INPLASY PROTOCOL

Corresponding author:
Xiqing Sun
sunxiqing1191@163.com

Author Affiliation:
Shandong University of Traditional Chinese Medicine

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Conflicts of interest:
The authors declare no conflicts of interest.

Effectiveness comparisons of acupuncture treatments for Bell palsy in adults: A protocol for systematic review and Bayensian network meta-analysis

Bing, L[1]; Xiqing S[2]; Jun G[3]; Wenjie S[4]; Yiran C[5]; Jie L[6].

Review question / Objective: To evaluate the most effective acupuncture treatment for Bell palsy.

Condition being studied: Bell palsy (BP), also known as idiopathic facial palsy or facial neuritis, is an idiopathic facial weakness or paralysis originating from the peripheral nerve, with acute onset.BP affects people of all ages and genders, with incidence rates ranging from 20-30 per 100000 population years, and 1 out of every 60 individuals will be affected during their lifetime. Study shows that 71% of BP patients return to normal facial function while 29% leave symptoms of semi-facial weakness, in which is severe and disfiguring in more than half of these cases. Besides, one third of patients yield anxiety and depression, and delay recognition of emotional facial expressions. Studies have shown that BP can increase the risk of cardio-cerebrovascular disease, depression, anxiety disorder and so on. It has a significant incidence of recurrences, which not only affects the physical and mental health of patients, but also affects the social economy.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 April 2020 and was last updated on 04 April 2020 (registration number INPLASY202040019).

INTRODUCTION

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the risk of cardio-cerebrovascular disease, depression, anxiety disorder and so on. It has a significant incidence of recurrences, which not only affects the physical and mental health of patients, but also affects the social economy.

METHODS

Search strategy: We will search the English and Chinese databases: The Cochrane Library, PubMed, Web of Science, EMBASE, CBM, CNKI, VIP and Wanfang database. In addition, we will search data from literature reviews and meta-analysis and we will also search ongoing trial registers in the trial registry websites. If multiple systematic reviews of the same topic are found, we will use the latest version for the evaluation. The search strategy will be constructed in the form of Medical Subject Headings (MeSH) combine with keywords, including "bell palsy, idiopathic facial palsy, facial neuritis, acupuncture, acupuncture therapy, electroacupuncture, warm acupuncture, fire acupuncture, plum blossom acupuncture, humans, randomized controlled trial", etc.

Participant or population: We will include patients more than18 years old with Bell palsy, the diagnostic criteria will be based on the definition by American Academy of Otolaryngology-Head and Neck Surgery(AAO-HNS)[23] or any other recognized diagnostic guidelines. Gender, race, nationality and duration will not be restricted.

Intervention: The interventions of the experimental group will include manual acupuncture, electroacupuncture, warm acupuncture, fire acupuncture, plum blossom acupuncture, used alone or combination of any two methods, or in combination with western medicine, which must be the same as the control group. The principles related to acupuncture will be limited to traditional Chinese medicine, so non-traditional laser acupuncture, thread-embedding, bee venom acupuncture, and unrelated methods such as acupoint application and bloodletting therapy will be

excluded. There will be no special requirements for acupuncture manipulation, frequency and duration.

Comparator: The control group will include virtual acupuncture, western medicine or other acupuncture method different from the experimental group, and other interventions will be excluded.

Study designs to be included: We will include all clinical randomized controlled trials (RCTs) of acupuncture in the therapy of Bell palsy in adults, regardless of whether or not u.

Eligibility criteria: The eligibility criteria will be the following:(1) Patients with Bell palsy received acupuncture treatment; (2) randomized controlled trials that included manual acupuncture, electroacupuncture, warm acupuncture, fire acupuncture, plum blossom acupuncture, used alone or combination of any two methods, or in combination with western medicine; (3) studies that evaluated the effects of acupuncture on at least one of the outcomes.

