INPLASY PROTOCOL

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Conflicts of interest:
None declared.

A systematic review and meta-analysis of the treatment of peripheral facial paralysis by haomehuo acupuncture

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Review question / Objective: **The purpose of this study is to investigate the curative effect of hao huo acupuncture therapy on peripheral facial paralysis, and the research method is RCT experiment.**
Condition being studied: **Key results include the effectiveness of the House-Brackmann facial nerve grading system. Secondary outcomes will include Sunnybrook Facial nerve Grading System, Portmann Score, Facial Disability Index Scale, and adverse events. Two reviewers will independently conduct study selection, data extraction, data synthesis and quality assessment. Bias risk assessment and data synthesis will be performed using Review Manager 5.3 software. A rating system will be used to assess the quality of evidence.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 April 2022 and was last updated on 18 April 2022 (registration number INPLASY202240107).

INTRODUCTION

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METHODS

Search strategy: PFP using ACE will be searched from four international electronic databases (PubMed, Cochrane Library, EMBASE and Web of Science) and four Chinese electronic databases (China National Knowledge Infrastructure, VIP, Wanfang and China Biomedicine) Randomized controlled clinical trials (RCTS) were searched in the literature. We included only studies published from inception to January 2021.

Participant or population: Patients with peripheral facial paralysis.

Intervention: The filiform-fire needle.

Comparator: Other TCM treatments.

Study designs to be included: RCT.

Eligibility criteria: Efficiency based on house-Brackmann facial nerve grading system. Secondary outcomes will include Sunnybrook Facial nerve Grading System, Portmann Score, Facial Disability Index Scale, and adverse events.

Information sources: PubMed, Cochrane Library, EMBASE and Web of Science, National Knowledge Infrastructure of China, VIP, Wanfang and China Biomedicine searched for literature on randomized controlled clinical trials using ACE for PFP. Only studies published between now and January 2021 are included.

Main outcome(s): Based on the effectiveness of the House-Brackmann Facial nerve Grading System, Sunnybrook Facial Nerve Grading System, Portmann Score, Facial Disability Index Scale, and adverse events.

Quality assessment / Risk of bias analysis: The quality assessment process will involve 2 reviewers and any significant differences will be resolved through discussion to determine the final set of studies to be included. Two evaluators will independently assess the risk of bias for included studies by considering the following characteristics: random sequence generation, treatment allocation concealment, blindness, integrity of outcome data, selective outcome reporting, and other sources of bias. In addition, the Cochrane Collaboration's bias risk assessment tool will be used to assess the quality of individual included studies.

Strategy of data synthesis: If the included studies are sufficiently homogeneous, we will use Review Manager 5.3 software for quantitative synthesis. Mean difference or standardized mean difference will be used for continuous data. The risk ratio (RR) will be used to analyze the dichotomous data. We give 95% confidence intervals. In the case of homogenous data, if $I^2 \leq 50\%$ and $P > .1$, the fixed effects model was used for meta-analysis. Otherwise, the source of heterogeneity will be further analyzed. After excluding significant clinical heterogeneity, a random-effects model was used for a meta-analysis. Sensitivity and bias risk analysis will also be performed using Review Manager 5.3 software for bias risk assessment and data synthesis.

Subgroup analysis: Some planned subgroup analyses will be performed: The efficacy of ACE alone for PFP and ACE in combination with other therapies for PFP, different stages of PFP (e.g., ≤3 months, >3 months), and different duration of ACE treatment for PFP (e.g., ≤1 month, >1 month) were studied according to disease course =6 months.

Sensitivity analysis: Sensitivity analyses will be performed to determine the robustness and stability of pooled results by eliminating low-quality studies. Review Manager 5.3 software.

Country(ies) involved: China.

Keywords: Milli-fire needle, peripheral facial paralysis, curative effect.

Contributions of each author:

Author 1 - Zhao Boyi - Author 1 drafted the manuscript.
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