

国际中医技术操作规范

调神益智针刺法治疗中风后轻度认知障碍

国际组织标准编制说明

Formulation Explanations

一、工作简况

主要起草单位：天津中医药大学第一附属医院、国家中医针灸临床医学研究中心。

参与起草的单位：美国亚利桑那州针灸研究所、慕尼黑中医诊所、马来西亚国家癌症中心、英国梅德斯通中医中心、长沙市中医医院、长春市中医院、内蒙古科技大学包头医学院第二附属医院、长治市中医研究所附属医院。

主要起草人：石学敏、杜宇征。

参与起草人（按姓氏拼音排序）：

中国：布赫、戴晓霁、杜革术、石江伟、施晓瑜、王彦红、张丽丽。

美国：刘静。

德国：Florian von Damnitz。

马来西亚：钟尚烨。

英国：赵俊红。

澳大利亚：王占奎。

二、标准起草过程简介

该项目于 2022 年 4 月启动，成立“国际中医技术操作规范 调神益智针刺法治疗中风后轻度认知障碍”开发小组，明确分工、布置任务。经过文献检索、证据评价、多次小组会议讨论、征求专家意见合成推荐意见，形成初稿。2022 年 7 月，根据世界中医药学会联合会发布的 SCM 1.1-2021《标准化工作导则 第 1 部分：标准制修订与发布》，标准起草小组组织审稿会，认真修改、审查，确认全部资料严谨、科学、符合要求。2022 年 11 月 29 日，国家中医针灸临床医学研究中心组织召开天津市中医针灸专科联盟启动会暨针灸联盟优势病种培训会，期间课题组成员线上、线下参与“调神益智针刺法治疗卒中后轻度认知障碍”专题培训课，明确“调神益智”针刺法临床应用现状，明确指南落地目标。2022 年 12 月 24 日，该项目起草小组成员在天津召开标准内容修改会议，根据与会专家的意见和建议，该项目涉及的全体编写人员及专家最终确定草案内容，会后修改完善标准内容和格式。

三、主要技术内容介绍

1. 技术背景

“调神益智”针刺法是基于石学敏院士“醒脑开窍”针法并结合其学术思想发展而来，“醒脑开窍”针刺法在治疗血管性痴呆的研究中取得了良好的疗效，而“调神益智”针法在其基础上，采用“醒脑、补脑、调神、促智”并重治疗重点在于“调神”，首以“醒神”，开窍启闭（内关、水沟、三阴交、太冲、丰隆）；次以“养神”，斡旋神机（百会、四神聪、神门、四白、风池、完骨、天柱）两部分取。并结合“心-脑-肾轴”理论，归纳整理相关中西医理论及文献，提出阐释“调神益智”针法。

肾虚髓减是卒中后轻度认知障碍的病机根本，以补肾、益髓为本，通过针刺补益肾精、调和脏腑，使髓得精实而充、神得髓满而灵，继而神调智益、认知功能恢复正常，进一步佐证及天津中医药大学第一附属医院针灸学科是中国最大的针灸临床科研教学基地和国际交流中心，学科带头人为石学敏院士。学科始创于 1953 年，1962 年开设全国首个针灸病房，1988 年成为“全国针灸临床研究中心”，2002 年成为国家教育部重点学科，2008 年成为国家中医临床研究基地[中风病]，2018 年成为国家区域诊疗中心。拥有以院士为核心的教育部创新团队。“调神益智”针刺法的研究成果已在本院院内及全国多家医院得到应用，促进了针灸学科的发展。本研究为众多的中风后认知障碍患者提供了有效的针刺治疗方案，给患者带来了更多的治疗选择；进一步推广后可以使更多的患者受益，提高人民生活质量和健康水平。

