

Protocol

Acupoint stimulation for post-stroke spasticity: a systematic review protocol^{*}

穴位刺激治疗中风后痉挛状态的系统评价研究方案^{*}

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ABSTRACT

This systematic review is aim to comprehensively evaluate the efficacy of acupoint stimulation in managing of post-stroke spasticity. The eligible randomized controlled clinical trials (RCTs) and quasi-randomized controlled clinical trials (quasi-RCTs) will be searched from the following databases: the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Wanfang Database, Chinese BioMedical Literature Database (CBM). The Cochrane risk of bias tool will be used to assess the trials. No patients or their family will be bothered in this systematic review, so there is no need for the permission of institutional review board (IRB). The completed systematic review will be published in a peer-reviewed journal.

KEY WORDS: point; acupoint; post-stroke; spasticity; systematic review

INTRODUCTION

Stroke is a commonly seen problem causing death and also one of the major causes of long-term disabilities worldwide^[1-3]. Post-stroke spasticity is one of most common sequelae of stroke^[4]. It has been reported that equivalent to 20%–42% of stroke survivors are subjected to abnormal hypertonia^[5-10]. Performing as over excitation of the lower motor center, spasticity is ascribed to the damage of upper motor neuron center or pathway, where inhibition to the former is interrupted^[11]. The main manifestations

of spasticity after stroke are the flexion and adduction on the upper limbs, fixed stretching on the lower limbs, and increased resistance during the movement. Articular contracture and malformation would take place if there were no effective treatment. All above would affect the patients' self-care ability and quality of daily life seriously^[12-13], which also be disadvantaged to bring patients with hypermyotonia into early intervention of rehabilitation^[14-15]. Therefore, reducing muscle tension is the key point of treatment for stroke patients.

The current approaches which are mainly used for treating post-stroke spasticity comprise pharmacological agents, physical therapy (kinesitherapy, cryotherapy, ultrasound, electrical and vibratory stimulation, and biofeedback, et al.)^[16-21], and surgical therapy. Although these interventions for managing spasticity have been recommended, the efficacy of other rehabilitation therapies used either separately or in combination also remains to be proved by compelling evidence^[22], and the effect of pharmacological agents is still being observed, and of which side effects cannot be eliminated^[23]. Thus, utilitarian measures featured by safe and effective to replace conventional interventions managing the spasticity patients after stroke are urgently necessary.

A series of articles have demonstrated that acupuncture (including electroacupuncture, cutaneous needle, abdomen acupuncture, scalp acupuncture), moxibustion, transcutaneous electrical stimulation on acupuncture points, as well as massage could be beneficial to rehabilitation of post-stroke spasticity^[24-33], and all the modalities mentioned above can be categorized as acupoint stimulation in TCM. In fact, acupoint stimulation be used in stroke patients for many centuries in China, and many decades in the West^[34]. Researchers have found that acupoint stimulation could lower down the post-stroke hypermyotonia by coordinating the balance of tension among muscular group^[35], improving brain blood circulation by promoting the development of collateral circulation^[36], and affecting spinal sensitization^[37] as well as expression of receptors^[38]. However, the definite conclusion regarding to these interventions is needed, additionally, based on our searched consider revising, there is no systematic review focusing on acupoint stimulation for patients of post-stroke spasticity. The role of acupoint stimulation as a whole in treating abnormal hypertonia after stroke is not completely evaluated. Therefore, in order to fill this void, we turn to design a systematic review and meta-analysis on the efficacy of acupoint stimulation for post-stroke spasticity patients.

OBJECTIVES

This systematic review is aim to evaluate the efficacy of acupoint stimulation in managing of post-stroke spasticity.

METHODS AND ANALYSES

Study registration

This protocol of systematic review has

been registered on PROSPERO (number: CRD42014013296) http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014013296^[39], the review reporting will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines^[40].

Study design

(1) Types of studies

Published randomized controlled clinical trials (RCTs) and quasi-randomized controlled clinical trials (quasi-RCTs), comparing any form of acupoint stimulation with/without additional treatment against placebo or sham or no treatment or same additional treatment will be included in the review. Cross-over RCTs will be excluded in this review.

(2) Types of participants

Patients of any gender, age, race or nationality suffered from stroke, including ischemic stroke and hemorrhagic stroke, and were in the stage of spasticity.

(3) Types of interventions

Trials comparing any form of acupoint stimulation (acupuncture, acupressure, massage, electric stimulation, moxibustion, cupping, acupoint injection, acupotomy, wrist band stimulation, catgut-embedding, magnet stimulation, laser-irradiation, et al.) as the sole intervention or as an adjunct to other treatments with the accompanied treatments or placebo, or sham, or blank group, regardless of the treatment duration and manipulations will be included in the review. Those trials that compared different kinds of acupoint stimulation or adopted a combination therapy without assessing the sole effect of acupoint stimulation will be unconcerned.

