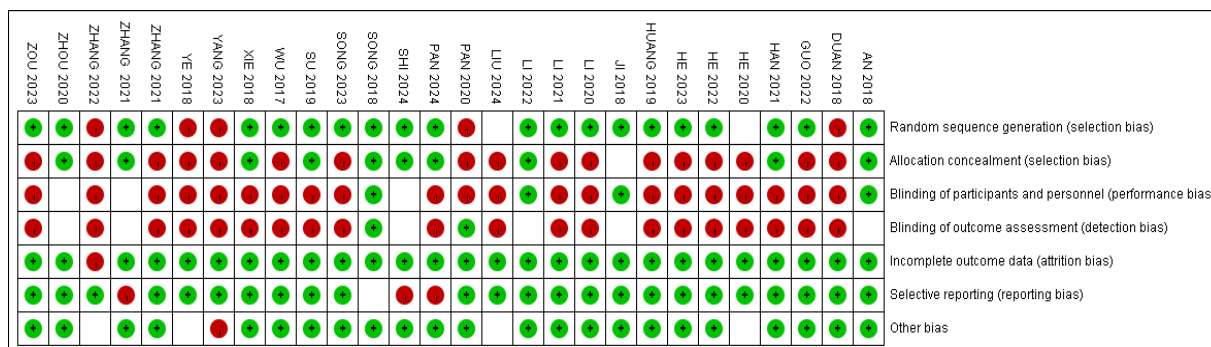


Figure 2. Literature quality evaluation chart

8.4. Meta-analysis of PSQI outcome indicators in patients with insomnia induced by umbilical therapy

Using PSQI as an outcome index, a total of 18 literatures were included. There were 737 people in the observation group and 735 people in the control group. Heterogeneity test indicated high heterogeneity ($\chi^2=261.62$, $I^2=94\%$, $P<0.01$), so random-effects model analysis was selected, and the results showed that the difference between the observation group and the control group was statistically significant [$Z=12.95$, $SMD=-0.78$, $95\%CI (-0.89, -0.66)$, $P<0.001$] (see Figure 3). The funnel plot of 18 articles with large heterogeneity (see Figure 4) was symmetrical and inverted funnel shape, and the OR value was mostly on the side less than 1, which was a protective factor and the risk of bias was low. It should be noted that the standard mean difference (SMD) is chosen instead of the useful weighted mean difference (WMD), because although the outcome measures of the studies are consistent, However, there are great differences in different intervention methods, intervention doses and intervention cycles. For example, the intervention methods include isolated moxibustion, isolated moxibustion + acupuncture/application/traditional Chinese medicine decoction, or lightning moxibustion/heat-sensitive moxibustion/moxibustion on moxibustion sticks, and then ginger moxibustion/salt-isolating moxibustion; The shortest intervention dose was 15min and the longest was 120min. The shortest intervention period was 10 days and the longest was 3 months.

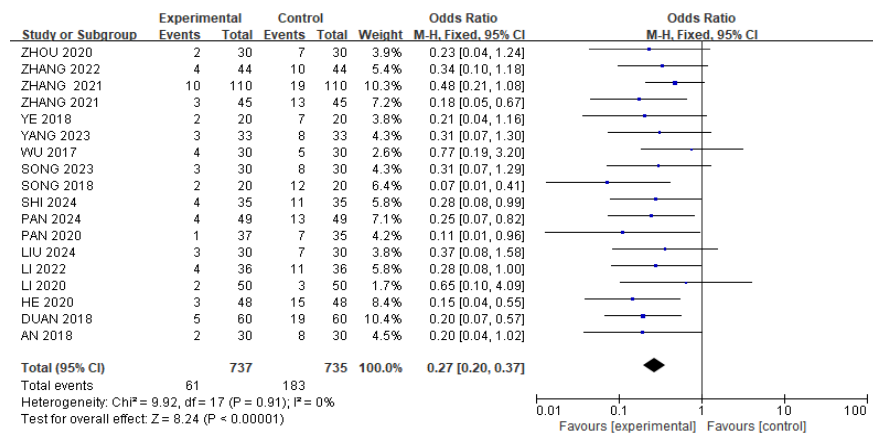


Figure 3. PSQI meta-analysis of outcome indicators (forest plot)

