

Consensus-based Clinical Case Reporting Guideline Extension: CARE for Acupuncture Protocol

Liming Lu^{#1}, Yuting Duan^{#1}, Juexuan Chen¹, Jingjing Deng¹, Qianmei Wang¹, Ioannis Solos², Yaolong Chen^{*3,4,5,6}, Chunzhi Tang^{*1}

1 Clinical Research Center, South China Research Center for Acupuncture and Moxibustion, Medical College of Acu-Moxi and Rehabilitation, Guangzhou University of Chinese Medicine

2 Department of Orthopedics and Traumatology, Guangzhou Zhongxing Sports Trauma Hospital

3 Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, Lanzhou, China;

4 Key Laboratory of Evidence Based Medicine and Knowledge Translation of Gansu Province, Lanzhou, China;

5 Chinese GRADE Center, Lanzhou, China;

6 WHO Collaborating Centre for Guideline Implementation and Knowledge Translation

Liming Lu and Yuting Duan contributed equally.

Corresponding author:

1. Chunzhi Tang, jordan664@163.com, Clinical Research Center, South China Research Center for Acupuncture and Moxibustion, Medical College of Acu-Moxi and Rehabilitation, Guangzhou University of Chinese Medicine. No.232 Waihuan Dong Road, Guangzhou 510006, China.

2. Yaolong Chen, chenaolong21@163.com, Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, Lanzhou, China.

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INTRODUCTION

Acupuncture, as part of traditional medicine, is now widely used around the world¹. According to a 2013 World Health Organization (WHO) report², 103 of the WHO's member countries have approved the use of acupuncture. Moreover, a 2013 survey conducted by World Federation of Acupuncture-moxibustion Societies (WFAS)³ showed that 183 (91%) of the 202 countries surveyed application of acupuncture. Acupuncture is available in 178 (93%) of the 192 member countries of the United Nations (UN) of which 59 (31%) have partial or full insurance coverage.

However, high quality randomized controlled trials with a large sample size were rarely conducted because of the difficulty in implementing control groups, blinding, and collecting sufficient samples⁵⁻⁷. Therefore, case reports still are an important resource to provide evidence on acupuncture to clinicians and researchers. Apart from these, case reports also have special advantages. For example, it can better present the real situation of clinical practice, reflect the individualized treatment characteristics of acupuncture treatment, and inherit the experience of prominent traditional medicine doctors, etc.

This reporting guideline is a key area of research in evidence-based medicine and is particularly important for improving the quality and transparency of research reports by providing a standard format for clear, explicit

and systematic presentation of research reports or literature⁸⁻¹⁰. In June 2010, the “Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT Statement”¹¹ was published. The project, currently under study, entitled "Systematic Review and Meta-analysis of Acupuncture and Moxibustion: PRISMA of the Acupuncture Checklist", has received considerable attention¹². In 2013, Consensus-based Clinical Case Reporting Guideline: CAse Report (CARE) guidelines were published¹³. Although there was a reporting checklist for case reports, there were some barriers in their applicability to acupuncture due to its specificity in terms of manipulations, locations and channels compared to other health care interventions. It is necessary to standardize the reporting checklist for case reports on acupuncture as an extended version of the CARE guidelines, which has the following advantages: 1) To provide regulations for case reports researchers; 2) To obtain more precise and clear guidelines for readers and clinical practitioners; and 3) To evaluate the reporting quality of case reports on acupuncture and improve the transparency of research reports for editors and reviewers.

Aims

To develop an extension of the CARE guidelines for case reports on acupuncture.

Methods

The project will be implemented using the methodological guidance developed in the reporting guidelines recommended by the EQUATOR Network¹⁴ and adapted accordingly, resulting in five implementation phases. (Figure 1)

1. Project Initiation

1.1 Research Team and Declaration of Interests

The CARE for Acupuncture research team consists of three groups: the Development Group, the Delphi Panellists Group and the Advisor Group.

