Reporting and data-sharing level of acupuncture randomised controlled trials: a cross-sectional study protocol

Yuting Duan, Zhirui Xu, Xinyu Li, Pinge Zhao, Shengwei Wu, Zewei Chen, Jiewen Guo, Yiye Zhou, Chunzhi Tang, Lin Yu

ABSTRACT

Introduction Randomised controlled trials (RCTs) play an important role in evidence-based medicine. However, an article with low reporting quality may mislead both experts and the general public into an erroneous decision. Data sharing can contribute to the truthfulness and transparency of trials. Acupuncture RCTs have been increasing rapidly these years, but the reporting quality and data-sharing level of acupuncture RCTs are not clear. Thus, this study will provide the current status of the reporting quality and data-sharing level of acupuncture RCTs.

Methods and analysis A cross-sectional study will be conducted. The seven databases including MEDLINE, EMBASE, CENTRAL, CDM, CNKI, Wanfang Database and VIP will be searched between 1 January 2012 and 15 October 2022 to identify acupuncture RCTs. The basic characteristics of included trials will be summarised. The reporting quality for included RCTs will be assessed by the Consolidated Standards for Reporting Trials (CONSORT) statement and the Standards for Reporting Interventions in Controlled Trials of Acupuncture. The data-sharing level will be assessed by open science practices.

Ethics and dissemination Ethical approval is not required for this study. This protocol has been registered in Open Science Framework Registries. The findings of this study will be submitted to a peer-reviewed academic journal.

BACKGROUND

According to the second global survey in 2012 conducted by WHO, acupuncture is being used as the most common therapy of traditional and complementary medicine practice reported by 113 member states among 133 replied countries. As it gained more attention, existing academic research in acupuncture has been steadily increasing and the diverse applications of acupuncture are extensive from pain syndrome to multiple medical disciplines including neuroscience, obstetrics and gynaecology, as well as rehabilitation.

Randomised controlled trials (RCTs), at the top of the pyramid of the highest strength of clinical evidence, are often considered the gold standard for evaluating the efficacy of interventions. However, only adequate reporting of RCTs can provide reliable information and credible conclusions that may aid in policy and medical decision-making. Acupuncture therapies are typically complex during the implementation of RCTs. For an acupuncture RCT, there are many key points needed to be strengthened reporting, which are different from other RCTs, for example, the participants’ compliance, the setting of blinding, the standardisation of acupoint location and the method of needle insertion. Despite the increasing number of acupuncture RCTs published in international high-impact journals, the reporting quality and data-sharing level of these RCTs are not clear.

To improve transparency and accuracy of the interpretation and replication of RCTs, the Consolidated Standards for Reporting Trials (CONSORT) was first published in 1996, updated in 2001, and the latest version was published in 2010, comprising
a checklist, a flow diagram, and an Explanation and Elaboration document. The Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) was drafted in 2001 and revised in 2010, designed as an extension of the CONSORT for acupuncture to increase the reporting for accurate and standardised acupuncture interventions in detail. These two reporting guidelines have the goal of improving research transparency and completeness of reporting, which can help editors and readers fully understand the study process and results.

In 2004, the International Committee of Medical Journal Editors (ICMJE) proposed to adopt a trial registration policy requiring investigators to register in a public repository before patient enrolment. Then ICMJE published a proposal that clinical trials must contain a data-sharing statement both in the registration and manuscript submission. These proposals establish a favourable environment for clinical trial data disclosure, which can promote evidence dissemination and reusage and avoid research waste.

The aim of this study is to assess the reporting quality and the data-sharing level of acupuncture RCTs published between 2012 and 2022 by using the CONSORT 2010 checklist and STRICTA, and open science practices, respectively.

METHODS
This protocol is registered and publicly available via Open Science Framework (registration DOI: https://doi.org/10.17605/OSF.IO/2WTE6). This cross-sectional study will be written according to the Strengthening the Reporting of Observational Studies in Epidemiology. The study is expected to be conducted between 22 November 2022 and 31 December 2024.

Eligibility criteria
All published RCTs with two parallel study groups applied to humans that only used acupuncture therapy in the intervention group will be included. The types of the control group include (1) no intervention or waiting list, (2) sham acupuncture or placebo, (3) western medicine, and (4) other interventions such as psychotherapy or rehabilitation and physical therapy guided by modern medical theory. It will also be included if there is a combination with any usual care or conventional therapy in both groups.