石学敏院士学术团队以人类重大疾病“中风”为切入点开始进行研究，中风后轻度认知障碍是中风后常见的并发症，一种介于正常认知与血管性痴呆的中间状态。大约有 33% 的患者出现认知障碍是在中风发生后 3 个月至半年内，约 1/3 中风后轻度认知障碍患者会发展为痴呆。因此，基于中风病“窍闭神匿，神不导气”的病机，石学敏院士指出卒中后认知障碍的病机为“脑髓空虚，神机失用”，病位在脑。在临床实践和科研积淀基础上，根据中医针灸学的学科特点，研究适用于针灸临床实践指南制订的方法，从古代文献、现代文献、现代名医经验等方面多角度收集证据，并客观科学地辨别证据、评价证据。石学敏院士将“调神益智”针刺法配伍腧穴操作进行量学规范。研究团队开展了大量临床研究，本指南规定了“调神益智”针法治疗中风后轻度认知障碍的术语和定义、治疗原则、应用范围、腧穴组方、操作步骤与要求、注意事项与禁忌等，规范手法量学操作，严格手法量学标准。

2. 临床试验

天津市科技计划项目“针刺治疗血管性认知障碍的临床研究”，进行多中心随机对照临床研究，在全国五家医院对针刺治疗卒中后认知障碍进行有效性和安全性评价，共纳入 355 例患者，利用中央随机方法，按 1:1:1 将受试者随机分入针刺组、假针组、等待治疗组，治

疗 3 个月，随访 6 个月，以认知功能的恢复情况：简易智能精神状态检查量表（MMSE）、蒙特利尔认知评估量表（MoCA）、临床痴呆评定量表（CDR）及痴呆发生率为主要疗效指标，以精神症状评价—神经精神症状问卷（NPI），生活质量评价—生活质量量表（WHOQOL-BREF），日常生活活动能力评价—功能活动问卷（FAQ）为次要指标，从认知功能、生活质量、痴呆转化率等方面评价“调神益智”针刺治疗方案治疗卒中轻度认知障碍的有效性及安全性。结果显示“调神益智”针刺法可提高卒中后轻度认知障碍患者的认知功能，刺治疗可进一步改善患者的认知功能（MMSE 改变值、MoCA 评分），其效果优于对照组，且针刺效应可持续 3-6 个月。随着时间的延长，卒中患者的痴呆发生率随之增加，然而“调神益智”针刺法可有效降低痴呆发生率，延缓痴呆进展并提高卒中后轻度认知障碍患者的生活质量。

此外，为观察“调神益智”针法治疗卒中后轻度认知障碍的单中心临床疗效，课题组以 126 例卒中后轻度认知障碍患者为研究对象，随机分为“调神益智”针刺法组、药物尼莫地平组。治疗 12 周，观察“调神益智”针刺法和尼莫地平治疗脑梗死后轻度认知障碍的临床疗效。通过评估 MoCA 量表、非认知功能评价指标（神经精神指数 NPI、汉密尔顿抑郁量表 HAMD）、生活力量表（ADL、FAQ）、血管性痴呆中医辨证量表（SDSVD），评价“调神益智”针法临床疗效及安全性。临床试验证明，“调神益智”针刺法能明显改善卒中后轻度认知障碍患者的神经功能和生活质量。针刺组经过 12 周的治疗后，MoCA 评分、ADL 评分、FAQ 评分均优于对照组。其中，与尼莫地平相比，针刺改善卒中后轻度认知障碍的优点体现在视空间/执行功能、命名、定向力及生活质量方面的明显改善。

3. 机制研究

课题组对“调神益智”针刺法主穴百会穴治疗卒中后轻度认知障碍的中枢机制展开研究，选取卒中后轻度认知障碍患者 18 人，招募在年龄、性别、受教育程度与试验组患者相匹配的健康人 15 人为健康对照组。对试验组进行 3 个月“调神益智”针刺法的治疗，并在其入组时、最后一次治疗结束后各做一次磁共振成像（MRI）数据采集，健康人于匹配成功后做一次 MRI 数据采集。影像学研究发现与健康人比较，卒中后轻度认知障碍患者存在自发活动异常脑区，针刺可诱发大脑认知相关脑区的自发活动性发生改变，证明了针刺治疗卒中后轻度认知障碍的机制与改变大脑自发活动性有关。

4. 专家调查

4.1 调查表发给海内外专家

邀请海内外专家根据自己的经验，提出“调神益智”针刺法对中风后轻度认知障碍治疗意见，然后对专家意见反馈的调查表汇总整理，形成初步草案，与课题组通过既往课题研究

获得的信息资料相结合，将这两者进行分析处理，撰写标准草案。完成后，再次发给专家，收集整理专家意见。形成“国际中医技术操作规范调神益智针刺法治疗中风后轻度认知障碍”初定稿。

