INPLASY PROTOCOL

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None declared.

Comparison of Manual Acupuncture and Sham Acupuncture in Migraine Without Aura Treatment: A Protocol for Systematic Reviews and Meta-Analyses

Yu, DB[1]; Jin, X[2]; Huang, K[3]; Zhang, LX[4]; Lin, J[5]; Chen, J[6].

Review question / Objective: To evaluate the efficacy of Manual Acupuncture in the treatment of Migraine Without Aura.

Eligibility criteria: We included trials with individualized strategies when the average number of treatments was at least five. Additionally, to assure the clinical efficacy of acupuncture treatments, the acupuncturist administering the treatments in the study should have a relevant acupuncture qualification or practice qualification. In addition, the acupuncturist should have prior clinical experience.

Information sources: We intend to publish the data in the following databases: PubMed, Web of Science, CINAHL, Cochrane, CBM, CPVIP, CNKI, and Wan Fang.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 September 2022 and was last updated on 14 September 2022 (registration number INPLASY202290063).

INTRODUCTION

Review question / Objective: To evaluate the efficacy of Manual Acupuncture in the treatment of Migraine Without Aura.

Rationale: Acupuncture, a natural treatment derived from ancient Chinese medical theory over 3, 000 years ago, has been used by over a third of the world's population and is a standard non-pharmacological treatment for migraine

without aura. Acupuncture therapy works by inserting thin silver or steel needles into specific areas of the body (acupuncture points) to balance the body's energy or promote the flow of vital energy, called Qi or Chi (Chee), to prevent, control, and improve symptoms and disease. During the operation, the acupuncturist uses a variety of specific finger manipulations, known as "manual acupuncture," to drive the needle to lift, insert, rotate or vibrate. This acupuncture technique can dynamically change the extracellular environment, lead to the rotation and deformation of fascia tissue, and stimulate acupoint specificity, which is considered the fundamental condition and critical factor for the effect of acupuncture.

Condition being studied: Migraine has afflicted more than one billion people in 2016, worldwide statistics. It is considered the leading cause of disability under 50 and is associated with stress, sleep disorders, and suicide, making it a public health problem. Migraine without aura, which accounts for approximately 75% of these cases, is a type that does not have any antecedent features but has a wide range of causes. Due to the complex and poorly understood mechanisms of migraine without aura, there are currently no specific drugs or therapies available for clinical management. Although different classes of drugs, with slightly different mechanisms of action, are widely used in migraine without aura and are now used worldwide. However, their effects are short-lived; they have significant gastrointestinal adverse effects and can lead to rebound headaches. Therefore, clinicians and patients prefer natural, non-pharmacological therapies to achieve symptom relief in routine practice. Acupuncture in China is an easy, quick, and effective non-pharmacological treatment. Some meta-analyses have found that acupuncture, moxibustion, electroacupuncture, auricular acupuncture, and acupressure (all acupuncture therapies) are relatively safer than pharmacological treatments in the treatment and prevention of MWoA. However, their effectiveness remains uncertain. Several RCTs have demonstrated the superiority of MA in long-term treat MWoA long-term. According to ancient traditional Chinese medical texts, the stimulation of diagnostic and therapeutic effects of meridians and acupuncture points in the body requires manual manipulation of the acupuncture needles with vibrations, rotations, lifts, and insertions to stimulate the "Qi" of the points in order to achieve therapeutic purposes. Acupuncture therapy's clinical effects are largely attributed to this phenomenon, known as "De Qi". Animal studies have demonstrated that acupuncture needle rotation triggers the release of adenosine and endogenous opioids, which modulate the analgesic effects of MA. However, meta-analyses showing the effectiveness of MA in migraine sufferers without aura are lacking. Thus, we compared the effectiveness of MA and SA in MWoA.

METHODS

Search strategy: We intend to publish the data in the following databases: PubMed, Web of Science, CINAHL, Cochrane, CBM, CPVIP, CNKI, and Wan Fang. The terms, controlled and free, were combined by means of the Boolean operators OR and AND as follows: ((((((hemicrani*[Title/Abstract]) OR (migrain*[Title/Abstract])) OR (headach*[Title/Abstract])) OR (((migraine without aura[MeSH Major Topic]) OR (migraine[MeSH Major Topic])) OR (headache[MeSH Major Topic]))) AND (((acupuncture[MeSH Major Topic]) OR (acupuncture therapy[MeSH Major Topic])) OR ((acupuncture[Title/Abstract]) OR (acupuncture therapy[Title/Abstract])))) AND (((((randomized[Title/Abstract]) OR (placebo[Title/Abstract])) OR (randomly[Title/Abstract])) OR (trial[Title/Abstract])) OR (groups[Title/Abstract])) or ((randomized controlled trial[Publication Type]) OR (controlled clinical trial[Publication Type]))).

Participant or population: We explicitly defined the selection criteria as MWoA and a diagnosis as MWoA according to the 234rd edition of the International

Classification of Headache Disorders (ICHD-2, 3, 4).

Intervention: Manual Acupuncture.

Comparator: Sham Acupuncture.

Study designs to be included: Randomized Controlled Trial.

Eligibility criteria: We included trials with individualized strategies when the average number of treatments was at least five. Additionally, to assure the clinical efficacy of acupuncture treatments, the acupuncturist administering the treatments in the study should have a relevant acupuncture qualification or practice qualification. In addition, the acupuncturist should have prior clinical experience.

Information sources: We intend to publish the data in the following databases: PubMed, Web of Science, CINAHL, Cochrane, CBM, CPVIP, CNKI, and Wan Fang.

Main outcome(s): 1) The number of migraine attacks and days of migraine attacks during each assessment interval. 2) The migraine score (VAS score and any other available measures) at each assessment interval.

Additional outcome(s): The intensity of pain severity was recorded as the outcome of pain intensity using a numerical/verbal scale, for example, the mean headache severity during each assessment period.

Data management: The selected studies were imported into EndNote X9. Additionally, Endnote automatically removed duplicate articles, case reports, non-RCT studies, animal studies, and articles related to other diseases and interventions. The remainder of the references will be listed in the order of the first author's name, and the screening process will be repeated by two reviewers. According to the PRISMA guidelines, to manage records and data.

Quality assessment / Risk of bias analysis: We will independently assess the risk of bias for each included RCTs using the Cochrane Collaboration's bias risk tool. Disagreements will be resolved by discussion or consensus with a third reviewer.

Strategy of data synthesis: To explore differences in clinical outcomes between the intervention and control groups, the primary outcome is headache frequency and headache score at the end of treatment and follow-up to address differences in clinical outcomes between the intervention and control groups. Headache intensity was also extracted as a secondary outcome at the end of treatment and follow-up. Mean difference (MD) and standard deviation (SD) will be removed and calculated as effect estimates for these continuous results. Suppose the mean difference (MD) or standard deviation (SD) is not reported after contacting the author and is not available. We will use open data, such as median or p-value and confidence interval CI, and attempt to recalculate MD and SD from this information recorded in the study. Negative values indicated better results in the acupuncture group. The heterogeneity of the included studies will be assessed using the I^2 statistic test. At least 75% of the cutoff points in the I^2 statistic will be considered significantly heterogeneous. When heterogeneity exists random effects are selected to merge data; when there is no heterogeneity choose fixed effect to merge data.

Subgroup analysis: The studies that showed clinical heterogeneity ($I^2 > 75\%$) were subjected to a subgroup analysis based on the time of treatment, clinical characteristics of sex, age, disease course, etc.

Sensitivity analysis: After deleting any one of them, the merging results of the literature are not significantly different from those without deletion which means that the sensitivity analysis is passed.

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