We define the term ‘acupuncture therapy’ as the interventions stimulating specific body areas (called acupuncture points) by needling, which is based on the traditional Chinese medicine theories, regardless of the difference in instrument size, stimulating spots and needling manipulation, such as body acupuncture, electroacupuncture, auricular acupuncture and acupotomy.

The following studies will be excluded: (1) if the intervention is acupuncture stimulation, and the stimulation does not pierce the skin (such as auricular pressure, acupuncture application); (2) the sample size of the study is less than or equal to 10 in each group; (3) authors of the trial are fewer than three; (4) unavailable or no full-text studies (such as conference abstracts, protocols, preprint articles); (5) duplicative articles.

Databases and search strategy
A systematic search will be conducted on three English databases (MEDLINE, Excerpta Medica Database, Cochrane Central Register of Controlled Trials) and four Chinese databases (Chinese Biomedical Literature Service System, China National Knowledge Infrastructure, Wanfang Data and VIP Chinese Medical Journal Database) on 15 October 2022. There is no restriction to the language of publication. The time range will be limited from 1 January 2012 to 15 October 2022. The detailed search strategy is shown in online supplemental material 1.

Literature screening
EndNote (V.X7.1) and Rayyan (https://www.rayyan.ai/) will be used to screen the Chinese and non-Chinese literature records, respectively.

The titles and abstracts of included RCTs will be screened by two researchers (XL and PZ) independently based on eligibility criteria. Then, the full texts will be screened by two researchers (XL and PZ) independently based on inclusion and exclusion criteria. Discrepancies will be resolved through discussion or by asking two senior investigators (YD and LY).

Basic characteristics extraction
An information extraction table with a Microsoft Excel spreadsheet (Microsoft Excel V.2019 MSO 2210 Build 16.0.15726.20188 32) will be made for data extraction.

The basic information includes: (1) title, (2) authors, (3) language, (4) publication (year and the journal), (5) country and region where the research was carried out, (6) study design (superiority, non-inferiority or equivalence), (7) sample size, (8) participants (including age, gender), (9) disease system and detailed disease, (10) types of intervention and controls (dose, frequency and duration), (11) study and follow-up period, (12) outcome measures, (13) adverse event (number, type, severity), (14) the main research purpose, (15) funding (industry, independent or none) (16) conflict of interest and (17) registration information.

The data will be extracted by two researchers (ZX and PZ) independently, and two senior investigators (YD and LY) may make a decision if there exist any differences.

Assessment and data analysis
The overall reporting scores will be analysed using descriptive statistics (mean and 95% CI). The categorical data will be presented as a number (n) and per cent (%).

Pretest
Before the formal evaluation, evaluators will be trained and three rounds of pretests will be performed to improve the consistency and accuracy between the investigators.
Only when the kappa coefficients >0.75 will we enter the formal evaluation.

Two researchers will complete the formal evaluation independently (ZX and XL). When disagreement happens, the judgement will be discussed or arbitrated by two senior investigators (YD and LY).

**CONSORT statement and STRICTA checklist reporting scores**

The CONSORT 2010 statement and STRICTA checklist will be used for assessing the reporting quality of included acupuncture RCTs. The specific rules for 37 items of CONSORT scoring will be made according to CONSORT Explanation and Elaboration document. The 17 items of the STRICTA checklist will be scored based on the revised STRICTA. Each item is scored in terms of two possibilities: ‘1’ for ‘reported’ or ‘not applicable’, ‘0’ for ‘insufficiently reported’ or ‘unreported’. Each item score of two checklists for each trial will be summed to provide a total score severally, and the percentage of items reported will be also calculated. The detailed evaluation criteria are shown in online supplemental material 2.

**Open science practices**

The data-sharing level will be assessed by open science practices, including the following items:
1. Whether there is registration information, including registration number, with accessible protocol. Whether there is a completion date in the registration.
2. Whether there is a data-sharing statement, and whether the statement fulfils the ICMJE requirements.
   a. Will individual participant data be available (including data dictionaries)?
   b. What data will be shared?
   c. What other documents will be available?
   d. When will data be available (start and end dates)?
   e. Whether there is a contact person for the data.
   f. For what types of analyses?
   g. By what mechanism will data and code/algorithms/software be made available?
   h. Whether there is a direct link to the data (such as a data citation).