4.2 召开专家会议

项目中标后，召开撰写小组会议，学习、培训研究方法，制定研究方案，明确分工，形成“国际中医技术操作规范调神益智针刺法治疗中风后轻度认知障碍”初稿后，组织海内外专家，召开专家论证会。收集整理专家对初稿的意见，修改完善初稿。完善后再次征求专家意见，一致同意后定稿。

四、重大分歧意见的处理经过和依据

无

五、其他应说明的事项

无

International Standardized Manipulations of Chinese Medicine

Tiaoshen Yizhi acupuncture therapy for mild cognitive impairment after stroke

Formulation Explanations

1. Standard development units

Main drafting units: First Teaching Hospital of Tianjin University of Traditional Chinese Medicine, National Clinical Research Center for Chinese Medicine Acupuncture and Moxibustion

Units involved in drafting: State of Arizona Acupuncture Institute, Munich Chinese Medicine Clinic, National Cancer Society Malaysia, Maidstone Chinese Medicine Center, Changsha Hospital of Traditional Chinese Medicine, Changchun Hospital of Traditional Chinese Medicine, the Second Affiliated Hospital of Baotou Medical College of Inner Mongolia University of Science and Technology, and the Affiliated Hospital of Changzhi Institute of Traditional Chinese Medicine.

Main drafters: Shi Xuemin, and Du Yuzheng

Drafters (listed in an alphabetic order of the surname):

China: Bu He, Dai Xiaoyu, Du Geshu, Shi Jiangwei, Shi Xiaoyu, Wang Yanhong, and Zhang Lili

USA: Liu Jing

Germany: Florian von Damnitz

Malaysia: Zhong Shangye

UK: Zhao Junhong

Australia: Wang Zhankui

2. Standard developing process

The project was launched in April, 2022 when the development group of the “International Standardized Manipulations of Chinese Medicine-- Tiaoshen Yizhi acupuncture therapy for mild cognitive impairment after stroke” (hereinafter referred to as the Standard) was established, and the responsibilities and tasks of each member were determined and assigned. The recommendation opinions were formed and the initial draft was completed after literature retrieval, evidence evaluation, multiple group meetings and discussions, and expert consultation. In July 2022, the Standard drafting group organized review

meetings to carefully revise and review the draft, and confirmed that all data are rigorous, and scientific, and met the requirements, following the Directives for Standardization Part 1: Procedures for Standard Development, Revision and Publication (SCM 1.1-2021) issued by the World Federation of Chinese Medicine Societies. On November 29, 2022, the National Clinical Research Center for Chinese Medicine Acupuncture and Moxibustion organized the Launch Meeting of Tianjin Chinese Medicine Acupuncture and Moxibustion Alliance and the Alliance Advantageous Disease Training, during which members of the project were trained with the course of "Tiaoshen Yizhi acupuncture therapy for mild cognitive impairment after stroke" online or on site, and clarified the clinical application status of "Tiaoshen Yizhi" acupuncture therapy. The targets for the Standard development were set. On December 24, 2022, members of the drafting group held a meeting in Tianjin to revise the contents of the Standard. All the drafters and experts involved in the project finalized the draft content based on the opinions and suggestions of the participating experts, and they revised and improved the Standard content and format after the meeting.

3. Main techniques involved

3.1 Technique background

"Tiaoshen Yizhi (regulating the spirit to improve intelligence)" acupuncture therapy was developed based on Academician Shi Xuemin's "Xingnao Kaiqiao (opening the orifices to awaken the mind)" acupuncture therapy and his academic thoughts. "Xingnao Kaiqiao" acupuncture therapy has proved to be effective on vascular dementia by studies, on the basis of which, "Tiaoshen Yizhi" acupuncture therapy pays equal attention to "awakening mind, replenishing brain, regulating spirit, and improving intelligence". While "regulating spirit" is the focus through two ways, firstly "awakening the mind" by opening obstructed orifices via Neiguan (PC 6), Shuigou (GV 26), Sanyinjiao (SP 6), Taichong (LR 3), and Fenglong (ST 40); and secondly "nourishing the spirit" to regulate the mind via Baihui (GV 20), Sishencong (EX-HN 1), Shenmen (HT 7), Sibai (ST 2), Fengchi (GB 20), Wangu (GB 12), and Tianzhu (BL 10). The theory of "heart-brain-kidney axis" was combined, and the relevant theories and literature of traditional Chinese and Western medicines were summarized to put forward and illustrate the "Tiaoshen Yizhi" acupuncture therapy.

