

# INPLASY PROTOCOL

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**Corresponding author:**  
Jingling Chang

17812051068@163.com

**Author Affiliation:**  
Dongzhimen Hospital,  
Beijing University of Chinese  
Medicine, Beijing (100700),  
China

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**Conflicts of interest:**  
None.

## INTRODUCTION

**Review question / Objective:** The aim of this review is to explore the effectiveness of electrical stimulation therapy in the treatment of Vascular cognitive impairment

## Electrical stimulation therapy for improving cognitive functioning in people of vascular cognitive impairment after stroke: A Systematic Review with Meta-analysis of Clinical Trials

Xu, M<sup>1</sup>; Chang, J<sup>2</sup>.

**Review question / Objective:** The aim of this review is to explore the effectiveness of electrical stimulation therapy in the treatment of Vascular cognitive impairment after stroke. Secondary, to determine whether any effect of treatment of Vascular cognitive impairment after stroke with electrical stimulation therapy is influenced by any treatment parameters or patient features, including: the type of electrical stimulation therapy, the duration of treatment, electrical waveform, pulse duration, frequency, location, electrodes and the patient's type or severity of cognitive impairment.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 October 2020 and was last updated on 19 October 2020 (registration number INPLASY2020100070).

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stimulation therapy, the duration of treatment, electrical waveform, pulse duration, frequency, location, electrodes and the patient's type or severity of cognitive impairment.

**Condition being studied:** Cognitive impairment is a frequent consequence of stroke, with an estimated 35% of patients presenting with cognitive impairment within 3 months following a stroke. Cognitive impairment after stroke is progressive, a previous study reported that about half of patients with vascular cognitive impairment(49%) progress to dementia and the mortality rate of patients with vascular dementia within 5 years as high as 60%. Finding ways to improve cognitive functions is of all times, Many clinical trials have reported that various medications are effective in improving vascular cognitive impairment, but there are few medications that are officially licensed. There has been a rise in research exploring the potential of electrical stimulation therapy for improving cognitive functions in cognitive impairment after stroke, such as transcranial direct current stimulation (tDCS), electroacupuncture (EA), fastigial nucleus stimulation(FNS) etc. These methods usually apply a weak current through some stainless steel needles or electrodes located on the scalp or somewhere part of the body to deliver electrical stimuli and has been reported to improve cognitive impairment. To our knowledge, no meta-analysis has systematically study the effects of all types of electrical stimulation therapy currently used in cognitive impairment of post-stroke vascular impairment on cognitive function and the feature of various electrical stimulation.

## METHODS

**Participant or population:** The report will include patients with cognitive impairment after stroke of any type. The patients are of either sex and of any age. The presence and type of cognitive impairment after stroke is identified according to the any diagnostic criteria, such as classifications provided by the Diagnostic and Statistical

Manual of Mental Disorders, Fourth Edition (APA 1994) and the International Classification of Diseases. In the absence of the criteria relevant rating scale such as the Mini-Mental State Examination, psychiatric evaluation, psychological evaluation, or a medical evaluation are considered acceptable; 2)stroke diagnosis confirmed by CT and/or MRI of the brain; We will include participants regardless of initial level of impairment, duration of illness.

**Intervention:** In this update, we define electrical stimulation as a pulse of current lasting more than a minute that is applied to the brain through a conductive substance to stimulate the affected hemisphere or inhibit the healthy hemisphere, and this will be the primary intervention. We included any type of electrical stimulation and any stimulation protocol (e.g.intensity, electrical waveform, location, electrodes, frequency and duration of stimulation). If studies contain three experimental groups with only one group receiving electrical stimulation therapy, the electrical stimulation group will be chosen as the intervention group and the nonelectrical stimulation treatment group was chosen as the control group.

**Comparator:** In addition to the electric stimulation, the treatment measures in control group Will be the same as the electric stimulation group, Includes routine medical care, rehabilitation, western medicine with sham electrical stimulation or nonelectrical stimulation.

**Study designs to be included:** We will include randomised controlled trials (RCTs) and randomised controlled cross-over trials.

**Eligibility criteria:** This study will only include randomised controlled trials and randomised controlled cross-over trials of electric stimulation therapy in the patients with vascular cognitive impairment after stroke. If studies contain three experimental groups with only one group receiving electrical stimulation therapy, the electrical stimulation group will be chosen as the

intervention group and the nonelectrical stimulation treatment group be chosen as the control group. Trials will be excluded if they meet any of the following criteria: (1) electrical stimulation therapy used in both the treatment group and the control group; (2) standardized indices of curative effect or detailed results of treatment not included; and (3) comparison of the intervention group with the control group in addition to treatment methods other than electrical stimulation therapy, such as drugs or other forms of Traditional Chinese Medicine.

**Information sources:** We will search articles from the following major databases: PubMed (MEDLINE), Cochrane Library, EMBASE, Google Scholar and the Chinese database China National Knowledge Infrastructure (CNKI), VIP, Wan fang Data Knowledge Service Platform, China Biology Medicine(CBM). All the publications from January 2000 to October 2020 will be searched, without any restriction of countries. The electronic database search will be supplemented by a manual search of the reference lists of included articles. The search string will be built as follows: (vascular dementia OR cognitive impairment OR cognitive disorders) AND (stroke OR cerebrovascular accident) AND (electrical stimulation OR electroacupuncture OR electric stimulation therapy OR neuromuscular electrical stimulation).

**Main outcome(s):** Our primary outcomes are measures of cognitive function. We identify formal outcome measures. We prioritise the outcome measures in the following order: 1. Mini-Mental State Examination (MMSE); 2. Montreal Cognitive Assessment (MoCA); 3. Hasstgawa Dementia Scale(HDS); 4. Alzheimer 's disease assessment scale (ADAS-cog ) Depending on the data provide by the studies and researchers, all the review authors discuss and reach consensus on which measures to be included in the analysis for the primary outcome.

**Quality assessment / Risk of bias analysis:** The risk of bias mainly comes from: 1.

Different daily nurse; 2. The data of electroacupuncture, transposition cerebellar nucleus stimulation and transposition vestibular stimulation are mostly from eastern countries; 3. The use of sham stimulation or non-stimulation as the control group may result in performance and detection biases, respectively.

**Strategy of data synthesis:** Efficacy data will be synthesized and statistically analyzed in R3.5.1. For continuous outcomes, data will be analyzed by using a standard mean difference (SMD) with 95% CIs or a weighted mean difference (WMD). The WMD will be used for the same scale or the Same assessment instrument; SMD will be used for different assessment tools. A consistency examination will be taken using the Z test. We will calculate the P-value to find out whether there are inconsistencies among the comparison of direct and indirect. If the  $p > 0.05$ , there is no statistical significance, so the comparison of direct and indirect is consistency; on the contrary, inconsistency is considered.

**Subgroup analysis:** If the necessary data are available, subgroup analyses will be done for people with different electrical stimulation methods and patient features.

**Sensibility analysis:** We will preside over sensitivity analysis to identify the robustness and stability of study findings by excluding low quality trials.

**Country(ies) involved:** China.

**Keywords:** electrical stimulation therapy; electroacupuncture; vascular cognitive impairment; vascular dementia; stroke; systematic review; Meta-analysis;

**Contributions of each author:**

Author 1 - Minjie Xu.

Author 2 - Jingling Chang.