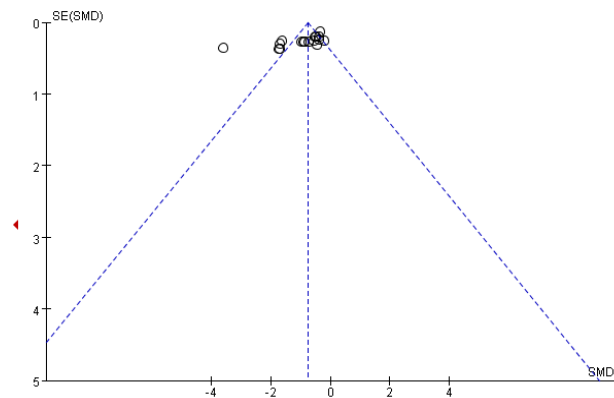


Figure 4. PSQI meta-analysis of outcome indicators (funnel plot)

8.5. Meta-analysis of the efficacy evaluation of umbilical therapy

The 24 literatures included used efficacy evaluation as the outcome index, 947 people in the observation group and 945 people in the control group. Heterogeneity test indicated high homogeneity ($\chi^2=29.55$, $I^2=19\%$, $P=0.20$), so fixed-effect model analysis was selected, and the results showed that the difference between the observation group and the control group was statistically significant [$Z=10.76$, $MD=0.27$, $95\%CI$ (0.21, 0.34). $P<0.001$] (see Figure 5). In addition, the funnel diagram (see Figure 6) has a symmetrical inverted funnel shape, and the OR value is mostly on the side less than 1, which is a protective factor and the risk of bias is low.

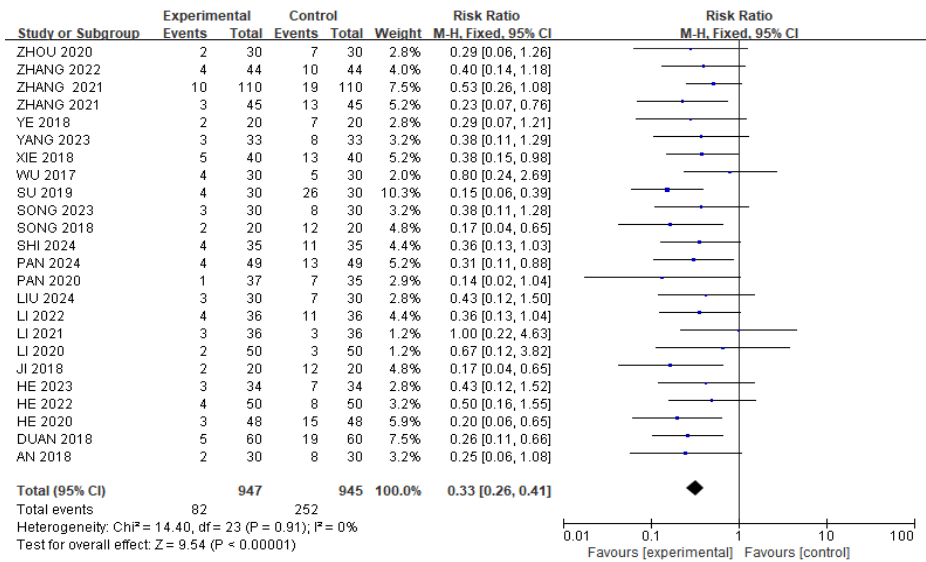


Figure 5. Meta-analysis of efficacy evaluation (forest plot)

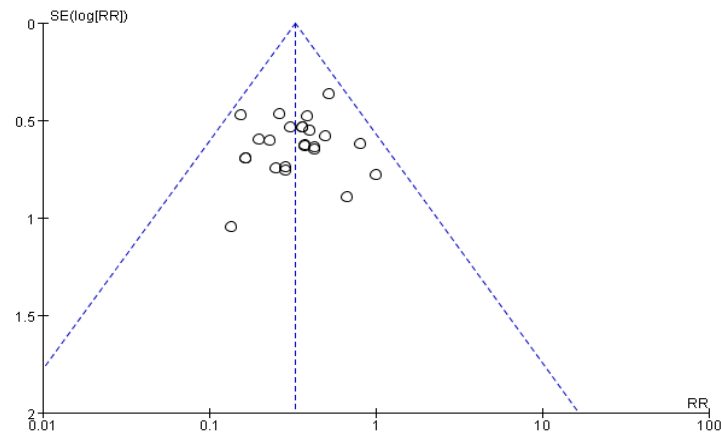


Figure 6. Meta-analysis of efficacy evaluation (funnel plot)

