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ORIGINAL ARTICLE

RIGHT for acupuncture: An extension of the RIGHT statement for clinical practice guidelines on acupuncture

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Abstract

Objective: In 2017, the 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). Given the original tool was developed in 2017 and demanded in developing and reporting high quality of acupuncture CPGs, an extension with a focus on a specific reporting checklist was warranted.

Study Design and Setting: The study was designed based on the methodology recommended by the Enhancing the Quality and Transparency Of Health Research (EQUATOR) Network with modification accordingly. A reporting checklist and its elaboration and explanations for users were developed.

Results: A checklist of seven sections (Basic information, Background, Evidence, Recommendations, Funding, Declaration and management of interest, Other information), twenty-three first level items and forty-three second level items was developed. We clarified the rationales of the items and provided explanations and examples of each item for additional guidance.

Conflicts of Interest: There is no competing interest to declare.

[#] These authors contributed equally to this work

[§] Members of the RIGHT for Acupuncture Working Group and their responsibility are listed in Table 1 & eTable 1.

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Conclusion: The RIGHT for Acupuncture checklist identifies a set of items to be reported when reviewing clinical practice guidelines on acupuncture. This extension can be expected to improve the reporting quality of CPGs on acupuncture.

Keywords: Clinical practice guidelines; Acupuncture; Reporting guideline; RIGHT extension; Reporting quality; Traditional Chinese medicine

1. Introduction

Acupuncture, as a part of traditional medicine, is now widely used around the world [1]. According to a report published by the World Health Organization (WHO) in 2013 [2], 103 of WHO member countries applied acupuncture in medical practice. The 2013 survey of World Federation of Acupuncture-moxibustion Societies (WFAS) [3] stated that acupuncture treatment was partially or fully covered by health insurance in 59 (29%) of 202 countries.

With the widespread use of acupuncture, more and more national organizations have developed CPGs to facilitate its optimal use. CPGs on acupuncture [4–6] have been developed for more than 20 common diseases over the last decades. However, the reporting quality of CPGs on acupuncture is suboptimal and needs to be improved [7]. It is therefore essential to develop a guidance for acupuncture CPGs that provides a clear, explicit, standardized and systematic presentation of how acupuncture CPGs should be developed to improve the quality and transparency of reporting.

Reporting standards for systematic reviews and clinical trials on acupuncture have already been published (e.g. "Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT Statement" [8] and the ongoing project of "Reporting items for systematic reviews and meta-analyses of acupuncture: the PRISMA for Acupuncture checklist" [9]). However, a reporting guideline of CPGs is still absent. 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 [10]. Barriers exist in the applicability of acupuncture due to its specific features compared to other health care interventions, which include differences in the composition of panels, guideline development process, sources of evidence, considerations of recommendations and characteristics of interventions. Therefore, there is an urgent need to develop an extension of the RIGHT checklist for CPGs on acupuncture.

The aim of the RIGHT for Acupuncture checklist is to optimize the reporting of guidelines having acupuncture as the main intervention (s). The checklist can also be used for some recommendations in other guidelines that include acupuncture.

The main group of target users of "RIGHT for Acupuncture" are authors of guidelines on acupuncture, journal editors, peer reviewers, policy makers, and methodologists. As with other reporting guidelines, the RIGHT for Acupuncture can also assist early design when developing acupuncture guidelines.

2. Methods

First, we set up a research team, including three groups (the development group, the Delphi panelists group, and the advisory group). Then, we identified the research framework, registered it on "Enhancing the QUAlity and Transparency Of health Research" (EQUATOR) network [11], and conducted a corresponding systematic review to form an initial set of items. After two rounds of Delphi surveys and consensus meetings, the final items were formed by e-mail re-confirming. We established a final version of "RIGHT for Acupuncture" checklist and developed an explanation and elaboration document. The development process is described in detail in the protocol [12]. The flow chart of the development process is presented in Fig. 1.

3. Project initiation

We first established three research groups: the development group, the Delphi panelists group, and the advisory group. Members of each group were selected according to strict inclusion criteria and were assigned clear responsibilities (see details in Table 1). The core development group consisted of professors and graduate students from Guangzhou University of Chinese Medicine and Lanzhou University. The advisory group (5 experts) and Delphi panelists group (13 experts) from nine countries and regions, namely Canada, United States, Brazil, Sweden, United Kingdom, Korea, Australia, Hong Kong, and mainland China. These experts included methodologists, acupuncture CPG developers, and acupuncture clinical practitioners. The detailed information of the experts, including the affiliation, title, research direction, and geographical distribution, are presented in Fig. 2 and eTable 1.