Kidney deficiency with reduced marrow is the fundamental pathogenesis of mild cognitive impairment after stroke. With tonifying kidney and replenishing marrow as the fundamental treatment principle, the acupuncture therapy is used

to tonify kidney essence and harmonize *zang-fu* organs, so that the marrow is enriched with supplemented essence and the intelligence is improved with enriched marrow, achieving the effects of regulating spirit and improving intelligence, and the cognitive function recovers to normal. The acupuncture and moxibustion discipline of the First Teaching Hospital of Tianjin University of Chinese Medicine, led by Academician Shi Xuemin, is the largest clinical research and teaching base of acupuncture and moxibustion in China and also an international exchange center. Founded in 1953, it set up the first acupuncture ward in China in 1962, which later became the National Acupuncture Clinical Research Center in 1988. The discipline was certified as a key discipline of China Ministry of Education in 2002, and the center became the National Clinical Research Base of Traditional Chinese Medicine (Stroke) in 2008. In 2018, it became the national regional diagnosis and treatment center. The center owns Ministry of Education Innovation Team with academicians being the core. The research results of "Tiaoshen Yizhi" acupuncture method have been applied in the First Teaching Hospital of Tianjin University of Chinese Medicine and many other hospitals in China, promoting the development of the acupuncture and moxibustion discipline. This research provides an effective acupuncture treatment plan for patients with post-stroke cognitive impairment, bringing another treatment option to patients. Further promotion can benefit more patients and improve people's quality of life and health.

The study of academic team of Shi Xuemin began with stroke, one of the major human disease. Mild post-stroke cognitive impairment is a common complication after stroke, which is an intermediate state between normal cognition and vascular dementia. About 33% of patients develop cognitive impairment within 3 to 6 months after stroke, and about one-third of patients with mild post-stroke cognitive impairment progress to dementia. Based on the pathogenesis of stroke in Chinese medicine as "obstructed orifices and hidden spirit which fails to guide qi", Shi Xuemin believes that the pathogenesis of post-stroke cognitive impairment is "deficient or depleted brain marrow with malfunction of spirit", with the brain being the disease location. On the basis of clinical practice and scientific researches, the team of Shi Xuemin explored the method suitable for formulating clinical practice guidelines of acupuncture and moxibustion according to the discipline characteristics of acupuncture and moxibustion, and collected the evidence from ancient literature, modern literature, modern famous doctors' experience and other dimensions, and objectively and scientifically screened and evaluated the evidence. Shi Xuemin also carried out quantitative standardization on the operation at acupoints with the acupuncture method of "Tiaoshen Yizhi". The research team has carried out a

large number of clinical studies. This Standard stipulates the terms and definitions, treatment principles, application scope, acupoint recipe, operation steps and requirements, precautions and contraindications of the "Tiaoshen Yizhi" acupuncture method for the treatment of mild cognitive impairment after stroke, standardizes the manipulation quantitative operations, and strictly follows the manipulation quantitative standards.

