



Protocol

A protocol for developing a clinical practice guideline for treating dysphagia after stroke using acupuncture

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ABSTRACT

Introduction: Dysphagia or trouble swallowing is experienced by many stroke survivors at some point after experiencing a stroke, warranting the need for treatment. As a complementary approach, acupuncture may be able to effectively treat dysphagia after stroke. However, the lack of clinical practice guidelines (CPGs) has prompted the need for a publication regarding the guidance on acupuncture used for the treatment of dysphagia after stroke.

Methods: A new CPG will be developed in accordance with the Appraisal of Guidelines for Research & Evaluation II (AGREE II), Reporting Items for practice Guideline in HealThcare (RIGHT) and within the framework of the Grade of Recommendations Assessment, Development and Evaluation (GRADE), and recommendations thereof will be made on the basis of systematic reviews. We will establish a Guideline Development Group, draft clinical questions in light of Population, Intervention, Comparison, Outcomes (PICO), conduct a literature search and appraise the quality of evidence. Following two or three rounds of modified Delphi surveys, we will ask patients about their values and preferences, conduct peer review and note patients' declarations of interest in developing CPG.

Results: This study is ongoing, so there are no results to report.

Conclusions: These guidelines will enable clinical acupuncturists achieve better results in treating post-stroke dysphagia with acupuncture.

1. Introduction

Dysphagia after stroke is the most common complication of acute stroke, which affects 80% of patients, and 11%–50% of patients continue to suffer from the condition after 6 months [1,2]. Delayed recovery of swallowing function may lead to increased difficulty in oral feeding and result in dehydration, malnutrition, community-acquired pneumonia and other adverse symptoms [3–5]. Patients with a swallowing disorder may cough or cough frequently while drinking water, or the tongue cannot assist in directing food into the throat, resulting in severe swallowing obstructions [6,7].

Current treatments for post-stroke dysphasia include drugs, non-invasive neurostimulation therapies, acupuncture, swallowing rehabilitation, etc. [8–13]. Acupuncture is an ancient traditional Chinese therapy and a common method for treating stroke in China. From the perspective of anatomical physiology, the theoretical basis and clinical

practice involves observation of the tongue, throat and neck muscles, identifying blood vessels and nerve distribution for acupuncture using local acupoints. At present, the commonly used local acupoints are *Lianquan*, *Fengchi*, *Yifeng*, *Jinjin* and *Yuye*. Through a preliminary literature search, we found that more than 200 RCTs have used acupuncture to treat swallowing disorders after stroke, and it appears that there are sufficient studies to conduct CPG.

2. Objective

The aim was to develop a protocol for the systematic development of evidence-based clinical practice guideline (CPG) for acupuncture treatment of post-stroke dysphagia. The CPG will set the standards for acupuncture treatment of dysphagia after stroke.

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3. Methods

3.1. Principle

The CPG follows the World Health Organization guidelines [14], GRADE system [15], AGREE II instrument [16], and RIGHT checklist [17], and was registered on the International Practice Guidelines Registry Platform (<http://www.guidelines-registry.org/>) with the registration number, IPGRP-2019CN017.

3.2. Participating institutions, end-users and target population

The CPG was launched at the Clinical Research Center, South China Research Center for Acupuncture and Moxibustion, Medical College of Acu-Moxi and Rehabilitation, Guangzhou University of Chinese Medicine. The guideline will be titled, 'Guideline for acupuncture for dysphagia after stroke'. The guideline's target end-users are acupuncturists, stroke physicians and journal editors. Patients with dysphagia after stroke, and who can be treated with acupuncture comprise the target population. This guideline explores acupuncture method for selection, clinical safety and effectiveness of acupuncture treatment. The flow diagram about the process of the CPG is in Appendix 1 in Supplementary material.