4. Activities before and during the consensus meeting

4.1. Literature review

Before searching the literature, we formulated a conceptual framework for literature inclusion. Items from two types of literature were included: reporting checklists for acupuncture, and CPGs for acupuncture. Benefiting from

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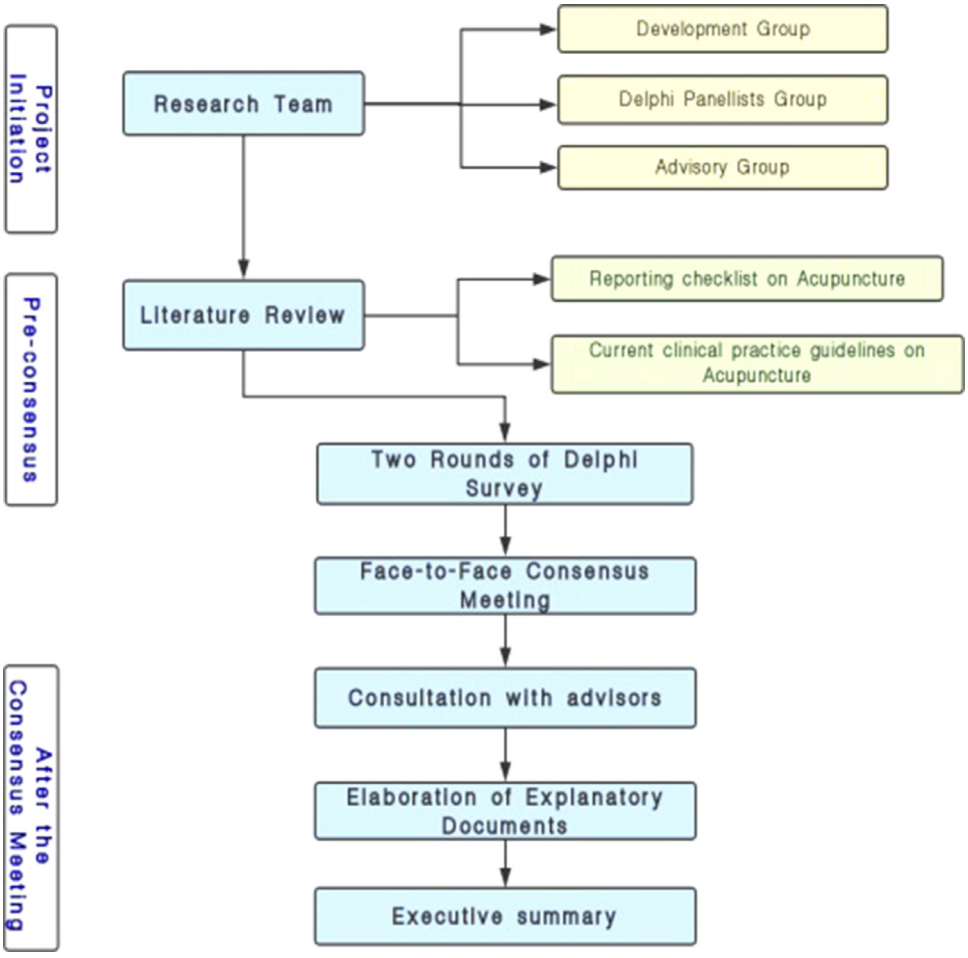

Fig. 1. Flow diagram for reporting guideline development.

Table 1. The responsibility of each group members

Development Group	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.
Delphi Panellists Group	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.
Advisory group	1) Recruitment of the Delphi Panellists Group members; 2) Providing consultation and assistance; and 3) Conducting quality assurance.

the process of the evidence summary, we established an initial item pool for the reporting checklist of CPGs on acupuncture. The detailed search strategy of two types of literature review is shown in eTable 2&3.