1.1.1 Development Group

The Development Group will lead the CARE for acupuncture development process and ensure its completion according to the set timeline. Specifically, the Reporting Items Development Group will be responsible for the following: 1) Drafting the proposal and conducting literature reviews; 2) Proposing suggested items and designing the questionnaire for the Delphi exercise; 3) Organizing and conducting the Delphi exercise; 4) Collecting and analysing the feedback and data from the Delphi exercise; 5) Drafting the final report and manuscript for submission to a peer-reviewed journal; 6) Seeking and addressing feedback from users of CARE items; 7) Encouraging and supporting endorsement, adoption, and adherence to CARE; 8) Evaluating the impact of the reporting guideline; and 9) Updating the reporting guideline.

Team leader: Liming Lu, South China Research Center for Acupuncture and Moxibustion, Medical College of Acu-Moxi and Rehabilitation, Guangzhou University of Chinese Medicine, Guangzhou, China

1.1.2 Delphi Panellists Group

The Delphi Panellists Group will be a multidisciplinary group. We will invite 11-19 panellists using the following criteria: 1) Clinical practitioners of acupuncture and moxibustion; 2) Researchers of reporting checklists on acupuncture; and 3) Clinical epidemiologists and statisticians. The Delphi Panellists Group

will be specifically responsible for the following 1) Reviewing the proposal and providing comments and suggestions; 2) Deciding which items should be included (participate in several rounds of Delphi processes); 3) Deciding the number of items included in final guideline; and 4) Reviewing the final document and report. We will adhere to the principle of anonymity and will not disclose the names of team members to other team members until the Delphi process is completed. This approach prevents participants from being influenced by the authority, personality, or reputation of other participants.

1.1.3 Advisory Group

Members of the Advisory Group have the same qualifications as the Delphi Panellists Group. 1) Recruitment of the Delphi Panellists Group members; 2) Providing consultation and assistance; and 3) Conducting quality assurance. The above will be done by the Advisory Group.

Team leader: Chunzhi Tang, South China Research Center for Acupuncture and Moxibustion, Guangzhou University of Chinese Medicine, Guangzhou, China.

1.1.4 Declaration of competing interests

All participants will sign the declaration of interest forms, which will be assessed by the CARE for Acupuncture Working Group. The group will discuss each form and decide whether it has conflicts of interest to disclose.

1.2 Funding

This project is funded by the First-class Discipline Construction Foundation of Guangzhou University of Chinese Medicine, Guangdong Province, Guangzhou, China, the Translation and Training Cooperation Base for Standards of Traditional Chinese Medicine of Belt and Road Initiative (GZYYGJ2018042), Young Top Talent Project of Scientific and Technological Innovation in Special Support Plan for Training High-level Talents in Guangdong (No. 2017TQ04R627) and Guangdong Natural Science Foundation (Project No.2016A030310290).

2. Pre-consensus

2.1 Literature Review

Before confirming the literature, we will formulate and pre-test a conceptual framework for literature inclusion. The collection of items from two types of literature will be included: reporting checklist for the acupuncture area, and case reports for the acupuncture area. Benefitting from the process of gathering evidence and items, we will consider a conceptual framework for the reporting checklist of case reports on acupuncture.

2.1.1 Identify Reporting checklist on Acupuncture

Literature Search: We will search eight databases: Medline, Embase, the Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Wan Fang database, Chinese BioMedicine database (CBM), China National Knowledge Infrastructure (CNKI), and VIP; additional supplementary searches will be performed on the EQUATOR network website, tracking references to included studies, and on Google academics and Medlive.

Inclusion Criteria: include reporting checklist on acupuncture.

Exclusion Criteria: exclude previous version of reporting checklist.

Search strategy: We will use a combination of keywords and free words to search. Search terms include the following: “guideline*, guidance, standard*, recommendation*, criteri*, reporting, requirement*, presentation.” An example of a specific search strategy in Medline is presented in Table 1.

