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

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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, CBM, 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 2010 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.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study will collect acupuncture randomised controlled trials (RCTs) including a broad range of diseases without the restriction of the publication language.
⇒ The study will use Consolidated Standards for Reporting Trials statement and Standards for Reporting Interventions in Controlled Trials of Acupuncture guideline to assess the reporting quality of included acupuncture RCTs.
⇒ The study will use open science practices to assess the data-sharing level of included acupuncture RCTs.
⇒ We will conduct a training and three rounds of pretests to confirm the consistency of assessing results between the two researchers.
⇒ Due to the limitation of manpower and time, we only include the representative study design, two groups and parallel RCTs.

BACKGROUND

According to the second global survey in 2012 conducted by WHO,[1] 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[2] and the diverse applications of acupuncture are extensive from pain syndrome[3] to multiple medical disciplines[4] including neuroscience,[5] obstetrics and gynaecology,[6] as well as rehabilitation.[7]

Randomised controlled trials (RCTs), at the top of the pyramid of the highest strength of clinical evidence,[8] 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.[9] Despite the increasing number of acupuncture RCTs published in international high-impact journals,[10–13] 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,[14] updated in 2001[15 16] and the latest version was published in 2010,[17 18] comprising

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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[19] and revised in 2010,[20] 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,[21] 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[22] 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[23] (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.[24] 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 acupoints) 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 acupoint stimulation, and the stimulation does not pierce the skin (such as auricular pressure, acupoint 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 the: (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.

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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/algorithm/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[25–28] have demonstrated an increase in all the items over time since the introduction and influence of the conception of reporting quality. Svenkerud and MacPherson[29] 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[30] and its complications,[31] stroke and post-stroke rehabilitation,[32 33] pain,[34 35] primary insomnia,[36] diabetes,[37] chronic obstructive pulmonary disease,[38] herpes zoster[39] and vascular dementia[40] among different languages.[41] A systematic review by Ma *et al*[27] 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[30] 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[41] of Korean literature drew a conclusion that the completeness of reporting 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*[28] 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.[42] 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,[43] traumatic stress[44] and gambling,[45] 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[46] 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.[47] Since acupuncture is a practitioner-dependent, experience-required intervention,[48] the use of acupuncture in different regions[49] can vary from regional characteristics, cultural differences, economic

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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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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, ZC, 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.

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