**DISCUSSION**

Several systematic reviews of the use of CONSORT and STRICTA checklists have demonstrated an increase in all the items over time since the introduction and influence of the conception of reporting quality. Svenkerud and MacPherson revealed that the mean STRICTA score increased from 4.27 in the 1994–1995 period to 5.53 in 2014–2015 with an 18% improvement, while the mean CONSORT score rose from 1.01 to 3.32 with an increment of 46%.

Previous researchers have evaluated the reporting quality in RCTs concerning various diseases such as cancer and its complications, stroke and post-stroke rehabilitation, pain, primary insomnia, diabetes, chronic obstructive pulmonary disease, herpes zoster and vascular dementia among different languages. A systematic review by Ma et al investigated published RCTs between 2004 and 2012 in China and found that the reporting of the sample estimate (1.2%), ethical committee approval (less than 1%) and conflicts of interest (0%) was inadequate. An assessment of 88 papers on acupuncture for patients with cancer resulted in a conclusion that the reporting of STRICTA items in present studies was generally good but there were weaknesses related to details of other interventions administered to the acupuncture group and details of the acupuncturists administering treatments. Similarly, another systematic review of Korean RCTs of acupuncture was suboptimal, especially the items of sample size calculation (2.9%), allocation concealment (5.8%), ancillary analyses (0.0%) and generalisability of findings (1.9%) in CONSORT as well as the items of setting/context (24.6%) and practitioner background (27.9%) in the STRICTA. Recently, Xiu et al compared the reporting quality of Chinese and English RCTs and emphasised the urgency of the improvement of Chinese articles.

Open science can be used to assess the credibility and rigour of the articles by preregistration and transparency for replication of studies. Preregistration is thought to reduce publication bias toward significant findings. Replication supports researchers to ensure the programmes do not deviate significantly from the desired plan. Besides, it can enhance knowledge innovation based on previous data and code from others, even to correct mistakes. However, there is limited evidence in this field, which is concentrated in a very small number of diseases such as eating disorders, traumatic stress and gambling with the findings suggesting a large potential for growth in open science practice usage. To our knowledge, there is no formal study that has explored the data-sharing level of the published acupuncture RCTs to date.

Hence, our study is the first comprehensive study to evaluate the reporting quality and data sharing on articles comprising acupuncture RCTs across all types of diseases according to the CONSORT 2010 and STRICTA, and the open science practices.

The principles in the Declaration of Helsinki require researchers involving human experimentation to perform ethical responsibility to make their findings publicly available with complete and accurate description. However, the problem of poor research reporting is not unusual and can be subdivided into several types including missing or incomplete information, misleading or selective presentation, obscure language or inconsistent argument with a logical fallacy.

Among 50% of the research, the reporting was insufficient or incomplete, which is a barrier to the generalisation of strong evidence from research results to support clinical practice. Since acupuncture is a practitioner-dependent, experience-required intervention, the use of acupuncture in different regions can vary from regional characteristics, cultural differences, economic...
restrictions, value orientations or religions; sufficient details of technical manipulation and study contexts should be delivered to enable readers to understand and replicate the operational processes in other research or practices. Adequate and accurate reporting of acupuncture RCTs can not only guarantee the reliability of both the published study and systematic reviews, or clinical practice guidelines based on them but also improve transparency and reduce the risk of interpretation bias, which is essential to medical decision-making and scientific advancement.

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3School of Chinese Medicine, Hong Kong Baptist University, Hong Kong SAR, China
4Key Laboratory of Neurogenetics and Channelopathies of Guangdong Province and the Ministry of Education of China, The Affiliated Brain Hospital of Guangzhou Medical University, Guangzhou, Guangdong, China

Contributors YD and LY conceptualised and supervised the study. YD and ZX developed the search strategies and made the assessment standards. YD, ZX, XL and PZ screened, extracted and analysed data. YD and ZX drafted the manuscript. LY, PZ and XL revised the manuscript. SW, CZ, JG, YZ and CT provided critical comments and substantially improved the quality of the manuscript. All authors provided detailed comments on earlier drafts and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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Chunzhi Tang http://orcid.org/0000-0003-3127-578X

REFERENCES
Search Strategy for Acupuncture RCTs

English databases:

MEDLINE, EMBASE, CENTRAL through OVID

1. exp Acupuncture Therapy/
2. exp Acupuncture/
3. Acupuncture Analgesia.ab,ti.
4. Acupuncture Point$.ab,ti.
5. Needle$.ab,ti.
6. Electroacupuncture.ab,ti.
8. body acupuncture.ab,ti.
9. body-acupuncture.ab,ti.
10. scalp acupuncture.ab,ti.
11. scalp-acupuncture.ab,ti.
12. Scalp Acupuncture Therapy.ab,ti.
13. Ear Acupunctures.ab,ti.
15. wrist-ankle acupuncture.ab,ti.
16. Umbilical acupuncture.ab,ti.
17. navel needling therapy.ab,ti.
18. Buccal acupuncture.ab,ti.
19. thumbstack needle.ab,ti.
20. Acupotom$.ab,ti.
22. Acupressure.ab,ti.
23. acupoint$.ab,ti.
24. filiform needle.ab,ti.
25. eye acupuncture.ab,ti.
26. fire needle.ab,ti.
27. bee acupuncture.ab,ti.
28. plumblossom needle.ab,ti.
29. silver needle.ab,ti.
30. Blade acupuncture.ab,ti.
31. silver needle.ab,ti.
32. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
33. exp randomized controlled trial/
34. random.ab,ti.
35. randomly.ab,ti.
36. placebo.ab,ti.
controlled clinical trial, ab, ti.
allocation, random, ab, ti.
randomized controlled trials as topic, ab, ti.
clinical trial, ab, ti.
randomly allocated, ab, ti.
randomly assigned, ab, ti.
allocated at random, ab, ti.
assigned at random, ab, ti.
allocated by random, ab, ti.
assigned by random, ab, ti.
allocated randomly, ab, ti.
assigned randomly, ab, ti.
33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48
exp animals/
not 50
32 and 51

Chinese databases:

CNKI
SU=('针灸' OR '针刺' OR '针' OR '电针' OR '体针' OR '头针' OR '耳针' OR '脐针' OR '腹针' OR '颊针' OR '刀针' OR '随机对照' OR '随机对照研究') and SU=('随机对照试验' OR '随机化')

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M=('针灸' OR '针刺' OR '针' OR '电针' OR '体针' OR '头针' OR '耳针' OR '脐针' OR '腹针' OR '颊针' OR '刀针' OR '随机对照' OR '随机对照研究') and M=('随机对照试验' OR '随机化')

CBM
(('针灸' OR '针刺' OR '针' OR '电针' OR '体针' OR '头针' OR '耳针' OR '脐针' OR '腹针' OR '颊针' OR '刀针' OR '随机对照' OR '随机对照研究') AND ('随机对照试验' OR '随机化'))

wanfang
检索表达式（中英文扩展&主题词扩展）：((主题='针灸') OR '针刺') OR 主题='针刺疗法' OR 题名或关键词='针灸' OR 题名或关键词='针刺' OR 题名或关键词='电针' OR 题名或关键词='体针' OR 题名或关键词='头针' OR 题名或关键词='耳针' OR 题名或关键词='脐针' OR 题名或关键词='腹针' OR 题名或关键词='随机对照' OR '随机对照试验' OR '随机化')
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# CONSORT Evaluation Criteria