2.1.2 Identify Current Case Reports on Acupuncture

Literature Search: We will search eight databases: Medline, Embase, AMED, CINAHL, Wan Fang, CBM, CNKI, and VIP; additional supplementary searches will be performed on the EQUATOR network website, tracking references to included studies, and on Google academics and Medlive.

Inclusion Criteria: include research on the field of acupuncture.

Exclusion Criteria: exclude non-clinical research.

Search strategy: We will use the combination of keywords and free words to search. Search terms include the following: “case report*, case stud*, consensus, acupuncture, pharmacoacupuncture, electroacupuncture, needl*, acupotomy (Table 2).

2.2 Items Collection by Thematic Analysis

The thematic analysis method is widely used in qualitative research, and it is suitable for researchers with lower interpretation level, which means that it does not require complicated theoretical explanation¹⁵. Therefore, our items formulation group will use thematic analysis to de-duplicate, refine and expand the items collected by the “Literature Review” in accordance with the thematic framework of current CARE items, resulting in items related to our topic.

2.3 Modified Delphi Consensuses

We will conduct 3 rounds of modified Delphi surveys¹⁶⁻¹⁸. Following each of the 3 rounds, the mode (most frequent) score for each item will be tabulated. Items will be categorized as follows: (1) mode score of 1 to 3 but for less than 66% of participants, proceed to next round of Delphi process (or to a meeting discussion if this occurs during round 3 of the Delphi process); (2) consensus score of 1 or 2, do not include; (3) consensus score of 3, discuss at meeting; (4) mode score of 4 or 5 but for less than 66% of participants, discuss at meeting; and (5) consensus score of 4 or 5, include in CARE for Acupuncture (but discuss at meeting to confirm exact wording). All participants will be provided with an anonymized summary of the results after each round of the process. The survey will be administered by SurveyMonkey Inc.

3 Face-to-Face Consensus Meeting

After the Delphi process, we will create a draft checklist with the included items. Over 75% of the members of Delphi Panellists Group, including acupuncture practitioners, clinicians, methodologists and reporting guideline developers, will be invited to attend a one-day face-to-face meeting. During the meeting, the study background and progress and the results of the Delphi process will be presented, followed by a discussion and revision of each item. The participants will then vote about the inclusion of each proposed item and decide the precise wording. We will present only the aggregated results to maintain the anonymity of the participants. At the end of the meeting, experts will review the checklist of items again to confirm that their comments were appropriately understood and considered. The checklist will then be developed in accordance with the EQUATOR template and presented in line with the CARE guidelines.

4 After the Consensus Meeting

4.1 Draft the Final Checklist

Based on the results of the face-to-face consensus meeting, we will draw up the final checklist and send an email to the experts who participated in the Delphi surveys and face-to-face consensus meeting to ensure the accuracy of the items.

4.2 Consultation with advisors

After the face-to-face meeting, we will circulate the manuscript to the advisory experts for additional comments. During consultations with the advisory experts, the wording and presentation of the checklist and manuscript will be further discussed and revised. Following this step, the checklist will be applied in pilot tests.

4.3 Pilot tests

To identify any practical challenges with any of the items, members of the CARE for Acupuncture development group will apply the checklist to investigate the reporting condition of a sample of case reports published in 2018. In addition, we will conduct an online survey of the corresponding authors of the case reports on acupuncture to obtain further comments on the utility and clarity of the checklist. Feedback from all pilot tests will be used to refine the wording and presentation of the final checklist.

4.4 Elaboration of Explanatory Documents

To ensure accurate implementation, we will develop a detailed description and explanatory documents to promote the use of CARE for Acupuncture.

4.5 Formulation of publication Strategy

We will publish the detailed process, checklist and explanatory documents of CARE for Acupuncture in a peer-reviewed journal as an academic paper.

