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None declared.

Lingguibafa in the treatment of insomnia: Meta analysis

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Review question / Objective: **To evaluate the difference of clinical efficacy between Lingguibafa and conventional dialectical acupoint selection in the treatment of insomnia by meta-analysis, so as to provide evidence-based medical basis for Lingguibafa in the treatment of insomnia.**
Information sources: **Relevant studies will be searched from the databases of PubMed, Web of Science, EMBASE, Cochrane Library, China Knowledge Resource Integrated Database(CNKI), Weipu Database for Chinese Technical Periodicals(VIP), SinoMed, and Wanfang Database until December 18, 2020. If the information is incomplete, we will contact author by email.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2022 and was last updated on 26 April 2022 (registration number INPLASY202240152).

INTRODUCTION

Review question / Objective: **To evaluate the difference of clinical efficacy between Lingguibafa and conventional dialectical acupoint selection in the treatment of insomnia by meta-analysis, so as to provide evidence-based medical basis for Lingguibafa in the treatment of insomnia.**

Condition being studied: **Insomnia is the most common sleep disorder.Global incidence rate of insomnia in 10 countries investigated in 2005 showed that 31.6% of the world's population met the insomnia score of the self testing AIS scale.Although insomnia is not critical, it has a great impact on the quality of life of patients, and can aggravate or induce palpitations, chest**

pain, headache, vertigo, stroke and other diseases.Acupuncture and moxibustion is effective in the treatment of insomnia. Acupoint selection is mainly based on syndrome differentiation, which is simple and has no adverse reactions. It can effectively regulate nerves and enhance the immune ability of the body. Linggui Bafa selected acupoints according to the law of time, which is consistent with the circadian rhythm of sleep.In recent years, more and more doctors have applied it to the treatment of insomnia, and the clinical report shows that the effect is remarkable. However, there is no multicenter, large sample randomized controlled trial to provide clinical evidence, and there is no systematic review of this therapy to provide evidence support. Therefore, the author collected the clinical research literature of Linggui Bafa in the treatment of insomnia at home and abroad for quality evaluation and meta-analysis, in order to provide evidence-based medical basis for Linggui Bafa in the treatment of insomnia.To evaluate the difference of clinical efficacy between Lingguibafa and conventional dialectical acupoint selection in the treatment of insomnia by meta-analysis, so as to provide evidence-based medical basis for Lingguibafa in the treatment of insomnia.

METHODS

Search strategy: Computer retrieval of CNKI, Wanfang academic journal full text database (Wanfang), VIP Chinese Sci tech journal database (VIP), China biomedical literature database (SinoMed), PubMed, Cochrane Library and Google Scholar. The retrieval period is from the establishment of the database to March, 2021. The language is limited to Chinese and English. The retrieval method is the combination of subject words and free words:("sleep initiation and maintenance orders"or"insomnia"or"early awakening"or"disorders of initiating and maintaining sleep (DIMS)"and"Linggui Bafa"or"Linggui eight methods" and"randomized controlled trial"or"randomized controlled").Chinese search words correspond to English.

Participant or population: Inclusion: 1)Participants were diagnosed with insomnia.2) Between 16 and 80 years of age.3)No restrictions on gender, race, economic status and education.There is no clear exclusion criteria for the time being.

Intervention: Inclusion:1) Acupoint selection is Linggui Bafa plus dialectical selection or only Lingguibafa.2)The operation method is routine acupuncture. Exclusion:1)Lingguibafa was not the main intervention measure.2)There were other intervention measures except dialectical acupoint selection.2)The operation method is not routine acupuncture.

Comparator: 1)Linggui Bafa plus dialectical acupiont selection & dialectical acupiont selection;2)Linggui Bafa acupiont selection & dialectical acupiont selection.

Study designs to be included: Randomized controlled trials (RCT) or clinical controlled trials (CCT) were included in the studyRCT or CCT.