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<tr>
<th>Reporting Item</th>
<th>Evaluation Criteria</th>
<th>Scoring Rules</th>
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<tbody>
<tr>
<td><strong>Title and Abstract</strong></td>
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<tr>
<td><strong>Title</strong></td>
<td>Identification as a randomized trial in the title.</td>
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</table>
| **Abstract** | Structured summary of trial design, methods, results, and conclusions | 1. Author: Contact information for corresponding author.  
2. Study design: Description of the study design (e.g. parallel trial, group trial, non-inferiority trial, etc.).  
3. Methods:  
3.1 Participants: Eligibility criteria for participants and location of data collection.  
3.2 Interventions: Interventions planned for each group.  
3.3 Objective: Specific objective or hypothesis.  
3.4 Outcome measures: Clear description of the primary outcome measure for the study.  
3.5 Randomization methods: How participants were allocated to each intervention group.  
3.6 Blinding: Whether the grouping information was blinded to participants, healthcare providers, and outcome assessors.  
4. Results:  
4.1 Sample size: Number of participants randomized to each group.  
4.2 Recruitment: Clinical trial status regarding participant recruitment.  
4.3 Analysis population: Number of participants in each group for analysis.  
4.4 Outcomes: Results of the primary outcome measure for each group, including effect estimate and precision.  
5. Harm: Significant adverse events or side effects.  
6. Conclusion: Summary interpretation of the results.  
7. Trial registration: Clinical trial registration number and registry name.  
8. Funding: Funding sources. | (1) "Fully Reported": reporting six or more criteria  
"Partial Reported": reporting three to five criteria  
"Not Reported": reporting two or fewer criteria.  
(2) Within each detailed criteria, completion of more than half of the sub-items would be classified as " Reported".  
e.g. If the participants, interventions, objective and outcome measures were all reported in criteria No.3 " Methods", it would be classified as " Reported". |
<table>
<thead>
<tr>
<th>Introduction</th>
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<tr>
<td><strong>Background and objectives</strong></td>
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<th>Methods</th>
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<td><strong>Trial design</strong></td>
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(1). “Not Reported”: did not report criteria No. 1-2. (i.e. criteria no. 1-2 were mandatory)  
“Partial Reported”: reporting criteria No.1-2 but did not fully report criteria No. 3-5 although they were applicable  
“Fully Reported”: reporting criteria No. 1-5 when applicable or reporting criteria No. 1-2 when criteria No. 3-5 was not applicable  
(2). For criteria No.3, completion of three or more sub-items will be classified as “Reported”.
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<td><strong>Intervention measure</strong></td>
<td>should be provided in accordance with the above requirements.</td>
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<td><strong>Outcomes</strong></td>
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<td>6a</td>
<td>Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed</td>
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<td>Primary outcomes (including secondary outcomes):</td>
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<td>1. Definition of outcome measures.</td>
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<td>2. Time when outcome measures were measured.</td>
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<td>3. Who evaluated the outcome measures.</td>
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<td>4. Number of evaluators.</td>
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<td>“Fully Reported”: reporting three or more criteria</td>
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<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
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<td><strong>Sample size</strong></td>
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<td>7a</td>
<td>How sample size was determined.</td>
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<td>1. Explanation of how sample size was determined.</td>
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<td>2. If formal power calculation was used:</td>
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<td>2.1 Identification of the primary outcome measure used for the calculation.</td>
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<td>2.2 All parameters used in the calculation.</td>
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<td>2.3 Target sample size for each group calculated.</td>
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<td>(1). “Fully Reported”: reporting either of the two criteria</td>
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<td>“Not Reported”: did not report any of the criteria.</td>
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<td>(2). For criteria No.2, completion of two or more sub-items will be classified as “Reported”.</td>
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<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
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<td><strong>Randomization - Sequence generation</strong></td>
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<tr>
<td>8a</td>
<td>Method used to generate the random allocation sequence.</td>
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<td>Type of randomization; details of any restriction (such as blocking and block size)</td>
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<tr>
<td>Randomization - Allocation concealment mechanism</td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
</tr>
<tr>
<td>Randomization - Implementation</td>
<td>10</td>
<td>Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
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<tr>
<td>Blinding</td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.</td>
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<tr>
<td></td>
<td>11b</td>
<td>If relevant, description of the similarity of interventions</td>
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</table>

1. Who generated the random allocation sequence.  
2. Who recruited participants.  
3. Who assigned participants to interventions.  

"Fully Reported": reporting three criteria  
"Partial Reported": reporting two criteria  
"Not Reported": reporting one or fewer criterion.  

1. Who was blinded in the study.  
2. How was the blinding implemented in the study.  

"Fully Reported": reporting two criteria  
"Partial Reported": reporting one criterion.  
"Not Reported": did not report any criterion. It was mandatory to provide descriptions of blinding, regardless of whether a blind method is used or not. The absence of descriptions will be regarded as "Not Reported."  

It should be noted the similarities between the interventions, such as their appearance, taste, odor, administration method, etc.  

"Fully Reported": any descriptions  
"Not Reported": no descriptions
### Statistical methods

| 12a | Statistical methods used to compare groups for primary and secondary outcomes |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |

If a correction analysis was chosen, it should be stated:
1. Which variables were selected for correction.
2. How continuous variables were handled.
3. Whether the analysis was pre-planned or selected based on data.

When applicable:
- "Fully Reported": reporting three criteria
- "Partial Reported": reporting two criteria
- "Not Reported": reporting one or fewer criteria.

### Results

| 13a | Participant flow diagram (strongly recommended) |
| 13b | For each group, losses and exclusions after randomization, together with reason |

1. Describe the number of cases that were excluded and rejected in each group.
2. Explain the reasons for exclusion and rejection.