(4) Types of outcome

Primary outcomes^[41-43]

- a. Ashworth Scale;
- b. Modified Ashworth Scale;
- c. Modified Modified Ashworth Scale;

Secondary outcomes^[44-48]

- a. Modified Tardieu Scale;
- b. Fugel-Meyer Motor Assessment Scale (FMA);
- c. Activity of Daily Living (ADL);
- d. Barthel Index (BI);
- e. The quality of life (QoL);
- f. Brunnstrom recovery stages;
- g. Neurological deficit evaluation (ND);
- h. Any recorded adverse events;

(5) Search methods

Electronic databases searches There will be seven databases to search from their inception to July 2015. They are as followings: the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Wanfang Database, Chinese BioMedical Literature Database (CBM).

Search strategy

The search strategy for MEDLINE is as below, and we will apply similar search strategies for other electronic databases.

#1. acupuncture [Title/Abstract] OR needle [Title/Abstract] OR needling [Title/Abstract] OR electroacupuncture [Title/Abstract] OR electric stimulation [Title/Abstract] OR acupoint [Title/Abstract] OR acupuncture point [Title/Abstract] OR acupressure [Title/Abstract] OR finger pressure [Title/Abstract] OR massage [Title/Abstract] OR tuina [Title/Abstract] OR catgut-embedding [Title/Abstract] OR catgut implantation [Title/Abstract] OR acupotomy [Title/Abstract] OR small needle-knife [Title/Abstract] OR moxibustion [Title/Abstract] OR moxa [Title/Abstract] OR warm needling [Title/Abstract] OR pyonex [Title/Abstract] OR cupping [Title/Abstract] OR magnet [Title/Abstract] OR laser-irradiation [Title/Abstract]

#2. spasticity[Title/Abstract] OR hypermyotonia [Title/Abstract] OR hypertonia [Title/Abstract] OR muscle rigidity [Title/Abstract] OR spastic paralysis [Title/Abstract] OR muscle tension [Title/Abstract] OR increased muscle tone [Title/Abstract] OR motor dysfunction after stroke [Title/Abstract]

#3. stroke [Text Word] OR apoplexy [Text Word] OR post-stroke [Text Word] OR cerebral infarction [Text Word] OR cerebral hemorrhage [Text Word] OR cerebrovascular accident[Text Word] OR cerebrovascular disease [Text Word] OR cerebral thrombosis [Text Word] OR cerebral embolism [Text Word] OR apoplexia [Text Word] OR brain infarction [Text Word] OR cerebrovascular disorders [Text Word] OR brain ischemia [Text Word]

#4. random [Text Word] OR randomized [Text Word] OR control [Text Word] OR controlment [Text Word] OR trial [Text Word] AND “humans” [MeSH Terms]

#5. #1 AND #2 AND #3 AND #4

(6) Study Selection

Based on the prespecified strategy on collecting the articles, the author GUO Sheng-nan will download all the full text. After that, two authors WANG Jun and CHEN Sheng will respectively browse the titles, abstracts and full text to judge whether these articles meet the inclusion criteria. Studies that involve any form of acupoint stimulation (acupuncture, acupressure, massage, electric stimulation, moxibustion, cupping, acupoint injection, acupotomy, wrist band stimulation, catgut-embedding, magnet stimulation, laser-irradiation, et al.) as the sole intervention or as an adjunct to other treatments will be selected. However, studies in which acupoint stimulation is not used as a major therapy will be excluded. Studies in which one form of acupoint stimulation is compared with another form will be excluded. If any disagreements happen, the arbiter ZHAO Ji-ping will make the decision. Detailed process is shown in the PRISMA flow diagram (Figure 1).

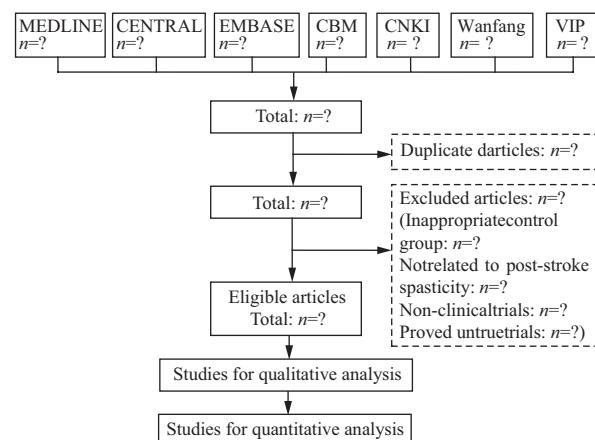


Figure 1 Study selection flow diagram

(7) Data extraction

Two authors WANG Jan and CHEN Sheng will respectively and independently extract data on the following items: type of study (RCT or quasi-RCT), size number, randomized method, participants, interventions, comparison, outcomes, frequency, duration, observation points, results, follow-ups and adverse events. All the information on a designed data extraction form will be recorded.