8.6. Meta-analysis of umbilical therapy on TCM symptom score of patients

The included 6 literatures used TCM symptom score as outcome index, 188 people in the observation group and 188 people in the control group. Heterogeneity test indicated high heterogeneity ($\chi^2=75.76$, $I^2=93\%$, $P<0.01$), so random-effects model analysis was selected, and the results showed that the difference between the observation group and the control group was statistically significant [$Z=7.75$, $MD=-0.69$, $95\%CI (-0.87, -0.52)$, $P<0.001$] (see Figure 3-8). The funnel plot (see FIG. 3-9) has an incomplete symmetrical inverted funnel shape, and the OR value is mostly on the side less than 1, which is a protective factor and has a certain risk of bias. On the one hand, the inclusion of less than 10 literatures may have an impact on the funnel plot. On the other hand, the six literatures with large heterogeneity showed low heterogeneity after removing Wu Xiaoli's [8] literatures ($\chi^2=12.04$, $I^2=67\%$, $P=0.02$), which may indicate the possibility of publication, positioning, inclusion or other bias in the studies, or the influence of differences in scores and typing of different TCM symptoms of insomnia.

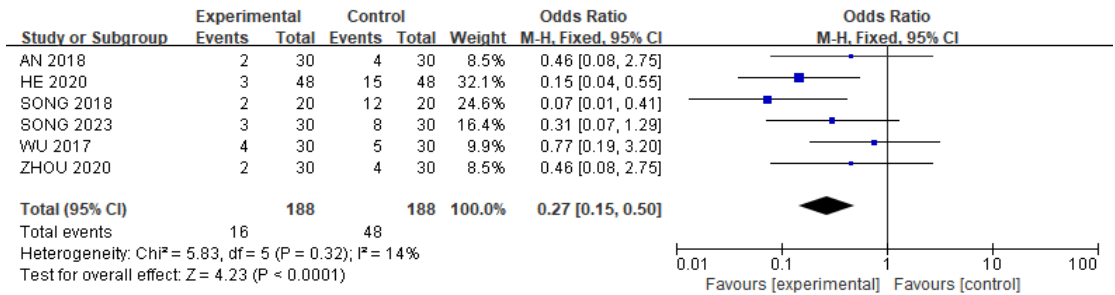


Figure 7. Meta-analysis of TCM symptom scores (forestplot)

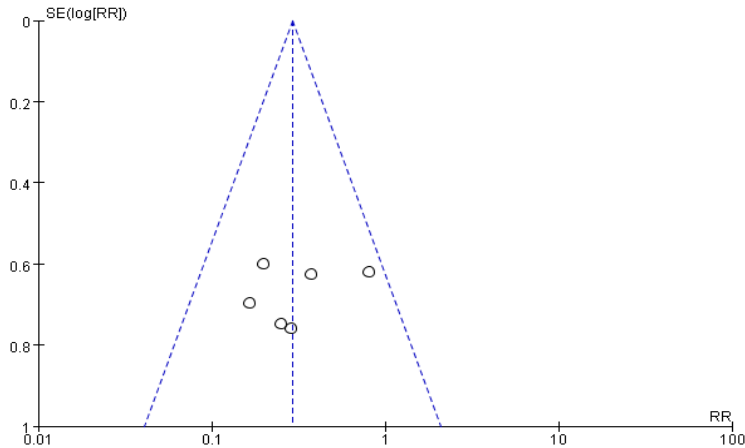


Figure 8. Meta-analysis of TCM symptom scores (funnel plot)

8.7. Safety evaluation of umbilical therapy

In terms of safety, there were 14 statements, of which 4 mentioned safety but were not reported, and 4 cases had no adverse reactions. The remaining 6 items are as follows: Song Shuai [13] During this trial, 18 cases and 22 adverse reactions occurred in the observation group, but no serious adverse events occurred; there were 3 adverse events related to drug use in the observation group, all of which were mild diarrhea. Song Qinqin [29] 3 cases of hematoma were related to acupuncture, not umbilical moxibustion. During the study of An Ruidan [27], there were no adverse reactions such as panic and aggravation of chest tightness in the two groups, while skin scalding occurred in the treatment group, which was attributed to the excessively long moxibustion time of 90min/ time. Huang Hailong [15] treated 1 case of dizziness and 1 case of fatigue. Su Shijie [16] had 1 case of umbilical hypersensitivity. Li Jing [20] In the separation moxibustion umbilical group, there was 1 patient with obvious red halo at the moxibustion site, which disappeared during treatment the next day. Umbilical therapy did not occur serious adverse reactions, appropriate control of moxibustion time, or place appropriate ginger tablets, can avoid burns, so the application of umbilical therapy in patients is safe and effective.