"Fully Reported": reporting two criteria
"Partial Reported": reporting one criterion.
"Not Reported": did not report any criterion.
<table>
<thead>
<tr>
<th>Recruitment</th>
<th>14a</th>
<th>Dates defining the periods of recruitment and follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Describe the duration of the recruitment period.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Describe the length of the follow-up period.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Specify the exact dates.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Fully Reported&quot;: reporting three criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Partial Reported&quot;: reporting two criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Not Reported&quot;: reporting one or fewer criterion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recruitment</th>
<th>14b</th>
<th>Why the trial ended or was stopped</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Explain why the trial was terminated.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Describe any factors outside of the trial that influenced the decision to terminate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Who made the decision to terminate the trial?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Discuss the role of the funding agency in the deliberation and decision to terminate the trial.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Fully Reported&quot;: reporting three or more criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Partial Reported&quot;: reporting two criteria</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Not Reported&quot;: reporting one or fewer criterion.</td>
</tr>
</tbody>
</table>

| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group |

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<table>
<thead>
<tr>
<th>Numbers analysed</th>
<th>16</th>
<th>For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. All analyses should provide the sample size for each group of subjects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. For outcome variables those were binary, such as risk ratio and risk difference, the denominator or incidence rates should also be reported.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Whether the initial grouping were used for analysis should be specified.</td>
</tr>
</tbody>
</table>

(1) If criteria 2 are applicable
"Fully Reported": reporting three criteria
"Partial Reported": reporting two criteria
"Not Reported": reporting one or fewer criterion.

(2) If criteria 2 are not applicable,
"Fully Reported": reporting two criteria
"Partial Reported": reporting one criterion.
"Not Reported": did not report any criterion.

<table>
<thead>
<tr>
<th>Outcomes and estimation</th>
<th>17a</th>
<th>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Results for primary and secondary outcome measures.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Estimates of effect size (for binary outcome measures, effect size may be reported as risk ratio or relative risk, odds ratio, or risk difference; for survival time data, hazard ratio or difference in median survival time may be reported; for continuous variable data, the difference in means is typically reported).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Precision.</td>
</tr>
</tbody>
</table>

"Fully Reported": reporting three criteria
"Partial Reported": reporting two criteria
"Not Reported": reporting one or fewer criterion.

<table>
<thead>
<tr>
<th>Ancillary analyses</th>
<th>18</th>
<th>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</th>
</tr>
</thead>
</table>
### Harms

<table>
<thead>
<tr>
<th></th>
<th>19</th>
<th>All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>List adverse events and provide definitions, referencing relevant standards as necessary.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>The methods used for collecting adverse event data and determining causality should be described.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>The absolute risk of each adverse event should be reported (appropriate statistical methods should be used for recurrent events).</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>The number of participants who withdrew due to harm should be reported.</td>
<td></td>
</tr>
</tbody>
</table>

“Fully Reported”: reporting three or more criteria

“Partial Reported”: reporting two criteria

“Not Reported”: reporting one or fewer criterion.

---

### Discussion

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Limitations:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1 Summarize the main results.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 Raise possible mechanisms and explain the experimental results.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 Compare the relevant results of this study with other published studies (including a systematic review that combines the results of all relevant studies to date).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4 Discuss the limitations of this study (and the measures taken to reduce and address these limitations).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 Provide a brief summary of the clinical and research implications of the study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Reasons for imprecision.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) “Fully Reported”: reporting two criteria

“Partial Reported”: reporting one criterion.

“Not Reported”: did not report any criterion.

(2) For criteria No.1, completion of three or more sub-items will be classified as “Reported”.

---

### Generalisability

<table>
<thead>
<tr>
<th></th>
<th>21</th>
<th>Generalisability (external validity, applicability) of the trial findings</th>
</tr>
</thead>
</table>

---

### Interpretation

<table>
<thead>
<tr>
<th></th>
<th>22</th>
<th>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The ideal reporting format was to include a formal systematic review in the results or discussion section of the trial report, or to cite a systematic review of similar clinical trials.</td>
<td></td>
</tr>
</tbody>
</table>
Registration

Registration number and name of trial registry

1. Authors should provide the name of the register and the unique trial registration number.
2. If their clinical trial had not been registered, authors should state this fact and provide the reason why.

Other information

Protocol

Where the full trial protocol can be accessed, if available

Funding

Sources of funding and other support (such as supply of drugs), role of funders

*Items without evaluation criteria do not have "Partial Reported". It will be considered as "Fully Reported" when reporting the item and no reporting is considered as "Not Reported".