Eligibility criteria: All randomized clinical trials (RCTs) will be included in this meta-analysis. Case studies, case series, qualitative studies and uncontrolled trials will be excluded.

Information sources: Relevant studies will be searched from the databases of PubMed, Web of Science, EMBASE, Cochrane Library, China Knowledge Resource Integrated Database(CNKI), Weipu Database for Chinese Technical Periodicals(VIP), SinoMed, and Wanfang Database until December 18, 2020.If the information is incomplete, we will contact author by email.

Main outcome(s): 1) The Pittsburgh Sleep Quality Index (PSQI): Sleep disturbance was assessed using the Pittsburgh Sleep Quality Index (PSQI) pre- and post-treatment. The 19-item PSQI instrument produces a global sleep quality score and

seven specific component scores: quality, latency, duration, disturbance, habitual sleep efficiency, use of sleeping medications, and daytime dysfunction. Global scores range from 0 to 21 with higher scores indicating poor sleep quality and high sleep disturbance. Used PSQI to assess sleep quality. Score between 8 and 12 showed slight insomnia; between 13 and 17, moderate insomnia; and between 18 and 21, severe insomnia. Selected the patients with PSQI ≤8 and compared their scores before and after the treatment. 2) Clinical effective rate：The clinical effective rate of each trial was recorded according to the curative effect evaluation index.

Additional outcome(s): 1) Hamilton Depression Rating Scale (HAMD): Depression was assessed using Hamilton Depression Rating Scale (HAMD) pre- and post-treatment. Scores above 7 meant a possibility of depression; scores between 17 and 23 showed slight or moderate depression; and score above 24 was severe depression. 2) Self-rating Anxiety Scale (SAS)：Anxiety was assessed using Self-rating Anxiety Scale (SAS) pre- and post-treatment. The SAS standard score is 50, in which 50-59 is classified as mild anxiety, 60-69 as moderate anxiety, and over 70 as severe anxiety. Global scores range from 0 to 100 with higher scores indicating anxiety and high anxious disturbance.

Data management: Two reviewers will check the titles, abstracts and full-texts of the initial search results independently. Recorded data variables were as follows: (1) First author's name, year of publication, study design (2) Basic information of participants (gender, age range, course of disease (years) range, mean); (3) Outcome measures and adverse event reports. Any discrepancies that emerged in these procedures were discussed and resolved by involving a third reviewer.

Quality assessment / Risk of bias analysis: 2 reviewers will independently assess the risk of bias of included studies according to The Cochrane Handbook for systematic Review of Interventions.7 domains will be included:random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome date, selective outcome reporting and other bias.Each item will be judge as high, low and unclear.Any disagreement will be resolved through discussion with a third reviewer.

Strategy of data synthesis: Data synthesis and analysis will use RevMan5.3.All literatrue will use I^2 and P to determine the heterogeneity.If $P \geq 0.05$ and $I^2 \leq 50\%$, it means there is no obvious heterogeneity, then fixed-effected model would be adopted.If $P < 0.05$ and $I^2 > 50\%$, it indicates there is heterogeneity, then random-effect model would be selected and a subgroup analysis will be conducted to analyze the source of heterogeneity.If the heterogeneity is large and the source is unknown, only descriptive will be performed.Mean difference (MD) or standardized mean difference (SMD) will be used for the continuous date : VAS, NRS, JOA low back pain scale and SF-36.The odds rations (OR) will be used for dichotomous data : clinical effective rate.Both of them will be present 95% confidence intervals(CI).

Subgroup analysis: If the necessary data are available, subgroup analyses will be done for different Interventions or different outcome measures separately.

Sensitivity analysis: In order to test the stability of the results of this study, sensitivity analysis was carried out by eliminating single study one by one and re evaluating.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: Lingguibafa; Insomnia; Dialectical acupoint selection; Acupuncture; Meta analysis; Randomized controlled trial.

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