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Protocol

Developing an extension of the RIGHT statement for clinical practice guidelines on acupuncture: RIGHT for acupuncture – A protocol

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ABSTRACT

Introduction: The 2017 International Standard for Reporting Items for practice Guideline in HealThcare (RIGHT) published reporting guidelines to enhance transparency and clarity in the process of developing clinical practice guidelines (CPGs). As there are some barriers in the applicability of these guidelines to acupuncture due to its specificity in terms of manipulations, locations and channels compared to other health care interventions, we aim to develop a specific reporting checklist for the development of CPGs on acupuncture.

Methods: The study design will refer to the methodology recommended by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network and will be modified as appropriate. We will conduct a literature review and establish an international multidisciplinary team, including a Development Group, a Delphi Panellists Group and an Advisory Group. We will run three rounds of modified Delphi surveys, face-to-face consensus meetings, consultations with advisors, pilot tests of the draft list of reports and promotion of the checklist. We plan to update regularly.

Results: The study is ongoing and there are no complete results. We will update it in time if there is any result.

Conclusions: This work will be relevant to a broad range of CPGs addressing questions of reporting standards on CPGs on Acupuncture, which will have the following advantages: 1) To provide regulations for guideline developers; 2) To obtain more precise and clear guidelines for readers and clinical practitioners; and 3) To evaluate reporting quality of CPGs on acupuncture and improve transparency of research reports for editors and reviewers.

1. Introduction

Acupuncture, as part of traditional medicine, is now widely used around the world [1]. According to a 2013 World Health Organization (WHO) report [2], 103 of the WHO's member countries have approved the use of acupuncture. According to a 2013 survey conducted by World Federation of Acupuncture-moxibustion Societies (WFAS) [3], 183 (91%) of the 202 countries surveyed use acupuncture, while 178 (93%) of the 192 member countries of the United Nations (UN) have acupuncture practices, and 59 (31%) have partial or full insurance coverage.

There is a growing body of clinical evidence and systematic reviews on acupuncture, which provide a good foundation for acupuncture clinical practice guidelines (CPGs). Supported by this evidence, CPGs on acupuncture [4–6] have been developed for more than 20 common diseases. However, the reporting quality of CPGs on acupuncture is low and needs to be improved.

The reporting guideline is a standardized format to provide a clear,

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explicit and systematic presentation of research studies or documents and is a key research area for evidence-based medicine, playing an important role in improving the quality and transparency of research reports [7–9]. In June 2010, the "Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT Statement" [10] was published. The project, "Reporting items for systematic reviews and meta-analyses of acupuncture: the PRISMA for Acupuncture checklist" is currently being researched [11].

In 2017, the International Standard for Reporting Items for practice Guideline in HealThcare (RIGHT) statement was published to enhance transparency and clarity in the process of developing CPGs [12]. Although there was a reporting checklist for health care guidelines, 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 CPGs on acupuncture as an extended version of the RIGHT.

2. Aims

To develop an extension of the RIGHT statement for acupuncture.

3. Methods

The project will be implemented using the methodological guidance developed in the reporting guidelines recommended by the EQUATOR Network [13] and adapted accordingly, resulting in five implementation phases. (Fig. 1)

4. Project initiation

4.1. Research team

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

4.1.1. Development group

The Development Group will lead the RIGHT 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 RIGHT items; 7) Encouraging and supporting endorsement, adoption, and adherence to RIGHT; 8) Evaluating the impact of the reporting guideline; and 9) Updating the reporting guideline.

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

4.1.2. Delphi panellists group

The Delphi Panellists Group will be a multidisciplinary group. The panelists from other countries besides China will consist of above 60%. We will invite 11–19 panellists using the following criteria: 1) Clinical practitioners of acupuncture and moxibustion; 2) Researchers of CPGs on acupuncture; 3) Researchers of reporting checklists for CPGs on acupuncture; and 4) Clinical epidemiologists and statisticians. Specifically, the Delphi Panellists Group will be responsible for 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 on the number of items to be included in final guideline; and 4) Reviewing the final document and report. We will not disclose panellists' names to other panellists until we have finished the Delphi process, as anonymity is one of the most important principles of the Delphi method. This approach prevents the authority, personality, or reputation of some participants from dominating others in the process.

4.1.3. Advisory group

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

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

5. Pre-consensus

5.1. 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 CPGs for the acupuncture area (For example, Table 1). Benefitting from the process of gathering evidence and items, we will consider a conceptual framework for the reporting checklist of CPGs on acupuncture.