### STRICTA evaluation criteria

<table>
<thead>
<tr>
<th>Item</th>
<th>Detail</th>
<th>evaluation criteria</th>
<th>Scoring rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acupuncture rationale</td>
<td>1a) Style of acupuncture (e.g. Traditional Chinese Medicine, Japanese, Korean, Western medical, Five Element, ear acupuncture, etc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate</td>
<td>1. Describe the reasons for choosing the concrete acupuncture treatment 2. Introduce the historical background of the treatment 3. Describe the literature sources and/or consensus formation methods</td>
<td>&quot;Fully Reported&quot;: reporting three criteria  &quot;Partial Reported&quot;: reporting two criteria  &quot;Not Reported&quot;: reporting one or fewer criterion.</td>
</tr>
<tr>
<td></td>
<td>1c) Extent to which treatment was varied</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 2. Details of needling | 2a) Number of needle insertions per subject per session (mean and range where relevant) | 1. For designs that focus more on explanatory purposes, the acupoint selection in the prescription should be simply reported as the total number of needle insertions.
2. For designs that focus more on practical effectiveness and adopt individualized treatment, the mean and range should be reported.

"Fully Reported": reporting either of the two criteria
"Not Reported": did not report any of the criterion.

| 2b) Names (or location if no standard name) of points used (uni/bilateral) | 1. Describe the location of acupoints used in treatment with a recognized name (if there is no recognized name, describe based on anatomical location).
2. Indicate whether unilateral or bilateral needling was used.
3. Describe the treatment protocol.
3.1 For treatment protocols that implement partially individualized prescriptions:
3.1.1 List any required or optional acupoints specified in the prescription.
3.1.2 Describe the acupoints used at each visit and all acupoints used based on a particular rationale in the conclusion section (if the list is broad, report the most commonly used acupoints as a percentage).
3.2 For treatment protocols that implement fully individualized prescriptions:
3.2.1 Report the acupoints used (may list all acupoints used by all participants or the most commonly used acupoints).

"Fully Reported": reporting three criteria
"Partial Reported": reporting two criteria
"Not Reported": reporting one or fewer criterion.

| 2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level |

| 2d) Response sought (e.g. de qi or muscle twitch response) |
**2e)**  
Needle stimulation (e.g. manual, electrical)  
1. Describe the needling stimulation techniques for all acupoints.  
2. If manual stimulation is used, describe the techniques of lifting, thrusting, or twirling needles to control the deqi sensation.  
3. If electrical stimulation is used, describe the current intensity, amplitude and frequency.  
*“Fully Reported”: reporting criteria No.1+2 or 1+3 or 1-3 as applicable.  
*“Not Reported”: reporting one or fewer criterion.

**2f)**  
Needle retention time

**2g)**  
Needle type (diameter, length, and manufacturer or material)  
1. Describe the diameter of the needle.  
2. Describe the length of the needle.  
3. Describe the manufacturer or material used.  
*“Fully Reported”: reporting three criteria  
*“Partial Reported”: reporting two criteria  
*“Not Reported”: reporting one or fewer criterion.

**3. Treatment regimen**

**3a)**  
Number of treatment sessions

**3b)**  
Frequency and duration of treatment sessions  
1. Describe the frequency of the stimulation unit.  
2. Describe the duration of treatment unit.  
*“Fully Reported”: reporting two criteria  
*“Partial Reported”: reporting one criteria  
*“Not Reported”: did not report any of the criterion.

**4. Other components of treatment**

**4a)**  
Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)

**4b)**  
Setting and context of treatment, including instructions to practitioners, and information and explanations to patients
| 5. Practitioner background | 5) | Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience) | 1. Describe the qualification of the acupuncturist.  
2. Describe the industry in which the acupuncturist practices.  
3. Describe the number of years the acupuncturist has in acupuncture practice.  
*Fully Reported*: reporting three criteria  
*Partial Reported*: reporting two criteria  
*Not Reported*: reporting one or fewer criterion. |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Control or comparator interventions</td>
<td>6a)</td>
<td>Rationale for the control or comparator in the context of the research question, with sources that justify this choice</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6b)</td>
<td>Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above</td>
<td></td>
</tr>
</tbody>
</table>

*Items without evaluation criteria do not have "Partial Reported". It will be considered as "Fully Reported" when reporting the item and no reporting is considered as "Not Reported".*