Information sources: We will search the English and Chinese databases: The Cochrane Library, PubMed, Web of Science, EMBASE, CBM, CNKI, VIP and Wanfang database. In addition, we will search data from literature reviews and meta-analysis and we will also search ongoing trial registers in the trial registry websites. If multiple systematic reviews of the same topic are found, we will use the latest version for the evaluation.

Main outcome(s): The primary outcome will be the recovery of facial muscles defined by House-Brackmann Grading Scale (HBGS), which classifies the facial nerve function into six levels (normal, mild, moderate, moderate to severe, severe, and complete dysfunction), it is also a scale of 1 to 6 points, of which 6 represents complete paralysis. The advantage of the evaluation system is that the classification method is simple and convenient, it can be widely used and includes a variety of symptoms

such as mouth-eye linkage and hemifacial spasm.

Additional outcome(s): The additional outcomes will include: (1) sequelae (including hemifacial spasm, joint movement and crocodile tear syndrome); (2) Facial Disability Index (FDI)score, mainly conducts questionnaire surveys for patients. The body function (FDIP) and social life function (FDIS) associated with facial nerves and facial muscles will be evaluated by asking the patient's condition, which is a subjective self-assessment of the patient; (3) Sunnybrook facial grading system(SFGS), the system combines static, dynamic and joint movements of facial muscles to evaluate facial nerve function, from 0 to 100, of which 0 indicates the most severe paralysis and 100 indicates normal; (4) Portmann score, divided into two items, movement and quiet score, the movement mainly includes frown, close eyes, moving nose, whistling, smile, drumming cheeks, 3 points for each with a total of 18 points, plus the quiet score of 2 points, the total score is 20 points; (5) adverse events.

Quality assessment / Risk of bias analysis: The quality will be assessed by two reviewers independently with reference to the Cochrane Collaboration Risk of Bias Tool.[24] Seven items will be evaluated, each with three grades namely "high", "unclear" and "low". In the process of evaluation, if there are disagreements, consult a third party to resolve.

Strategy of data synthesis: Stata16.0 software will be used to map the network plot for the comparison of interventions for each outcome index. We will use WinBUGS1.4.3 software to analyze the data, using the Bayesian Markov Chain Monte Carlo (MCMC) random effect model. We will use one chain to simulate, the number of iterations will be set to 50 million times, in which the first 20 million times for annealing to eliminate the effect of the initial value while the last 30 million times for sampling. We will evaluate the convergence of the iteration by the Brooks-Gelman Rubin method, when the potential scale reduction factor (PSRF) tends to 1,

the degree of convergence is satisfactory. In the actual operation, we will adjust the iterations and annealing times. We will choose OR as the dichotomous variable and MD as the continuous variable, and calculate the 95% CI. The difference will be statistically significant when the 95% CI of OR value does not contain 1 or the MD value does not contain 0. We will draw a SUCRA for each outcome indicator to predict the order of curative effect of treatment measures, the larger the area under the curve, the better the treatment measures.

Subgroup analysis: If there is heterogeneity, we will analyze the causes of heterogeneity and conduct subgroup treatment according to different sources of heterogeneity. If it is caused by methodological quality, we will analyze it according to the quality level; if it is caused by different design schemes, we will conduct subgroup analysis according to the design scheme, country, year of publication, age, time of onset and duration can be used for subgroup analysis.

Sensibility analysis: We will use the exclusion method to analyze the sensitivity of all outcome indicators. If we find that heterogeneity changes with the exclusion of a certain article, then this article is the source of heterogeneity. It can be analyzed from the aspects of experimental design, sample size, outcome index, evaluation standard and so on. If the heterogeneity remains unchanged, the result is robust.

Language: English and Chinese

Countries involved: China

Keywords: Bell palsy; network meta-analysis; protocol; acupuncture.

Contributions of each author:
Author 1 - conceive and design this protocol.
Author 2 - Revise this protocol; search strategy.
Author 3 - Data collection; analysis of results.
Author 4 - Analysis of results.