(8) Quality assessment

Cochrane systematic review methods, the Cochrane risk of bias tool which is recommended by the Cochrane Reviewer's Handbook 5.0.24^[49] will be applied to assess the quality of the ultimate included studies. The specific items are as follows: random sequence generation, allocation concealment, blinding, completeness of outcome data, selective outcome reporting, and other bias. The risk of bias for each item

will be graded as “unclear risk of bias” “low risk of bias”, or “high risk of bias”. Authors’ judgments about each risk of bias item will be presented as percentages across all included studies. If we cannot get the information to do the assessment from the articles, corresponding author will be called to get the true situation. Two authors Federico Marmori and NAN Yinan will do this work independently, and if there is any disagreement take place, the arbiter ZHAO Ji-ping will do the final judge.

(9) Data analysis

The data of the studies will be divided into two cases, depending on whether the data is suitable to be done meta-analysis. If the meta-analysis is not adaptive because of the heterogeneity of different participants, interventions, comparisons, outcomes et al, a set of forms will be built to summaries and conduct a qualitative description. If the meta-analysis is suitable for the data, they will be collected because of their good performance in homogeneity, meta-analysis will be applied to conduct a quantitative analysis. Review Manager Software RevMan 5.0.24 will be used. Heterogeneity test will be done for the data for meta-analysis(using a standard *chi-squared* test^[50]). When there are sufficient similar studies of relatively high heterogeneity ($P > 0.10$, $I^2 \leq 50\%$), fixed-effect model will be considered to apply to do the data synthesis. For dichotomous data, relative risk (RR) and mean difference (MD) will be taken for continuous data^[51-52], both of them will be with 95% confidence intervals (CI). While if the studies are of relatively low heterogeneity ($P \leq 0.10$), the subgroup analysis or the sensitivity analysis will be done. At last, we will test the overall effect by using the Z score with the significance set at $P \leq 0.05$.

On the condition of including more than 10 trials, funnel plots will be applied to detect whether there is publication bias or not.

Subgroup analysis will be conducted to assess the heterogeneity between the studies, including:

① Intervention: different forms of acupoint stimulation such as: acupuncture, acupressure, electric stimulation, moxibustion, cupping, acupoint injection, acupotomy, wrist band stimulation, catgut-embedding, magnet stimulation, laser-irradiation, et al.;

② Duration and frequency of the treatment;

③ The observing time point of outcomes;

④ Stimulating intensity of acupoint stimulation

⑤ One side versus two sides for taking acupoint stimulation;

⑥ Affected versus unaffected side for taking

acupoint stimulation

DISCUSSION

According to our preliminary search, most of the currently relevant review articles focus on acupuncture treatment only. There is still no systematic review regarding acupoint stimulation as a whole for spasticity after stroke. This is the first protocol of a systematic review designed to assess the efficacy of acupoint stimulation in managing post-stroke spasticity patients. Although the related literature without language restrictions will be retrieved through an extensive and unbiased search of numerous databases, it is unsure that we could collect all relevant RCTs and quasi-RCTs studies. In addition, there may be a certain degree of difficulty for us in seeking the raw information from published sources, which may be another major cause for bias. Previous research regarding to acupuncture for post-stroke spasticity suggested that the number of RCTs was limited, and lots of articles were of low quality and methodological matters without consistency in measuring the regions of spasticity^[24]. However, other methods such as transcutaneous electrical stimulation on acupoints, moxibustion, and acupressure also play an active role in reducing hypertonia after stroke. By extending the searching range of intervention measures, we hope to evaluate whether acupoint stimulation is effective in relieving the post-stroke spasticity as complete as possible, and believe that the results of this article would benefit patients and practitioners.

CONTRIBUTORSHIP STATEMENT

CHEN Sheng and GUO Sheng-nan conceived the study, developed the criteria and searched the literature, performed data analysis and wrote the protocol. WANG Jun, Nan Yi-nan and ZHAO Ji-ping assisted in searching the literature and extracting data. Federico Marmori and CHEN Sheng wrote the introduction of this protocol. ZHAO Ji-ping advised on the protocol design and revised the manuscript. All authors have read and approved the final manuscript.

COMPETING INTERESTS

None.

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DATA SHARING STATEMENT

No additional unpublished data are available.

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ABSTRACT IN CHINESE

[摘要] 为完成一篇全面评价穴位刺激治疗中风后痉挛状态疗效的系统综述而作的研究方案。计划检查Cochrane对照试验中心注册库、MEDLINE、EMBASE数据库、中国知网、中国科学期刊数据库、万方数据库和中国生物医学文献数据库检索数据，筛选并纳入合格的随机对照临床试验和半随机对照临床试验，使用Cochrane偏倚风险评估工具对纳入文献进行评价。由于没有打扰到病人及其家庭，本研究不需要经过伦理委员会的许可，系统评价完成后将发表在同行评议期刊上。

[关键词] 穴位 胃穴 中风后 痉挛 系统评价