INPLASY PROTOCOL

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The efficacy and safety of filiform-fire needle for peripheral facial paralysis A protocol for systematic review and meta-analysis

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Review question / Objective: The randomized controlled trials (RCTs) has indicated the potential efficacy of filiform-fire needle as therapy for the treatment of PFP, while medical evidence is still lacked to date. Hence, this study aims to systematically evaluate the efficacy and safety of filiform-fire needle in the treatment of PFP, as well as summarize the relevant studies and literature with RCTs, for providing certain reference for clinical trials.

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.Pertinent literature is collected on four international electronic databases (PubMed, Cochrane Library, EMBASE, Web of Science) and four Chinese electronic databases (CNKI, VIP, Wanfang, SinoMed). For purpose of avoiding missing any ongoing clinical trials, 2 following trial registries will be searched to identify relevant studies: Chinese Clinical Trials Registry (www.chictr.org.cn/index.aspx), ongoing Trials Registry of NIH (www.chictr.org.cn/index.aspx). clinicaltrials.gov), World Health Organization International Clinical Trials Registry Platform (www.who.int/trialsearch), where the studies are required to be published in English or Chinese.

INTRODUCTION

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systematically evaluate the efficacy and safety of filiform-fire needle in the treatment of PFP, as well as summarize the relevant studies and literature with RCTs, for providing certain reference for clinical trials.

Condition being studied: Peripheral facial paralysis. Two reviewers were supposed to independently conduct the process of study selection, data extraction, data integration, and quality assessment. Review Manager 5.3 will be applied for performing the risk of bias assessment and data synthesis. Adm a ranking system will be exploited for assessment of the evidence quality.

METHODS

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.

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

Quality assessment / Risk of bias analysis: 2 reviewers will attend in the quality assessment process and any major disagreements will be resolved by discussion to determine the final study set included. Two reviewers will evaluate the methodological quality of the included literature according to the tool for risk of bias assessment provided in the Cochrane Collaboration Evaluation Manual, assessing the risk of bias, mainly referring to the generation of random serials, the implementation of allocation concealment and blinding, and the completeness of the result data, selected report results, other sources of bias, etc.

Strategy of data synthesis: If the studies included were sufficiently homogeneous, the quantitative integration was performed by Review Manager 5.3. The incorporative results of enumeration data were represented by relative risk (RR), and continuous variables were merged for statistic by mean difference (MD) with 95% confidence interval (CI). If $I2 \leq 50\%$, $P > .1$, meta-analysis was conducted in a fixed-effects model. Otherwise, the sources of heterogeneity will be further analyzed. A random-effects model was applied for meta-analysis after excluding significant clinical heterogeneity, as well as the analysis of sensitivity and risk of bias. $P<0.05$ was regarded as the standard of statistical significance.

Subgroup analysis: Several planned subgroup analyses will be performed: the efficacy of filiform-fire needle therapy alone and in combination with other therapies for

PFP, respectively, different stages of PFP (e.g., ≤3 months, >3 months), different treatment duration of filiform-fire needle therapy for PFP (e.g., ≤1 month, >1 month), and different sizes of the fire needles (e.g., the length and diameters of the fire needle).

Sensitivity analysis: A sensitivity analysis will be performed to verify the robustness and stability of the pooled results by eliminating low-quality studies.

Country(ies) involved: China.

Keywords: peripheral facial paralysis, filiform-fire needle, meta-analysis, protocol, systematic review.

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