3.2 Clinical trials

In the project of Tianjin Science and Technology Plan "Clinical Study of Acupuncture in the Treatment of Vascular Cognitive Impairment", a multi-center randomized controlled clinical trial was conducted to evaluate the effectiveness and safety of acupuncture on post-stroke cognitive impairment in five hospitals across the country. A total of 355 patients were included, and the subjects were randomly divided into acupuncture group, fake acupuncture group and waiting treatment group according to 1:1:1 by using a central randomized method. The patients were treated for 3 months and followed up for 6 months. The recovery of cognitive function-- Mini-Mental State Examination (MMSE), Clinical Dementia Rating scale (CDR), and Montreal Cognitive Assessment scale (MoCA), and the incidence of dementia were considered as the main therapeutic indexes. The evaluation of mental symptoms-- Neuropsychiatric Inventory (NPI), World Health Organization Quality of Life Scale-Brief Form Questionnaire (WHOQOL-BREF), and activities of daily living evaluation-- Functional Activities Questionnaire (FAQ) were the secondary indicator. The effectiveness and safety of "Tiaoshen Yizhi" acupuncture therapy on mild post-stroke cognitive impairment were evaluated from the aspects of cognitive function, quality of life, conversion rate to dementia, etc. Results showed that "Tiaoshen Yizhi" acupuncture method could improve the cognitive function of patients with mild cognitive impairment after stroke (MMSE changing values and MoCA scores), the effect of which was better than that of the control group, and the acupuncture effect lasted for 3-6 months. The incidence of dementia in stroke patients increases with time. "Tiaoshen Yizhi" acupuncture method can effectively reduce the incidence of dementia, delay the progression of dementia, and improve the quality of life of patients with mild post-stroke cognitive impairment.

Additionally, in order to observe the single-center clinical efficacy of "Tiaoshen Yizhi" acupuncture therapy on mild post-stroke cognitive impairment, 126 patients were selected and randomly divided into "Tiaoshen Yizhi" acupuncture group and Nimodipine group. After 12 weeks of treatment, the clinical effects of the two groups were observed. The clinical efficacy and safety of "Tiaoshen Yizhi" acupuncture method were evaluated by MoCA scale,

non-cognitive function evaluation indexes (neuropsychiatric index [NPI], and Hamilton Depression Scale [HAMD]), life ability scale (activity of daily living [ADL], and FAQ), and TCM Syndrome Differentiation Scale of vascular Dementia (SDSVD). This clinical trial has proved that “Tiaoshen Yizhi” acupuncture method can significantly improve the neurological function and quality of life of patients with mild cognitive impairment after stroke. After 12 weeks of treatment, MoCA, ADL and FAQ scores in the acupuncture group were better than those of the control group. Compared with nimodipine, the advantage of acupuncture in improving mild post-stroke cognitive impairment represents in significantly improved visuospatial/executive functions, naming, orientation, and quality of life.

3.3 Mechanism studies

The research group conducted a study on the central mechanism of the main point Baihui (GV 20) of the “Tiaoshen Yizhi” acupuncture in the treatment of mild post-stroke cognitive impairment. Eighteen patients with mild cognitive impairment after stroke were selected, and 15 healthy counterparts matching the age, gender and education level with the treatment group were recruited as the healthy control group. The treatment group was treated with “Tiaoshen Yizhi” acupuncture method for 3 months, and magnetic resonance imaging (MRI) data were collected once at the time of their enrollment and once after the last treatment, while the MRI data of healthy controls were collected once after the successful matching. Imaging studies have found that compared with healthy people, patients with mild cognitive impairment after stroke have abnormal spontaneous activities in certain brain regions, and acupuncture can induce changes in the spontaneous activity of cognition-related brain regions, proving that the mechanism of acupuncture treatment for mild cognitive impairment after stroke is related to changes in brain spontaneous activity.

3.4 Experts investigation

3.4.1 Questionnaires sent to experts at home and abroad

Experts at home and abroad were invited to put forward their opinions on the treatment of mild cognitive impairment after stroke by “Tiaoshen Yizhi” acupuncture method according to their own experience, and then their feedback were summarized to form an initial draft, which was combined with the information obtained by the project group through its previous researches. Both of them were analyzed and processed to write the Standard draft. After completion, the draft was sent to experts again for advice and feedback. The

preliminary version of "International Standardized Manipulations of Chinese Medicine-- Tiaoshen Yizhi acupuncture therapy for mild cognitive impairment after stroke" was then finalized.

3.4.2 Expert meetings

After winning the bid, a writing group meeting was held for research methods learning and training, research plan formulation, and task division. After completing the first draft of the Standard, experts at home and abroad were organized for demonstration meetings. The initial draft was revised based on experts' advice collected and summarized. After the revision, experts were consulted again, and the draft was finalized after unanimous agreement.

4. Process and basis for handling major disagreements

None

5. Others should be explained

None