9. Discuss

9.1. Umbilical therapy can improve the overall sleep quality of patients

Whether in patients with simple insomnia, or for patients with menopausal insomnia, or patients with thyroid dysfunction, as well as patients with diabetes, stroke and coronary heart disease, ginger umbilical moxibustion, drug umbilical moxibustion, salt umbilical moxibustion, simple therapy or combined intervention can improve the quality of sleep in patients, showing its effectiveness. Especially for outcome indicators such as the Pittsburgh Sleep Quality Scale (PSQI), efficacy evaluation, and TCM symptom scores. However, the common problem is that clinical studies on umbilical therapy in insomniacs still lack large sample and multi-center studies, and the literature quality is not high, and umbilical therapy is mostly used in combination with other traditional Chinese medicine therapies. Umbilical therapy alone is mostly used in combination with other suitable Chinese medicine techniques, such as ginger umbilical moxibustion, salt umbilical moxibustion and moxibustion on moxibustion alone. Evidence for the effectiveness of intervention is still lacking. Therefore, in nursing clinic, it is hoped that umbilical moxibustion alone can be used for scientific research, and can provide evidence for evidence-based medicine.

9.2. The standardization of umbilical therapy intervention deserves further study

Public health around the world is facing the problem of high incidence, long course and high cost of insomnia, which seriously affects the recovery process of patients. Umbilical therapy in clinical more than acupuncture, acupoint massage, ear embedding beans, cupping, acupoint application, Qigong, guidance and other traditional Chinese medicine therapy combined use; Umbilical therapy is also used in combination with acupoint application; Umbilical moxibustion is also used alone, but the moxibustion method is the basic operation. There is no uniform standard for clinical application and research of umbilical moxibustion therapy, including the limitation of the place of implementation of umbilical moxibustion therapy; The implementer of the operation is not clearly stated; There are great differences in the operation and implementation of umbilical moxibustion, the course of umbilical moxibustion, the selection of moxibustion method, the selection of moxibustion materials, the selection of moxibustion tools, and the dose of moxibustion. The outcome indexes of umbilical moxibustion are too single and insufficient. At the present stage, clinical research on umbilical moxibustion pays attention to its effectiveness, and the research on moxibustion dose is still lack of standardization, including moxibustion intensity, moxibustion area, and moxibustion time. Under the premise of constant moxibustion intensity and moxibustion area, moxibustion time determines the dose of moxibustion. The standardized plan of umbilical moxibustion has not been established, and there is clinical demand.

9.3. Septal moxibustion can increase the safety of umbilical therapy intervention

Moxibustion is a treatment that anyone can perform, but some precautions should be taken. Indirect moxibustion, is a good choice, indirect moxibustion refers to the moxibustion between the moxa pillar and the skin on the spacer, commonly used spacer ginger, garlic, salt or aconite, respectively called ginger moxibustion, garlic moxibustion, salt moxibustion and aconite moxibustion. Ginger moxibustion is the most commonly used, the most convenient method, but also the most acceptable choice, if the moxibustion feel burning pain, or too hot, you can lift the ginger slightly, leave the skin for a moment, or add a layer of ginger to avoid the danger of being burned during the moxibustion process. Moxibustion time can be customized according to time and place, and it can be controlled within a certain period of time, for the elderly, heat-insensitive patients, but not too long, during the process of moxibustion, closely observe the patient's reaction, so as not to cause burns, allergies and other adverse events.

10. Summary

Through this meta-analysis, it was shown that umbilical therapy was safe and effective, and could reduce patients' PSQI score, reduce TCM symptom score, and improve treatment effect, and no serious adverse reactions were reported. Shenque point is the most clearly located acupoint of human body. Umbilical therapy has many advantages such as convenience, simplicity, simplicity, honesty and testing. Therefore, the umbilical moxibustion treatment of patients, following the traditional Chinese medicine concept of "moxibustion umbilical, through all the sutras and cure all diseases", not only conforms to the national "Healthy China 2030" plan, but also low cost and simple operation. Through this meta-analysis, we hope to provide evidence-based evidence for the clinical research and implementation of umbilical therapy, and stimulate researchers to conduct in-depth research on the standardization of umbilical therapy.

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