4.2. Modified Delphi process

We conducted two rounds of modified Delphi surveys for evaluating the initial items of "RIGHT for Acupuncture" checklist. If the item was approved by more than 66% of participants it proceeded into the next round of the Delphi process. If not, it was subject to further discussion [12,13]. The rules for the evaluation of items used in the specific Delphi survey are shown in eTable 4. Following each of the two rounds, the most frequent score for each item was tabulated. All participants were provided with a summary of the results after both rounds of the process. The survey was administered through e-mails that

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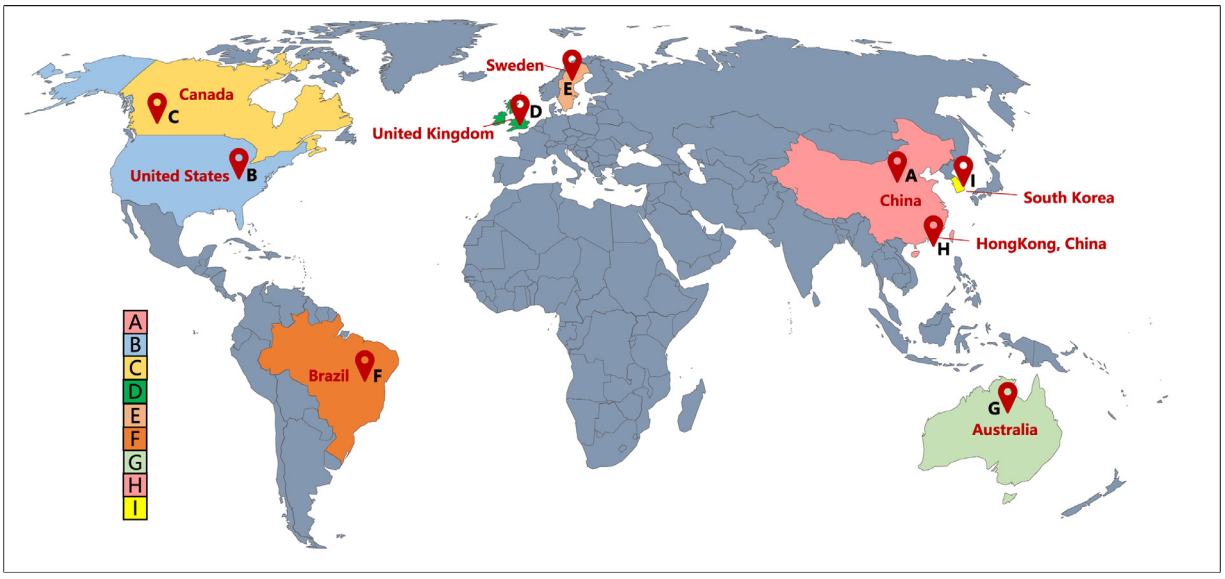

Fig. 2. Geographical distribution of Delphi members.

were sent separately to each participant, thus the participants could not know and communicate with each other.

5. Face-to-face consensus meeting

After the Delphi process, we created a draft checklist with the included items and sent the invitation of attending face-to-face consensus meeting to all members of Delphi panelists group and advisory group.

During the meeting, the study background, the progress and results of the Delphi process were presented, followed by a discussion and revision of each item. The participants then voted about the inclusion of each proposed item and decided the precise wording. We present only the aggregated results to maintain the confidentiality of the participants' responses. At the end of the meeting, experts reviewed the checklist of items again to confirm that their comments were appropriately understood and considered.

6. After the consensus meeting

6.1. Consultation with advisors

After the consensus meeting, we sent the checklist to the members in the Delphi panelists group and advisory group for final confirmation. During the consultation of the advisory experts, the wording and presentation of the checklist and manuscript were further discussed and revised. This step was administered by e-mail correspondence.

6.2. Elaboration of explanatory documents

To ensure accurate implementation, we included a detailed description of the items with explanations to promote the use of RIGHT for Acupuncture.

7. Results

A checklist of seven sections (Basic information, Background, Evidence, Recommendations, Review and Quality Assurance, Funding, declaration and management of interests, and Other information), 23 first level items and 43 second level sub-items was formulated. Clarified rationales of the items and examples are provided for each item for additional guidance.

7.1. Literature review

After conducting the literature review on current reporting guidelines and CPGs on Acupuncture, we formed an initial "RIGHT for Acupuncture" checklist (eTable 5).

7.2. Delphi process

Based on the results of the collection of initial items (n = 23), we included 23 items for the first round of the Delphi process. The process of the Delphi survey is shown in Fig. 3.