5.1.1. 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, GIN, NICE, AHRQ, and SIGN

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 2.

5.1.2. Identify current CPGs on acupuncture

Literature Search: We will search eight databases: Medline, Embase, AMED, CINAHL, Wan Fang, CBM, CNKI, and VIP; tracking references to included studies, and on Google academics and Medlive, GIN, NICE, AHRQ, and SIGN

Inclusion Criteria: include research on the field of acupuncture.

Exclusion Criteria: exclude previous version of acupuncture practice guidelines.

Search strategy: We will use the combination of keywords and free words to search. Search terms include the following: "guideline*, guidance, recommendation*, consensus, acupuncture, pharmacoacupuncture, electroacupuncture, needl*, acupotomy (Table 3).

5.2. 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 explanation [16]. Therefore, our items formulation group will use thematic analysis

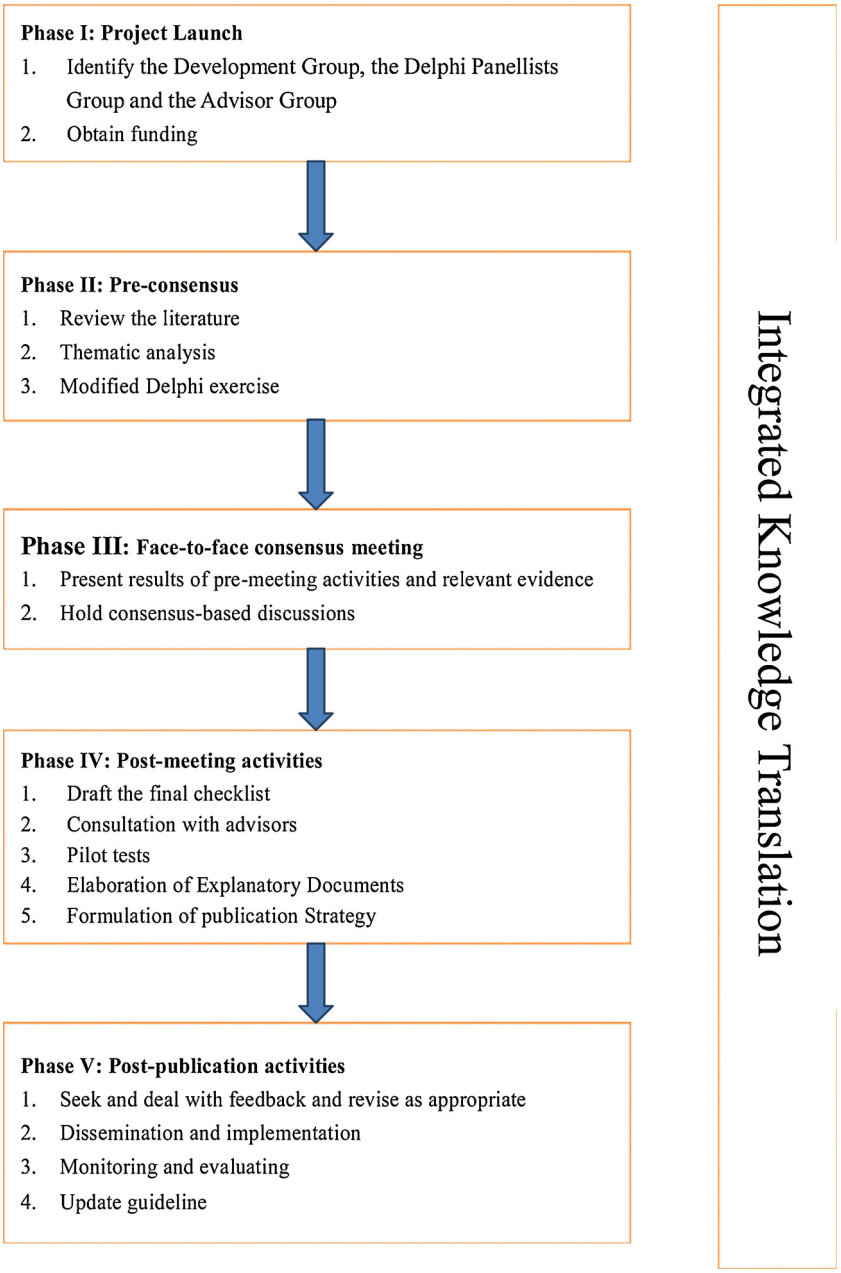

Fig. 1. Flow diagram for reporting guideline development.

Table 1
Examples of the relevant literature.