3.3. Guideline working group

The Guideline Working Group set up in March 2019, is composed of three groups—the Guideline Development Group, the Guideline Steering Group and the Guideline Secretary Group. To ensure equitable representation of gender and geography, the Guideline Development Group will include 20 members from several fields of specialisation as follows: 11 acupuncturists (especially professional stroke rehabilitation), 2 traditional Chinese medicine (TCM) physicians, 2 physiotherapists, 2 medical clinicians, 1 editor, 1 health economist physician and a nurse. The Guideline Development Group will be assigned the following tasks: (1) to determine the scope of the guidelines and draft Population, Intervention, Comparison and Outcomes (PICO); (2) to rate the quality of evidence; (3) to write up an elementary proposal; (4) to create a draft guideline and (5) to promote the guideline. The Guideline Steering Group will comprise 8 members, including 3 acupuncturists, 1 expert in evidence-based medicine, 1 TCM physician, 2 physiotherapists and a health economist physician. The Guideline Steering Group will be assigned the following tasks: (1) to authorise the PICO; (2) to monitor literature search and systematic reviews; (3) to examine the quality of evidence; (4) to adopt the revised Delphi approach for the formulation of final recommendations; and (5) to approve the release of the guidelines. The Guideline Secretary Group will comprise 6 members, including 3 experts in evidence-based medicine, 2 acupuncturists and a statistician. The Guideline Secretary Group will be assigned the following tasks: (1) to conduct a literature search and complete systematic reviews and (2) to ask patients about their values and preferences.

3.4. Declaration of interests and funding support

To identify their underlying conflicts of interest, all members of the Guideline Working Group will be asked to fill out the declaration of conflicts of interest forms.

3.5. Identifying questions and selecting outcomes

After the Guideline Development Group defines the scope of the guidelines that will be ratified by the Guideline Steering Group, the PICO will be finalised. The current version of PICO is in Appendix 2 Supplementary material. The Guideline Development Group will select outcomes and conduct consensus classifications based on their

importance. The outcomes will be scored on a scale of 1–9, wherein, 7–9 will be regarded as critical, 4–6 as important and 1–3 as not important. [15] Questions will be drafted based on PICO principle after rating the outcomes. For example:

Can electroacupuncture be applied to patients with dysphagia after stroke?

P: all patients with dysphagia after stroke

I: patients who received electroacupuncture therapy

C: patients who not received electroacupuncture therapy

O: dysphagia severity rating scale [DSRS]; functional oral intake scale [FOIS]; adverse effects.

3.6. Evidence retrieval and synthesis

3.6.1. Databases

Literature published in MEDLINE, Embase, PubMed, Cochrane library, CNKI (China), SinoMed, Wanfang (China) and VIP (China) will be systematically reviewed from the date of inception to 31 May 2019.

3.6.2. Search terms

In order to balance search sensitivity and specificity, our search terms were a combination of free words and MeSH terms, 'acupuncture' and 'dysphagia after stroke'. We used the search terms (randomised controlled trial or meta-analysis or observational study or practice guideline or retrospective study or outcome research or systematic review or clinical article) AND (post-stroke dysphagia or swallowing dysfunction or pseudobulbar palsy) AND (acupuncture or electroacupuncture or scalp acupuncture or ear acupuncture or body acupuncture or fire acupuncture). We will develop and confirm detailed retrieval strategies with the help of evidence-based medical experts prior to literature research. There will be no restrictions on the language of publication. The retrieval strategy is shown in Appendix 3 Supplementary material.

3.6.3. Pilot search

In order to ensure the consistency of the literature selection process, the authors of the systematic reviews update will conduct a predictive test. This test is expected to provide a better understanding of the inclusion and exclusion criteria for each systematic review.

3.6.4. Literature selection

Correlation studies, including systematic review, meta-analysis, reticular meta-analysis and original studies, will be included. Irrelevant studies will be excluded based on the title, and full-length manuscripts will be reviewed. For systematic review, meta-analysis and reticular meta-analysis, we will use PRISMA [18] to assess the quality of the studies. And for original studies, we will use CONSORT [19] and risk of bias.

3.6.5. Evidence syntheses

Systematic reviews following PRISMA guidelines published during the last 3 years will be directly used. In the event that the quality of systematic reviews is low or if there none published, new systematic reviews using currently available evidence will be conducted.