After the first Delphi process, two of the 23 items were put into discussion for they were approved by less than 66% of the participants. One was the item 10a. (Describe how all contributors to the guideline development were selected and their roles and responsibilities e.g., steering group, guideline panel, external reviewers, systematic review team and methodologists). The other one was the item 15d (Describe whether the references to classic ancient books, prestigious TCM physician's experience and technical specifications are also mentioned when forming recommendations). The experts gave their feedback for revising the remaining items, and no additional items were suggested by the panel. Acupuncturists were consulted

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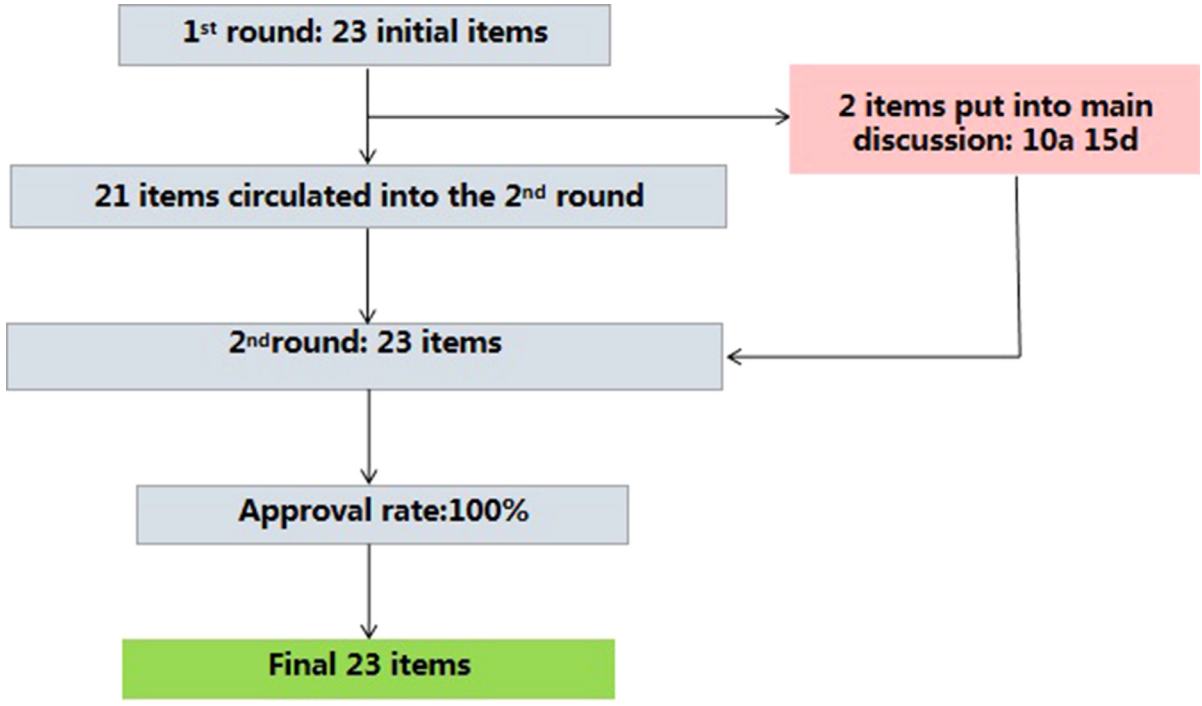

Fig. 3. The process of Delphi survey.

for adjusting the description about the implementation of acupuncture based on feedback from the first round.

For the remaining 21 items, we modified the structure of expression, combined or split some items into subitems, and revised the wording according to the feedback from the first round. Two lowest-scoring items (10a and 15d) were surveyed in the second round after revision, and the results showed a high consensus on most items with no major changes. All twenty-three items scored greater than 66% in the second round and were included.

After analyzing the feedback from the second round of the Delphi process, no items were excluded or additional items were needed to be added. The third round of Delphi survey was thus not needed due to the high consensuses of panelists. The results of the two rounds of Delphi process are shown in eTables 6–9.

7.3. Consensus meeting and consultation with advisors

On April 17, 2019, "RIGHT for Acupuncture" Consensus Meeting was successfully held at Guangzhou University of Chinese Medicine. Thirty experts, including members of three groups, attended the consensus meeting. Over 75% of the members in the Delphi panelists group and advisory group attended the meeting.

This consensus meeting was presided over by Professor Chunzhi Tang and Associate Professor Liming Lu. After reviewing the existing literature, the items formed by the two rounds of Delphi survey were introduced one by one. After a thorough discussion, a consensus was reached. A photo of the consensus meeting can be seen in eFig. 1. The summary of two rounds of Delphi survey and consensus meeting are attached in eTables 10 and 11.