Type of article	Examples of relevant article
1.Reportingchecklistof acupuncture	Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT Statement.10 Reporting items for systematic reviews and meta-analyses of acupuncture: the PRISMA[14] for Acupuncture checklist.11*(Under development)*
2.Guidelines of acupuncture	Practice guidelines for acupuncturists using acupuncture as an adjunctive treatment for anorexia nervosa.6 Guidelines for providing acupuncture treatment for cancer patients–a peer-reviewed sample policy document.5 Clinical practice guideline of acupuncture for herpes zoster.[15]

Table 2
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.	Pharmacoacupuncture [tiab]
#27.	Acupotomy [tiab]
#28.	Acupotomies [tiab]
#29.	Electroacupuncture [tiab]
#30.	Needl* [tiab]
#31.	OR/#24-#30
#32.	#23 AND #31

Table 3
CPGs on Acupuncture Search Strategy (Medline).

#1.	"Guidelines as Topic"[Mesh]
#2.	"Guideline" [pt]
#3.	Guideline*[tiab]
#4.	Guidance[tiab]
#5.	recommendation*[tiab]
#6.	consensus[tiab]
#7.	OR/#1-#6
#8.	"Acupuncture Therapy"[Mesh]
#9.	Acupuncture [tiab]
#10.	Pharmacoacupuncture [tiab]
#11.	Acupotomy [tiab]
#12.	Acupotomies [tiab]
#13.	Electroacupuncture[tiab]
#14.	Needl*[tiab]
#15.	/OR #8-#14
#16.	#7 AND #15

to de-duplicate, refine and expand the items collected by the "Literature Review" in accordance with the thematic framework of current RIGHT items, resulting in items related to our topic.

5.3. Modified delphi consensuses

We will conduct 3 rounds of modified Delphi surveys [17–19]. 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 1–3 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 RIGHT 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 sending E-mails.

6. 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 RIGHT statement.

7. After the consensus meeting

7.1. 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.

7.2. 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.

7.3. Pilot tests

To identify any practical challenges with any of the items, members of the RIGHT for Acupuncture development group will apply the checklist to investigate the reporting condition of a sample of AGs published in 2017. In addition, we will conduct an online survey of the corresponding authors of the acupuncture guidelines 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.

7.4. Elaboration of explanatory documents

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

7.5. Formulation of publication strategy

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

8. Post publication

8.1. Seek and deal with feedback and revise as appropriate

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

8.2. 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 developers of acupuncture CPGs through Academic Conferences or Working Groups; and 3) Contacting the editors of the journal that published CPGs of acupuncture and the institutions that developed the guidelines, such as the China Association of Acupuncture-Moxibustion, WFAS, and WHO.

8.3. Monitoring and evaluation

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

8.4. Update guideline

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

9. Results

The study is in progress and the results are not yet complete. We will update it in time if there is any result.

10. Discussion

This work will be relevant to a broad range of CPGs addressing questions of reporting standards on CPGs on Acupuncture. This work will not only helpful for clinical practitioners, CPGs developers, but also for editors and peer-reviewers. The RIGHT for acupuncture statement can be applied to the following two types of acupuncture guidelines. First, the statement could be applied to guidelines for treating certain diseases in the field of acupuncture. Secondly, the statement could be applied to the part of acupuncture treatment mentioned in the guidelines for certain diseases.

10.1. Limitations

This study only provides guidance for the development of acupuncture field guidelines and is not applicable to other fields.

11. Conclusions

The “RIGHT for Acupuncture” project will achieve the following advantages: 1) To provide regulations for guideline developers; 2) To obtain more precise and clear guidelines for readers and clinical practitioners; and 3) To evaluate the reporting quality of CPGs on acupuncture and improve the transparency of research reports for editors and reviewers.

Ethics approval

The study protocol was approved by the ethics council of Medical college of Acu-Moxi and Rehabilitation, Guangzhou University of Chinese Medicine.

Consent for publication

All authors consent for publication.

Availability of data and material

We commit to the long-term preservation and availability for use by other research teams of the high-quality data produced by this project. The data will be prepared to allow independent usage. The Clinical Research Center, South China Research Center for Acupuncture and Moxibustion, Medical College of Acu-Moxi and Rehabilitation, Guangzhou University of Chinese Medicine is well placed to host this work. It has full University support for this project and the RIGHT Group is close at hand to assist where needed. All data will be safely stored and backed up at the Clinical Research Center.

Conflict of interests

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

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Authors' contributions

NGX, YLC, CZT and LML conceptualised the study design. YTD, YZ, QZ, XFL 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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