3.6.6. Evidence assessment

The quality of evidence will be evaluated using the GRADE instrument, which will enable drafting recommendations. The GRADE tool divides the quality of evidence into high, moderate, low and very low, and the evidence from each study will be evaluated on the basis of outcomes. Guideline methodologists will evaluate the quality of evidence, and summaries will be drawn up and submitted to the Guideline Working Group.

3.7. Patients' values and preferences

Patients with dysphagia after stroke were consulted to investigate the value and preference regarding acupuncture. When formulating recommendations, the Guideline Steering Group and the Guideline Development Group will take patients' values and preferences into consideration. We will confirm the basic information of the patient, including age, education level, residence, occupation, family income, past medical history, etc. In the study of patients' values and preferences, our guideline will divide the influencing factors into four areas: effectiveness factors, safety factors, prognostic factors and other aspects (including patients' treatment costs, doctors' experience and advice, etc.). In this study, we will evaluate the reliability of the questionnaire concerning patients' values and preferences before the formal survey, and the acceptability of the questionnaire will also be considered. In addition to the above contents, patients will be required to sign the informed consent form and will be trained to understand the relevant knowledge of the questionnaire before the investigation.

3.8. Developing recommendations

After evaluating the evidence through GRADE, the Guideline Development Group will draft an elementary proposal taking into account the quality of evidence, the weighting of the advantages and disadvantages and the patients' values and preferences. The Guideline Development Group will adopt 2–3 rounds of Delphi process [20] to develop the draft recommendations and will submit it to the Guideline Steering Group for final approval for publication. To achieve consensus, the GRADE Grid instrument [21] will be used, wherein five choices will be available for each recommendation ('strong recommendation', 'weak recommendation', 'unclear recommendation', 'weak no recommendation' and 'strong no recommendation'). Consensus on a recommendation is attained if more than 66% of the experts voted for any of the options, except 'unclear', or if more than 66% of the experts voted for one of the two options on the same side. Otherwise, the item needs will be considered controversial, requiring another round of Delphi process.

3.9. Peer review

The guideline, thus developed, will be subjected to peer review by external specialists, whose recommendations and the review process will be gathered and recorded by the Guideline Development Group. The strengths of the reviewer's recommendations will be evaluated through discussions.

3.10. Publishing of the guideline

The guidelines, expected to be published in 2020, will be reported in accordance with the format recommended in the RIGHT checklist. The publication will appear in Chinese and English in related journals and will be updated regularly.

3.11. Promotion of the guideline

Upon publication of the guideline, Guangzhou University of Chinese Medicine will promote it through several means: (1) the guideline will be proposed for 3 years at stroke-related conferences; (2) the Guideline Working Group will write and publish articles related to the guideline and (3) Chinese and English versions of the guideline will be posted on official health websites. We will update the guidelines every three years

4. Results

This is an ongoing study, and there are no complete data.

5. Discussion

The principles and standards of evidence-based medicine will be followed when developing guidelines for the treatment of post-stroke dysphagia by acupuncture. It is expected that these guidelines will be used by clinical acupuncturists not only for treating patients with post-stroke dysphagia but also for teaching activities.

5.1. Limitations

The literature search should acknowledge the differences and similarities of the acupuncture method adopted by each country.

6. Conclusion

This guideline would be the first CPG for acupuncture therapy for post-stroke dysphagia in China and is in concordance with new guideline definition adopted by the Institute of Medicine and using the GRADE tool to rate and recommend the quality of the evidence. Importantly, the guidelines will help develop inclusion and exclusion criteria for acupuncture treatment of dysphagia after stroke.

Ethical approval

Not Applicable.

Data availability statement

Not Applicable.

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Declaration of Competing Interest

The authors have no conflicts of interest to declare.

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Yu Zhang and Zhijie Wang contributed equally to this work. This protocol was drafted by Yu Zhang, Zhijie Wang and Xudong Jiang, and revised by Nenggui Xu and Liming Lu. Lin Wang and Shuqi Yao played an important role in protocol development. All authors gave final approval for the version to be published.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.eujim.2019.100947>.