We sent the revised checklist following the suggestions in the consensus meeting to the members in Delphi panelists group and advisory group for final confirmation by e-mail. After collecting and discussing the feedback from the experts, we formed the final checklist (Table 2) as follows.

7.4. Elaboration and explanations

We provided a detailed point-to-point explanation and guidance to the users of "RIGHT for Acupuncture" checklist in the attached document *"RIGHT for Acupuncture Explanation and Elaboration: Guidance for Reporting Clinical Practice Guidelines."*

8. Discussion

As an extension of the original RIGHT statement, RIGHT for Acupuncture checklist aims to improve the reporting quality of acupuncture guidelines. by providing regulations for guideline developers, obtaining more precise and clear guidelines for clinical practitioners and health policy makers, evaluating the reporting quality of CPGs on acupuncture and improve the transparency of research reports for editors and reviewers. In order to easily understand RIGHT for Acupuncture checklist, we also provide explanations and examples for revised or complementary items.

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Table 2. "RIGHT for acupuncture" checklist

Section/topic	Number	Item
Basic Information		
Title/subtitle	1a	Identify the report as a guideline in the title, with "guideline(s)" or "recommendation(s)", together with the term "acupuncture".
	1b	Provide the year of publication of the guideline.
	1c	Describe the focus of the guideline, such as treatment, prevention, management, or others.
Executive summary	2	Provide a summary of the recommendations contained in the guideline.
Abbreviations and acronyms	3	Define new and key terms; provide a list of abbreviations and acronyms as well as acupoint codes using an international standard defined by an authority such as WHO, WFAS or WFCMS; and (if applicable), explain the new concepts clearly.
Corresponding developer	4	Identify at least one corresponding developer or author who can be contacted for questions related to the guideline. At least one of the corresponding developers should be an acupuncture clinical specialist.
Background		
Brief description of the health problem(s)	5	Describe the basic epidemiology of the problem, such as the prevalence/incidence, morbidity, mortality, and burden (including financial) resulting from the problem.
Overview of acupuncture treatment	6a	Summarize the diagnosis and treatment of the diseases under consideration in classic texts.
	6b	Describe the status of expert consensus including the experience among traditional medicine (TM) physicians, as well as technical specifications and previous recommendations for acupuncture treatment.
	6c	Describe the limitations of conventional treatment and the potential advantages of acupuncture and its complementary role.
Aim(s)of the guideline and specific objectives	7	Describe the aim(s) of the guideline and specific objectives, such as improvements in health indicators (e.g. mortality and disease prevalence), quality of life, or cost savings.
Target population(s)	8a	State the targets of the acupuncture guideline(s) in terms of a Western medicine-defined disease, a TM pattern, or a Western medicine–defined disease with a specific TM pattern. The TM pattern should be defined in terms of the WHO ICD-11 TM Chapter.
	8b	Describe any subgroups that are given special consideration in the guideline (e.g. a specific TM pattern and stage of disease).
End users and settings	9a	Describe the intended primary users of the guideline (e.g. individual practitioners, public health practitioners, health policy decision makers and payers) and other potential users of the guideline.
	9b	Describe the setting(s) for which the acupuncture guideline is intended, such as qualifications and sanitary conditions which are required for the acupuncture treatment.
Guideline development groups	10a	Describe "Construction of Panel", how all contributors to the guideline development were selected and their roles and responsibilities (e.g., steering group, guideline panel, external reviewers, systematic review team and methodologists).
	10b	List all individuals involved in developing the guideline, including their title, role(s), and institutional affiliation(s), geographical location and acupuncture related information.
Evidence		
Health care question	11a	11a.1 Target: a Western medicine–defined disease, a TM pattern, or a Western medicine–defined disease with a specific TM pattern. 11a.2 Interventions: ①Style of acupuncture (e.g. manual acupuncture, electroacupuncture, fire acupuncture, ear acupuncture, or scalp acupuncture, etc.) ②Details of the acupuncture treatment (e.g. selection of points, operation, treatment procedures and auxiliary intervention measures) ③Practitioner background (e.g. qualification or professional affiliation, years in acupuncture practice and other relevant experience). 11a.3 Control or comparator interventions (if applicable): ①Indicate the rationale for the control or comparator in the context of the research question. ②Describe precisely description the control or comparator. If sham acupuncture or any other type of acupuncture-like controls are used, please provide details mentioned in 14a.2 below. 11a.4 Outcomes: outcome indicators related to TM syndrome type and safety evaluation.
	11b	Indicate how the outcomes were selected.

