INPLASY PROTOCOL

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Conflicts of interest:
None.

Effectiveness and safety of Tongue three-needle on post-stroke pseudobulbar paralysis: Protocol for a systematic review and meta analysis

Xia, Y[1].

Review question / Objective: **The review will provide comprehensive evidence of the safety and efficacy of tongue three-needle therapy in the treatment of post-stroke pseudobulbar paralysis, to the benefit of patients, medical workers, and policymakers.**
Condition being studied: **Many clinical studies suggested that tongue three-needle could significantly improve the effectiveness of the treatment of PBP after stroke and perfect the related symptom scores compared with rehabilitation training, routine acupuncture, moxibustion and herbal. But other studies showed that the efficacy of tongue three-needle was less effective than some treatments, for example, electrical stimulation. In addition to the small sample size, the different conclusions of relevant literatures, the conclusions of a single study are of limited significance, and there is no targeted systematic evaluation of the literatures. Therefore, we will assume systematic evaluation and meta-analysis to evaluate the efficacy and safety of tongue three-needle in the treatment of PBP after stroke, providing a reliable reference for future clinical treatment.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 November 2020 and was last updated on 28 November 2020 (registration number INPLASY2020110130).

INTRODUCTION

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METHODS

Participant or population: Patients diagnosed with only poststroke pseudobulbar palsy will be included in the review. The diagnosis must be consistent with general diagnostic criteria for stroke and PBP, and confirmed by diagnostic imaging. Trials studies of pseudobulbar palsy due to other inducements such as syphilis, Parkinson's disease, multiple sclerosis, carbon monoxide poisoning, encephalitis, brain tumors, or brain trauma will be excluded.

Intervention: As follow: 1.Control group will recruit conventional treatment, no treatment, placebo, unproven control treatment or other acupuncture except tongue-three needle, as intervention group will only receive tongue-three needle therapy. 2. Control interventions will include conventional treatment, no treatment, placebo, unproven control treatment or other acupuncture except tongue-three needle. While Interventions group will be added tongue-three needle therapy based on control group.

Comparator: The efficacy and safety of the experimental group and the control group were compared.

Study designs to be included: Regardless of the race, region, gender, age, disease severity or disease duration, we will collect all randomised controlled trials (RCTs) that evaluated the curative effects and safety of tongue-three needle for post-stroke pseudobulbar palsy patients. Furthermore, animal experiments, case series, qualitative studies, Observational studies, reviews and comments will not be included.

Eligibility criteria: Patients diagnosed with only poststroke pseudobulbar palsy will be included in the review. The diagnosis must be consistent with general diagnostic criteria for stroke and PBP, and confirmed by diagnostic imaging. Trials studies of pseudobulbar palsy due to other inducements such as syphilis, Parkinson's disease, multiple sclerosis, carbon monoxide poisoning, encephalitis, brain tumors, or brain trauma will be excluded.

Information sources: Articles will be retrieved from these following databases: PubMed, Embase, Cochrane Library, Allied and Complementary Medicine Database, China Biology Medicine disc, Chinese National Knowledge Infrastructure, Wanfang Data and VIP Database. Their publication period will be from inception to November 2020.

Main outcome(s): Articles included will contain at least one of these following outcome measures: Improvement of dysphagia and dysarthria will be the primary outcome measures.The most common symptoms of pseudobulbar palsy are dysphagia and dysarthria, hence we will select both of them as the primary direction of assessment. these outcome measures we select have been wildly used in published cases. For dyephagia, we will adopt total effective rate and apparent rate cccording to Watian Drinking Water Test. Some common assessments or scares will be included as well, such as sub-water test score, Standardized Swallowing Assessment(SSA), Gugging Swallowing Screen(GUSS), Mann Assessment of Swallowing Ability(MASA), etc. As the golden standard for evaluating dysphagia and its alternate standard, video fluroscopic swallowing study(VFSS) and fiberoptic endoscopic examinations of

swallowing(FEES) will not be ignored;19 The evaluation of dysarthria has not been unified, so we will choose the most common ones in the world—Frenchay Dysarthria Assessment(FDA). Scale describing the improvement of symptoms related to pseudobulbar palsy after stroke, including emotional and cognitive impairment, etc, can be attributed to this part.

Quality assessment / Risk of bias analysis: Risk of bias assessment categories will include as follow: random sequence generation; allocation concealment; identification of blindness; blindness of participants; selective outcome reporting; other biases. Further, risk will be classified into 3 levels: low, high, or unclear risk of bias.

Strategy of data synthesis: We will use Stata V.14.0 to process the data. For the enumeration data, relative risk (RR) and 95% confidence interval (95% CI) will be used; For the measurement data, weighted mean difference (WMD) and 95% CI will be used if the measurement is consistent. While standardized mean difference (SMD) and 95% CI will be used if the measurements are inconsistent. Subgroup analysis will be conducted according to the heterogeneity of patients characteristics or therapeutic methods. Heterogeneity among included studies will be assessed using the Q and I2 test statistics . For the I2 statistic, I250% indicates significant heterogeneity, and random effect model will be conducted in this case.

Subgroup analysis: The subgroup analysis will be conducted based on various study characteristics, such as study type, study location, study quality, intervention type, treatment duration for the purpose of discover latent sources of heterogeneity. If the data extraction is not sufficient, we will make a qualitative synthesis instead of quantitative synthesis.

Sensibility analysis: We will carry out sensitivity analysis, with the aim to remove low-quality studies. Subgroup analysis and meta-regression will be considered if there is significant heterogeneity.

Country(ies) involved: China.

Keywords: Tongue three-needle, post-stroke, pseudobulbar paralysis, meta analysis.

Contributions of each author:
Author 1 - Yuge Xia.