References

- [1] R. Martino, N. Foley, S. Bhogal, N. Diamant, M. Speechley, R. Teasell, Dysphagia after stroke—Incidence, diagnosis, and pulmonary complications, *Stroke* 36 (12) (2005) 2756–2763, <https://doi.org/10.1161/01.str.0000190056.76543.eb>.
- [2] D.L. Cohen, C. Roffe, J. Beavan, B. Blackett, C.A. Fairfield, S. Hamdy, D. Havard, M. McFarlane, C. McLaughlin, M. Randall, K. Robson, P. Scutt, C. Smith, D. Smithard, N. Sprigg, A. Warusevitane, C. Watkins, L. Woodhouse, P.M. Bath, Post-stroke dysphagia: a review and design considerations for future trials, *Int. J. Stroke* 11 (4) (2016) 399–411, <https://doi.org/10.1177/1747493016639057>.
- [3] E.J. Roth, L. Lovell, R.L. Harvey, A.W. Heinemann, P. Semik, S. Diaz, Incidence of and risk factors for medical complications during stroke rehabilitation, *Stroke* 32 (2) (2001) 523–529, <https://doi.org/10.1161/01.str.32.2.523>.
- [4] G. Mann, G.J. Hankey, D. Cameron, Swallowing function after stroke: prognosis and prognostic factors at 6 months, *Stroke* 30 (4) (1999) 744–748, <https://doi.org/10.1161/01.str.30.4.744>.
- [5] J. Almirall, L. Rofes, M. Serra-Prat, R. Icart, E. Palomera, V. Arreola, P. Clavé,