(*continued on next page*)

Table 2 (*continued*)

Section/topic	Number	Item
Systematic reviews	12a	Indicate whether the guideline is based on new systematic reviews (SR) or overviews of SRs that were specifically conducted for the purpose of this guideline, or whether existing SRs were used.
	12b	If the guideline developers used existing SRs or overviews of SRs, please reference these and describe how those reviews were identified and assessed (provide the search strategies and the selection criteria, and the evaluation process of the quality of SRs) and how recent the evidence is.
Assessment of the certainty of the body of evidence	13	Describe the approach used to assess the certainty of the body of evidence.
Recommendations		
Recommendations	14a	Provide clear, precise and actionable recommendations. Describe the recommended intervention and its target summarized from 11a.1 and 11a.2.
	14b	Present specific recommendations for different subgroups if the evidence suggests that there are important differences in factors influencing the recommendations, particularly in the balance of benefits and harms across subgroups.
	14c	Indicate the strength of recommendations and the certainty of the supporting evidence.
Rational e/explanation for recommendations	15a	Describe whether the underlined values and preferences of the target population(s) were stated in the formulation of each recommendation. If yes, describe the approaches and methods used to elicit or identify these values and preferences.
	15b	Describe whether cost and resource implications were considered in the formulation of the recommendations. If yes, describe the specific approaches and methods used (such as cost-effectiveness analysis) and summarize the results. If resource issues were not considered, provide an explanation.
	15c	Describe other factors taken into consideration when formulating the recommendations, such as equity, feasibility and acceptability.
	15d	Described whether, and how, classical books, TM physicians' experience and technical specifications influenced the recommendations.
Evidence to decision processes	16	Describe the processes and approaches used by the guideline development group to make decisions; particularly the formulation of recommendations (such as how consensus was defined and achieved and whether voting was used).
Review and Quality Assurance		
External review	17	Indicate whether the draft guideline underwent independent review and, if so, how the review was executed and the comments considered and addressed. The external review panel, e.g. senior acupuncture specialists, clinical first-line acupuncturists and methodologists should be listed if applicable.
Quality assurance	18	Indicate whether the guideline was subject to a quality assurance process. If yes, describe the process. Submit a letter of opinion to the relevant health institution, the acupuncture professional society or the relevant organization (if applicable) for approval.
Funding and Declaration and Management of Interests		
Funding source(s) and role(s)of the funder	19a	Describe the specific sources of funding for all stages of guideline development.
	19b	Describe the role of funder(s) in the different stages of guideline development and in the dissemination and implementation of the recommendations.
Declaration and management of conflict interest	20a	Describe the conflicts of interest (financial and non-financial) that were relevant to guideline development.
	20b	Describe how conflicts of interest were evaluated and managed and how users of the guideline can access the declarations.
Other Information		
Access	21	Describe where the guideline, its appendices, and other related documents can be accessed.
Suggestions for further research	22	Describe the gaps in the evidence and/or provide suggestions for future research.
Limitations of the guideline	23	Describe any limitations in the guideline development process (such as the development groups were not multidisciplinary or patients' values and preferences were not sought), and indicate how these limitations might have affected the validity of the recommendations.

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8.1. Comparison with the original RIGHT checklist

Although the structure and content of RIGHT for Acupuncture is based on the original RIGHT statement, several differences exist. In the "Basic information" section, we require specific names of acupuncture interventions to appear in the title or subtitle. This change is conducive to researchers to easily find the acupuncture guidelines when searching the literature. Second, in terms of the specificity of acupuncture, we require that the guidelines should give abbreviations and acronyms which are recognized by international authorities in order to make it easier to understand the acupuncture guidelines.

Due to the unique diagnostic and therapeutic system of acupuncture, we added the "Overview of Acupuncture Treatment" item into the “Background” section, which stipulates that the guide needs to give an overview description of the principles, methods and means of diagnosis and treatment of acupuncture. Therefore, users can have a general understanding of the basic knowledge of acupuncture therapy as well as diagnostic and therapeutic means of the intervention.