5 Post Publication

5.1 Seek and Deal with Feedback and Revise as Appropriate

We will obtain feedback on CARE for Acupuncture by the following pathways: 1) Relevant personnel involved in the development of the guidelines; 2) Peer-reviewed journals that use CARE for Acupuncture as reporting guidelines for case reports on acupuncture; and 3) Practitioners (clinicians, acupuncture practitioners, acupuncture researchers, etc.).

5.2 Dissemination and implementation

We will disseminate the checklist through the following channels: 1) Promoting the reporting checklist through the EQUATOR website or library; 2) Training the researchers of case reports on acupuncture through Academic Conferences or Working Groups; and 3) Contacting the editors of the journal that published case reports of acupuncture.

5.3 Monitoring and evaluation

We will focus on the use of CARE for Acupuncture in the following four ways: 1) Monitoring how many core journals support the use of CARE for Acupuncture and list it in the journal policy; 2) Confirming how many case reports on acupuncture follow CARE for Acupuncture and report quality; 3) Conducting retrospective studies to evaluate the effects of the publication of CARE for Acupuncture on the reporting quality of case reports on acupuncture; and 4) Conducting questionnaires with stakeholders to investigate their awareness and use of CARE for Acupuncture.

5.4 Update Guideline

We will gather relevant experts to update CARE for Acupuncture based on stakeholder feedback and the results of the monitoring and evaluation of the acupuncture statement.

Patient and Public Involvement

Not applicable.

Contributors and sources

CZT, YLC, LML and YTD conceptualised the study design. LML, YTD, JXC, JJD and QMW wrote the draft and complement the methods of this study. All authors provided input on the direction of the study and content of the manuscript. All authors approved the final version of the manuscript.

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Table 1. Reporting Checklist on Acupuncture Search Strategy (Medline)

- #1. reporting guideline* [tiab]
- #2. guideline* [ti] AND reporting [ti]
- #3. guidance [tiab] AND reporting [tiab]
- #4. reporting requirement* [tiab]
- #5. guideline* [ti] AND publication* [ti]
- #6. standard* [ti] AND reporting [ti]
- #7. practice [ti] AND reporting [ti]
- #8. design [ti] AND reporting [ti]
- #9. conduct [ti] AND reporting [ti]
- #10. reporting [ti] AND criteri* [ti]
- #11. reporting [ti] AND recommendation* [ti]
- #12. research reporting [tiab]
- #13. transparen* [tiab] AND reporting [tiab]
- #14. responsible [ti] AND report* [ti]
- #15. clarity [ti] AND report* [ti]
- #16. presentation [ti] AND publication [ti]
- #17. analys* [ti] AND reporting [ti]
- #18. presentation [ti] AND standard* [ti]
- #19. presentation [ti] AND guideline* [ti]
- #20. minimum information [tiab]
- #21. reporting [ti] AND method* [ti]
- #22. reporting [ti] AND experiment* [ti]
- #23. OR/#1-#22
- #24. "Acupuncture Therapy"[Mesh]
- #25. Acupuncture [tiab]
- #26. Pharmacopuncture [tiab]
- #27. Acupotomy [tiab]
- #28. Acupotomies [tiab]
- #29. Electroacupuncture [tiab]
- #30. Needl* [tiab]
- #31. OR/#24-#30
- #32. #23 AND #31

[Table 2. Case Reports on Acupuncture Search Strategy \(Medline\)](#)

- #1. Case stud*[tiab]
- #2. Case report*[tiab]
- #3. #1OR#2
- #4. "Acupuncture Therapy"[Mesh]
- #5. Acupuncture [tiab]
- #6. Pharmacoacupuncture [tiab]
- #7. Acupotomy [tiab]
- #8. Acupotomies[tiab]
- #9. Electroacupuncture[tiab]
- #10. Needl*[tiab]
- #11. OR/#4-#10
- #12. #3 AND #11

Figure 1. Flow diagram for reporting guideline development