- Oropharyngeal dysphagia is a risk factor for community-acquired pneumonia in the elderly, *Eur. Respir. J.* 41 (4) (2012) 923–928, <https://doi.org/10.1183/09031936.00019012>.
- [6] N. Rommel, S. Hamdy, Oropharyngeal dysphagia: manifestations and diagnosis, *Nat. Rev. Gastroenterol. Hepatol.* 13 (1) (2015) 49–59, <https://doi.org/10.1038/nrgastro.2015.199>.
- [7] L.J. Woodhouse, P. Scutt, S. Hamdy, D.G. Smithard, D.L. Cohen, C. Roffe, D. Berezcki, E. Berge, C.F. Bladin, V. Caso, H.K. Christensen, R. Collins, A. Czlonkowska, A.D. Silva, A. Etribi, A.C. Laska, G. Ntaios, S. Ozturk, S.J. Phillips, K. Prasad, S. Sztamari, N. Sprigg, P.M. Bath, Route of feeding as a proxy for dysphagia after stroke and the effect of transdermal glyceryl trinitrate: data from the efficacy of nitric oxide in stroke randomised controlled trial, *Transl. Stroke Res.* 9 (2) (2017) 120–129, <https://doi.org/10.1007/s12975-017-0548-0>.
- [8] R. Dziewas, R. Stellato, I. van der Tweel, E. Walther, C.J. Werner, T. Braun, G. Citerio, M. Jandl, M. Friedrichs, K. Nötzel, M.R. Vosko, S. Mistry, S. Hamdy, S. McGowan, T. Warnecke, P. Zwittag, P.M. Bath, PHAST-TRAC investigators, Pharyngeal electrical stimulation for early decannulation in tracheotomised patients with neurogenic dysphagia after stroke (PHAST-TRAC): a prospective, single-blinded, randomised trial, *Lancet Neurol.* 17 (10) (2018), [https://doi.org/10.1016/s1474-4422\(18\)30255-2](https://doi.org/10.1016/s1474-4422(18)30255-2).
- [9] C.F. Chiang, M.T. Lin, M.Y. Hsiao, Y.C. Yeh, Y.C. Liang, T.G. Wang, Comparative efficacy of noninvasive neurostimulation therapies for acute and subacute post-stroke dysphagia: a systematic review and network meta-analysis, *Arch. Phys. Med. Rehabil.* (2018), <https://doi.org/10.1016/j.apmr.2018.09.117>.
- [10] P.M. Bath, H.S. Lee, L.F. Everton, Swallowing therapy for dysphagia in acute and subacute stroke, *Cochrane Database Syst. Rev.* (2018), <https://doi.org/10.1002/14651858.CD000323.pub3>.
- [11] L. Li, K. Deng, Y. Qu, Acupuncture treatment for post-stroke dysphagia: an update meta-analysis of randomized controlled trials, *Chin. J. Integr. Med.* (2018), <https://doi.org/10.1007/s11655-018-3005-3>.
- [12] Q. Ye, Y. Xie, J. Shi, Z. Xu, A. Ou, N. Xu, Systematic review on acupuncture for treatment of dysphagia after stroke, *Evid. Based Complement. Altern. Med.* (2017), <https://doi.org/10.1155/2017/6421852>.
- [13] P.M. Bath, P. Scutt, J. Love, P. Clavé, D. Cohen, R. Dziewas, H.K. Iversen, C. Ledl, S. Ragab, H. Soda, A. Warusevitane, V. Woisard, S. Hamdy, Swallowing Treatment Using Pharyngeal Electrical Stimulation (STEPS) Trial Investigators, Pharyngeal electrical stimulation for treatment of dysphagia in subacute stroke, *Stroke* 47 (6) (2016) 1562–1570, <https://doi.org/10.1161/strokeaha.115.012455>.
- [14] D. Sinclair, R. Isba, T. Kredon, B. Zani, H. Smith, P. Garner, World health organization guideline development: an evaluation, *PLoS One* 8 (5) (2013) e63715, <https://doi.org/10.1371/journal.pone.0063715>.
- [15] G.H. Guyatt, A.D. Oxman, G.E. Vist, R. Kunz, Y. Falck-Ytter, P. Alonso-Coello, H.J. Schünemann, GRADE Working Group, GRADE: an emerging consensus on rating quality of evidence and strength of recommendations, *BMJ* 336 (7650) (2008) 924–926, <https://doi.org/10.1136/bmj.39489.470347.ad>.
- [16] M.C. Brouwers, K. Kerkvliet, K. Spithoff, The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines, *BMJ* 352 (2016) i1152, <https://doi.org/10.1136/bmj.i1152>.
- [17] Y. Chen, K. Yang, A. Marušić, A. Qaseem, J.J. Meerpohl, S. Flottorp, E.A. Akl, H.J. Schnemann, E.S. Chan, Y. Falck-Ytter, F. Ahmed, S. Barber, C. Chen, M. Zhang, B. Xu, J. Tian, F. Song, H. Shang, K. Tang, Q. Wang, S.L. Norris, RIGHT (Reporting Items for Practice Guidelines in Healthcare) Working Group, A reporting tool for practice guidelines in health care: the RIGHT statement, *Ann. Intern. Med.* 166 (2) (2017) 128–132, <https://doi.org/10.7326/m16-1565>.
- [18] D. Moher, A. Liberati, J. Tetzlaff, D.G. Altman, Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement, *BMJ* 339 (2009) b2535, <https://doi.org/10.1136/bmj.b2535>.
- [19] D. Moher, A. Jones, L. Lepage, Use of the CONSORT statement and quality of reports of randomized trials: a comparative before-and-after evaluation, *JAMA* 285 (15) (2001) 1992–1995.
- [20] M.D.F. McInnes, D. Moher, B.D. Thoms, T.A. McGrath, P.M. Bossuyt, the PRISMA-DTA Group, T. Clifford, J.F. Cohen, J.J. Deeks, C. Gatsonis, L. Hooft, H.A. Hunt, C.J. Hyde, D.A. Korevaar, M.M.G. Leeflang, P. Macaskill, J.B. Reitsma, R. Rodin, A.W.S. Rutjes, J.P. Salameh, A. Stevens, Y. Takwoingi, M. Tonelli, L. Weeks, P. Whiting, B.H. Willis, Preferred reporting items for a systematic review and meta-analysis of diagnostic test accuracy studies: the PRISMA-DTA statement, *JAMA* 319 (4) (2018) 388, <https://doi.org/10.1001/jama.2017.19163>.
- [21] R. Jaeschke, G.H. Guyatt, P. Dellinger, H. Schünemann, M.M. Levy, R. Kunz, S. Norris, J. Bion, GRADE Working Group, Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive, *BMJ* 31 (337) (2008) a744, <https://doi.org/10.1136/bmj.a744>.