The "Evidence" section requires that the guidelines report the detailed treatment process of acupuncture intervention in a comprehensive and detailed manner, including manipulation, operating environment, needle use, and acupoint selection. The purpose is to make it easier for the users of the guidelines to repeat the treatment more exactly. Due to the uneven quality and diverse sources of evidence for acupuncture, the guideline is required to make a specific evaluation of the quality of evidence. For example, the recommendations on acupuncture mentioned in classical books need to be evaluated by relevant criteria before they can be included in the guidelines.

The section of "Recommendation" was not changed essentially. The main change is that the recommendations should highlight the factors specific for acupuncture, e.g. appropriate traditional medicine syndromes for acupuncture treatment, acupuncture point selection, acupuncture details, and needling requirements.

Finally, the "Funding, declaration and management of interest" and "Other Information" do not differ from the original checklist. These two sections of the original RIGHT can be applied in acupuncture CPGs directly.

We also provide complete and clear explanations and examples for the main expanded items. These explanations and examples enable users to grasp the application of RIGHT for Acupuncture more quickly and exactly, and ensure the efficiency and accuracy in the evaluation process. Compared with the original RIGHT, RIGHT for Acupuncture is more targeted and thus more suitable for the actual situation of clinical practice guidelines of acupuncture.

8.2. Comparisons with other reporting standard extensions

As a published extension of CONSORT, STRICTA focused on the reporting standard of clinical trials, mainly extending item 5 "Interventions" in detail, including acupuncture rationale, details of needling, and treatment regimen. The main extended areas of RIGHT for Acupuncture can be summarized as "Basic Information," "Background," and "Evidence" and “Recommendations,” which provided a whole reporting guidance for clinical practice guidelines.

8.3. Suggestions for subsequent acupuncture guidelines

Poorly reported guidelines may result in misinterpretation and inappropriate application in clinical settings. Correspondingly, an explicit, accurate, and transparent report in guidelines can help to better disseminate, interpret and transform them. In order to maximize this potential, we hope that academic journals and acupuncturists can decisively and clearly support the RIGHT for Acupuncture, which offers a standard to follow in the formation of acupuncture evidence, recommendations, and guidelines. In addition, we encourage journals to implement guidelines to encourage authors to comply with the reporting guidelines so that acupuncture therapies can be incorporated into the diagnosis and treatment of diseases by an increasing number of healthcare communities.

8.4. Study strengths

Our proposal has several strengths. The development of the checklist was comprehensive, including the use of previous methodological evidence, engagement of the multidisciplinary, and representative international guideline community. We collected the views and experience from different stakeholders, including methodologists, guideline developers, policy makers and guideline users. The guideline developers consist of the developers of acupuncture CPGs and the developers of reporting guidelines. We ensured the diversity of participants in terms of the geographical representation, different disciplines, and types of expertise. These allowed us to incorporate with the different stakeholders’ perspective about items of the extension. To minimize the non-response bias, we allowed three months for responding to the survey, and sent two reminders prior to the round’s closing date.

9. Conclusion

RIGHT for Acupuncture expands the original RIGHT checklist by applying its principles to the reporting of

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acupuncture CPGs. We hope that this checklist will promote better reporting in preparing CPGs on acupuncture. We will periodically reappraise and further update RIGHT for Acupuncture to guarantee its better guidance for the acupuncture CPGs developers.

Ethics and dissemination

Not applicable.

Consent for publication

All authors have given their 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 and Data 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 and Data Center.

Authors' contributions

Conception and design: Chunzhi Tang, Liming Lu, Yaolong Chen, Gordon Guyatt, Nenggui Xu. Analysis and interpretation of the data: Liming Lu, Yuting Duan, Yu Zhang, Yuqing Zhang, Ze Chen, Jingchun Zeng, Shuqi Ge, Hao Wen, Xiaorong Tang, Weixuan Zhao, Yaolong Chen.

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Final approval of the article: Chunzhi Tang, Liming Lu, Yuting Duan, Yu Zhang, Yuqing Zhang, Ze Chen, Jingchun Zeng, David Riley, Myeong Soo Lee, Yong-Suk Kim, Hong Zhao, Gaetano Marrone, Xiaoshu Zhu, Shuqi Ge, Hao Wen, Xiaorong Tang, Weixuan Zhao, Ioannis Solos, Yaolong Chen, Gordon Guyatt, Nenggui Xu.

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Author Statement

All authors have given their consent for publication.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jclinepi.2021.05.021.

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